DDD = degenerative disc disease.
NDI = Neck Disability Index.
NR = not reported.
SF-36 = Short Form 36.
VAS = visual analog scale.
*Study design is determined relative to the exposures being compared.
†Demographics are before loss to follow-up, unless otherwise noted.
‡Patients included are those with 24 months of follow-up at time of paper preparation; of the original group, 160 of 168 ADR and 140 of 165 ACDF patients had passed the 24 month point in the course of their treatment.
§Follow-up n's are from table 13 of report (based on number of patients who complete trial); percent is calculated from those n's.

Table G4. Demographics and characteristics in included nonrandomized studies for C-ADR

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Amit (2007)	case-series (IV) London, England	N = 22 male %: 59.1 mean age: 51 years (39-79)	mean F/U: 15 months (range, 12-20 months) F/U %: NR	• cervical spondylosis with myelopathy (n = 4) or radiculopathy (n = 18)	• single level anterior decompression and Bryan ADR	• VAS pain • SF-36 • myelopathy disability index (MDI) • NDI • Odom's criteria • Cobb angle measured at 6 months and 12 months
Bertagnoli (2005)	case-series (IV) multicenter trial	N = 16 male %: 50 mean male age: 45.6 years (33-60) mean female age: 51 years (32-59) overall median age: 50.5 years	median F/U: 12.7 months (12-14 months, range) F/U%: 100	• one or two level cervical spondylosis with: 1) severe axial neck pain of greater than 6 months' duration and secondary to intervertebral DDD without radicular and/or myelopathic symptoms (n = 4); and 2) with persistent radicular symptoms of greater than 2 months' duration with axial neck pain and absent or minimal clinical signs of myelopathy (n = 12) • overall median duration of pain: 50 months (6 weeks to 400 months, range) • previous anterior cervical ADR with Bryan disc experiencing ASD (n = 2)	• Prodisc C ADR via anterior approach • spinal segment: C4-5 (n = 3) C5-6 (n = 7) C6-7 (n = 6)	Patients assessed preoperatively and postoperatively at 3 and 6 weeks and at 3, 6, and 12 months • ODI for disability • VAS for pain • patient satisfaction • general neck pain • radicular pain • medication usage • approach-related complications • radiographic assessment of ROM, intervertebral disc height of affected and adjacent levels, device related complications
Bertagnoli (2005)	case-series (IV) multicenter trial	N = 27 male %: 48 mean age: 49 years (31-66)	F/U: 12 months F/U %: NR	• single level cervical DDD	• Prodisc-C ADR • spinal segment C4-5 (n = 2) C5-6 (n = 16) C6-7 (n = 9)	Patients assessed preoperatively and postoperatively at 3 and 6 weeks and at 3, 6, and 12 months • NDI • VAS pain • patient satisfaction • general neck pain • radicular pain • medication usage • complications • radiographic assessment of ROM, device-related loosening, dislodgment, or subsidence

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes

Bryan (2002)
 	
population same as Goffin 2002 with different f/u and outcomes
	case-series (IV)
	
	multicenter trial
		N = 97
		male %: 42
		age range: 26-79 years
			number of eligible and lost to follow-up not reported
			
			*at time of publication 49 patients had reached 1 year f/u and 10 had reached 2 year f/u
				• single level cervical DDD
				• disc herniation (n = 75) or spondylosis (n = 33) with radiculopathy (n = 90) and/or myelopathy (n = 13)*
				• failing conservative treatment
				• duration of symptoms (range) = 6 weeks to 24 months
				
				*several patients presented with multiple diagnoses and/or cause
					• Bryan cervical ADR via anterior cervical discectomy
					• spinal segment:
					C4-5 (n = 11)
					C5-6 (n = 42)
					C6-7 (n = 44)
						• Cervical Spine Research Study (CSRS) questionnaire
						• SF-36 questionnaire
						• relief of objective neurological signs as assessed by physician in a neurological exam preoperatively, postoperatively, and then 6 weeks, and 3, 6, 12 and 24 months:
						  • motor strength on five point scale (right and left sides)
						  • gait on four point scale
						  • reflexes on four point scale (right and left sides)
						  • sensory function on four point scale (right and left sides)
						  • neck pain severity
						  • arm pain severity
						  • ability to function with respect to activities of daily living
						• radiographic evaluation to assess stability, subsidence, or migration of the prosthesis
						• results categorized according to a modified version of Odom's Criteria: excellent, good, fair, poor

Duggal (2004)	case-series (IV) Canada	N = 26 male %: 62 mean age (SD): 43.3 (7.9) years (30-67)	mean F/U: 12.3 months (1.5-27 months, range) F/U%: 100	• cervical DDD with radiculopathy and/or myelopathy whose main symptom was arm pain and NOT neck pain • mean duration of symptoms for radiculopathy = 12.5 months (2.5- 60 months, range) • mean duration of symptoms for myelopathy = 6.2 months (1-14 months, range) • failed nonsurgical medical therapy: activity modification, nonsteroidal anti-inflammatory medications, physiotherapy, massage • preoperative motion at the symptomatic level	• **Bryan** cervical ADR via anterior approach and a transverse skin incision made on the right side of the neck • number of levels: monolevel at C5-6 or C6-7: (n = 22) bilevel at C5-6 & C6-7: (n = 4) • spinal segment C4-5 (n = 1) C5-6 (n = 13) C6-7 (n = 16)	• neurological examination • Oswestry NDI (self-administered) • SF-36 (self-administered) • static and dynamic cervical X-rays • duration of surgery • blood loss • complications

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
				• previous anterior cervical discectomy and fusion (n = 4)		
Fong (2006)	case-series (IV) Canada	N = 10 male %: 60 mean age: 44 years (36-52) subpopulation from larger, ongoing, prospective study	median F/U: 4 months (3-12 months, range) F/U %: 100	• single level disease with cervical radiculopathy and/or myelopathy • duration of symptoms ranged from 6-36 months • disc herniation was the cause of foraminal or central canal stenosis, or both, in all patients • previous anterior discectomy and fusion (n = 1)	• Bryan ADR via a standard right-sided cervical exposure through a transverse incision • spinal segment: C5-6 (n = 7) C6-7 (n = 3)	• Oswestry NDI • SF-36 questionnaire • radiographic evaluation to determine endplate angle, functional spinal unit angle and height, Cobb angle

Goffin (2003)	case-series (IV)
	
	Belgium
		single level study:
		N = 103
		male %: 41
		age range: 26-79 years
		
		bilevel study:
		N = 43
		male %: 58
		age range: 28-62 years
			F/U: 24 months
			
			single level study*:
			12 month F/U%: 97.1
			24 month F/U%: 49.5
			
			bilevel study*:
			12 month F/U%: 67.4
			24 month F/U%: 2.3
			
			*% F/U based on author's report of patients who had reached 12 & 24 month F/U at time of publication
				• disc herniation or spondylosis with radiculopathy and or myelopathy
				• failed conservative treatment during at least 6 weeks
					• Bryan ADR	• primary outcome: classification based on relief of each preoperative symptom as assessed by the patient using the Cervical Spine Research Society questionnaire and relief of each objective neurologic sign as assessed by the physician in a neurologic examination.
						• surgeons assessments preoperatively and postoperatively, then 6 weeks, 3, 6, 12, 24 months after surgery:
						  • motor strength in 5-point scale (left and right sides)
						  • Reflexes in 4-point scale (right and left sides)
						  • Sensory in 4-point scale (right and left sides)
						  • Babinski's Sign
						  • Spurling's Sign
						  • Clonus
						  • Hoffman's Sign
						  • patient assessments preoperatively and postoperatively and then 6 weeks, and 3, 6, 12, and 24 months after surgery. Assessed were neck pain severity in 6-point scale, arm pain severity in 6-point scale, and ability to function at activities of daily living in 4-point scale
						• all outcomes categorized according to Odom's criteria: excellent, good, fair, or poor

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Goffin (2002) population same as Bryan 2002 with different f/u and outcomes	case-series (IV) multicenter trial	N = 97 male %: 42.2 age range: 26-79 years	number of eligible and lost to follow-up not reported *at time of publication 60 patients had reached 6 month f/u and 10 had reached 12 month f/u	• single level cervical DDD • disc herniation (n = 75) or spondylosis (n = 33) with radiculopathy (n = 90) and/or myelopathy (n = 13)* • failing conservative treatment • duration of symptoms (range) = 6 weeks to 24 months *several patients presented with multiple diagnoses and/or cause	• Bryan cervical ADR via anterior cervical discectomy • spinal segment: C4-5 (n = 11) C5-6 (n = 42) C6-7 (n = 44)	• primary outcome: Cervical Spine Research Study and SF-36 questionnaires and relief of each objective neurologic sign as assessed by the physician • surgeons assessments preoperatively and postoperatively, then 6 weeks, 3, 6, and 12 months after surgery: • Motor strength in 5-point scale (left and right sides) • Reflexes in 4-point scale (right and left sides) • Sensory in 4-point scale (right and left sides) • Babinski's Sign • Spurling's Sign • Clonus • Hoffman's Sign • patients assessments preoperatively and postoperatively and then 6 weeks, and 3, 6, and 12 months after surgery. Assessed were neck pain severity in 6-point scale, arm pain severity in 6-point scale, and ability to function at ADL in 4-point scale • radiographic evaluation to assess stability, subsidence, or migration of the prosthesis • Odom's criteria: excellent, good, fair, or poor
Heidecke (2008)	case-series (IV) Germany	N = 54 male %: 41% mean age: 47 years (26-58)	F/U: 2 years F/U %: NR	• disc herniation and/or spondylosis with preserved mobility in the affected segment • cervical radiculopathy and/or myelopathy with or without neck pain • exclusion criteria included: advanced kyphotic deformity, spondylolisthesis, translational instability of the cervical spine, insulin-dependent diabetes, advanced osteoporosis, ankylosing spondylitis, rheumatoid arthritis, age > 60 years	• Bryan cervical disc prosthesis in standard anterior cervical discectomy • number of levels treated single level (n = 49) two levels (n = 5) • 59 total spinal segments replaced: C4-5 n = 18 discs C5-6 n = 33 discs C6-7 n = 8 discs	• radiographic evaluation to assess migration, dislocation • heterotopic ossification • intraoperative or early postoperative complications related to disc • neurological symptoms • Odom's criteria: excellent, good, fair, or poor

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Jollenbeck (2004)	case-series (IV) Germany	N = 50 male%: 52 mean age: 46.2 years (32-65)	number of eligible patients not reported F/U: range, 1-14 months 6 month F/U%: 82 12 month F/U%: 26	• prolapse or protruding degenerative cervical disc with local neck pain and radicular pain (n = 13), sensory loss and some motor deficits (n = 38), and myelopathy with gait ataxia and increased tendon reflexes (n = 7)	• unspecified cervical disc used for ADR via anterior approach (? Bryan) • number of levels: monolevel (n = 49) bilevel (n = 1) • spinal segments C3-4 (n = 2) C4-5 (n = 2) C5-6 (n = 35) C6-7 (n = 10) C5-6 & C6-7 (n = 1)	• VAS for duration and intensity of neck ache, radicular pain, and difficulties swallowing daily for 7 days post-op • rate of hemorrhage and infection • duration of hospital stay • radiological and neurological f/u and assessment of ROM at 3, 6, and 12 months • self-assessment of pain and return to work via Odom's scale at all f/u intervals
Kim (2007)	case-series (IV) Korea	N = 23 male %: 70 mean age: 43 years (31-62)	mean F/U: 6 months F/U %: NR	• cervical DDD with axial pain, radiculopathy, or myelopathy (n = 8) • mean symptom duration: 7.5 months (2 weeks to 36 months, range) • previous anterior cervical fusion (n = 2)	• Mobi-C cervical ADR via anterior approach, with anterior cervical interbody fusion also in different levels (n = 6) • number of levels: monolevel (n = 22) bilevel (n = 1) • spinal segment: C3-4 (n = 2) C4-5 (n = 4) C5-6 (n = 11) C6-7 (n = 6)	• radiographic analysis to determine Cobb's angle, functional spinal unit angle, and ROM • VAS for axial pain and radiculopathy • modified Japanese Orthopaedic Association (JOA) scoring system for severity of myelopathy • Prolo economic and functional rating scale • results scored according to modified Odom's criteria: excellent, good, fair, poor
Lafuente (2005)	case-series (IV) United Kingdom	N = 46 male %: 61 mean age (SD): 47.6 (10.5) years (33-70)	mean F/U: 14 months F/U%: 100	• single level disease with either radiculopathy or myelopathy • failing nonsurgical treatment • mean (SD) duration of symptoms = 13.8 (11.9) months (1-6 months, range) • previous lumbar discectomy (n = 2) and cervical fusion at one level (n = 3)	• **Bryan** ADR via anterior cervical discectomy • number of levels: all between C3-5 and C6-7	• neurological examination • radiological evaluation to assess movement, stability, and subsidence or the prosthesis • VAS for pain • SF-36 for general health • Oswestry NDI for functionality • results were categorized as excellent, good, fair, or poor according to modified Odom's criteria

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Leung (2005)	case-series (IV) multicenter trial	N = 103 male%: 43 mean age (SD): 45 (9.8) years (26-79)	F/U: 12 months x-ray F/U%: 87.3 clinical F/U%: 86.4	• disc herniation or spondylosis with radiculopathy and/or myelopathy • failed conservative treatment: relative rest, soft collar, physiotherapy, and medication for at least 6 weeks	• Bryan cervical ADR	• McAfee classification for heterotopic ossification (OH) • Odom's criteria: poor = unfavorable; fair, good, and excellent = favorable • SF-36
Liu (2007)	retrospective cohort (III)	N = 30 male: NR age: NR	NR	• normal subjects (n = 10) • patients treated with an anterior cervical decompression and fusion (ACDF) (C5–C6) (n = 10) • patients having cervical artificial disc replacement (CADR) (C5–C6) (n = 10)	• full flexion to extension motions under fluoroscopic surveillance in the sagittal plane • kinematic data were obtained from the fluoroscopic images • kinetic data were derived based on an inverse dynamic model of the entire cervical spine.	Intersegmental ROM
Mehren (2006)	case-series (IV) multicenter trial	N = 54 male%: NR mean age: NR	F/U: 12 months F/U%: NR	• disc herniation or other degenerative changes leading to neurological deficits, and/or arm and/or neck pain	• Pro-disc C ADR via anterior approach • number of levels: monolevel (n = 34) bilevel (n = 17) trilevel (n = 3) • spinal segment: C3-4 (n = 3) C4-5 (n = 9) C5-6 (n = 36) C6-7 (n = 29)	• radiography to determine McAfee classification for heterotopic ossification (OH) • VAS for neck and arm pain • NDI
Pickett (2006)	case-series (IV) multicenter trial	N = 74 male %: 50 mean age: 44 years	mean F/U: 12 months (maximum 39 months) F/U%: NR	• cervical disc herniation or spondylosis with radiculopathy and/or myelopathy or neck pain • 12 patients had prior neck surgery, 11 of whom had ACDF	• Bryan ADR	• NDI • Oswestry NDI • VAS for pain • SF-36 • patient satisfaction (ie, would have the procedure again) • radiographic parameters • complications

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Pimenta (2004)	case-series (IV) Brazil	N = 53 male %: 40 mean age: 45 years (28-68)	F/U: 12 months F/U %: NR	• DDD (n = 43), degenerative adjacent segment disease (n = 10) • Radicular or medullary compression symptoms • Age 20-70 years • Neurological compression of one, two or three levels from C3-C4 to C7-T1 • Herniation of the nucleus pulposus • Cervical spondylosis • Nontraumatic segmental instability • Exclusion criteria included metabolic and bone diseases, terminal phase of chronic disease, pyogenic infection or active granulomatosis, neoplasty or traumatic disease of the cervical column, biomechanical instability of traumatic origin	• PCM (Cervitech) discs implanted by PRESS FIT Model or Flange Fixed Model • 81 discs in 53 patients One level in n = 28 Two level in n = 22 Three level in n = 3 • Levels receiving implants: C3-C4 n = 28 C4-C5 n = 15 C5-C6 n = 34 C6-C7 n = 22 C7-T1 n = 2	• VAS for pain • NDI • Treatment Intensity Gradient Test • Odom's criteria: excellent, good, fair, bad • radiographic parameters • heterotopic ossification
Pointillart (2001)	case-series (IV) France	N = 10 male %: 50% mean age: 36 years (25-49)	F/U: 1 year F/U %: NR	• cervicobrachial pain for over 3 months • soft disc herniation by MRI • exclusion criteria included intervertebral instability	• prototype prosthesis (not otherwise specified) • levels receiving implants: C5-C6 n = 6 C6-C6 n = 4	• further procedures • pain • mobility • complications
Rabin (2007)	retrospective cohort (III)	N = 20 male: 80% age: 34.8 (ACDF) 35.8 (AD)	ACDF: 24.8 months AD: 15 months	• single-level Bryan cervical disc (n = 10) • single-level ACDF matched based on age and sex (n = 10)	• lateral neutral, flexion and extension cervical x-rays were obtained preoperatively and at regular intervals up to 24 months postoperatively.	ROM at operated level

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Robertson (2004) pilot study and extension of the Wigfield 2002 study, 2 additional patients enrolled	case-series (IV) United States	N = 17 male %: 59 mean age (SD): 50.1 (11.4) years (31.9-74.5)	F/U: 36 and 48 months x-ray F/U% at 36 months: 64.7 x-ray F/U% at 48 months: 70.5 clinical F/U% at 48 months: 82.4	• radiculopathy or myelopathy with cervical disc herniation or posterior vertebral body osteophytes AND have either a previous adjacent-level surgical or congenital spinal fusion or radiologic evidence of ASD • previous surgical fusions (n = 9)	• Prestige I ADR • discs inserted between C3-4 and C6-7	• radiological evaluation to assess motion preservation and device stability • neurological examination • VAS for arm and neck pain • NDI • SF-36 physical and mental component scores • European myelopathy scale (EMS)
Robertson (2005)	retrospective cohort using nonconcurrent controls (III)	ADR N = 310 male: 41% age: 55.9 years (28-79) fusion: N = 202 male: 49% age: 44.5 years	24 months F/U %: 75	• symptomatic single level disc herniation or spondylosis (C2-3 to C7-T1) with radiculopathy and/or myelopathy	• Bryan ADR (n = 74) or fusion using an Affinity Anterior Cervical Cage System (n = 158) • anteroposterior, neutral, and lateral flexion-extension x-rays were collected pre-, peri-, and postoperatively at 6 weeks, and 3, 6, 12, and 24 months	*Bryan protocol:* • Odom criteria • Cervical Spine Research Study outcome forms • qualitative scale of the SF-36 *Affinity system protocol:* • neck disability score • VAS pain scores • qualitative scale of the SF-36 rate of adjacent segment disease based on new anterior osteophyte formation or enlargement of existing osteophytes, increased or new narrowing of a disc space, and new or increasing ALL calcification
Sekhon (2004)	case-series (IV) Australia	N = 11 male %: 64 mean age: 43.7 years (31-55) 7 patients presented in a previous report with shorter f/u	mean F/U: 18.4 months (10-32 months, range) F/U%: 100	• spinal cord compression and/or clinically confirmed cervical myelopathy • mean duration of symptoms = 15.2 months (.75-72 months, range)	• Bryan ADR via left-sided transverse cervical incision or an oblique left-sided paramedian incision for a bilevel disease • number of levels: single level (n = 7) bilevel (n = 4) • spinal segment: C3-4 (n = 1) C4-5 (n = 1) C5-6 (n = 2) C6-7 (n = 3) C4-5, C5-6 (n = 2) C5-6, C6-7 (n = 2)	• neurological exam • Nurick grading • Oswestry NDI assessment • neck and arm symptoms rated on a scale from 0 (none), 1 (mild), 2 (moderate), and 3 (severe) • results were categorized using Odom's criteria

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Shim (2006)	case-series (IV) Korea	N = 61 male %: 70 mean age: 45.6 years (32-64) (% male and mean age available for only 47 patients with 3 months f/u)	mean F/U: 6 months F/U%: 77	• cervical radiculopathy or myelopathy with (n = 41) or without (n = 6) soft disc herniation	• Bryan cervical ADR (n = 43) in combination with ACDF (n = 4) • number of levels: monolevel (n = 39) bilevel (n = 8)	• NDI • VAS for neck and shoulder/arm pain • patient's subjective improvement rate of symptoms • patient's satisfaction with procedure • radiological evaluation to determine segmental angle, total sagittal alignment, and ROM
Wigfield (2002)	case-series (IV) United Kingdom	N = 15 male %: 67 mean age (SD): 47.6 (18.1) years	F/U: 24 months F/U%: 93.3	• radiculopathy or myelopathy with cervical disc herniation or posterior vertebral body osteophytes AND have either a previous adjacent-level surgical or congenital spinal fusion or radiologic evidence of ASD • previous surgical fusions (n = 9) • mean (SD) duration of symptoms = 5 (5.4) years	• Frenchay ADR via a standard anterolateral approach using the Smith and Robinson technique • discs inserted between C3-4 and C6-7	• operative time • blood loss • infection • radiological evaluation to assess motion preservation and device stability • neurological examination • VAS for arm and neck pain • NDI • SF-36 physical and mental component scores • European myelopathy scale (EMS)
Yang (2007)	case-series (IV) China	N = 12 male %: 58% mean age 50 years (35-62)	mean F/U: 5.2 months (2-8) F/U %: NR	• cervical spondylotic myelopathy (n = 5) and cervical disc herniation (n = 7)	• Bryan cervical disc prosthesis • 14 replacements in 12 patients • Single level n = 10 • Two-level n = 2	• Japanese Orthopedic Association (JOA) scores • Odom's criteria: excellent, good, fair, poor • Radiographic and MRI evaluation for device stability and HO

Author (year)	Study design (LoE)	Demographics	Follow-up	Characteristics	Interventions	Outcomes
Yoon (2006)	case-series (IV) Seoul, Korea	N = 46 male %: 52.2 mean age: 42.3 years (26-58)	mean F/U: 11.8 months (range, 2.9-19.5) F/U %: NR	• herniated cervical disc (n = 39) or cervical stenosis (n = 6) with radiculopathy or myelopathy • failed conservative treatment	• Bryan ADR following anterior cervical discectomy • number of levels monolevel (n = 34) bilevel (n = 12) • spinal segment C4-5: (n = 4) C5-6: (n = 32) C6-7: (n = 10)	• VAS pain • self-administered NDI • complications

NDI = Neck Disability Index.
NR = not reported.
ODI = Oswestry Disability Index.
ROM = range of motion.
SF-36 = Short Form 36.
VAS = Visual Analog Scale.

APPENDIX H. Evidence Tables: Results of Included Studies for ADR

Table H1. Efficacy and outcomes other than adverse events or complications for included RCTs for L-ADR

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion
Blumenthal (2005) McAfee (2005) Geisler (2004) Statistical Review for Expedited PMA (2004) Summary of Safety and Effectiveness (2004)	• four-point success measure using sponsor's ODI criterion* ADR: 57.1% (100/176) fusion: 46.5% (34/74) *P* < .0001 • four-point success measure using FDA's ODI criterion* ADR: 52.1% (92/176) fusion: 44.4% (33/74) *P* = NR FDA table	• ODI improved ≥ 25% from baseline ADR: 63.9% (112/176) fusion: 50.5% (37/74) *P* = 0.004 • ODI improved ≥ 15 points from baseline ADR: 57.1% (100/176) fusion: 47.5% (35/74) *P* = NR • mean % improvement in ODI compared to baseline† *6 weeks* ADR: 23.9% fusion: 12.7% *P* = .02 *3 months* ADR: 40.2% fusion: 25.7% *P* = .001 *6 months* ADR:46.2% fusion:30.8% *P* = .002 *12 months* ADR: 48.8% fusion: 37.9%	• mean improvement in VAS compared to baseline† *6 weeks* ADR:35.9 fusion:27.7 *P* = .02 *3 months* ADR:35.7 fusion:27.4 *P* = .02 *6 months* ADR:39.0 fusion:28.2 *P* = .004 *12 months* ADR:39.1 fusion:30.9 *P* = .04 *24 months* ADR:40.6 fusion:34.1 *P* = .1 • still using narcotics for pain‡ ADR: 64% (73)	• physical SF-36 improved ≥ 15% from baseline ADR: 72% (127/176) fusion: 63% (47/74) *P* = NR • mental SF-36 improved ≥ 15% from baseline ADR: 50% (88/176) fusion: 51% (38/74) *P* = NR • report they would have procedure again ADR: 69.9% fusion: 50.0% *P* = .006 • report they are "satisfied"§ ADR: 73.7% fusion: 53.1% *P* = .001	• employed *baseline* ADR: 53.2% fusion: 57.6% *P* = NR *24 months* ADR: 62.4% fusion: 65% *P* = .6	• mean flexion-extension: *Pre-op:* 6.6° *Post-op*: 7.5°

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion
		P = .04 *24 months* ADR: 48.5% fusion: 42.4% *P* = .3	fusion: 80% (37) *P* = .04			
Zigler (2007)	• ten-point success measure using sponsor's ODI criterion** ADR: 63.5% (94/148) fusion: 45.1% (32/71) *P* = .005 • ten-point success measure using FDA's ODI criterion** ADR: 53.4% (79/148) fusion: 40.8% (29/71) *P* = .04 *using FDA report demographics	• ODI ≥ 15% improved from baseline ADR: 77.2% fusion: 64.8% *P* = .04 • ODI ≥ 25% improved from baseline ADR: 69.1% (110/159) fusion: 54.9% (40/73) *P* = .04 • ODI improved ≥ 15 points from baseline ADR: 67.8% (108/159) fusion: 54.9% (40/73) *P* = .04 • any improvement in ODI ADR: 91.8% fusion: 84.5% *P* = NR • mean ODI†† *baseline* ADR: 63.4 fusion: 62.7 *P* = .6 *6 weeks*	• mean reduction in VAS from baseline ADR: 39mm fusion: 32mm *P* = .08†† • narcotic use ADR: baseline: 84% successful: 39% unsuccessful: 79% fusion: baseline: 76% successful: 31% unsuccessful: 76% *P* = NR	• any improvement in composite SF-36 *6 weeks* ADR: 72.1% fusion: 56.4% *P* = .02 *3 months* ADR: 86.6% fusion: 70.0% *P* = .004 *6 months* ADR: 80.4% fusion: 75.0% *P* =.2 *12 months* ADR: 81.0% fusion: 76.7% *P* = .3 *18 months* ADR: 79.1% fusion: 74.5% *P* = .3 *24 months* ADR: 79.2% (126/159) fusion: 70.0% (51/73)	• employed *baseline* ADR: 83.5% fusion: 78.1% *P* = NS *24 months*†† ADR: 92.4% fusion: 83.5% *P* = .05 • participating in recreation *baseline* ADR: 42.4% fusion: 49.3% *P* = NS *24 months*†† ADR: 87.4% fusion: 77.3% *P* = .03	• mean flexion-extension: *Post-op:* 7.7° • restoration to normal flexion-extension at implanted level ADR: 93.7% • greater flexion-extension (than baseline) at implanted level ADR: 89.5%

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion
		ADR: 42 fusion: 48 *P* ≤ .02 *3 months* ADR: 37 fusion: 46 *P* ≤ .02 *6 months* ADR: 37 fusion: 42 *P* ≤ .02 *12 months* ADR: 40 fusion: 35 *P* = NR *24 months* ADR: 34.5 fusion: 39.8 *P* = .06		*P* = .09 • would have again ADR: 81% fusion: 69%		

Outcomes are at final f/u and means and percentages are based on intent-to-treat analysis, unless otherwise noted.
NS = no statistically significant difference.
NA = not applicable.
NR = not reported.
ODI = Oswestry Disability Index.
*Clinical success was defined as 1) substantially improved function as measured by ODI, 2) no device failure, 3) no major complications, and 4) no neurologic deterioration. The sponsor considered function to be substantially improved if an individual had an ODI score ≥ 25% higher at 24 months than at baseline. The FDA considered function to be substantially improved if an individual had an ODI score ≥ 15 points higher at 24 months than at baseline. The authors did not report definitions for "major complications" or "neurologic deterioration".
†All intragroup comparisons between follow-up and baseline were significant at the level *P* < .001.
‡ Narcotic use is only reported for patients meeting the four criteria for clinical success.
§ Response options included "satisfied", "somewhat satisfied", "somewhat dissatisfied", and "dissatisfied". Only those responding "satisfied" are included here.
** Clinical success was defined as 1) substantial improvement in function as measured by ODI, 2) device success (no reoperation to modify or remove device nor supplemental fixation), 3) maintenance or improvement on all neurologic evaluations, 4) any improvement in composite SF-36 score, 5) no device migration, 6)

no subsidence, 7) no radiolucency, 8) no loss of disc height, 9) fusion status (no spontaneous fusion in ADR subjects, successful union in fusion subjects), and 10) restoration of 6-20° flexion-extension at L3-4 or L4-5, or 5-20°at L5-S1. The sponsor considered function to be substantially improved if an individual had an ODI score ≥ 15% higher at 24 months than at baseline. The FDA considered function to be substantially improved if an individual had an ODI score ≥ 15 points higher at 24 months than at baseline.

††All intragroup comparisons of ODI, VAS pain, employment, and recreation relative to baseline are significant at the level $P < .0001$. Mean ODI scores are approximated from a graph for time-points other than baseline and 24 months.

Table H2. Efficacy and outcomes other than adverse events or complications for included nonrandomized studies for L-ADR

Author (year)	Range of motion	Occurrence of ASD
Bertagnoli (2006)	NR	NR
Bertagnoli (2006)	ROM at disc level: preoperative: 3° postoperative: 12° *P* = .004	adjacent level disc heights did not change
Cakir (2005)	NR	mean Cobb angle of global lumbar lordosis: preoperative: 53.7° postoperative: 55.9° P = .084 mean Cobb angle of segmental lumbar lordosis: preoperative: 17.9° postoperative: 26.3° P < .001 change in Cobb angle of global lumbar lordosis: decrease: 0 (0%) no change: 4 (13.8%) increase: 25 (86.2%) change in Cobb angle of segmental lordosis: decrease: 2 (6.9%) no change: 23 (79.3%) 4 (13.8%)
Caspi (2003)	average range of segmental motion: 3°-9°	NR
Chung (2006)	mean sagittal ROM per operative segment L5-S1: baseline: 7.1° ≥ 24 months: 11.2° *P* = .008 L4-5: baseline: 11.4° ≥ 24 months: 14.6°	NR

Author (year)	Range of motion	Occurrence of ASD
	P = .006	
Chung (2006)	mean ROM preoperatively: 9.7° 1 year: 13.0° 2 years: 12.7° *P* = .001	NR
David (2007)	mean segmental flexion-extension : 10.1° L4-L5: 12.2° L5-S1: 9.4° mean segmental lateral bending: 4.4° L4-L5: 6.0° L5-S1: 3.9°	The adjacent-level reoperation rate was 2.8% (3/106). Two patients experienced a disc herniation above their index surgical level and were treated successfully with microdiscectomy at 4 and 5 years postsurgery, respectively. One patient developed spinal stenosis 5 years postsurgery and required a decompression and fusion procedure.
Fraser (2004)	NR NR	
Kim (2007)	flexion-extension at level of intervention ± sd: *baseline* L3-4: 4.23° ± 3.12° L4-5: 3.66° ± 2.47° L5-S1: 3.12° ± 1.56° *6 months* L3-4: 7.11° ± 2.53° L4-5: 6.45° ± 3.70° L5-S1: 3.23° ± 1.89° *24 months* all levels: 4.78° L3-4: 6.81° ± 3.76°, *P* = .04 L4-5: 6.09° ± 2.11°, *P* = .03	NR

Author (year)	Range of motion	Occurrence of ASD
	L5-S1: 2.86° ± 1.26°, *P* = .2 no patient or operative factors correlate with ROM except level of surgery high or low ROM doesn't correlate with ODI or VAS pain flexion-extension at adjacent segments: no significant changes, although tendency toward progressive increase in segment above when ADR performed at L5-S1	
Le Huec (2005)	mean flexion-extension L3-4: 7.1° L4-5: 9.4° L4-5 with L5-S1 arthrodesis: 7.4° L5-S1: 7.9°	NR
Leivseth (2006)	rotational ROM 1 year f/u L1-2 (n = 1): 6.4° L2-3 (n = 3): 6.1° L3-4 (n = 7): 7.9° L4-5 (n = 20): 7.1° L5-S1 (n = 23): 3.0° 2 year f/u L1-2 (n = 1): 5.2° L2-3 (n = 3): 8.9° L3-4 (n = 7): 8.0° L4-5 (n = 20): 8.0° L5-S1 (n = 23): 3.5°	NR

Author (year)	Range of motion	Occurrence of ASD
Lemaire (2005)	mean ROM: all patients: • flexion-extension = 10.3° • lateral bending = 5.4° patients with a single L4-L5 replacement: • flexion-extension = 9.7° • lateral bending = 4.6° • axial rotation in was 1.3° asymptomatic volunteers: • flexion-extension = 8.2° • lateral bending = 3.4° • axial rotation in was 1.6°	There were 2 (1.9%) cases of adjacent level degeneration. These two cases could be explained by an underlying functional overload compensating for a kyphosis of the dorsolumbar hinge joint of about 25°, concomitant in one case with the appearance of T12–L3 degenerative lumbar scoliosis after 10 years.
Putzier (2006)	preserved segmental motion with no ASD or spontaneous fusion or heterotopic ossification (HO) but were significantly less satisfied with their outcome compared with those with sponateous ankylosis or fused motion after implant failure 9/53 (17%)	radiographic ASD 9/53 (17%) ASD occurred only in those who had spontaneous fusion with or without heterotopic ossification (HO)
SariAli (2006)	mean vertebral rotation: 5.75° ± 1.8° mean right axial motion: healthy: 1.6°± 2° (0°-5°) ADR at L4-5: 4.3° ± 4.7° mean lateral bending: healthy: 8.2° (1.4°-13°) ADR at L4-5: 9.7° mean flexion: healthy: 2.5° (0°-6°) ADR at L4-5: 4.6° increased mobility healthy: none (definition) ADR: 6° (n = 17, 35%) monolevel: 0° (n = 5, 0%) bilevel: 6° (n = 12, 50%)	NR

Author (year)	Range of motion	Occurrence of ASD
Shim (2007)	Charite preoperatively mean ROM at L4-5: 9.3° (range, 1.7°-20.5°) mean ROM at L5-S1: 8.8° (range, 0.8°-19.5°) postoperatively mean ROM at L4-5: 11.7° (range, 2.6°-23.8°) mean ROM at L5-S1: 11.2° (range, 4.2°-20°) Prodisc preoperatively mean ROM at L4-5: 6.5° (range, 0°-18.4°) mean ROM at L5-S1: 7.7° (range, 0.4°-17.5°) postoperatively mean ROM at L4-5: 11.9° (range, 3.3°-21.8°) mean ROM at L5-S1: 5.6° (range, 0.3°-11.5°)	Charite: (n = 6 of 31 segments, 19.4%) Prodisc (n = 6 of 21 segments, 28.6%)
Siepe (2007)	average flexion/extension all patients: preoperative: 5.9° (0°-19.3°) postoperative: 6.5° (0°-14.5°) L5/S1 replacement (n = 26): 5.9° (0°-14.5°) L4-5 replacement (n = 7): 7.2° (0°-13.2°) bilevel replacement (L4-5/S1, n = 3) mean 13.4° at L4-5, 9.9° at L5/S1 (n = 2); < 1° (n = 1)	NR
Tortolani (2007) Regan (2006)	*Tortolani* change in degrees flexion-extension ± sd early subjects: 1.26° ± 5.66° late subjects: 0.98° ± 6.24° final degrees flexion-extension early subjects: 7.28° ± 4.60° late subjects: 7.58° ± 5.35° postoperative range of motion exceeded the preoperative range in all of the patients with heterotopic ossification	NR

Author (year)	Range of motion	Occurrence of ASD
	Regan mean flexion-extension: preoperative: nonrandomized: 6.02° (4.32°) randomized: 6.60° (5.02°) postoperative (24 months): nonrandomized: 7.28° (4.60°) randomized: 7.58° (5.35°) change: nonrandomized: 1.26° (5.66°) randomized: 0.98° (6.24°)	
Tropiano (2003)	average flexion-extension at ADR level (range): L4-5: 10° (8°-18°) L5-S1: 8° (2°-12°)	no degenerative changes were seen at the levels adjacent to the disc replacement or at the facet joints
Tropiano (2005) Huang (2006)	flexion-extension at ADR level ± sd (range): overall: 3.8°± 2.0° (0°-18°) in subjects with ASD: 1.6°± 1.3° (0°-4°) in subjects without ASD: 4.7°± 4.5° (0°-18°)	overall: 24% in subjects with ROM < 5°: 10 (n = 29, 34.5%) in subjects with ROM > 5°: 0 (n = 13, 0%)
Xu (2004)	†anterior flexion: 9.8° ± 1.7 †posterior extension: 5.1° ± 1.1	intervertebral space stenosis: intervertebral height ± sd‡: preoperative: 0.95 ± 0.10 postoperative: 1.14 ± 0.12 P < 0.01 foramen size ± sd‡: preoperative: 0.92 ± 0.08 postoperative: 1.16 ± 0.07

All outcomes are at final follow-up, unless otherwise noted.
*Mayer and Wiechart also report on a series of patients receiving fusion surgeries for other indications (spondylolisthesis, spinal stenosis, and more), but only DDD patients receiving ADR are included here.
†Measured only in those with ADR performed at L4-5 (n = 25).
‡Measured on in those with ADR performed at L4-5 who had grade I-II spinal stenosis (n = 15).

Table H3. Adverse events and complications from RCTs of L-ADR

Author (year)	Patient Characteristics	Intervention	Complications
Blumenthal (2005) McAfee (2005) Geisler (2004) Statistical Review for Expedited PMA (2004) Summary of Safety and Effectiveness (2004)	• age 18-60 years • symptomatic DDD confirmed by discogram • single level L4-5 (n = 61) or L5-S1 (n = 144) • ODI ≥ 30 • VAS pain ≥ 40 • failed ≥ 6 months conservative treatment • negative for extensive list of medications and diagnoses • able to comply informed consent	• Charite artificial disc via the anterior retroperitoneal approach • ALIF with BAK cages at 1 or 2 contiguous levels	• death ADR: 1 (0.5%) fusion: 0 (0%) P = NR • approach-related* ADR: 20 (9.8%) fusion: 10 (10.1%) NS P = .7 • infection† ADR: 26 (12.7%) fusion: 8 (8.1%) P = NR • nonunion or graft site pain ADR: NA fusion: 27 (27.3%) P = NA • device collapse, subsidence or displacement ADR: 8 (3.9%) fusion: 1 (1.0%) P = NR • additional surgery at index level ADR = 11 (5.4%) fusion = 9 (9.1%) P = 0.4 • catastrophic device failure ADR = 0 (0%) fusion = 0 (0%) P = NA • neurological complications ADR: NR fusion: NR P = .32

			• ossification or calcification ADR: 2 (1.0%) fusion: NA P = NA
Zigler (2007)	• age 18-60 years • symptomatic DDD confirmed by any of several radiographic confirmations • single level L3-S1 • ODI ≥ 40 • failed ≥ 6 months conservative treatment • negative for extensive list of diagnoses • able to comply • informed consent	• Prodisc-L total disc replacement per IDE No. G010133 • circumferential fusion	• death ADR: 0 (0%) fusion: 0 (0%) *P* = NA • clinically significant blood loss (1500cc) ADR: 0 (0%) fusion: 2 (2.7%) *P* = NR • major vessel injury ADR: 0 (0%) fusion: 0 (0%) *P* = NA • retrograde ejaculation ADR: 2 (1.2%) fusion: 0 (0%) *P* = NR • DVT ADR: 2 (1.2%) fusion: 1 (1.3%) *P* = NR • infection ADR: 0 (0%) fusion: 2 (2.7%) *P* = NR • nonunion ADR: NA fusion: 2 (2.7%) *P* = NA • device migration or subsidence ADR:4 (2.5%) fusion:1 (1.3%) *P* = 1

			• loss of disc height or radiolucency ADR: 0 (0%) fusion: 6 (8.0%) *P* = .003 • neurologic damage ADR: 0 (0%) fusion: 0 (0%) *P* = NA • nerve root injury ADR: 0 (0%) fusion: 0 (0%) *P* = NA • spontaneous fusion ADR: 0 (0%) fusion: NA *P* = NA

*Approach-related = venous injury, retrograde ejaculation, ileus, perioperative vein thrombosis, clinically significant blood loss (> 1500cc), incisional hernia, epidural hematoma, dural tear, deep vein thrombosis, arterial thrombosis.
†Infection = superficial wound with incision site pain, other nonwound related, UTI, wound swelling, pulmonary, peritonitis, graft site.

Table H4. Adverse events and complications from nonrandomized trials of L-ADR

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
Caspi (2003)	N = 20 male %: 55 age range: 24–50 years	duration of F/U: 48 months F/U %: NR	• low back pain with or without radicular pain • mean duration of disease = 5 years	• Charite SB III • number of levels: monolevel: n = 17 bilevel: n = 3	• prosthesis migration, n = 2 (10.0%) • laceration of the ureter & arterial thrombosis, n = 1 (5.0%) • spontaneous ossification of the intervertebral anterior ligament, n = 2 (10.0%) • secondary fusion, n = 1 (5.0%)
Cinotti (1996)	N = 46 male%: 46% age: 36 years (27-44)	mean F/U: 3.2 years (2-5) F/U%: NR	• disc degeneration (n = 22) and failed disc excision (n = 24) • Degenerated disc at one or two levels • Exclusion criteria included degenerative changes of the facet joints, disc degeneration adjacent to a fused area, spondylolisthesis	• Charite SB III • single level n = 36 L5-S1 n = 20 L4-L5 n = 14 L3-L4 n = 2 • two levels n = 10 L4-L5, L5-S1 n = 8 • L3-L4, L4-L5 n = 2	•back pain or leg symptoms requiring medication n = 16/46 (35%) •fusion n = 8 (out of 17 with unsatisfactory results) •bilateral radicular pain after surgery n = 1/46 (2%) •anterior dislocation of implant 6 days after surgery n = 1/46 (2%) •perianular ossifications n = 7/46 (15%) •malposition of prosthesis in the sagittal plane n = 3/46 (7%) •collapse into the vertebral bodies of the undersized prosthesis n = 4/46 (9%) •no degenerative changes at adjacent levels in 10 patients with MRI at f/u
David (2007)	N = 108 male %: 41.7 mean age: 36.4 years (23-50)	mean F/U: 13.2 years (10.0-16.8) F/U%: 98.1	• single level DDD with (n = 68) or without (n = 44) radiculopathy • failed ≥ 6 months conservative treatment	• Charite SB III • spinal segments L3-4: n = 1 L4-5: n = 25 L5-S1: n = 82	• index-level with secondary fusion procedure, n = 8/106 (7.5%) • symptomatic facet arthrosis with posterior fusion 5 (4.7%) • continued axial low back pain (nonfacet) with posterior fusion, n = 1 (1.0%) • subsidence with posterior fusion, n = 1 (1.0%) • sciatica with drop foot with prosthesis removal and 360° fusion, n = 1 (1.0%) • index-level with prosthesis replacement, n = 3/106 (2.8%) • early core subluxation with prosthesis replacement, n = 2 (1.9%) • late core failure with prosthesis replacement, n = 1 (1.0%) • index-level without reoperation, n = 8/106 (7.5%) • partial device ossification, n = 4 (3.8%) • complete ossification, spontaneous fusion, n = 2

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
					(1.9%) • subsidence with spontaneous fusion, n = 1 (1.0%) • subsidence with no spontaneous fusion, n = 1 (1.0%)
Lemaire (2005)	N = 107 †male %: 41 †mean age: 39.6 years (24-51)	mean F/U: 11.3 years (10.0-13.4) F/U %: 93.4 (100/107)	• DDD with intractable low back pain • failed nonsurgical treatment • mean duration of disease = 6 years	• Charité SB III • number of levels: monolevel: n = 54 bilevel: n = 45 trilevel: n = 1 • spinal segment: L3-4: n = 6 L4-5: n = 69 L5-S1: n = 72	• vessel laceration, n = 2 (1.9%) • retrograde ejaculation in males, n = 1 (n = 44, 2.3%) • acute leg ischemia, n = 1 (0.9%) • subsidence, n = 2 (1.9%) • loss of disc height, n = 1 (0.9%) • additional surgery at index level, n = 5 (4.7%) • neurologic damage, n = 1 (0.9%) • ossification, n = 3 (2.8%) • arthritis, n = 4 (3.7%)
Punt (2008)	N = 75 male %: 45% age: 42 years (30-51)	F/U: at least 1 year F/U %: NR	• serious and constant back and leg pain in DDD	• Charite SB III L2-L3 n = 1 L3-L4 n = 3 L4-L5 n = 22 L5-S1 n = 30 L3-L4, L5-S1 n = 1 L4-L5, L5-S1 n = 16 L3-L4, L4-L5, L5-S1 n = 1 L2-L3, L4-L5, L5-S1 n = 1	late complications : • subsidence n = 39/75 (52%) • disc prosthesis too small n = 24/75 (32%) • adjacent disc degeneration n = 36/75 (48%) • degenerative scoliosis n = 11/75 (15%) • facet joint degeneration on CT scan n = 25/75 (33%) • anterior migration n = 6/75 (8%) • posterior migration n = 2/75 (3%) • breakage metal wire n = 10/75 (13%) • wear n = 5/75 (7%) • severe osteolysis n = 1/75 (1%) • subluxation PE core n = 1/75 (1%)
Putzier (2006)	N = 71 (84 segments) male %: 38 (after loss to f/u) age 44 years (30-59) (after loss to f/u)	mean F/U: 17.3 years (14.5-19.2) F/U%: patients 74.6% (53/71) segments 75.0% (63/84)	• DDD at 1 or 2 levels • moderate to severe osteochondrosis • some with previous disc surgery or history of spondylolisthesis	• Charite Type I, II or III • Type I: n = 15 Type II: n = 22 Type III: n = 16 • number of levels monolevel: n = 43 bilevel: n = 10 • spinal segments L3-4: n = 2 L4-5: n = 25 L5-S1: n = 16	• spontaneous fusion radiographically, n = 4 (8.3%) • fusion secondary to implant failure (n = 7) or pain (n = 5) n = 12 (23%) • implant failure requiring secondary operation with instrumentation , n = 5 (9.4%) subsidence 2 implant fracture 1 implant dislocation 1 pain with progressive degeneration 1

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
				L4-S1: n = 10	
Xu (2004)	N = 34 male %: 59 mean age: 41.1 years (21-65)	mean F/U: 18.6 months (3-28) F/U %: 100	• DDD	• Charite SB III • number of levels: monolevel: n = 27 bilevel: n = 7 • spinal segment: L3-5: n = 2 L4-5: n = 18 L5-S1: n = 7 L3-4, L4-5: n = 1 L4-5, L5-S1: n = 6	• laceration in iliac vein, n = 1 (2.9%) • anterior subluxation of the inferior endplate, n = 1 (2.9%) • mild low back pain after operation n = 2 (5.9%) • depression and sensation of heat and pain in waist, n = 1 (2.9%)
Zeegers (1999)	N = 50 male %: 40% age: 43 years (24-59)	Mean F/U: 2 years F/U%: 92% (n = 46/50)	• medically refractory lumbar discopathies • exclusion criteria included predominant symptoms or deficits in the legs related to the involvement of the nerve roots • failed conservative management	• Link SB Charite • 75 disc prostheses in 50 patients One level n = 29 Two levels n = 18 Three levels n = 3 • operated level include: L5-S1 n = 8 L4-L5 n = 16 L4-S1 n = 12 L3-S1 n = 5 L3-L5 n = 5 • L5-S1 and L3-L4 n = 1	•52 complications reported in 30/46 patients at 2 year F/U including: •dysaesthesia of legs n = 7 (3 permanent) •paresis/muscle weakness n = 1 •cramps in legs n = 2 •painful/numb scar n = 5 •haematoma n = 12 •retroperitoneal haematoma n = 1 •visceral dysfunction n = 1 •abdominal pain n = 1 •low back or leg pain n = 5 •sympathectomy effect n = 7 (4 permanent) •disturbance of miction n = 1 •aortal lesion at removal of prosthesis n = 1 •infection of urinary tract n = 4 •impotence, retrograde ejaculation n = 1 •deep venous thrombosis n = 1 •malposition of prosthesis n = 2 (1 permanent) •reoperations for complications: 7 surgeries in 3/50 patients • all reoperations: 24 reoperations in 12/50 patients
Bertagnoli (2002)	N = 108 male%: 54 age: 41.5 years (34-65)	duration of F/U: range of 3 months to 2 years F/U%: NR	• disc degeneration (n = 67), failed disc surgery syndrome (n = 35), transition zone syndrome (TZS, n = 6) • exclusion criteria included severe osteoporosis, physiological	• Prodisc II • 134 prosthetic discs replaced in 108 patients L5/S1 n = 61 L5/L6 n = 3	• residual leg pain or back pain including facet joint pain n = 9/108 (8%) • analgesics required more than 2 weeks n = 45/108 (42%); of whom 12 required regular analgesics 6 months-1 year, and 33 only occasionally • systemic septicemia n = 1/108 (1%)

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			dysfunction, hisotry of previous disc infection, severe posterior element pathologies, fracture of the vertebra, tumor	L4/L5 n = 31 L3/L4 n = 7 L2/L3 n = 3 L4/L5 and L5/S1 n = 10 L2/L3 and L4/L5 n = 1 L3/L4, L4/L5 and L5/S1 n = 2	
Bertagnoli (2005)	N = 29 male%: 60% (15/25) age: 49 years (30-60) smokers: 24%	median F/U: 31 months (25-41) F/U%: 86% (n = 25/29)	• average duration of pain 70 months (9-210) • prior posterior surgery in 68% (laminoforminotomies, laminectomies) • age 18-60 years • disabling and recalcitrant discogenic low back pain • minimal radicular pain secondary to multilevel lumbar disc disease from L1 to S1 • complete 2 year follow-up data included • exclusion criteria included spinal stenosis, osteoporosis, prior fusion surgery, chronic infections, metal allergies, pregnancy, facet arthrosis, inadequate vertebral endplate size, neuromuscular disease, pregnancy, Workers' Compensation, spinal litigation, body mass index > 35, and/or any isthmic or degenerative spondylolisthesis > Grade 1 • failed conservative treatment for a minimum of 9 months	• Prodisc • triple segmental L3-L4, L4-L5, L5-S1 n = 10 • double segmental: L4-L5, L5-S1 n = 8 L3-L4, L4-L5 n = 5 L2-L3, L4-L5 n = 1 L3-L4, L5-S1 n = 1	• partial implant subsidence n = 1/25 (4%) • anterior extrusion of a polyethylene component n = 1/25 (4%) • no other loosenings, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries (0%) • subcutaneous sterile inflammatory suture reaction n = 1/25 (4%) • temporary retrograde ejaculation n = 1/25 (4%) • no cases of vascular injury, ureteral injury, or other neurologic injury (0%)
Bertagnoli (2005)	N = 118 male%: 45 (n = 47/104) median age: 47.5 years smokers: 31%	median F/U: 31 months (24-45) F/U%: 88% (n = 104/118)	• age 18-60 years • average duration of pain 104 monhts (6-400) • prior posterior surgery in 57% • disabling discognic low back pain • with or without radicular	• Prodisc • Level of surgery L5-S1 n = 80 L4-L5 n = 17 L3-L4 n = 7	• no device-related complications: no loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries • retroperitoneal hematomas n = 2/104 (2%) • single subcutaneous hematoma n = 1/104 (1%) • temporary retrograde ejaculation n = 1/104 (1%)

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			symptoms • complete 2 year follow-up data included • DDD • Exlusion criteria included: spinal stenosis, osteoporosis, prior fusion surgery, chronic infections, metal allergies, pregnancy, facet arthrosis, inadequate vertebral endplate size, more than one level of spondylosis, neuromuscular disease, pregnancy, Worker's Compensation, spinal litigation, body mass index > 35, and/or any isthmic or degenerative spondylolisthesis > Grade 1 • Failed conservation treatment for a minimum of 9 months		• no vascular injury, ureteral injury or neurologic injury (0%) • persistent leg pain following application of an L5-S1 implant n = 1/80 (13%)
Cakir (2005)	N = 29 male %: 34 mean age ± sd: 40.8 years ± 6.4 (29-56)	mean F/U: 15.3 months (12-35) F/U%: 100	• symptomatic DDD (n = 21) or postdiscectomy syndrome (n = 8) • low back pain ≥ 12 months • failed ≥ 6 months conservative treatment	• Prodisc • number of levels: monosegmental: all	• loosening, subsidence, migration or spontaneous fusion, n = 0 (0%)
Chung (2006)	N = 38 †male %: 44.4 †mean age: 43 years (25-58)	mean F/U: 37 months (25-42) F/U %: 94.7	• 18-60 years of age • symptomatic DDD at 1 or 2 levels • primary complaint of back pain • disc height ≥ 4mm • ODI ≥ 40 • failed ≥ 6 months conservative treatment	• Prodisc II • number of levels monolevel: n = 25 bilevel: n = 11 • spinal segments L3-4: n = 2 L4-5: n = 24 L5-S1: n = 25	• major vein injury, n = 2/36 (5.6%) • increased radicular pain (resolved by 6 weeks), n = 3/36 (8.3%)
Hannibal (2007)	N = 59 male %: 64% mean age: 39 years	F/U: 2 years F/U %: 92% (n = 45/59)	• minimum 2 years follow-up • age 18-60 years • failed conservative treatment for at least 6 months	• Prodisc II • 1 level replacement (n = 25/27 at F/U) L5-S1 n = 17	• complications not reported

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			• minimum ODI score of 40 • no more than 1 or 2 levels of lumbar DDD • exclusion criteria included severe facet arthropathy, compromised vertebral bodies, fusion patients, others not specified	L4-L5 n = 10 • 2 level replacement (n = 29/32 at F/U) L4-L5, L5-S1 n = 29 L3-L4, L4-L5 n = 3	
Kim (2007)	N = 32 male%: 40% age: 39 years (24-60)	mean F/U: 30 months (24-41) F/U %: 94% (n = 30/32)	• intractable discogenic pain • DDD from L3 to S1 • age range 18-60 years • inadequate conservative treatment for minimum of 6 months • exclusion criteria included spinal stenosis, advanced facet arthrosis, osteoporosis, prior fusion, obesity, instability, deformity, chronic infection, pregnancy, improvement in back pain after facet block	• Prodisc II • 1 level replacement n = 19 • 2 level replacement n = 11	• no radioluent or sclerotic lines • no disc narrowing, instability, or change in facet configuration at adjacent levels • other complications not reported
Mayer, (2002)‡	N = 26 ADR male %: 42 mean age (range): 44 years (25.2-65)	average F/U: 6 months (3-18) F/U%: NR	• DDD with discogenic lower back pain	• Prodisc II • spinal segment L5-S1: n = 24 L5-6: n = 2	• L5 root irritation, n =1 (3.8%) • extrusion of the polyethylene inlay, n =1 (3.8%)
Siepe (2006) population may overlap with Siepe 2007	N = 192 male%: 33% for n = 92 age: 43 years (22-66) for n = 92	mean F/U: 34.2 months (24-62) F/U %: 48% (n = 92/192)	• DDD with or without modic changes • Exclusion criteria included central or lateral spinal stenosis, facet joint arthrosis, symptomatic facet joint problems, spondylolysis, spondylolisthesis, spinal instability, major deformity/curvature deviations, metabolic bone disease, previous operation with severe scarring and radiculopathy, compromised vertebral body, previous/latent infection, metal allergy, spinal	• Prodisc II • number of levels monolevel n = 77 bilevel n = 14 three levels n = 1 • spinal segment L5-S1 n = 57 L5-L6 n = 5 L4-L5 n = 12 L4-L5-S1 n = 13 L2-L3 n = 1 L5-L6-S1 n = 1 L4-S1 n = 2	• overall complications : n = 18/92 (20%) • retrograde ejaculation n = 2 (2%) • sympathectomy related dysesthesia n = 1 (1%) • DVT + LAE + lysis n = 1 (1%) • superficial wound healing impaired n = 1 (1%) • extraforaminal disc protrusion following TDR n = 1 (1%) • neuropathy L5 n = 1 (1%) • heterotopic ossification n = 1 (1%) • primary suboptimal implantation n = 1 (1%) • inlay dislocation n = 1 (1%) • implant subsidence n = 2 (2%) • segmental hyperlordosis persisting n = 1 (1%) • persisting facet joint problems n = 2 (2%)

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			tumor, post-traumatic segments	L3-L4-L5-S1 n = 1	• secondary spinal canal stenosis n = 1 (1%) • adjacent segment disc herniations leading to reop n = 2 (2%) • reoperations required at index level n = 8 (9%)
Siepe (2007) population may overlap with Siepe 2006	N = 99 male %: NR mean age: NR	F/U: ≥ 12 months F/U %: NR	• DDD without accompanying pathologies or transitional vertebrae • low back pain > sciatica • failed conservative treatment	• Prodisc II • number of levels monolevel: n = 79 bilevel: n = 20 • spinal segment L4-5: n = 42 L5-S1: n = 77	• overall : n = 17/99 (17%) • sympathectomy related dysesthesia n = 1 (1%) • L5 neuropathy n = 2 (2%) • hematoma of the abdominal wall n = 1 (1%) • superior hypogastric plexus lesion n = 2 (2%) • heterotopic ossification n = 1 (1%) • inlay dislocation n = 1 (1%) • persisting facet joint problems n = 2 (2%) • primary suboptimal implantation n = 1 (1%) • segmental hyperlordosis with persisting problems n = 1 (1%) • adjacent segment disc herniation n = 2 (2%) • secondary spinal canal stenosis (same segment) n = 1 (1%) • superficial wound healing imipaired n = 1 (1%) • seroma, retroperitoneal n = 1 (1%) • overall reoperations n = 8 (8%)
Tropiano (2003)	N = 53 male %: 34 mean age: 45 years (28-67)	F/U: 1.4 years (1-2) F/U %: 100	• DDD (n = 33) or failed spine surgery (n = 20) • 6 months severe back pain • failed conservative treatment	• Prodisc II • number of levels monolevel: n = 40 bilevel: n = 11 trilevel: n = 2 • spinal segment L3-4: n = 4 L4-5: n = 26 L5-S1: n = 38	• postoperative vertebral body fracture n = 1 (1.9%) • implant malposition n = 2 (3.8%) • persistent radicular pain without evident neural compression n = 2 (3.8%) • reoperation n = 3 (5.7%)
Tropiano (2005)§ Huang (2006)§	N = 64 †male %: 54.5% †mean age: 46 years (25-65)	mean F/U ± sd (range): 8.7 years ± 1 (6.9 – 10.7) F/U %: overall: 85.9% with complete ASD and ROM data: 65.6%	• symptomatic DDD confirmed by any of several radiographic criteria • discogenic back pain • failed ≥ 6 months conservative treatment • no facet arthrosis, central or lateral recess stenosis, osteoporosis, sagittal or coronal plane deformity, absence of posterior elements, sequestrated	• Prodisc I • number of levels monolevel: n = 35 bilevel: n = 17 trilevel: n = 3 • spinal segment L3-4: n = 8 L4-5: n = 43 L5-S1: n = 28	surgical complications, n = 5 (7.8%) including: • DVT, n = 1 (1.6%) • iliac vein laceration, n = 1 (1.6%) • transient retrograde ejaculation, n = 1 (1.6%) • incisional hernias, n = 2 (3.1%) other complications included: • migration, n = 0 • transiently increased radicular pain, n = 5 (7.8%) • mechanical failures, n = 0 (0%) • radiolucency or substantial loss of disc height 0 (0%) • end-plate penetration

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			herniated nucleus		≤ 2mm, n = 15 (23.4%) > 2mm, n = 2 (3.1%)
Shim (2007)	N = 61 Charite: n = 33 Prodisc: n = 24 (data available on 57 patients followed) male %: 52.6 Charite: 51.5 Prodisc: 54.2 mean age Charite: 44.4 years (31-63) Prodisc: 44 years (31-66)	mean F/U Charite: 41 months (36-48) Prodisc: 38 months (36-40) clinical F/U %: 93 (57/61) radiographic F/U %: 91.2 (52/57)	• DDD • low back pain • failed conservative treatment ≥ 6 months • disc herniation and significant space narrowing	• Charite or Prodisc • number of levels monolevel: n = 50 bilevel: n = 7 • spinal segment L4-5: n = 36 L5-S1: n = 14 L4-5/L5-S1: n = 7	• tear of the great vein during surgical approach Charite: n = 1 (3%) Prodisc: n = 1 (3.7%) • subsidence Charite: n = 1 (3%) Prodisc: n = 2 (7.4%) • incisional hernia Charite: n = 1 (3%) Prodisc: none
Fraser (2004)	N = 28 AcroFlex I: n = 11 AcroFlex II: n = 17 male%: 50 mean age: 41years (30-54)	duration of F/U: 24 months F/U %: NR	• 30-55 years of age • symptomatic DDD, with or without leg symptoms, confirmed by discography • failed ≥ 6 months conservative treatment • consenting, able to f/u • no previous lumbar surgery • lumbosacral angle not too steep • no significant lateral or recess spinal stenosis • no spondylolisthesis, systemic disease that would limit ability to assess in f/u, morbid obesity, EtOH or drug abuse, structural scoliosis • < 3 positive Waddell signs • no major psych disorder or other condition limiting ability to comply	• AcroFlex • number of levels monolevel: n = 24 bilevel: n = 4 • spinal segments L4-5: n = 9 L5-S1: n = 23	• pulmonary embolism, n = 1 (3.6%) • retrograde ejaculation, n = 1 (3.6%) • nerve root irritation, n = 2 (7.4%) • autofusion, n = 1 (3.6%) • partial anterior disc expulsion, n = 1 (3.6%) • minor anterior polyolefin tear, n = 7 (25.0%) • large anterior polyolefin tear, n = 3 (10.7%) • revision surgery, n = 8 (28.6%)

Author (year)	Demographics*	Follow-up	Patient Characteristics	Type of ADR	Complications
			• no current litigation		
Le Huec (2005)	N = 64 male %: 39 mean age: 44 years (20-60)	mean F/U: 18 months (12-26) F/U%: 100	• chronic back pain • failed ≥ 12 months conservative treatment • received medical and rheumatologic follow-up and rehabilitation physiotherapy	• Maverick • number of levels monolevel: all • spinal segment: L5-S1 (n = 35) L4-5 (n = 27) L3-4 (n = 2)	• visceral lesion, n = 1 (1.6%) • superficial infection, n = 1 (1.6%) • spinal pain in other than the lumbar region 3 (4.7%) • postoperative root pain, n = 4 (6.3%) • posterior facet infiltration, n = 17 (26.6%) • minor intraoperative complications due to surgical approach, n = 11 (17.2%) • device migration axially 3–5 mm, n = 5 (7.8%) • subsidence stable at 1 year, n = 3 (4.7%) • heterotopic ossification, n = 3 (4.7%)

*Demographics are before loss to follow-up, unless otherwise noted.
†Demographics reported in this study are after loss to follow-up.
‡ Mayer and Wiechart also report on a series of patients receiving fusion surgeries for other indications (spondylolisthesis, spinal stenosis, and more), but only DDD patients receiving ADR are included here.
§Tropiano et al and Huang et al studied the same patients. Tropiano et al evaluated whether gender, age, previous surgery or multiple levels were associated with clinical and radiographic outcomes. Huang et al reported the frequency of ASD and whether it was associated with ROM or clinical outcome. Not all patients in the entire series reported by Tropiano et al had complete ASD and ROM data to be included in Huang et al's analysis, but distribution of age, gender, number of levels and segment treated were similar in both reports.

Table H5. Efficacy and outcomes other than adverse events or complications for included RCTs for C-ADR

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
Bryan Panel meeting 2007 (24 month assessments)	• Over success at 24 months: ADR n = 129/160 (80.6%); ACDF n = 99/140 (70.7%) • Subsequent surgical interventions: ADR n = 6/242 (2.5%); ACDF n = 9/221 (4.1%) • Physician global assessment excellent/good: ADR 93.8%; ACDF 89.3%	Neurological improvement: Successes: ADR n = 150/160 (93.7%); ACDF n = 128/140 (91.4%) Failures: ADR n = 10/160 (6.3%); ACDF n = 12/140 (8.6%) NDI score successes: ADR n = 134/160 (83.7%); ACDF n = 106/140 (75.7%)	Neck or arm pain n = 115/242 (47.5%); n = 96/221 (43.4%) Arm pain score (mean): ADR 19.3 (n = 159); ACDF 22.5 (n = 140)	• SF-36 PCS mean improvement from baseline: ADR 14.4; ACDF 14.5 • SF-36 MCS mean improvement from baseline: ADR 8.1; ACDF 7.3 • SF-36 PCS success rate: ADR 90.6%; ACDF 85.5% • SF-36 MCS success rate: ADR 72.5%; ACDF 69.8% • Patient global assessment (completely recovered or much improved): ADR 92.4%; ACDF 86.4%	• Median time to return to work: ADR 48 days; ACDF 61 days	Angular motion above treated segment: ADR 9.1°; ACDF 8.9° Angular motion below treated segment: ADR 6.4°; ACDF 6.2°	•
Mummaneni (2007)	• neurological status: motor function, sensory function, and deep tendon reflexes; maintenance or improvement in all three indicators is success ADR: 92.8% (207/223) at 24 months ACDF: 84.3% (167/198) at 24 months *P* = .005 failures ADR: 223-207 = 16	**NDI** *preoperative* ADR: 55.7 ACDF: 56.4 *6 weeks* ADR: 27.1 ACDF: 32.1 *P* = .0014 *3 months* ADR: 20.7 ACDF: 26.8 *P* = .0004 *6 months* ADR: 21.7 ACDF: 24.5 *P* = .0835	**Neck pain (VAS) †** *preoperative* ADR: 68 ACDF: 69 *6 weeks* ADR: 16 ACDF: 20 *P* = .0395 *3 months* ADR: 13 ACDF: 16 *P* = .0148 *6 months* ADR: 16 ACDF: 17 *P* = .3058	• NR	• work status *Preoperative* ADR: 66% ACDF: 63% *24 months* ADR: 75.4% ACDF: 74.7% • time to return to work (median): ADR: 45 days ACDF: 61 days *P* = 0.094 (log-rank test) *P* = 0.022 (Wilcoxon test)	data not included; NR	• reoperations for adjacent-segment disease disc: n = 3 (2 with symptoms at adjacent level above and 1 with symptoms at adjacent level below the arthroplasty site) ACDF: n = 11 (3 with symptoms at adjacent level above, 7 with symptoms at adjacent level below, 1 with

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
	ACDF: 198-167 = 31 • overall success (from NDI score, no serious implant associated or implantation procedure adverse event, no second surgery classified as a failure) 12 months ADR: 77.6% (206/265) ACDF: 66.4% (151/228) *P* = .0040 24 months ADR: 79.3% (177/223) ACDF: 67.8% (134/198) *P* = .0053 • NDI success only = ≥ 15 point improvement 12 months ADR: 82.4% (218/265) ACDF: 79.4% (181/228) *P* = .215 24 months ADR: 83.0% (185/223) ACDF: 80.1%	*12 months* ADR: 20.6 ACDF: 23.4 *P* = .0897 *24 months* ADR: 19.3 ACDF: 22.4 *P* = .0827 **SF-36 PCS †** *preoperative* ADR: 34 ACDF: 35 *6 months* ADR: 44 ACDF: 43 *P* = .0797 *12 months* ADR: 44 ACDF: 43 *P* = .0788 *24 months* ADR: 45 ACDF: 44 *P* = .1744 **SF-36 MCS†** *preoperative* ADR: 42 ACDF: 42 *6 months* ADR: 49 ACDF: 49 *P* = .5480 *12 months*	*12 months* ADR: 15 ACDF: 19 *P* = .0350 *24 months* ADR: 15 ACDF: 16 *P* = .3781 **Arm pain (VAS) †** *preoperative* ADR: 59 ACDF: 63 *6 weeks* ADR: 13 ACDF: 13 *P* = .5990 *3 months* ADR: 11 ACDF: 12 *P* = .3191 *6 months* ADR: 15 ACDF: 13 *P* = .6752 *12 months* ADR: 16 ACDF: 17 *P* = .2485 *24 months* ADR: 13 ACDF: 14 *P* = .4812 (composite score from multiplying intensity				symptoms both above and below the fusion)

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
	(159/198) *P* = .282	ADR: 50 ACDF: 48 *P* = .0529 *24 months* ADR: 49 ACDF: 50 *P* = .5621	and duration scores, 0-100)				
Nabhan (2007)	• NR •	NR	**neck pain (VAS)** *preoperative* disc: 6.0 +/- 1.2 ACDF: 6.2 +/- 0.9 *1 weeks* disc: 3.5 +/- 0.9 ACDF: 2.9 +/- 0.7 *3 weeks* disc: 3.4 +/- 0.6 ACDF: 2.2 +/- 0.7 *6 weeks* disc: 2.8 +/- 0.4 ACDF: 2.0 +/- 0.5 *12 weeks* disc: 2.4 +/- 0.5 ACDF: 1.8 +/- 0.6 *24 weeks* disc: 2.3 +/- 0.6 ACDF: 1.7 +/- 0.5 *52 weeks* disc: 1.8 +/- 0.3 ACDF: 2.0 +/- 0.3 *52 weeks change from preop* disc: *P* = .001 ACDF: *P* = .001	• NR	• NR	[mean (sd) for disc (n = 19) and ACDF (n = 21)] **mediolateral translation (mm)** *Postoperative 1 week* disc: 0.70 (0.9) ACDF: 0.25 (0.30) *3 weeks* disc: 0.40 (0.16) ACDF: 0.12 (0.06) disc: *P* = .001 compared to 1 week ACDF: *P* = .03 compared to 1 weeks *6 weeks* disc: 0.30 (0.13) ACDF: 0.07 (0.018) *12 weeks* disc: 0.40 (0.18) ACDF: 0.06 (0.05)	• None at one year follow-up

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
			arm pain (VAS) *preoperative* disc: 7.3 +/- 1.0 ACDF 7.2 +/- 1.5 *1 weeks* disc: 1.4 +/- 0.4 ACDF: 1.4 +/- 0.3 *3 weeks* disc: 1.5 +/- 0.4 ACDF: 1.7 +/- 0.4 *6 weeks* disc: 1.4 +/- 0.2 ACDF 1.7 +/- 0.3 *12 weeks* disc: 1.3 +/- 0.3 ACDF: 1.5 +/- 0.3 *24 weeks* disc: 1.5 +/- 0.3 ACDF 1.7 +/- 0.3 *52 weeks* disc: 1.0 +/- 0.2 ACDF: 1.2 +/- 0.3 *change from 0 to 52 weeks* disc: *P* = .00 ACDF: *P* = .00			*24 weeks* disc: 0.33 (0.17) ACDF: 0.06 (0.09) *52 weeks* disc: 0.39 (0.17) ACDF: 0.06 (0.05) *from 6 to 52 weeks:* disc: *P* = .07 *from 3 to 52 weeks:* ACDF: *P* = .35 **Craniocaudal translation (mm)** *Postoperative 1 week* disc: 0.50 (0.15) ACDF: 0.30 (0.14) *3 weeks* disc: 0.27 (0.10) ACDF: 0.16 (0.05) disc *P* = .001 ACDF *P* = .04 *6 weeks* disc: 0.23 (.012) ACDF: 0.13 (0.1) *12 weeks* disc: 0.30 (0.1) ACDF: 0.06	

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
						(0.06) *24 weeks* disc: 0.27 (0.13) ACDF: 0.06 (0.03) *52 weeks* disc: 0.26 (0.13) ACDF: 0.06 (0.06) *from 6 to 52 weeks:* disc *P* = .44 *from 3 to 52 weeks:* ACDF *P* = .95 **Anteroposterior translation (mm)** *Postoperative 1 week* disc: 1.7 (0.73) ACDF: 0.42 (0.35) *3 weeks* disc: 1.1 (0.4) ACDF: 0.13 (0.05) disc *P* = .001 ACDF *P* = .01 *6 weeks* disc: 0.70 (0.38) ACDF: 0.2 (0.05) *12 weeks*	

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
						disc: 0.58 (0.3) ACDF: 0.11 (0.09) *24 weeks* disc: 0.56 (.042) ACDF: 0.07 (0.05) *52 weeks* disc: 0.66 (0.42) ACDF: 0.07 (0.05) *from 6 to 52 weeks* disc: *P* = .37 *from 3 to 52 weeks* ACDF: *P* = .25 **XYZ vector (segmental motion) translation (mm)** *Postoperative 1 week* disc: 2.3 (1.1) ACDF: 0.60 (0.2) *3 weeks* disc: 1.2 (0.37) ACDF: 0.25 (0.4) *6 weeks* disc: 1.1 (0.32) ACDF: 0.22 (0.30)	

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
						12 weeks disc: 0.74 (0.30) ACDF: 0.14 (0.27) *24 weeks* disc: 0.8 (0.41) ACDF: 0.13 (0.42) *52 weeks* disc: 0.8 (0.41) ACDF: 0.1 (0.3)	
Sun Peng-Fei (2008)	• NR	**JOA** *preoperative* ADR: 8.6 ACDF: 9 *postoperative* ADR: 15.8 ACDF: 16.2 *rate of improvement (ns)* ADR: 70% (8/12?) ACDF: 72% (9/12?) **Odom criteria** ADR*:* excellent, n = 6 good, n = 3 fair, n = 3 rate of excellent and good, 75% ACDF: excellent, n = 7	• NR •	NR •	NR averag	e in degrees (sd) *preoperative* ADR: 12.8 (5.7) ACDF: 11.9 (5.8) *postoperative* ADR: 11.2 (3.9) ACDF: 11.4 (4.9) *P* > .05	• NR

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
		good, n = 3 fair, n = 2 rate of excellent and good, 83% *P* > .05					
Prodisc-C FDA report (2007)	4 point success measure using sponsor's NDI criteria: • NDI ≥ 20% improvement • Neurological success, i.e. motor, sensory and reflexes are maintained or improved • No revisions, removals, reoperations, or supplemental fixation at the index level • No adverse events related to the implant or implantation ADR, n = 78, 77.2% (78/101) ‡ ACDF, n = 75, 74.3% (75/101) ‡ 4 point success measure using FDA's NDI criteria: • NDI ≥ 15 point improvement	**NDI** (table 13) NDI ≥ 20% improvement at 24 months ADR, n = 84/99 (84.9%) ACDF, n = 79/92 (85.9%) P = .6561 NDI ≥ 15 points improvement at 24 months ADR, n = 79/99 (79.8%) ACDF, n = 72/92 (78.3%) P = .4665 **SF-36** (table 23) improvement ≥ 15 points at 24 months *PCS* ADR, n = 51/99 (51.5%) ACDF, n = 31/90 (34.4%) *MCS* ADR, n = 36/99 (36.4%)	**VAS** (tables 25, 26, 27, 28) > 20mm improvement in pain intensity at 24 months *neck* ADR, n = 77 (78.6%) ACDF, n = 68 (75.6%) *arm* ADR, n = 70 (71.4%) ACDF, n = 69 (76.7%) >20 mm improvement in pain frequency at 24 months *neck* ADR, n = 75 (76.5%) ACDF, n = 71 (78.9%) *arm* ADR, n = 70 (71.4%) ACDF, n = 68 (76.4%)	**VAS** (table 29) patient satisfaction scores 80-100 mm at 24 months ADR, n = 67 (70.5%) ACDF, n = 60 (68.2%) Patients asked whether they would have same surgery again (figure 3): ADR, 86% ACDF, 81% ns	Employed currently (figure 4): ADR, 83% ACDF, 80% ns	ROM successes (≥ 4° of flexion/extension or maintenance of motion relative to baseline) in ADR patients: n = 81/96 (84.4%)	• NR

Author (year)	Overall success	Functional outcome	Pain relief	Patient satisfaction and QoL	Employment	Range of motion	Rate of ASD
	• Neurological success, i.e. motor, sensory and reflexes are maintained or improved • No revisions, removals, reoperations, or supplemental fixation at the index level • No adverse events related to the implant or implantation ADR: n = 73, 72.3% (73/101) ‡ ACDF: n = 69, 68.3% (69/101) ‡	ACDF, n = 38/90 (42.2%)					

ACDF = anterior cervical decompression and fusion.
HO = heterotopic ossification.
NDI = Neck Disability Index.
NR = not reported.
SF-36 = Short Form 36.
VAS = visual analog scale.
*In the Bryan device study, the data reported is interim data for that portion of the study population with 24 months of follow-up at the time of the report. Of the original group, 160 of 168 ADR and 140 of 165 ACDF patients had passed the 24 month point in the course of their treatment.
†In the Mummaneni study, SF-36 PCS and MCS, neck pain and arm pain (VAS) scores are estimated from graphs.
‡The denominator used for outcomes reflects all those patients with known outcomes at month 24.

Table H6. Efficacy and outcomes other than adverse events or complications for included nonrandomized studies for C-ADR

Author (year)	Range of motion	Occurrence of ASD
Amit (2007)	mean Cobb angle (C2-7): 14.6° (range, 6°-22°) mean ROM in flexion-extension: 8.4° (range, 3°-21°)	NR
Bertagnoli (2005)	ROM = 11.5° at 12 month f/u	no spontaneous fusions occurred at the affected or adjacent levels height of adjacent discs were not significantly changed
Bertagnoli (2005)	ROM = 10° at 12 month f/u showed a 240% improvement from preoperative condition	no spontaneous fusions occurred at the affected or adjacent levels
Bryan (2002)	with 1 year f/u (n = 43): =/> 2° in 38 patients, 88%; = 1° in 4 patients; not interpretable in 1 patient; average 8° ± 5° with 2 years f/u (n = 10): =/> 2° in 10 patients, 100%; average 11° ± 5°	no evidence of spondylotic bridging
Duggal (2004)	measured in a subset of 16 patients: mean sagittal ROM = 7.8°	symptomatic disc herniation adjacent to prior fusion (not related to ARD) 11.5% (n = 3)
Fong (2006)	data available for 9 patients mean ROM = 8° mean flexion = 4° mean extension = 4°	NR
Goffin (2003)	single level study: 6 month: average 8.3° ± 4.5° 12 month: average 7.9° ± 5.3° 24 month: average 9.0° ± 4.9° bilevel study: 6 month: average 7.3° ± 4.1° 12 month: average 7.4° ± 5.1°	single level study: 1 disc herniation at adjacent level causing radiculopathy – symptomatic ASD bilevel study: 1 residual foraminal stenosis

Author (year)	Range of motion	Occurrence of ASD
Goffin (2002)	with 6 months f/u (n = 57): =/> 2° in 53 patients, 93%; not interpretable in 4 patients; average 9° ± 4° with 12 months f/u (n = 24): =/> 2° in 21 patients, 88%; = 1° in 2 patients; not interpretable in 1 patient; average 9° ± 6°	NR
Jollenbeck (2004)	3 month f/u (n = 32): mean ROM = 7.8° (range, 2-11°) 6 month f/u (n = 21): mean ROM = 7.3° (range, 2-10°) 12 months f/u (n = 13): mean ROM = 8.1° (range, 2-11°)	no evidence for the formation of new osteophytes of the treated or adjacent segments
Kim (2007)	at 6 month f/u: mean C2-7 ROM = 52.56° mean FSU ROM = 14.55° mean shell ROM = 10.31°	ROM of upper adjacent vertebra showed hypermobility at 3 months and returned to preoperative ROM at 6 months
Lafuente (2005)	mean 7.72° (SD 4.5°)	bony ankylosis 4.3% (n = 2)
Leung (2005)	disc movement of < 2° on flexion-extension x-rays 11% (10/90) at 12 months - 4/10 of these pts with HO of grade 3 or 4	NR
Liu (2007)	average ROM normal: 80.56° ± 6.40° ACDF: 46.53° ± 14.55° CADR: 76.72° ± 17.46° average intersegmental ROM at the adjacent C6-7 and C4-5 levels during neck rotation from 20° flexion to 15° extension normal: 3.7° and 4.8° ACDF: 13.4° and 8.8° CADR: 5.8° and 3.2°	NR
Mehren (2006)	NR NR	

Author (year)	Range of motion	Occurrence of ASD
Pickett (2006)	mean ROM = 8.13	NR
Rabin 2007	early f/u Bryan: 6.7° ± 3.0° ACDF: 1.0° ± 1.4° late f/u: Bryan: 8.6° ± 3.5° ACDF: 0.89° ± 0.92°	NR
Robertson (2004)	mean ROM = 5.7° (range, 1-15°) at 48 months f/u (n = 12)	no evidence of ASD or radiological disc disease
Robertson (2005)	NR	*Bryan* new osteophytes formation: 10.8% (n = 8) osteophytes enlargement: 0% DDD increase: 1.3% (n = 1) new: 1.3% (n = 1) ALL calcification increase: 1.3% (n = 1) *Affinity cage* new osteophytes formation: 17.9% (n = 28) osteophytes enlargement: 8.9% (n = 14) DDD increase: 3.8% (n = 6) new: 1.9% (n = 3) ALL calcification increase: 1.9% (n = 3)
Sekhon (2004)	NR NR	
Shim (2006)	mean ROM = 8.5°	NR
Wigfield (2002)	mean ROM = 6.5° (range, 3-12°, SD, 3.8°) at 24 month f/u (n = 14)	brachialgia and removal of osteophytes at adjacent level 7.1% (1/14) – symptomatic ASD

Author (year)	Range of motion	Occurrence of ASD
Yoon (2006)	ROM of whole cervical spine 36.5° ± 11.0° at 1 month 55.1° ± 18.5° at 1 year ROM of treated segment 9.3° ± 3.7° at 1 month 14.4° ± 4.5° at 1 year ROM of adjacent segments 9.0° ± 3.2° at 1 month 15.7° ± 4.3° at 1 year	NR

ACDF = anterior cervical decompression and fusion.
CADR = cervical artificial disc replacement.
DDD = degenerative disc disease.
HO = heterotopic ossification.
NR = not reported.
ROM = range of motion.

Table H7. Adverse events and complications from RCTs of C-ADR

Author (year)	Patient Characteristics	Intervention	Complications
Bryan Panel meeting Executive Summary 2007	• DDD at single level between C3 and C7 • Disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy • 6 weeks minimum unsuccessful conservative unless myelopathy requiring immediate treatment • CT, myelography and CT, and/or MRI demonstration of need for surgical treatment • ≥21 years old • Preopearative NDI ≥ 30 and minimum one clinical sign associated with level to be treated • Willing to sign informed consent and comply with protocol	• ADR: BRYAN Cervical Disc • Standard anterior cervical discectomy and fusion (ACDF) using allograft and MEDTRONIC Sofamor Danek ATLANTIS Cervical Plate system • Treatment levels: C3-4 n = 3 C4-5 n = 29 C5-6 n = 250 C6-7 n = 181	**Total patients with any adverse event:** ADR n = 202/242 (83.5%); ACDF n = 174/221 (78.7%) • anatomical/technical difficulty: ADR n = 0/242; ACDF n = 1/ 221 (0.5%) • cancer: ADR 2 (0.8%); ACDF 0 • cardiovascular: ADR 4 (1.7%); ACDF 2 (0.9%) • carpal tunnel syndrome: ADR 12 (5%); ACDF 4 (1.8%) • death: ADR 0; ACDF 1 (0.5%) • dysphagia/dysphonia: ADR 26 (11%); ACDF 19 (8.6%) • gastrointestinal: ADR 9 (3.7%); ACDF 6 (2.7%) • infection: ADR 17 (7%); ACDF 10 (4.5%) • malpositioned implant: ADR 2 (0.8%); ACDF 0 • neurological: ADR 48 (20%); ACDF 46 (21%) • nonunion: ADR 0; ACDF 5 (2.3%) • other: ADR 59 (24%); ACDF 39 (18%) • other pain: ADR 29 (20%); ACDF 44 (20%) • pending nonunion: ADR 0; ACDF 5 (2.3%) • respiratory: ADR 4 (1.7%); ACDF 6 (2.7%) • spinal event: ADR 21 (8.7%); ACDF 20 (9%) • trauma: ADR 34 (14%); ACDF 22 (10%) • urogenital: ADR 6 (2.5%); ACDF 3 (1.4%) • vascular intra-op: ADR 2 (0.8%); ACDF 3 (1.4%) • neck or arm pain: ADR n = 115/242 (47.5%); ACDF n = 96/221 (43.4%) • potential HO (osteophytes or bone demineralization observed): ADR n = 42 (17%); ACDF n = 154 (70%) • subsequent surgical interventions: ADR n = 6/242 (2.5%); ACDF n = 9/221 (4.1%)
Mummaneni (2007)	• adults >18 years of age • single level symptomatic DDD between C3-7 • intractable radiculopathy, myelopathy or both • NDI scores ≥ 30 • VAS neck pain scores ≥ 20 • preserved motion at the symptomatic level found in all included patients • unresponsive to ≥ 6 weeks conservative treatment or progressive neurological worsening despite conservative treatment • no previous procedures at the	• Prestige ST Cervical Disc System prosthesis • interbody fusion with cortical ring allograft spacers and Atlantis Cervical Plate System	• revisions ADR: n = 0/276 (0%) ACDF: n = 5/265 (1.9%) *P* = .0277 • hardware removals ADR: n = 5/276 (1.8%) ACDF: n = 9/265 (3.4%) *P* = .2870 • supplemental fixations due to hardware fracture or migration ADR: n = 0/276 (0%) ACDF: n = 8/265 (9 events) (3.4%) *P* = .0031

Author (year)	Patient Characteristics	Intervention	Complications
	operative level • negative for several radiographic findings, medications, and diagnoses		• reoperations for adjacent-segment disease ADR: n = 3 (1.1%) including 2 with symptoms at adjacent level above and 1 with symptoms at adjacent level below the arthroplasty site ACDF: n = 11 (4.2%) including 3 with symptoms at adjacent level above, 7 with symptoms at adjacent level below, 1 with symptoms both above and below the fusion Reasons for hardware removals included: ACDF: suspected nonunion n = 7 graft fractures n = 5 migration of fusion construct n = 3 *P* = .0492 **perioperative adverse events total:** ADR: 6.2% (n = 17/276) ACDF: 4.2% (n = 11/265) **ADR adverse events:** • neurological (numbness, paresthesia, back and leg, paresthesia/pain (arm), Lhermitte phenomenon) n = 4 • infections (UTI and sinusitis) n = 2 • pain (bursitis, headaches, neck and/or arm pain) n = 3 • respiratory (sleep apnea) n = 1 • dysphagia/ dysphonia n = 2 • anatomical/technical (screw fixation) difficulty n = 1 • hematoma n = 2 • low bone density n = 1 • spinal fluid leak n = 1 **ACDF adverse events:** • venous bleeding n = 1 • neurological (lt arm numbness) n = 1 • pain (headaches) n = 2 • dysphagia/ dysphonia n = 3 • nausea n = 1 • vomiting n = 1 • CSF leaks n = 2

Author (year)	Patient Characteristics	Intervention	Complications
Nabhan (2007)	• monosegmental cervical DDD between C3-C7 • unresponsive to conservative treatment or presence of signs of nerve root compression with paresis • soft disc herniation • no myelopathy • age between 20-60 years • negative for specific radiographic findings, medications, and diagnoses • signed informed consent	• ADR: disc prosthesis implant: metal polyethylene ball-in-socket design with 2 metal fins; interface UHMW polyethylene inlay, and cobalt-chrome alloy with titanium surface superior and inferior plate (Synthes) • ACDF: with "Solis" cage (PEEK) and nonconstrained plate for anterior osteosynthesis	• mortality during surgery disc: n = 1 ACDF: n = 0 • no calcifications around disc prosthesis or in ACDF • no loosening of bone around disc prosthesis • no deformity in ACDF
Sun Peng-Fei (2008)	• single C5-6 intervertebral disc hernia • failed conservative treatment w/ worsening symptoms	• cervical ADR • interbody ACDF	• no neurological or vascular • no prosthesis subsidence or extrusion
Prodisc-C FDA report (2007)	• Symptomatic cervical disc disease (SCDD) in one level between C3-C7 • Age 18-60 years • Unresponsive to nonop treatment for six weeks or progressive symptoms • NDI ≥ 15/50 (30%) • Able to comply with protocol • Informed consent	• Prodisc-C ADR • ACDF • Treatment levels: C3-C4 n = 4 C4-C5 n = 16 C5-C6 n = 119 C6-C7 n = 70	• device failure (table 6) ADR n = 2/103 (1.9%) ACDF n = 12/106 (11.3%) calculated by subtracting those who had no device failure (ADR n = 101/103; ACDF n = 97/106) from total at study start (ADR n = 103; ACDF n = 106) • neurological failure (table 13) ADR n = 13/103 (12.6%) ACDF n = 25/106 (23.6%) calculated by subtracting those who had neurological success (ADR n = 90/99, 91%; ACDF n = 81/92, 88%) from total at study start (ADR n = 103; ACDF n = 106) • Bridging bone present on radiograph in n = 3/98 (3.0%) ADR patients • Bridging bone not present on radiograph in n = 8/92 (8.7%) of ACDF patients **All adverse events (patients) (Table 3):** ‡ ADR n = 84/103 (81.6%); ACDF n = 86/106 (81.1%); *P* = 1.000 • Adjacent level DDD or DJD: ADR n = 0 (0%); ACDF 4 (3.8%) • Burning or dysesthetic pain: ADR n = 1 (1.0%); ACDF 0 (0%) • Cancer: ADR n = 1 (1.0%); ACDF 0 (0%) • Cardiovascular: ADR n = 5 (4.9%); ACDF n = 7 (6.6%) • DDD progression (noncervical): ADR n = 1 (1.0%); ACDF n = 1 (0.9%) • Dermatological: ADR n = 1 (1.0%); ACDF n = 1 (0.9%) • Dizziness: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Dural tear: ADR n = 1 (1.0%); ACDF n = 0 (0%)

Author (year)	Patient Characteristics	Intervention	Complications
			• Dysphagia: ADR n = 6 (5.8%); ACDF n = 9 (8.5%) • Dysphonia: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Edema: ADR n = 2 (1.9%); ACDF n = 1 (0.9%) • Fatigue: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Fracture (vertebral): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Gastrointestinal: ADR n = 16 (15.5%); ACDF n = 15 (14.2%) • Genitourinary: ADR n = 5 (4.9%); ACDF n = 3 (2.8%) • Headache: ADR n = 18 (17.5%); ACDF n = 12 (11.3%) • Infection (non-wound): ADR n = 2 (1.9%); ACDF n = 6 (5.7%) • Infection (superficial wound): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Insomnia: ADR n = 6 (5.8%); ACDF n = 3 (2.8%) • Musculoskeletal: ADR n = 18 (17.5%); ACDF n = 16 (15.1%) • Musculoskeletal (back spasms): ADR n = 1 (1.0%); ACDF n = 1 (0.9%) • Musculoskeletal (neck spasms): ADR n = 3 (2.9%); ACDF n = 5 (4.7%) • Musculoskeletal (nonspecific spasms): ADR n = 3 (2.9%); ACDF n = 4 (3.8%) • Narcotics use: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Neurological: ADR n = 4 (3.9%); ACDF n = 1 (0.9%) • Numbness index level: ADR n = 0 (0%); ACDF n = 2 (1.9%) • Numbness nonindex level: ADR n = 11 (10.7%); ACDF n = 7 (6.6%) • Ossification: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Other: ADR n = 4 (3.9%); ACDF n = 6 (5.7%) • Pain (back): ADR n = 11 (10.7%); ACDF n = 8 (7.5%) • Pain (lower extremities): ADR n = 4 (3.9%); ACDF n = 2 (1.9%) • Pain (incision site): ADR n = 1 (1.0%); ACDF n = 1 (0.9%) • Pain (neck): ADR n = 16 (15.5%); ACDF n = 22 (20.8%) • Pain (neck and other): ADR n = 1 (1.0%); ACDF n = 0 (0%) • Pain (neck and shoulder): ADR n = 7 (6.8%); ACDF n = 6 (5.7%) • Pain (neck and upper extremities): ADR n = 3 (2.9%); ACDF n = 6 (5.7%) • Pain (neck and upper extremities with numbness): ADR n = 6 (5.8%); ACDF n = 6 (5.7%) • Pain (other): ADR n = 5 (4.9%); ACDF n = 7 (6.6%) • Pain (shoulder): ADR n = 9 (8.7%); ACDF n = 9 (8.5%) • Pain (upper extremities): ADR n = 8 (7.8%); ACDF n = 5 (4.7%) • Pain (upper extremities with numbness): ADR n = 4 (3.9%); ACDF n = 5 (4.7%) • Pseudoarthrosis: ADR n = 0 (0%); ACDF n = 2 (1.9%) • Psychological: ADR n = 4 (3.9%); ACDF n = 5 (4.7%) • Pulmonary infection: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Puritis: ADR n = 0 (0%); ACDF n = 2 (1.9%) • Reflex change: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Respiratory: ADR n = 4 (3.9%); ACDF n = 3 (2.8%) • Seizures: ADR n = 0 (0%); ACDF n = 2 (1.9%)

Author (year)	Patient Characteristics	Intervention	Complications
			• Sore throat: ADR n = 1 (1.0%); ACDF n = 1 (0.9%) • Surgery (index level): ADR n = 2 (1.9%); ACDF n = 10 (9.4%) • Surgery (other): ADR n = 12 (11.7%); ACDF n = 21 (19.8%) • Wound issues (other): ADR n = 3 (2.9%); ACDF n = 2 (1.9%) • No device migration, subsidence, or disc height decrease in either group at 24 months **Implant related adverse events (table 16): ‡** All: ADR n = 2/103 (1.9%); ACDF n = 7/106 (6.6%); *P* = 0.1708 • Dysphagia: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Infection (superficial wound): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Musculoskeletal: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Pain (neck): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Surgery (index level): ADR n = 2 (1.9%); ACDF n = 5 (4.7%) **Surgery related adverse events (table 17): ‡** All: ADR n = 11/103 (10.7%); ACDF n = 16/106 (15.1%); *P* = 0.411 • DDD progression, other cervical: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Dural tear: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Dysphagia: ADR n = 2 (1.9%); ACDF n = 4 (3.8%) • Edema: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Gastrointestinal: ADR n = 6 (5.8%); ACDF n = 4 (3.8%) • Genitourinary: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Pain (back): ADR n = 1 (1.0%); ACDF n = 0 (0%) • Pain (neck): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Pain (neck and upper extremities): ADR n = 0 (0%); ACDF n = 2 (1.9%) • Pain (upper extremities): ADR n = 2 (1.9%); ACDF n = 0 (0%) • Pseudoarthrosis: ADR n = 0 (0%); ACDF n = 2 (1.9%) • Surgery (index level): ADR n = 0 (0%); ACDF n = 2 (1.9%) • Wound issues (other): ADR n = 0 (0%); ACDF n = 2 (1.9%) **Severe or life-threatening adverse events (Table 17) : ‡** All: ADR n = 16/103 (15.5%); ACDF n = 32/106 (30.2%); *P* = 0.0137 • Cardiovascular: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Dermatological: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Dural tear: ADR n = 1 (1.0%); ACDF n = 0 (0%) • Gastrointestinal: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Infection (non-wound): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Infection (superficial wound): ADR n = 0 (0%); ACDF n = 1 (0.9%) • Other: ADR n = 0 (0%); ACDF n = 1 (0.9%) • Surgery (index level): ADR n = 2 (1.9%); ACDF n = 10 (9.4%) • Surgery (other): ADR n = 13 (12.6%); ACDF n = 21 (19.8%)

*Patients included are those with 24 months of follow-up at time of paper preparation; of the original group, 160 of 168 ADR and 140 of 165 ACDF patients had passed the 24 month point in the course of their treatment.

†Follow-up values for n are from table 13 of the FDA report (based on number of patients who have completed 24 months of follow-up); percentages are calculated from those values.
‡Adverse events are listed by numbers of patients having events in each category. Patients may have more than one adverse event. Severe or life-threatening adverse events may also be events that were implant related or surgery related.

Table H8. Adverse events and complications from nonrandomized trials of C-ADR

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
Amit (2007)	N = 22 male %: 59.1 mean age: 51 years (39-79)	mean F/U: 15 months (range, 12-20 months) F/U %: NR	• cervical spondylosis with myelopathy (n = 4) or radiculopathy (n = 18)	• single level anterior decompression and Bryan ADR	• osteolysis n = 0 • heterotopic calcification n = 0 • subsidence n = 0
Bertagnoli (2005)	N = 16 male %: 50 mean male age: 45.6 years (33-60) mean female age: 51 years (32-59) overall median age: 50.5 years	median F/U: 12.7 months (12-14 months, range) F/U%: 100	• one or two level cervical spondylosis with: 1) severe axial neck pain of greater than 6 months' duration and secondary to intervertebral DDD without radicular and/or myelopathic symptoms (n = 4); and 2) with persistent radicular symptoms of greater than 2 months' duration with axial neck pain and absent or minimal clinical signs of myelopathy (n = 12) • overall median duration of pain: 50 months (6 weeks to 400 months, range) • previous anterior cervical ADR with Bryan disc experiencing ASD (n = 2)	• Prodisc C ADR via anterior approach • spinal segment: C4-5 (n = 3) C5-6 (n = 7) C6-7 (n = 6)	• no device related complications were observed (ie, loosening, subsidence, and migration of the implant as well as metallic or polyethylene failure, allergic rejection/reaction, visceral or neurological injuries caused by the implant components, and/or infection) • no approach-related complications were observed (ie, fractures, hematomas, dural tears/leaks, postoperative airway compromise, esophageal or tracheal disruption, laryngeal nerve injury, and/or • sympathetic nerve dysfunction)
Bertagnoli (2005)	N = 27 male %: 48 mean age: 49 years (31-66)	F/U: 12 months F/U %: NR	• single level cervical DDD	• Prodisc-C ADR • spinal segment C4-5 (n = 2) C5-6 (n = 16) C6-7 (n = 9)	• No device-related or approach-related complications were observed (ie, loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries; intraoperative fractures, hematomas, dural tears/leaks, postoperative airway compromise, esophageal or racheal disruption, laryngeal nerve injury, or sympathetic nerve dysfunctions, or spontaneous fusions)
Bryan (2002) population same as Goffin 2002	N = 97 male %: 42 age range: 26-79 years	number of eligible and lost to follow-up not reported at time of publication 49 patients had reached 1 year f/u	• single level cervical DDD • disc herniation (n = 75) or spondylosis (n = 33) with radiculopathy (n = 90) and/or myelopathy (n = 13)* • failing conservative treatment • duration of symptoms (range) = 6 weeks to 24 months	• Bryan cervical ADR via anterior cervical discectomy • spinal segment: C4-5 (n = 11) C5-6 (n = 42) C6-7 (n = 44)	• wrong level operated on requiring second operation for unresolved pain after which temporary dysphonia occurred n = 1 • posterior foraminotomy due to pain as a result of insufficient far lateral decompression n = 1 • pain in the right shoulder, right arm,

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
		and 10 had reached 2 year f/u	• several patients presented with multiple diagnoses and/or cause		and sternum n = 1 • unresolved nonspecific left shoulder pain n = 1 • surgical intervention due to a drainage catheter that had loosened and ceased draining; a hematoma was seen n = 1 • device failures or explants n = 0
Duggal (2004)	N = 26 male %: 62 mean age (SD): 43.3 (7.9) years (30-67)	mean F/U: 12.3 months (1.5-27 months, range) F/U%: 100	• cervical DDD with radiculopathy and/or myelopathy whose main symptom was arm pain and NOT neck pain • mean duration of symptoms for radiculopathy = 12.5 months (2.5- 60 months, range) • mean duration of symptoms for myelopathy = 6.2 months (1-14 months, range) • failed nonsurgical medical therapy: activity modification, nonsteroidal anti-inflammatory medications, physiotherapy, massage • preoperative motion at the symptomatic level • previous anterior cervical discectomy and fusion (n = 4)	• Bryan cervical ADR via anterior approach and a transverse skin incision made on the right side of the neck • number of levels: monolevel at C5-6 or C6-7: (n = 22) bilevel at C5-6 & C6-7: (n = 4) • spinal segment C4-5 (n = 1) C5-6 (n = 13) C6-7 (n = 16)	• increased radicular pain 3.8% (n = 1/26) • transient unilateral vocal cord paralysis 3.8% (n = 1/26) • persistent dysphagia 3.8% (n = 1/26) • possible device migration 3.8% (n = 1/26) • symptomatic disc herniation adjacent to a pervious surgical fusion 11.5% (n = 3/26)
Fong (2006)	N = 10 male %: 60 mean age: 44 years (36-52) subpopulation from larger, ongoing, prospective study	median F/U: 4 months (3-12 months, range) F/U %: 100	• single level disease with cervical radiculopathy and/or myelopathy • duration of symptoms ranged from 6-36 months • disc herniation was the cause of foraminal or central canal stenosis, or both, in all patients • previous anterior discectomy and fusion (n = 1)	• Bryan ADR via a standard right-sided cervical exposure through a transverse incision • spinal segment: C5-6 (n = 7) C6-7 (n = 3)	• no prosthetic migration or subsidence associated with shell angulation • kyphosis (mean 8° ± 4, range 3-13°) through the prosthesis seen at latest follow-up, 90% (n = 9/10) • average segmental height loss of 1.7 mm
Goffin (2003) population same as Goffin	single level study: N = 103 male %: 41 age range: 26-79 years	F/U: 24 months single level study:† 12 month F/U%: 97.1	• disc herniation or spondylosis with radiculopathy and or myelopathy • failed conservative treatment during at least 6 weeks	• Bryan ADR	• Single level study group: • device migration n = 1 (suspected in a second patient) • prevertebral hematoma n = 1 • posterior foraminotomy without device involvement to treat residual

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
2002 and Bryan 2002 with the addition of 6 single level patients and all bilevel patients	bilevel study: N = 43 male %: 58 age range: 28-62 years	24 month F/U%: 49.5 bilevel study:† 12 month F/U%: 67.4 24 month F/U%: 2.3 % F/U based on author's report of patients who had reached 12 & 24 month F/U at time of publication			symptoms n = 1 • posterior decompression to treat residual myelopathic symptoms n = 1 • wrong level operated on; temporary dysphonia occurred after follow-up surgery n = 1 • pain in right shoulder, arm, and the sternum region n = 1 • unresolved unspecific left shoulder pain n = 1 • second device implanted at an adjacent level because of radiculopathy caused by disc herniation; severe dysphonia occurred following this surgery n = 1 • Bilevel study group: • cerebral spinal fluid leak n = 1 • epidural hematoma n = 1 • prevertebral hematoma n = 1 • pharyngeal tear/esophageal wound n = 1 • nerve root compression requiring anterior decompression n = 1 • device failures or explants n = 0
Goffin (2002) population same as Bryan 2002	N = 97 male %: 42.2 age range: 26-79 years	number of eligible and lost to follow-up not reported at time of publication 60 patients had reached 6 month f/u and 10 had reached 12 month f/u	• single level cervical DDD • disc herniation (n = 75) or spondylosis (n = 33) with radiculopathy (n = 90) and/or myelopathy (n = 13)* • failing conservative treatment • duration of symptoms (range) = 6 weeks to 24 months *several patients presented with multiple diagnoses and/or cause	• Bryan cervical ADR via anterior cervical discectomy • spinal segment: C4-5 (n = 11) C5-6 (n = 42) C6-7 (n = 44)	• wrong level operated on requiring second operation for unresolved pain after which temporary dysphonia occurred n = 1 • posterior foraminotomy due to pain as a result of insufficient far lateral decompression n = 1 • pain in the right shoulder, right arm, and sternum n = 1 • unresolved nonspecific left shoulder pain n = 1 • surgical intervention due to a drainage catheter that had loosened

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
					and ceased draining; a hematoma was seen n = 1 • device failures or explants n = 0
Heidecke (2008)	N = 54 male %: 41% mean age: 47 years (26-58)	F/U: 2 years F/U %: NR	• disc herniation and/or spondylosis with preserved mobility in the affected segment • cervical radiculopathy and/or myelopathy with or without neck pain • exclusion criteria included: advanced kyphotic deformity, spondylolisthesis, translational instability of the cervical spine, insulin-dependent diabetes, advanced osteopororsis, ankylosing spondylitis, rheumatoid arthritis, age > 60 years	• Bryan cervical disc prosthesis in standard anterior cervical discectomy • number of levels treated single level (n = 49) two levels (n = 5) • 59 total spinal segments replaced: C4-5 n = 18 discs C5-6 n = 33 discs C6-7 n = 8 discs	• no migration or dislocation lduring the follow-up • heterotopic ossification (grade 3 and 4) in n = 5 patients • heterotopic ossification (grade 1 and 2) in n = 12 levels of the remaining 52 segments • no intraoperative or early postoperative complications related to disc • early postoperative retropharyngeal haematoma n = 1 • radicular neurological symptoms at one year n = 1
Jollenbeck (2004)	N = 50 male%: 52 mean age: 46.2 years (32-65)	number of eligible patients not reported F/U: range, 1-14 months 6 month F/U%: 82 12 month F/U%: 26	• prolapse or protruding degenerative cervical disc with local neck pain and radicular pain (n = 13), sensory loss and some motor deficits (n = 38), and myelopathy with gait ataxia and increased tendon reflexes (n = 7)	• unspecified cervical disc used for ADR via anterior approach (? Bryan) • number of levels: monolevel (n = 49) bilevel (n = 1) • spinal segments C3-4 (n = 2) C4-5 (n = 2) C5-6 (n = 35) C6-7 (n = 10) C5-6 & C6-7 (n = 1)	• hemorrhage causing breathing difficulties requiring surgical removal of the hematoma n = 2 • minor difficulties in swallowing in all patients • no prosthesis dislocation was noted
Kim (2007)	N = 23 male %: 70 mean age: 43 years (31-62)	mean F/U: 6 months F/U %: NR	• cervical DDD with axial pain, radiculopathy, or myelopathy (n = 8) • mean symptom duration: 7.5 months (2 weeks to 36 months, range) • previous anterior cervical fusion (n = 2)	• Mobi-C cervical ADR via anterior approach, with anterior cervical interbody fusion also in different levels (n = 6) • number of levels: monolevel (n = 22) bilevel (n = 1) • spinal segment: C3-4 (n = 2) C4-5 (n = 4) C5-6 (n = 11)	• no complications or neurological deterioration including postoperative dysphasia, dysphonia, or hoarseness occurred • kyphotic FSU angle (mean -4.2° at 6 months) 11

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
				C6-7 (n = 6)	
Lafuente (2005)	N = 46 male %: 61 mean age (SD): 47.6 (10.5) years (33-70)	mean F/U: 14 months F/U%: 100	• single level disease with either radiculopathy or myelopathy • failing nonsurgical treatment • mean (SD) duration of symptoms = 13.8 (11.9) months (1-6 months, range) • previous lumbar discectomy (n = 2) and cervical fusion at one level (n = 3)	• Bryan ADR via anterior cervical discectomy • number of levels: all between C3-5 and C6-7	• worsening of muscle spasms 2.2% (n = 1/46) • mild postoperative dysphonia 6.5% (n = 3/46) • removal of prosthesis following a fall 2.2% (n = 1/46) • bony ankylosis at implanted disc level 4.3% (n = 2/46)
Leung (2005)	N = 103 male%: 43 mean age (SD): 45 (9.8) years (26-79)	F/U: 12 months x-ray F/U%: 87.3 clinical F/U%: 86.4	• disc herniation or spondylosis with radiculopathy and/or myelopathy • failed conservative treatment: relative rest, soft collar, physiotherapy, and medication for at least 6 weeks	• Bryan cervical ADR	• heterotopic ossification 17.8% (n = 16/90) • grade 1 and 2 11.1% (n = 10/90) • grade 3 and 4 6.7% (n = 6/90)
Liu (2007)	N = 30 male: NR age: NR	NR	• normal subjects (n = 10) • patients treated with an anterior cervical decompression and fusion (ACDF) (C5–C6) (n = 10) • patients having cervical artificial disc replacement (CADR) (C5–C6) (n = 10)	• full flexion to extension motions under fluoroscopic surveillance in the sagittal plane • kinematic data were obtained from the fluoroscopic images • kinetic data were derived based on an inverse dynamic model of the entire cervical spine.	• NR
Mehren (2006)	N = 54 male%: NR mean age: NR	F/U: 12 months F/U%: NR	• disc herniation or other degenerative changes leading to neurological deficits, and/or arm and/or neck pain	• Prodisc C ADR via anterior approach • number of levels: monolevel (n = 34) bilevel (n = 17) trilevel (n = 3) • spinal segment: C3-4 (n = 3) C4-5 (n = 9) C5-6 (n = 36) C6-7 (n = 29)	• heterotopic ossification: • grade 1 in 6 segments (7.8%, n = 1 monosegmental, n = 5 multisegmental) • grade 2 in 30 segments (39%, n = 13 mono, n = 17 multi) • leading to restricted range of motion in 8 segments (10.4%, n = 3 mono, n = 5 multi) • spontaneous fusion of the treated segment in 7 (9.1%, n = 5 multi)

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
Pickett (2006)	N = 74 male %: 50 mean age: 44 years	mean F/U: 12 months (maximum 39 months) F/U%: NR	• cervical disc herniation or spondylosis with radiculopathy and/or myelopathy or neck pain • 12 patients had prior neck surgery, 11 of whom had ACDF	• Bryan ADR	• venous bleeding requiring transfusion n = 2 • retropharyngeal hematoma n = 1 • neurological worsening n = 3 • intraoperative prosthesis migration n = 1 • delayed prosthesis migration n = 1 • heterotopic ossification (class 4) and spontaneous fusion n = 2 • partial dislocation of the prosthesis n = 1 • posterior migration of the prosthesis n = 1 • persistent neck and/or shoulder pain n = 19 • reoperation due to marked segmental kyphosis n = 1 • reoperation due to recurrent arm pain n = 2
Pimenta (2004)	N = 53 male %: 40% mean age: 45 years (28-68)	F/U: 12 months F/U %: NR	• DDD (n = 43), degenerative adjacent segment disease (n = 10) • Radicular or medullary compression symptoms • Age 20-70 years • Neurological compression of one, two or three levels from C3-C4 to C7-T1 • Herniation of the nucleus pulposus • Cervical spondylosis • Nontraumatic segmental instability • Exclusion criteria included metabolic and bone diseases, terminal phase of chronic disease, pyogenic infection or active granulomatosis, neoplasty or traumatic disease of the cervical column, biomechanical instability of traumatic origin	• PCM (Cervitech) discs implanted by PRESS FIT Model or Flange Fixed Model • 81 discs in 53 patients One level in n = 28 Two level in n = 22 Three level in n = 3 • Levels receiving implants: C3-C4 n = 28 C4-C5 n = 15 C5-C6 n = 34 C6-C7 n = 22 C7-T1 n = 2	• Anterior displacement by 4 mm of prosthesis n = 1/53 • Grade 1 heterotopic ossification n = 1/53
Pointillart (2001)	N = 10 male %: 50% mean age: 36 years (25-49)	F/U: 1 year F/U %: NR	• Cervicobrachial pain for over 3 months • Soft disc herniation by MRI • Exclusion criteria included	• Prototype prosthesis (not otherwise specified) • Levels receiving implants:	• Disc removal and fusion 6 months later for intractable cervical pain and referred pain in trapezius muscles n = 1/10

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
			intervertebral instability	C5-C6 n = 6 C6-C6 n = 4	• Postoperative neck pain n = 1/10
Rabin (2007)	N = 20 male: 80% age: 34.8 (ACDF) 35.8 (AD)	ACDF: 24.8 months ADR: 15 months	• single-level Bryan cervical disc (n = 10) • single-level ACDF matched based on age and sex (n = 10)	• lateral neutral, flexion and extension cervical x-rays were obtained preoperatively and at regular intervals up to 24 months postoperatively.	• NR
Robertson (2005)	ADR N = 310 male: 41% age: 55.9 years (28-79) fusion: N = 202 male: 49% age: 44.5 years	24 months F/U %: 75	• symptomatic single level disc herniation or spondylosis (C2-3 to C7-T1) with radiculopathy and/or myelopathy	• Bryan ADR (n = 74) or fusion using an Affinity Anterior Cervical Cage System (n = 158) • anteroposterior, neutral, and lateral flexion-extension x-rays were collected pre-, peri-, and postoperatively at 6 weeks, and 3, 6, 12, and 24 months	• Adjacent herniation cervical disc: ADR n = 1 with further surgery in n = 1; affinity n = 11 with further surgery in n = 3 • Further treatment for neck, shoulder, and/or arm pain: Bryan 1.3%; affinity 33% • Surgery at incorrect level: Bryan n = 1 • Surgery for explantation and fusion: Bryan n = 1 • Postoperative hematoma: Bryan n = 1 • No mortality or neurological deterioration due to procedure
Robertson (2004) pilot study and extension of the Wigfield 2002 study, 2 additional patients enrolled	N = 17 male %: 59 mean age (SD): 50.1 (11.4) years (31.9-74.5)	F/U: 36 and 48 months x-ray F/U% at 36 months: 64.7 x-ray F/U% at 48 months: 70.5 clinical F/U% at 48 months: 82.4	• radiculopathy or myelopathy with cervical disc herniation or posterior vertebral body osteophytes AND have either a previous adjacent-level surgical or congenital spinal fusion or radiologic evidence of ASD • previous surgical fusions (n = 9)	• Prestige I ADR • discs inserted between C3-4 and C6-7	• prosthesis removal at 12 months n = 1 • progression of myelopathy n = 1 • no adverse events reported on questionnaires or neurological exam during extended f/u period
Sekhon (2004)	N = 11 male %: 64 mean age: 43.7 years (31-55)	mean F/U: 18.4 months (10-32 months, range) F/U%: 100	• spinal cord compression and/or clinically confirmed cervical myelopathy • mean duration of symptoms = 15.2 months (.75-72 months, range)	• Bryan ADR via left-sided transverse cervical incision or an oblique left-sided paramedian incision for a	• worsening of preoperative hand and gait dysfunction 9.1% (n = 1/11) • persistent neck and arm pain with loss of motion at operated segment

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
	7 patients presented in a previous report with shorter f/u			bilevel disease • number of levels: single level (n = 7) bilevel (n = 4) • spinal segment: C3-4 (n = 1) C4-5 (n = 1) C5-6 (n = 2) C6-7 (n = 3) C4-5, C5-6 (n = 2) C5-6, C6-7 (n = 2)	due to spondylotic bridging 9.1% (n = 1/11) • myelopathic deterioration 9.1% (n = 1/11) • worsened alignment 27.3% (n = 3/11)
Shim (2006)	N = 61 male %: 70 mean age: 45.6 years (32-64) (% male and mean age available for only 47 patients with 3 months f/u)	mean F/U: 6 months F/U%: 77	• cervical radiculopathy or myelopathy with (n = 41) or without (n = 6) soft disc herniation	• Bryan cervical ADR (n = 43) in combination with ACDF (n = 4) • number of levels: monolevel (n = 39) bilevel (n = 8)	• continued neck or arm/shoulder pain 7 • persistent arm pain due to incomplete decompression requiring revision 1 • persistent neck pain due to inadvertent joint destruction 1 • device migration or subsidence 0
Wigfield (2002)	N = 15 male %: 67 mean age (SD): 47.6 (18.1) years	F/U: 24 months F/U%: 93.3	• radiculopathy or myelopathy with cervical disc herniation or posterior vertebral body osteophytes AND have either a previous adjacent-level surgical or congenital spinal fusion or radiologic evidence of ASD • previous surgical fusions (n = 9) • mean (SD) duration of symptoms = 5 (5.4) years	• Frenchay ADR via a standard anterolateral approach using the Smith and Robinson technique • discs inserted between C3-4 and C6-7	• 9 patients experienced significant interventions and adverse events: • persistence of preoperative radicular pain 2 • progression of myelopathy 2 • device removal for joint loosening, had been causing neck pain 1 • screw breakage, developed neck pain 2 years later 1 • brachialgia and removal of osteophytes at adjacent level 1 • hoarse voice (resolved) 2
Yang (2007)	N = 12 male %: 58% mean age 50 years (35-62)	mean F/U: 5.2 months (2-8) F/U %: NR	• cervical spondylotic myelopathy (n = 5) and cervical disc herniation (n = 7)	• Bryan cervical disc prosthesis • 14 replacements in 12 patients • Single level n = 10 • Two-level n = 2	• no device subsidence or excursion, no ossification in replaced levelsa

Author (year)	Demographics*	Follow-up	Characteristics	Interventions	Complications
Yoon (2006)	N = 46 male %: 52.2 mean age: 42.3 years (26-58)	mean F/U: 11.8 months (range, 2.9-19.5) F/U %: NR	• herniated cervical disc (n = 39) or cervical stenosis (n = 6) with radiculopathy or myelopathy • failed conservative treatment	• Bryan ADR following anterior cervical discectomy • number of levels monolevel (n = 34) bilevel (n = 12) • spinal segment C4-5: (n = 4) C5-6: (n = 32) C6-7: (n = 10)	• acute subdural hematoma 1

NDI = Neck Disability Index.
NR = not reported.
ODI = Oswestry Disability Index.
ROM = range of motion.
SF-36 = Short Form 36.
VAS = Visual Analog Scale.
*Demographics are before loss to follow-up, unless otherwise noted.
†Study design is determined relative to the exposures being compared.

Table H9. Detailed Evidence Tables For Economic Analysis Studies-Overview of studies

Author (year)	Study Design	Population	Alternatives Compared	Benefits Measured & Weighting	Cost Data Sources and discounting	Summary of Primary Results (including sensitivity analyses)
Levin (2007) Authors indicate no funding received for study	Hospital charge analysis of prospectively selected participants of one site in multi-site RCT evaluating Prodisc-L ADR compared with fusion for one- and two-level DDD	N = 53 Severe, disabling back pain Female 38%; Age 39 years (22-55) BMI overall mean 26.9 Patient inclusion/exclusion criteria for patients per Prodisc IDE trial	1-One-level L-ADR; n = 22 2-One-level fusion; n = 9 3-Two-level L-ADR; n = 14 4-Two-level fusion; n = 8	None- alluded to the idea that outcomes are equivalent	OR charges; inpatient charges; implant charges (adjusted to USD 2006) [Source: hospital records] Surgeon and anesthesiologist fees [source: Medicare reimbursement schedule]	Primary Results: *One-level disease:* Total charge L-ADR $35592 vs. fusion $46280 (p<0.0018) *Two-level disease:* Total charge L-ADR $55524 vs. fusion $56823 (p=0.55) Sensitivity Analyses: not reported
Guyer (2007) Authors acknowledge financial relationship with DePuy and use of DePuy consultant for the study	Direct cost models (a) hospital perspective (time = index hospitalization) (b) payer perspective (time = index hospitalization + two year followup) For each: DRG payment and per diem arms	214 claims for L-ADR 1145 claims for fusion (total), but no break down with respect to numbers of claims for each type of fusion Population characteristics not reported	1-ADR with Charite Artificial Disc 2-ALIF with iliac crest bone graft 3-ALIF with LT-Cages and INFUSE 4-Posterior lumbar interbody fusion with adjunct posterolateral fusion and transpedicular fixation (IPLIF)	None—benefits assumed equivalent	Peer-reviewed medical literature; pre-marketing approval materials; commercial payer claims data; clinical expert opinion Costs adjusted to USD 2006 No discounting reported	Primary Results: (a) Hospital perspective: Charite lowest cost $16601 vs. $18596 (2) vs. $22668 (3) vs. $22662 (4) (b) Payer perspective (DRG arm): Charite lowest cost $17614 vs. $32960 (2) vs. $32196 (3) vs. $35052 (4) Payer perspective (per diem arm): Charite $24885 vs. $23778 (2) vs. $28892 (3) vs. $31620 (4) Sensitivity Analyses: none reported

ADR = Artificial Disc Replacement.
ALIF = anterior lumbar interbody fusion.
DDD = degenerative disc disease.
DRG = diagnostic-related group.
OR = operating room.

Results and Detailed Cost Data Tables:

Table H10. Mean costs in 2006 USD comparing L-ADR with various fusion procedures from a hospital perspective - Details of Data form Levin (Prodisc) and Guyer (Charité)

Author (Year)	Charge Category	Comparitors				Comments
		ADR -1 level	**Fusion 1-level**	**ADR-2-level**	**Fusion 2-level**	
Levin (2007)	Implant charge*	13,800	13,990	23,000	18,460	CPT codes (1-level fusion): 22558, 22612, 22840, 20937 CPT Codes (2-level fusions): 22585, 22614, 22842 CPT Code (L-ADR): 22857
	Operating room†	12,000	18,950	15,340	20,560	
	Inpatient hospital‡	NR	NR	9427	11,430	
	Post-op charges§	7500	7000	16,000	10,000	
	Surgeon (Medicare Schedule)	1413	4917	2826	5857	
	Anesthesiologist (Medicare Schedule)	253	473	331	525	
	Total Costs per patient	35,592	46,280	55,524	56,823	
Guyer (2007)		**ADR**	**ALIF w/ICBG**	**ALIF w/ INFUSE**	**Instrumented PLIF**	Commercial payer claims Data for fusion from Milliman Data base; For L-ADR, commercial payer claims data for post-FDA approval from 71 hospitals
	Facility**	4632	7756	6589	6444	
	Therapy (Physical/Occupational)	177	267	256	201	
	Medical devices, supplies, pharmacy, anesthesia	10,914	9058	14,444	14,768	
	Diagnostic tests (CT, MRI, X-ray)	750	1393	1240	1067	
	Other (blood, cardiac, respiratory services)	127	121	138	186	
	Total Costs per patient	16,601	18,596	22,668	22,662	

ADR = Artificial Disc Replacement.
ALIF = anterior lumbar interbody fusion.
CPT = Current Procedural Terminology.
ICBG = iliac crest bone graft.
NR = not reported.
PLIF = posterior lumbar interbody fusion.
*ADR cost $10,000 each x institution's fusion cost -charge ratio of 1.38; Implants for fusion included: femoral ring allograft, 6.5 mm AO screw and washer, bone graft substitute such as Grafton Putty (anterior procedure) and pedicle screws, rods, caps (posterior procedure).
†Operating room charges included: gowns, gloves, drapes, disposable items, prep kits, medications, cell saver, and a fixed charge per unit time of operating room use.
‡Inpatient hospital charges included: room charges, medications, blood draws, physical therapy, and incidentals.
§Estimated from author figures 1 and 2. Unclear what this includes and how it factors into the total cost per patient.
**Facility costs included: operating room time, recovery room time, accommodation.

Table H11. Mean costs in 2006 USD comparing Charite ADR with various fusion procedures[68] from two different payer perspectives

	Payer perspective: DRG arm				Payer perspective: Per diem payment			
Cost Category	**Charité**	**ALIF/ICBG**	**ALIF/Infuse**	**PLIF/Instrument**	**Charité**	**ALIF/ICBG**	**ALIF/Infuse**	**PLIF/Instrument**
Index Procedure	9611 22,3	38	22,165	24,663	16,822	13,156	18,861	21,231
Successful Surgery care	6000 6824		6010	6010	6000 6824		6010	6010
Unsuccessful Surgery care	590 1023		1214	1214	590 1023		6824	6010
Revision surgery (rate)*	1218 (5.4%)	2053 (9.1%)	2437 (10.8%)	2437 (10.8%)	1218 (5.4%)	2053 (9.1%)	2437 (10.8%)	2437 (10.8%)
Complications	194 721		370	728	194 721		370	728
Total per patient cost	17,614 32,9	60	32,196	35,052	24, 885	23,778	18,892	31,620
Compared with Charité (%)	- 87.0		82.8	99.0	-	-.4.4	16.1	27.1

ALIF = anterior lumbar interbody fusion.
ICBG = iliac crest bone graft.
PLIF = posterior lumbar interbody fusion.
*****Revision rates provided by Guyer are based on the following references: Blumenthal et al[28] (ADR) and Brantigan et al[29], Burkus et al[32] (Fusion).

APPENDIX I. Excluded Studies for ADR

STUDIES EXCLUDED for L-ADR

Subset of clinical sites reporting preliminary data from a multicenter trial

Sasso RC, Foulk DM, Hahn M. Prospective, randomized trial of metal-on-metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. *Spine.* Jan 15 2008;33(2):123-131.

Auerbach JD, Wills BPD, McIntosh TC, Balderston RA. Lumbar disc arthroplasty versus fusion for single-level degenerative disc disease: Two-year results from a randomized prospective study. *Seminars in Spine Surgery.* Dec 2005;17(4):310-318.

Delamarter RB, Fribourg DM, Kanim LE, Bae H. Prodisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. *Spine.* Oct 15 2003;28(20):S167-175.

Guyer RD, McAfee PC, Hochschuler SH, et al. Prospective randomized study of the Charite artificial disc: data from two investigational centers. *Spine J.* Nov-Dec 2004;4(6 Suppl):252S-259S.

McAfee PC, Fedder IL, Saiedy S, Shucosky EM, Cunningham BW. Experimental design of total disk replacement-experience with a prospective randomized study of the SB Charite. *Spine.* Oct 15 2003;28(20):S153-162.

McAfee PC, Fedder IL, Saiedy S, Shucosky EM, Cunningham BW. SB Charite disc replacement: report of 60 prospective randomized cases in a US center. *J Spinal Disord Tech.* Aug 2003;16(4):424-433.

Zigler JE. Lumbar spine arthroplasty using the Prodisc II. *Spine J.* Nov-Dec 2004;4(6 Suppl):260S-267S.

Zigler JE, Burd TA, Vialle EN, Sachs BL, Rashbaum RF, Ohnmeiss DD. Lumbar spine arthroplasty: early results using the Prodisc II: a prospective randomized trial of arthroplasty versus fusion. *J Spinal Disord Tech.* Aug 2003;16(4):352-361.

Did not answer key questions

Geisler FH, Guyer RD, Blumenthal SL, et al. Patient selection for lumbar arthroplasty and arthrodesis: the effect of revision surgery in a controlled, multicenter, randomized study. *J Neurosurg Spine.* Jan 2008;8(1):13-16.

Yaszay B, Bendo JA, Goldstein JA, Quirno M, Spivak JM, Errico TJ. Effect of intervertebral disc height on postoperative motion and outcomes after Prodisc-L lumbar disc replacement. *Spine.* Mar 1 2008;33(5):508-512; discussion 513.

Regan JJ, McAfee PC, Blumenthal SL, et al. Evaluation of surgical volume and the early experience with lumbar total disc replacement as part of the investigational device exemption study of the Charite Artificial Disc. *Spine.* Sep1 2006;31(19):2270-2276.

STUDIES EXCLUDED for L-ADR

Biomechanical study

Moumene M, Geisler FH. Comparison of biomechanical function at ideal and varied surgical placement for two lumbar artificial disc implant designs: mobile-core versus fixed-core. *Spine.* Aug 1 2007;32(17):1840-1851.

Denoziere G, Ku DN. Biomechanical comparison between fusion of two vertebrae and implantation of an artificial intervertebral disc. *J Biomech.* 2006;39(4):766-775.

Did not report on primary outcome

Auerbach JD, Wills BP, McIntosh TC, Balderston RA. Evaluation of spinal kinematics following lumbar total disc replacement and circumferential fusion using in vivo fluoroscopy. *Spine.* Mar 1 2007;32(5):527-536.

Chin KR. Epidemiology of indications and contraindications to total disc replacement in an academic practice. *Spine J.* Jul-Aug 2007;7(4):392-398.

SariAli el H, Lemaire JP, Pascal-Mousselard H, Carrier H, Skalli W. In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-14 years follow up evaluation. *Eur Spine J.* Oct 2006;15(10):1501-1510.

Tournier C, Aunoble S, Le Huec JC, et al. Total disc arthroplasty: consequences for sagittal balance and lumbar spine movement. *Eur Spine J.* Mar 2007;16(3):411-421.

No relevant comparison group

Shim CS, Lee SH, Shin HD, et al. CHARITI versus Prodisc: A comparative study of a minimum 3-year follow-up. *Spine.* Apr 2007;32(9):1012-1018.

STUDIES EXCLUDED for C-ADR

Subset of clinical sites reporting preliminary data from a multicenter trial

Coric D, Finger F, Boltes P. Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. *J Neurosurg Spine.* Jan 2006;4(1):31-35.

Hacker RJ. Cervical disc arthroplasty: a controlled randomized prospective study with intermediate follow-up results. Invited submission from the joint section meeting on disorders of the spine and peripheral nerves, March 2005. *J Neurosurg Spine.* Dec 2005;3(6):424-428.

Sasso RC, Smucker JD, Hacker RJ, Heller JG. Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. *J Spinal Disord Tech.* Oct 2007;20(7):481-491.

Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: A prospective, randomized study with 2-year follow-up on 99 patients. *Spine.* Dec 2007;32(26):2933-2940.

Did not answer key questions

Bartels RH, Donk R, van der Wilt GJ, Grotenhuis JA, Venderink D. Design of the PROCON trial: a prospective, randomized multi-center study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty. *BMC Musculoskelet Disord.* 2006;7:85.

Biomechanical study

Chang UK, Kim DH, Lee MC, Willenberg R, Kim SH, Lim J. Changes in adjacent-level disc pressure and facet joint force after cervical arthroplasty compared with cervical discectomy and fusion. *J Neurosurg Spine.* Jul 2007;7(1):33-39.

Chang UK, Kim DH, Lee MC, Willenberg R, Kim SH, Lim J. Range of motion change after cervical arthroplasty with Prodisc-C and prestige artificial discs compared with anterior cervical discectomy and fusion. *J Neurosurg Spine.* Jul 2007;7(1):40-46.

Liu F, Cheng J, Komistek RD, Mahfouz MR, Sharma A. In vivo evaluation of dynamic characteristics of the normal, fused, and disc replacement cervical spines. *Spine.* Nov 1 2007;32(23):2578-2584.

Pickett GE, Rouleau JP, Duggal N. Kinematic analysis of the cervical spine following implantation of an artificial cervical disc. *Spine.* Sep 1 2005;30(17):1949-1954.

STUDIES EXCLUDED for C-ADR

Did not report on primary outcome

Sekhon LH, Duggal N, Lynch JJ, et al. Magnetic resonance imaging clarity of the Bryan, Prodisc-C, Prestige LP, and PCM cervical arthroplasty devices. *Spine.* Mar 15 2007;32(6):673-680.

No relevant comparison group

Johnson JP, Lauryssen C, Cambron HO, et al. Sagittal alignment and the Bryan cervical artificial disc. *Neurosurg Focus.* Dec 15 2004;17(6):E14.

Thome C, Leheta O, Krauss JK, Zevgaridis D. A prospective randomized comparison of rectangular titanium cage fusion and iliac crest autograft fusion in patients undergoing anterior cervical discectomy. *J Neurosurg Spine.* Jan 2006;4(1):1-9.

Duplicate report

Nabhan A, Ahlhelm F, Pitzen T, et al. Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. *Eur Spine J.* Mar 2007;16(3):423-430.

Preliminary data with minimal follow-up

Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus.* Sep 15 2004;17(3):E6.

APPENDIX J. Overview of Outcomes Measures

Oswestry Disability Index (ODI): Also called the Oswestry Low Back Pain Disability Questionnaire, is a standardized and validated patient-reported measure of disability. The ODI is a 10-item instrument; each item has 6 accompanying statements, which correspond to degrees of disability, and the respondent is asked to choose the statement that best describes his or her pain or discomfort. The 10 items are: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling. Scores range from 0-100; higher scores indicate greater disability.

Neck Disability Index (NDI): A validated patient-reported outcome questionnaire used to evaluate neck pain and its impact on disability in daily living tasks. The ten categories of recreation, sleeping, driving, work, concentration, pain intensity, self care, lifting, reading and headaches are scored on a 0 to 5 point scale. The total score is divided by the total number possible (50), and multiplied by 100%, to report a percentage of 0-100%, with a score of 10-28% representing mild disability, 30-48% moderate disability, 50-68% severe disability, and 72% or more complete disability.

***Visual Analog Scale (VAS)*:** Used to assess pain; patient asked to allocate his/her pain on a horizontal graphic rating scale (0-100), with the descriptions severe, moderate, and mild at equal intervals along a line that started with "pain as bad as it could be" and ended with "no pain". This was calculated as a percentage with 0% equivalent to "no pain" and 100% equivalent to "pain as bad as it could be".

***Short Form-36 (SF-36)*:** Standardized and validated questionnaire used to determine patients' healthcare-related quality of life (HRQOL). The SF-36 is composed of 36 items, with 8 domains that measure physical functioning, limitations in usual role of activities resulting from physical health problems, bodily pain, general health perceptions, vitality, social functioning, limitations in usual role activities because of emotional problems, and mental health; scored 0-100 (high score indicates positive health status). The eight domains are:

- Physical function
- Role-physical
- Bodily pain
- General health
- Vitality
- Social functioning
- Role-emotional
- Mental health

The Physical Component Summary (PCS) is a composite score which indicates physical status. Higher scores indicate better physical health status. Similarly, the Mental Component Summary (MCS) is a composite score which indicates mental status. Higher scores indicate better mental health status.

Japanese Orthopaedic Association score

	Grade
I. Motor function - arms	
Unable to feed oneself with chopsticks or a spoon	0
Able to feed oneself with a spoon but not with chopsticks	1
Able to use chopsticks	2
Slightly clumsy in using chopsticks	3
Normal 4	
II. Motor function - legs	
Unable to walk by any means	0
Unable to walk without a cane or others support on the level	1
Able to walk independently on the level but needs support on stairs	2
Slightly clumsy in walking	3
Normal 4	
III. Sensation	
Arms: definitely impaired	0
slightly impaired or subjectively numb	1
normal 2	
Trunk: 0-2 as above	
Legs: 0-2 as above	
IV. Bladder function	
Incontinent 0	
Great difficulty	1
Slight difficulty	2
Normal 3	
Total for normal patient	17

REFERENCE: Chapman JR, Hanson BP, Dettori JR, et a**l** (2007) *Spine Outcomes Measures and Instruments.* 1st ed. Stuttgart New York: Thieme. pp. 81-89, 249

Appendix K. Clinical and Peer Reviewers

Reviewer	Areas of expertise
Brian M. Drew, MD Assistant Clinical Professor Medical Director of Spine Unit Hamilton General Hospital (Ontario, Canada)	• Evidence-based practice • Spine fracture care • Adult spinal surgery • Spinal cord injury and clearance
Michael J. Lee, MD Assistant Professor, Orthopaedics & Sports Medicine University of Washington	• Orthopedic surgeon • Cadaveric/pathology correlation • Risk factor/complication evaluation
Jens Chapman MD Professor, Dept of Orthopedic Surgery, University of Washington School of Medicine	• Surgical treatment of spinal disorders • Disease severity • Spinal outcomes
Jennifer Mayfield, MD, MPH Primary Care and Preventative Medicine	• Clinical diabetes care • Quality assessment and improvement • Chronic disease registries • Electronic medical records • Primary care • Health Services Research
Ann Derleth, PhD, MSPH Health Services Researcher, Health Economics	• Quantitative methods for outcomes and economic analysis • Statistical methods for health services research including outcomes measures, disease severity and risk adjustment • Use of administrative data related to reimbursement policy
Sean D. Sullivan, PhD Director, Pharmaceutical Outcomes Research and Policy Program at University of Washington	• Research in pharmacy, health economics and outcomes and related areas

References

1. Food and Drug Administration (FDA). Clinical review for PMA (P040006) Charité artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004.
2. Food and Drug Administration (FDA). In-depth statistical review for expedited PMA (P040006) Charite artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004.
3. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED). Prosthesis intervertebral disc (report on the Internet). Edited, 2004.
4. Food and Drug Administration (FDA). New device approval: PRESTIGE cervical disc system - P060018 [report on the Internet]. Edited, 2007.
5. Food and Drug Administration (FDA). New device approval: ProDisc-C total disc replacement - P070001 [report on the Internet]. Edited, 2007.
6. Food and Drug Adminstration (FDA) Executive Summary, Bryan Cervical Disc. Edited, 2007.
7. NIH consensus conference: Total hip replacement. NIH Consensus Development Panel on Total Hip Replacement. *Jama,* 273(24): 1950-6, 1995.
8. NIH Consensus Statement on total knee replacement. *NIH Consens State Sci Statements,* 20(1): 1-34, 2003.
9. U.S. Artificial Disc Replacement Market to Reach $440 Million by 2013. In *Business Wire*. Edited, 2008.
10. Washington State Department of Health, Center for Health Statistics, Comprehensive Hospitalization Abstract Reporting System (2005-2007). Edited.
11. **Abd-Alrahman, N.; Dokmak, A. S.; and Abou-Madawi, A.:** Anterior cervical discectomy (ACD) versus anterior cervical fusion (ACF), clinical and radiological outcome study. *Acta Neurochir (Wien),* 141(10): 1089-92, 1999.
12. **Amit, A., and Dorward, N.:** Bryan cervical disc prosthesis: 12-Month clinical outcome. *British Journal of Neurosurgery,* 21(5): 478-484, 2007.
13. **An, H. S. et al.:** Introduction: disc degeneration: summary. *Spine,* 29(23): 2677-8, 2004.
14. **Anderson, P. A., and Rouleau, J. P.:** Intervertebral disc arthroplasty. *Spine,* 29(23): 2779-86, 2004.
15. **Andersson, G. B.:** The epidemiology of spinal disorders. In *The Adult Spine: Principles and Practice*, pp. 93-141. Edited by JW, F., 93-141, Philadelphia, Lippincott-Raven, 1997.
16. **Atkins, D. et al.:** Grading quality of evidence and strength of recommendations. *Bmj,* 328(7454): 1490, 2004.
17. **Badley, E. M.; Webster, G. K.; and Rasooly, I.:** The impact of musculoskeletal disorders in the population: are they just aches and pains? Findings from the 1990 Ontario Health Survey. *J Rheumatol,* 22(4): 733-9, 1995.
18. **Bartels, R. H.; Donk, R.; van der Wilt, G. J.; Grotenhuis, J. A.; and Venderink, D.:** Design of the PROCON trial: a prospective, randomized multi-center study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty. *BMC Musculoskelet Disord,* 7: 85, 2006.
19. **Bertagnoli, R.; Duggal, N.; Pickett, G. E.; Wigfield, C. C.; Gill, S. S.; Karg, A.; and Voigt, S.:** Cervical total disc replacement, part two: clinical results. *Orthop Clin North Am,* 36(3): 355-62, 2005.

20. **Bertagnoli, R., and Kumar, S.:** Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. *Eur Spine J,* 11 Suppl 2: S131-6, 2002.
21. **Bertagnoli, R. et al.:** Lumbar total disc arthroplasty utilizing the ProDisc prosthesis in smokers versus nonsmokers: a prospective study with 2-year minimum follow-up. *Spine,* 31(9): 992-7, 2006.
22. **Bertagnoli, R.; Yue, J. J.; Nanieva, R.; Fenk-Mayer, A.; Husted, D. S.; Shah, R. V.; and Emerson, J. W.:** Lumbar total disc arthroplasty in patients older than 60 years of age: a prospective study of the ProDisc prosthesis with 2-year minimum follow-up period. *J Neurosurg Spine,* 4(2): 85-90, 2006.
23. **Bertagnoli, R.; Yue, J. J.; Pfeiffer, F.; Fenk-Mayer, A.; Lawrence, J. P.; Kershaw, T.; and Nanieva, R.:** Early results after ProDisc-C cervical disc replacement. *J Neurosurg Spine,* 2(4): 403-10, 2005.
24. **Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.:** The treatment of disabling multilevel lumbar discogenic low back pain with total disc arthroplasty utilizing the ProDisc prosthesis: a prospective study with 2-year minimum follow-up. *Spine,* 30(19): 2192-9, 2005.
25. **Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.:** The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year minimum follow-up. *Spine,* 30(19): 2230-6, 2005.
26. **Blue Cross Blue Shield Association:** Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2007.
27. **Blue Cross Blue Shield Association:** Artificial vertebral disc replacement [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2005.
28. **Blumenthal, S.; McAfee, P. C.; Guyer, R. D.; Hochschuler, S. H.; Geisler, F. H.; Holt, R. T.; Garcia, R., Jr.; Regan, J. J.; and Ohnmeiss, D. D.:** A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. *Spine,* 30(14): 1565-75; discussion E387-91, 2005.
29. **Brantigan, J. W.; Steffee, A. D.; Lewis, M. L.; Quinn, L. M.; and Persenaire, J. M.:** Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial. *Spine,* 25(11): 1437-46, 2000.
30. **Brox, J. I. et al.:** Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. *Pain,* 122(1-2): 145-55, 2006.
31. **Brox, J. I. et al.:** Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. *Spine,* 28(17): 1913-21, 2003.
32. **Burkus, J. K.; Heim, S. E.; Gornet, M. F.; and Zdeblick, T. A.:** Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-CAGE lumbar tapered fusion device. *J Spinal Disord Tech,* 16(2): 113-22, 2003.
33. **Cabanela, M. E.; Campbell, D. C., 2nd; and Henderson, E. D.:** Total joint arthroplasty. The hip. *Mayo Clin Proc,* 54(9): 559-63, 1979.

34. **Carragee, E. J. et al.:** Treatment of neck pain: injections and surgical interventions: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine,* 33(4 Suppl): S153-69, 2008.
35. **Caspi, I.; Levinkopf, M.; and Nerubay, J.:** Results of lumbar disk prosthesis after a follow-up period of 48 months. *Isr Med Assoc J,* 5(1): 9-11, 2003.
36. **Chiou, C. F. et al.:** Development and validation of a grading system for the quality of cost-effectiveness studies. *Med Care,* 41(1): 32-44, 2003.
37. **Cho, K. J.; Suk, S. I.; Park, S. R.; Kim, J. H.; Kim, S. S.; Choi, W. K.; Lee, K. Y.; and Lee, S. R.:** Complications in posterior fusion and instrumentation for degenerative lumbar scoliosis. *Spine,* 32(20): 2232-7, 2007.
38. **Chou, W. Y.; Hsu, C. J.; Chang, W. N.; and Wong, C. Y.:** Adjacent segment degeneration after lumbar spinal posterolateral fusion with instrumentation in elderly patients. *Arch Orthop Trauma Surg,* 122(1): 39-43, 2002.
39. **Chung, S. S.; Lee, C. S.; and Kang, C. S.:** Lumbar total disc replacement using ProDisc II: a prospective study with a 2-year minimum follow-up. *J Spinal Disord Tech,* 19(6): 411-5, 2006.
40. **Chung, S. S.; Lee, C. S.; Kang, C. S.; and Kim, S. H.:** The effect of lumbar total disc replacement on the spinopelvic alignment and range of motion of the lumbar spine. *J Spinal Disord Tech,* 19(5): 307-11, 2006.
41. **Cihangiroglu, M.; Yildirim, H.; Bozgeyik, Z.; Senol, U.; Ozdemir, H.; Topsakal, C.; and Yilmaz, S.:** Observer variability based on the strength of MR scanners in the assessment of lumbar degenerative disc disease. *Eur J Radiol,* 51(3): 202-8, 2004.
42. **Cinotti, G.; David, T.; and Postacchini, F.:** Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine,* 21(8): 995-1000, 1996.
43. **Coric, D.; Finger, F.; and Boltes, P.:** Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. *J Neurosurg Spine,* 4(1): 31-5, 2006.
44. **Cunningham, B. W. et al.:** Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITE artificial disc compared with fusion. *J Neurosurg Spine,* 8(1): 7-12, 2008.
45. **David, T.:** Long-term results of one-level lumbar arthroplasty: minimum 10-year follow-up of the CHARITE artificial disc in 106 patients. *Spine,* 32(6): 661-6, 2007.
46. **de Kleuver, M.; Oner, F. C.; and Jacobs, W. C.:** Total disc replacement for chronic low back pain: background and a systematic review of the literature. *Eur Spine J,* 12(2): 108-16, 2003.
47. **Deyo, R. A.; Gray, D. T.; Kreuter, W.; Mirza, S.; and Martin, B. I.:** United States trends in lumbar fusion surgery for degenerative conditions. *Spine,* 30(12): 1441-5; discussion 1446-7, 2005.
48. **Dowd, G. C., and Wirth, F. P.:** Anterior cervical discectomy: is fusion necessary? *J Neurosurg,* 90(1 Suppl): 8-12, 1999.
49. **Drummond MF:** Methods for the economic evaluation of health care programmes. Edited, Oxford; New York, Oxford University Press, 2005.
50. **Duggal, N.; Pickett, G. E.; Mitsis, D. K.; and Keller, J. L.:** Early clinical and biomechanical results following cervical arthroplasty. *Neurosurg Focus,* 17(3): E9, 2004.
51. **Errico, T. J.:** Lumbar disc arthroplasty. *Clin Orthop Relat Res,* (435): 106-17, 2005.
52. **Etebar, S., and Cahill, D. W.:** Risk factors for adjacent-segment failure following lumbar fixation with rigid instrumentation for degenerative instability. *J Neurosurg,* 90(2 Suppl): 163-9, 1999.

53. **Fairbank, J.; Frost, H.; Wilson-MacDonald, J.; Yu, L. M.; Barker, K.; and Collins, R.:** Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. *BMJ,* 330(7502): 1233, 2005.
54. **Fernstrom, U.:** Arthroplasty with intercorporal endoprosthesis in herniated disc and in painful disc. *Acta Chir Scand Suppl,* 357: 154-9, 1966.
55. **Fong, S. Y.; DuPlessis, S. J.; Casha, S.; and Hurlbert, R. J.:** Design limitations of Bryan disc arthroplasty. *Spine J,* 6(3): 233-41, 2006.
56. **Fraser, R. D.; Ross, E. R.; Lowery, G. L.; Freeman, B. J.; and Dolan, M.:** AcroFlex design and results. *Spine J,* 4(6 Suppl): 245S-251S, 2004.
57. **Frelinghuysen, P.; Huang, R. C.; Girardi, F. P.; and Cammisa, F. P., Jr.:** Lumbar total disc replacement part I: rationale, biomechanics, and implant types. *Orthop Clin North Am,* 36(3): 293-9, 2005.
58. **Fritzell, P.; Hagg, O.; and Nordwall, A.:** Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group. *Eur Spine J,* 12(2): 178-89, 2003.
59. **Fritzell, P.; Hagg, O.; Wessberg, P.; and Nordwall, A.:** 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine,* 26(23): 2521-32; discussion 2532-4, 2001.
60. **Frymoyer, J. W.:** The economics of spinal disorders. In *The Adult Spine: Principles and Practice*, pp. 143-150. Edited by JW, F., 143-150, Philadelphia, Lippincott-Raven, 1997.
61. **Geisler, F. H.; Blumenthal, S. L.; Guyer, R. D.; McAfee, P. C.; Regan, J. J.; Johnson, J. P.; and Mullin, B.:** Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. *J Neurosurg Spine,* 1(2): 143-54, 2004.
62. **Ghiselli, G.; Wang, J. C.; Bhatia, N. N.; Hsu, W. K.; and Dawson, E. G.:** Adjacent segment degeneration in the lumbar spine. *J Bone Joint Surg Am,* 86-A(7): 1497-503, 2004.
63. **Gibson, J. N., and Waddell, G.:** Surgery for degenerative lumbar spondylosis
Surgery for degenerative lumbar spondylosis: updated Cochrane Review. *Cochrane Database Syst Rev.,* 30(4): CD001352., 2005.
64. **Goetz, C. G.:** Textbook of Clinical Neurology. Edited, Philadelphia, PA, Saunders Elsevier, 2003.
65. **Goffin, J.; Geusens, E.; Vantomme, N.; Quintens, E.; Waerzeggers, Y.; Depreitere, B.; Van Calenbergh, F.; and van Loon, J.:** Long-term follow-up after interbody fusion of the cervical spine. *J Spinal Disord Tech,* 17(2): 79-85, 2004.
66. **Goffin, J. et al.:** Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. *Spine,* 28(24): 2673-8, 2003.
67. **Guyer, R. D.; Geisler, F. H.; Blumenthal, S. L.; McAfee, P. C.; and Mullin, B. B.:** Effect of age on clinical and radiographic outcomes and adverse events following 1-level lumbar arthroplasty after a minimum 2-year follow-up. *J Neurosurg Spine,* 8(2): 101-7, 2008.

68. **Guyer RD, T. S., Regan JJ:** An economic model of one-level lumbar arthoplasty versus fusion. *Spine Journal,* 7(5): 558-562, 2007.
69. **Hallab, N.; Link, H. D.; and McAfee, P. C.:** Biomaterial optimization in total disc arthroplasty. *Spine,* 28(20): S139-52, 2003.
70. **Hambly, M. F.; Wiltse, L. L.; Raghavan, N.; Schneiderman, G.; and Koenig, C.:** The transition zone above a lumbosacral fusion. *Spine,* 23(16): 1785-92, 1998.
71. **Harris, W. H., and Sledge, C. B.:** Total hip and total knee replacement (1). *N Engl J Med,* 323(11): 725-31, 1990.
72. **Harris, W. H., and Sledge, C. B.:** Total hip and total knee replacement (2). *N Engl J Med,* 323(12): 801-7, 1990.
73. **Hartvigsen, J.; Christensen, K.; and Frederiksen, H.:** Back and neck pain exhibit many common features in old age: a population-based study of 4,486 Danish twins 70-102 years of age. *Spine,* 29(5): 576-80, 2004.
74. **Heidecke, V.; Burkert, W.; Brucke, M.; and Rainov, N. G.:** Intervertebral disc replacement for cervical degenerative disease--clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. *Acta Neurochir (Wien),* 150(5): 453-9; discussion 459, 2008.
75. **Herkowitz, H. N.; Kurz, L. T.; and Overholt, D. P.:** Surgical management of cervical soft disc herniation. A comparison between the anterior and posterior approach. *Spine,* 15(10): 1026-30, 1990.
76. **Hermsmeyer, J. T.:** Outcomes Measures and Instruments. In *Spine Outcomes Measures and Instruments*, pp. 114-115, 249. Edited by Chapman, J. R.; Hanson, B. P.; Dettori, J. R.; and Norvell, D. C., 114-115, 249, Stuttgart, New York, Thieme, 2007.
77. **Higgins, J. P., and Thompson, S. G.:** Quantifying heterogeneity in a meta-analysis. *Stat Med,* 21(11): 1539-58, 2002.
78. **Higgins, J. P.; Thompson, S. G.; Deeks, J. J.; and Altman, D. G.:** Measuring inconsistency in meta-analyses. *Bmj,* 327(7414): 557-60, 2003.
79. **Hilibrand, A. S.; Carlson, G. D.; Palumbo, M. A.; Jones, P. K.; and Bohlman, H. H.:** Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg Am,* 81(4): 519-28, 1999.
80. **Hoang, L.; Thongtrangan, I.; and Kim, D.:** Historical review of cervical arthroplasty. Edited, 2004.
81. **Huang, R. C.; Lim, M. R.; Girardi, F. P.; and Cammisa, F. P., Jr.:** The prevalence of contraindications to total disc replacement in a cohort of lumbar surgical patients. *Spine,* 29(22): 2538-41, 2004.
82. **Huang, R. C.; Tropiano, P.; Marnay, T.; Girardi, F. P.; Lim, M. R.; and Cammisa, F. P., Jr.:** Range of motion and adjacent level degeneration after lumbar total disc replacement. *Spine J,* 6(3): 242-7, 2006.
83. **Ishihara, H.; Kanamori, M.; Kawaguchi, Y.; Nakamura, H.; and Kimura, T.:** Adjacent segment disease after anterior cervical interbody fusion. *Spine J,* 4(6): 624-8, 2004.
84. **Jollenbeck, B.; Hahne, R.; Schubert, A.; and Firsching, R.:** Early experiences with cervical disc prostheses. *Zentralbl Neurochir,* 65(3): 123-7, 2004.
85. **Jones, C. A.; Voaklander, D. C.; Johnston, D. W.; and Suarez-Almazor, M. E.:** Health related quality of life outcomes after total hip and knee arthroplasties in a community based population. *J Rheumatol,* 27(7): 1745-52, 2000.
86. **Kanayama, M.; Hashimoto, T.; Shigenobu, K.; Harada, M.; Oha, F.; Ohkoshi, Y.; Tada, H.; Yamamoto, K.; and Yamane, S.:** Adjacent-segment morbidity after Graf

ligamentoplasty compared with posterolateral lumbar fusion. *J Neurosurg,* 95(1 Suppl): 5-10, 2001.
87. **Katsuura, A.; Hukuda, S.; Saruhashi, Y.; and Mori, K.:** Kyphotic malalignment after anterior cervical fusion is one of the factors promoting the degenerative process in adjacent intervertebral levels. *Eur Spine J,* 10(4): 320-4, 2001.
88. **Katz, J. N. et al.:** Association of hospital and surgeon volume of total hip replacement with functional status and satisfaction three years following surgery. *Arthritis Rheum,* 48(2): 560-8, 2003.
89. **Kim, D. H.; Ryu, K. S.; Kim, M. K.; and Park, C. K.:** Factors influencing segmental range of motion after lumbar total disc replacement using the ProDisc II prosthesis. *J Neurosurg Spine,* 7(2): 131-8, 2007.
90. **Kim, S. H.; Shin, H. C.; Shin, D. A.; Kim, K. N.; and Yoon do, H.:** Early clinical experience with the mobi-C disc prosthesis. *Yonsei Med J,* 48(3): 457-64, 2007.
91. **Kulkarni, V.; Rajshekhar, V.; and Raghuram, L.:** Accelerated spondylotic changes adjacent to the fused segment following central cervical corpectomy: magnetic resonance imaging study evidence. *J Neurosurg,* 100(1 Suppl Spine): 2-6, 2004.
92. **Kumar, M. N.; Jacquot, F.; and Hall, H.:** Long-term follow-up of functional outcomes and radiographic changes at adjacent levels following lumbar spine fusion for degenerative disc disease. *Eur Spine J,* 10(4): 309-13, 2001.
93. **Lafuente, J.; Casey, A. T.; Petzold, A.; and Brew, S.:** The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis: 46 consecutive cases. *J Bone Joint Surg Br,* 87(4): 508-12, 2005.
94. **Laupacis, A.; Bourne, R.; Rorabeck, C.; Feeny, D.; Wong, C.; Tugwell, P.; Leslie, K.; and Bullas, R.:** The effect of elective total hip replacement on health-related quality of life. *J Bone Joint Surg Am,* 75(11): 1619-26, 1993.
95. **Le Huec, J. C.; Mathews, H.; Basso, Y.; Aunoble, S.; Hoste, D.; Bley, B.; and Friesem, T.:** Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up. *Orthop Clin North Am,* 36(3): 315-22, 2005.
96. **Leivseth, G.; Braaten, S.; Frobin, W.; and Brinckmann, P.:** Mobility of lumbar segments instrumented with a ProDisc II prosthesis: A two-year follow-up study. *Spine,* 31(15): 1726-1733, 2006.
97. **Lemaire, J. P.; Carrier, H.; Sariali el, H.; Skalli, W.; and Lavaste, F.:** Clinical and radiological outcomes with the Charite artificial disc: a 10-year minimum follow-up. *J Spinal Disord Tech,* 18(4): 353-9, 2005.
98. **Leung, C.; Casey, A. T.; Goffin, J.; Kehr, P.; Liebig, K.; Lind, B.; Logroscino, C.; and Pointillart, V.:** Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. *Neurosurgery,* 57(4): 759-63; discussion 759-63, 2005.
99. **Levin, D. A.; Bendo, J. A.; Quirno, M.; Errico, T.; Goldstein, J.; and Spivak, J.:** Comparative charge analysis of one- and two-level lumbar total disc arthroplasty versus circumferential lumbar fusion. *Spine,* 32(25): 2905-9, 2007.
100. **Levin DA, B. J., Quirno M, Errico T, Goldstein J, Spivak J:** Comparative charge analysis of one- and two-level lumbar total disc arthroplasty versus circumferential lumbar fusion. *Spine* 32(25): 2905-9, 2007.
101. **Lin, E. L., and Wang, J. C.:** Total disk arthroplasty. *J Am Acad Orthop Surg,* 14(13): 705-14, 2006.

102. **Liu, F.; Cheng, J.; Komistek, R. D.; Mahfouz, M. R.; and Sharma, A.:** In vivo evaluation of dynamic characteristics of the normal, fused, and disc replacement cervical spines. *Spine,* 32(23): 2578-84, 2007.
103. **Lunsford, L. D.; Bissonette, D. J.; Jannetta, P. J.; Sheptak, P. E.; and Zorub, D. S.:** Anterior surgery for cervical disc disease. Part 1: Treatment of lateral cervical disc herniation in 253 cases. *J Neurosurg,* 53(1): 1-11, 1980.
104. **Martins, A. N.:** Anterior cervical discectomy with and without interbody bone graft. *J Neurosurg,* 44(3): 290-5, 1976.
105. **Mathers, C.:** The burden of disease and injury in Australia. Edited, Canberra, Australian Institute of Health and Welfare, 1999.
106. **Mayer, H. M.:** Total lumbar disc replacement. *J Bone Joint Surg Br,* 87(8): 1029-37, 2005.
107. **Mayer, H. M., and Wiechert, K.:** Microsurgical anterior approaches to the lumbar spine for interbody fusion and total disc replacement. *Neurosurgery,* 51(5 Suppl): S159-65, 2002.
108. **McAfee, P. C.:** The indications for lumbar and cervical disc replacement. *Spine J,* 4(6 Suppl): 177S-181S, 2004.
109. **McAfee, P. C. et al.:** A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. *Spine,* 30(14): 1576-83; discussion E388-90, 2005.
110. **McAfee, P. C. et al.:** Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. *Spine,* 31(11): 1217-26, 2006.
111. **McCullen, G. M., and Yuan, H. A.:** Artificial disc: current developments in artificial disc replacement. *Curr Opin Orthop,* 14: 138-143, 2003.
112. **Medical Services Advisory Committee (Australia):** Artificial intervertebral disc replacement (Total disc arthroplasty). Edited, Canberra, Commonwealth of Australia, 2006.
113. **Mehren, C.; Suchomel, P.; Grochulla, F.; Barsa, P.; Sourkova, P.; Hradil, J.; Korge, A.; and Mayer, H. M.:** Heterotopic ossification in total cervical artificial disc replacement. *Spine,* 31(24): 2802-6, 2006.
114. **Miyakoshi, N.; Abe, E.; Shimada, Y.; Okuyama, K.; Suzuki, T.; and Sato, K.:** Outcome of one-level posterior lumbar interbody fusion for spondylolisthesis and postoperative intervertebral disc degeneration adjacent to the fusion. *Spine,* 25(14): 1837-42, 2000.
115. **Mummaneni, P. V.; Burkus, J. K.; Haid, R. W.; Traynelis, V. C.; and Zdeblick, T. A.:** Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine,* 6(3): 198-209, 2007.
116. **Murphy, M. G., and Gado, M.:** Anterior cervical discectomy without interbody bone graft. *J Neurosurg,* 37(1): 71-4, 1972.
117. **Nabhan, A.; Ahlhelm, F.; Pitzen, T.; Steudel, W. I.; Jung, J.; Shariat, K.; Steimer, O.; Bachelier, F.; and Pape, D.:** Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. *Eur Spine J,* 16(3): 423-30, 2007.

118. **Nabhan, A.; Ahlhelm, F.; Shariat, K.; Pitzen, T.; Steimer, O.; Steudel, W. I.; and Pape, D.:** The ProDisc-C prosthesis: clinical and radiological experience 1 year after surgery. *Spine,* 32(18): 1935-41, 2007.
119. **Ofman, J. J.; Sullivan, S. D.; Neumann, P. J.; Chiou, C. F.; Henning, J. M.; Wade, S. W.; and Hay, J. W.:** Examining the value and quality of health economic analyses: implications of utilizing the QHES. *J Manag Care Pharm,* 9(1): 53-61, 2003.
120. **Patel, R. K., and Slipman, C. W.:** Lumbar degenerative disk disease. Edited, Omaha, 2007.
121. **Peng-Fei, S., and Yu-Hua, J.:** Cervical disc prosthesis replacement and interbody fusion: a comparative study. *Int Orthop,* 32(1): 103-6, 2008.
122. **Petersilge, C. A.:** Lumbar disc replacement. *Semin Musculoskelet Radiol,* 10(1): 22-9, 2006.
123. **Phillips, B.; Ball, C.; Sackett, D.; Badenoch, D.; Straus, S.; Haynes, B.; and Dawes, M.:** Levels of evidence and grades of recommendation. Available at: http://www.cebm.net/levels_of_evidence.asp. Edited, 2001.
124. **Piaggio, G.; Elbourne, D. R.; Altman, D. G.; Pocock, S. J.; and Evans, S. J.:** Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *Jama,* 295(10): 1152-60, 2006.
125. **Pickett, G. E.; Sekhon, L. H.; Sears, W. R.; and Duggal, N.:** Complications with cervical arthroplasty. *J Neurosurg Spine,* 4(2): 98-105, 2006.
126. **Pickett, G. E.; Van Soelen, J.; and Duggal, N.:** Controversies in cervical discectomy and fusion: practice patterns among Canadian surgeons. *Can J Neurol Sci,* 31(4): 478-83, 2004.
127. **Pimenta, L.; McAfee, P. C.; Cappuccino, A.; Bellera, F. P.; and Link, H. D.:** Clinical experience with the new artificial cervical PCM (Cervitech) disc. *Spine J,* 4(6 Suppl): 315S-321S, 2004.
128. **Pointillart, V.:** Cervical disc prosthesis in humans: first failure. *Spine,* 26(5): E90-2, 2001.
129. **Porchet, F., and Metcalf, N. H.:** Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus,* 17(3): E6, 2004.
130. **Punt, I. M.; Visser, V. M.; van Rhijn, L. W.; Kurtz, S. M.; Antonis, J.; Schurink, G. W.; and van Ooij, A.:** Complications and reoperations of the SB Charite lumbar disc prosthesis: experience in 75 patients. *Eur Spine J,* 17(1): 36-43, 2008.
131. **Putzier, M.; Funk, J. F.; Schneider, S. V.; Gross, C.; Tohtz, S. W.; Khodadadyan-Klostermann, C.; Perka, C.; and Kandziora, F.:** Charite total disc replacement--clinical and radiographical results after an average follow-up of 17 years. *Eur Spine J,* 15(2): 183-95, 2006.
132. **Rabin, D.; Pickett, G. E.; Bisnaire, L.; and Duggal, N.:** The kinematics of anterior cervical discectomy and fusion versus artificial cervical disc: a pilot study. *Neurosurgery,* 61(3 Suppl): 100-4; discussion 104-5, 2007.
133. **Rao, R. D.; Gourab, K.; and David, K. S.:** Operative treatment of cervical spondylotic myelopathy. *J Bone Joint Surg Am,* 88(7): 1619-40, 2006.
134. **Ratliff, J. K., and Cooper, P. R.:** Cervical laminoplasty: a critical review. *J Neurosurg,* 98(3 Suppl): 230-8, 2003.
135. **Regan, J. J.; McAfee, P. C.; Blumenthal, S. L.; Guyer, R. D.; Geisler, F. H.; Garcia, R., Jr.; and Maxwell, J. H.:** Evaluation of surgical volume and the early experience with

lumbar total disc replacement as part of the investigational device exemption study of the Charite Artificial Disc. *Spine,* 31(19): 2270-6, 2006.
136. **Robertson, J. T., and Metcalf, N. H.:** Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. *Neurosurg Focus,* 17(3): E10, 2004.
137. **Robertson, J. T.; Papadopoulos, S. M.; and Traynelis, V. C.:** Assessment of adjacent-segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study. *J Neurosurg Spine,* 3(6): 417-23, 2005.
138. **Rodts, M. F.:** Total disc replacement arthroplasty. *Orthop Nurs,* 23(3): 216-9, 2004.
139. **Roh, J. S.; Teng, A. L.; Yoo, J. U.; Davis, J.; Furey, C.; and Bohlman, H. H.:** Degenerative disorders of the lumbar and cervical spine. *Orthop Clin North Am,* 36(3): 255-62, 2005.
140. **SariAli el, H.; Lemaire, J. P.; Pascal-Mousselard, H.; Carrier, H.; and Skalli, W.:** In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-14 years follow up evaluation. *Eur Spine J,* 15(10): 1501-10, 2006.
141. **Sasso, R. C.; Foulk, D. M.; and Hahn, M.:** Prospective, randomized trial of metal-on-metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. *Spine,* 33(2): 123-31, 2008.
142. **Sasso, R. C.; Smucker, J. D.; Hacker, R. J.; and Heller, J. G.:** Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. *J Spinal Disord Tech,* 20(7): 481-91, 2007.
143. **Schwarzer, A. C.; Aprill, C. N.; Derby, R.; Fortin, J.; Kine, G.; and Bogduk, N.:** The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. *Spine,* 20(17): 1878-83, 1995.
144. **Seitsalo, S.; Schlenzka, D.; Poussa, M.; and Osterman, K.:** Disc degeneration in young patients with isthmic spondylolisthesis treated operatively or conservatively: a long-term follow-up. *Eur Spine J,* 6(6): 393-7, 1997.
145. **Sekhon, L. H.:** Cervical arthroplasty in the management of spondylotic myelopathy: 18-month results. *Neurosurg Focus,* 17(3): E8, 2004.
146. **Sekhon, L. H., and Ball, J. R.:** Artificial cervical disc replacement: principles, types and techniques. *Neurol India,* 53(4): 445-50, 2005.
147. **Shim, C. S.; Lee, S. H.; Park, H. J.; Kang, H. S.; and Hwang, J. H.:** Early clinical and radiologic outcomes of cervical arthroplasty with Bryan Cervical Disc prosthesis. *J Spinal Disord Tech,* 19(7): 465-70, 2006.
148. **Shim, C. S. et al.:** CHARITI versus ProDisc: A comparative study of a minimum 3-year follow-up. *Spine,* 32(9): 1012-1018, 2007.
149. **Siepe, C. J.; Mayer, H. M.; Heinz-Leisenheimer, M.; and Korge, A.:** Total lumbar disc replacement: different results for different levels. *Spine,* 32(7): 782-90, 2007.
150. **Siepe, C. J.; Wiechert, K.; Khattab, M. F.; Korge, A.; and Mayer, H. M.:** Total lumbar disc replacement in athletes: clinical results, return to sport and athletic performance. *Eur Spine J,* 16(7): 1001-13, 2007.
151. **Singh K, V. A., Albert TJ:** Assessing the potential impact of total disc arthroplasty on surgeon practice patterns in North America. *Spine Journal,* 4(6S): S195-201, 2004.
152. **Snapinn, S. M.:** Noninferiority trials. *Curr Control Trials Cardiovasc Med,* 1(1): 19-21, 2000.

153. **Span, M. M.; TenVergert, E. M.; van der Hilst, C. S.; and Stolk, R. P.:** Noninferiority testing in cost-minimization studies: Practical issues concerning power analysis. *Int J Technol Assess Health Care,* 22(2): 261-6, 2006.
154. **Teramoto, T.; Ohmori, K.; Takatsu, T.; Inoue, H.; Ishida, Y.; and Suzuki, K.:** Long-term results of the anterior cervical spondylodesis. *Neurosurgery,* 35(1): 64-8, 1994.
155. **The Medical Advisory Secretariat:** Artificial discs for lumbar and cervical degenerative disc disease - update. Edited, Toronto, Ministry of Health and Long Term Care, 2006.
156. **Tortolani, P. J.; Cunningham, B. W.; Eng, M.; McAfee, P. C.; Holsapple, G. A.; and Adams, K. A.:** Prevalence of heterotopic ossification following total disc replacement. A prospective, randomized study of two hundred and seventy-six patients. *J Bone Joint Surg Am,* 89(1): 82-8, 2007.
157. **Tropiano, P.; Huang, R. C.; Girardi, F. P.; Cammisa, F. P., Jr.; and Marnay, T.:** Lumbar total disc replacement. Seven to eleven-year follow-up. *J Bone Joint Surg Am,* 87(3): 490-6, 2005.
158. **Tropiano, P.; Huang, R. C.; Girardi, F. P.; and Marnay, T.:** Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. *J Spinal Disord Tech,* 16(4): 362-8, 2003.
159. **Truumees, E., and Herkowitz, H. N.:** Cervical spondylotic myelopathy and radiculopathy. *Instr Course Lect,* 49: 339-60, 2000.
160. **West, S., King V, Carey TS, et.al.:** Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment No. 47 (Prepared by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center, Contract No. 290-97-0011). Edited, Agency for Healthcare Research and Quality, Rockville, MD, 2002.
161. **Wigfield, C.; Gill, S.; Nelson, R.; Langdon, I.; Metcalf, N.; and Robertson, J.:** Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. *J Neurosurg,* 96(1 Suppl): 17-21, 2002.
162. **Wigfield, C. C.; Gill, S. S.; Nelson, R. J.; Metcalf, N. H.; and Robertson, J. T.:** The new Frenchay artificial cervical joint: results from a two-year pilot study. *Spine,* 27(22): 2446-52, 2002.
163. **Wright, J. G.; Swiontkowski, M. F.; and Heckman, J. D.:** Introducing levels of evidence to the journal. *J Bone Joint Surg Am,* 85-A(1): 1-3, 2003.
164. **Xu, Y. C.; Liu, S. L.; Huang, D. S.; Shen, H. Y.; Li, C. H.; and Ma, R. F.:** Correlated evaluation on the spinal segment motion scope and the alteration of the corresponding parameters after artificial lumbar intervertebral disc replacement. *Ch J of Clin Rehab,* 8(32): 7294-96, 2004.
165. **Yang, S.; Hu, Y.; Zhao, J.; He, X.; Liu, Y.; Xu, W.; Du, J.; and Fu, D.:** Follow-up study on the motion range after treatment of degenerative disc disease with the Bryan cervical disc prosthesis. *J Huazhong Univ Sci Technolog Med Sci,* 27(2): 176-8, 2007.
166. **Yoon, D. H.; Yi, S.; Shin, H. C.; Kim, K. N.; and Kim, S. H.:** Clinical and radiological results following cervical arthroplasty. *Acta Neurochirurgica,* 148(9): 943-950, 2006.
167. **Young, W. F.:** Cervical spondylotic myelopathy: a common cause of spinal cord dysfunction in older persons. *Am Fam Physician,* 62(5): 1064-70, 1073, 2000.
168. **Yue, W. M.; Brodner, W.; and Highland, T. R.:** Long-term results after anterior cervical discectomy and fusion with allograft and plating: a 5- to 11-year radiologic and clinical follow-up study. *Spine,* 30(19): 2138-44, 2005.
169. **Zdeblick, T. A.:** The treatment of degenerative lumbar disorders. A critical review of the literature. *Spine,* 20(24 Suppl): 126S-137S, 1995.

170. **Zeegers, W. S.; Bohnen, L. M.; Laaper, M.; and Verhaegen, M. J.:** Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. *Eur Spine J,* 8(3): 210-7, 1999.

171. **Zigler, J. et al.:** Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine,* 32(11): 1155-62; discussion 1163, 2007.

Displaying 1 - 50 of 50 responses << Prev Next >> **Jump To:** 1 Go >>

	Comment Text	Response Date
Find	**1.** I'm moreinterested in the meeting content and the orogram in general than I am about making the meeting a vacation.	Wed, 10/15/08 3:36 PM
Find	**2.** I go to the meeting for the educational value only. The high costs of resorts, golf, etc. are negatives. I'd prefer urban, middle cost, locations. There are nice places with room rates under $200!	Tue, 10/14/08 2:59 PM
Find	**3.** Hawaii should be considered as another choice. It is near for us Japanese, easy to play golf and many people in Hawaii can hear Japanese. With no doubt, many Japanese would attend the meeting.	Mon, 10/13/08 8:38 AM
Find	**4.** Unfortunately, my present medical condition does not permit to attend this meeting. Thank you. Joseph M. Waltz, MD	Sun, 10/12/08 10:35 AM
Find	**5.** Can a ski resort be accomodated?	Sat, 10/11/08 2:40 PM
Find	**6.** Please do not ever go to Orlando again!!! Most people despise it. In fact, I tend not to go to the meeting when it is in Orlando. In fact, I pretty much hate Orlando!!!!!	Fri, 10/10/08 4:20 PM
Find	**7.** The Marriott in Phoenix has been a great venue.	Thu, 10/9/08 11:34 PM
Find	**8.** From the standpoint of overseas participants, the venue of the annual meeting is most important. For example, Orlando is a very attractive place, however it takes hours to reach from Asia including Japan. I hope you will kindly consider this point. (I personally love Disney.)	Wed, 10/8/08 1:38 AM
Find	**9.** Tired of Orlando.	Tue, 10/7/08 6:55 PM
Find	**10.** Perhaps some new venues where there is skiing - Colorado, Utah Need a broader, more encompassing perspective by the speakers. Seems like the same old group of speakers (most of which are conflicted) that say the same thing at every conference. How about having more international speakers, try to include more South American spine surgeons. Definitely need a section of the conference that addressed "Emerging technologies", so we can keep up Europe and have a sense of what is coming.	Tue, 10/7/08 6:45 PM
Find	**11.** I am retired military with a daughter who needs a wheelchair. and places friendly to the military makes many cities like San Francisco off limits for me and my family.	Tue, 10/7/08 6:45 PM
Find	**12.** Having a place where my family can have things to do while I am at the meeting is key.	Tue, 10/7/08 4:57 PM
Find	**13.** In todays economy you ignore costs at your own peril	Tue, 10/7/08 4:12 PM
Find	**14.** Usually my children are not off for spring break during the spine section. With increase costs and reduced remuneration, I think room costs and air travel costs will be important.	Tue, 10/7/08 2:26 PM
Find	**15.** Academic content is still my #1 priority.	Tue, 10/7/08 1:46 PM
Find	**16.** sun and sea in Feb and March	Tue, 10/7/08 12:46 PM

Find	**17.** Dan -- I have four kids and not enough money. I need a meeting relatively close to New England. I'm still trying to pay off all the debt I racked up at Pitt. My wife does not let me golf. And she keeps me working all the live-long day so it's important that I can hop on a cheap flight and be back in time to work, work, work. Thanks, J.Wahlig	Tue, 10/7/08 10:35 AM
Find	**18.** Meeting always tends to fall on or around spring break. It is hard to take 2 weeks off in one month. I would rather see the meeting fall in Feb and maybe have a ski meeting, or have it in Florida.	Tue, 10/7/08 10:27 AM
Find	**19.** I have children in school. If the conference can be centered around school breaks that would be helpful. I can not take a week off with my family and then take another week off two weeks later.	Tue, 10/7/08 10:23 AM
Find	**20.** maintain these meetings in the southeast and southwest as you have been doing	Tue, 10/7/08 9:08 AM
Find	**21.** In this economy, the cost of lodging is very important. I believe that the days of staying at ultra-expensive resorts is over.	Tue, 10/7/08 8:27 AM
Find	**22.** If it is going to be in Orlando, very convenient to be able to walk to Downtown Disney. That is very desirable - to be within walking distance of things away from hotel.	Tue, 10/7/08 7:39 AM
Find	**23.** Need more hands on courses, ie, updates on USING different types of instrumentation, particularly posterior cervical instrumentation.	Tue, 10/7/08 7:14 AM
Find	**24.** I like the JW marriott. Phoenix is a great site!	Mon, 10/6/08 10:57 PM
Find	**25.** I'm not going because I already am gone too much. for meetings.	Mon, 10/6/08 10:16 PM
Find	**26.** At this time, this meeting is not that important to me to attend	Mon, 10/6/08 9:56 PM
Find	**27.** I can do without Disney World	Mon, 10/6/08 9:52 PM
Find	**28.** spa access for my wife.	Mon, 10/6/08 9:30 PM
Find	**29.** Go for economy. I attend the meeting for the education, not the recreation. I can get that on my vacation in a place of my choosing. A resort venue is unimportant and overly costly. In the future it will be a deterance to my attendance.	Mon, 10/6/08 8:48 PM
Find	**30.** This is a scientific meeting. The more family activities you have, the less you will see the doctors.	Mon, 10/6/08 8:43 PM
Find	**31.** Important to have the meeting in a "warm" locale as is currently the case.	Mon, 10/6/08 8:43 PM
Find	**32.** large cities, cultural activities, opera, symphony,art museums, good restarants. thanks	Mon, 10/6/08 8:03 PM
Find	**33.** Keep the charges low!! There is no need to have Disney or golf involved. There are numerous nice locations in the US besides Phoenix and Orlando!!!!	Mon, 10/6/08 7:53 PM
Find	**34.** Beach	Mon, 10/6/08 7:43 PM
Find	**35.** let us bring the meeting back to miami -	Mon, 10/6/08 7:16 PM
Find	**36.** Family does not go with me to meetings, which is not the same as a	Mon, 10/6/08 6:52 PM

	vacation.	
Find	**37.** Some of us are tired of the same old cities, such as Orlando and Phoenix. Why not consider Salt Lake City, Lake Tahoe, or San Antonio?	Mon, 10/6/08 6:50 PM
Find	**38.** Want to go to warm weather. It would actually be best if there was not such a clique controlling what papers are presented and who is invited to speak. That is the bigger influence. A better intellectual interchange so that the meeting more closely resembles the CSRS would be good. Omit the golf, Disney-a nice place on the beach with easy access would do	Mon, 10/6/08 6:39 PM
Find	**39.** Locations without direct flights (smaller cities) are very difficult. Accommodations at Disney (Caribbean Princess) have been atrocious.	Mon, 10/6/08 6:34 PM
Find	**40.** I really dislike Orlando as there is no culture there at all and am very unlikely to attend any meeting there. Locations with actual cities with culture are much more attractive.	Mon, 10/6/08 6:29 PM
Find	**41.** Good easy connections for airlines, cheaper hotels and avoid the resort like environments. Lets go to Chicago, san francisco, northern states, Atlanta but please avoid orlando	Mon, 10/6/08 5:31 PM
Find	**42.** Prefer convenient travel, lodging at meeting site--family does not like to come with me to medical meetings...they don't see me..	Mon, 10/6/08 5:30 PM
Find	**43.** The purpose of the "small" sections should be to increase true fellowship amongst professionals with a common interest. In my opinion all attendees and their spouses should have the option of attending the chairmans dinner and reception.	Mon, 10/6/08 5:18 PM
Find	**44.** There are too many meetings already, and I am too pressed for time to attend a four day meeting. If the purpose of the meeting is education and collaboration, I think it could be done much more efficiently and economically than the current "meeting as a family vacation" paradigm.	Mon, 10/6/08 5:13 PM
Find	**45.** enough is enough already with orlando; let's try something different	Mon, 10/6/08 5:05 PM
Find	**46.** We come to the meeting to come to the meeting. The rest is fluff. If it costs a lot of money, it should be trashed.	Mon, 10/6/08 4:57 PM
Find	**47.** These meetings often offer little that is not available from other sources without the cost of shutting down ones practice and the cost of travel.	Mon, 10/6/08 4:56 PM
Find	**48.** It is also very important to have nonbiased presentations. Some of the people presenting do a poor job at being neutral or presenting believable information. Some of the audience has more time in the OR than the presenters. Some of the people in the audience have done full spine fellowships.	Mon, 10/6/08 4:50 PM
Find	**49.** Hotel amenities; dining options, spa access and workout facilities are always desirable.	Mon, 10/6/08 4:47 PM
Find	**50.** Your website page is malfunctioning, and will only allow one entry per column above. Therefore, I have only filled out the ones I could. The answer to #2, #3, and #7 should also be "very important".	Mon, 10/6/08 4:44 PM

100 responses per page

Spine Section Annual Meeting Location Survey 2008

1. Did you plan to attend the meeting in 2009?			
		Response Percent	**Response Count**
Yes		**65.7%**	151
No		34.3%	79
	answered question		**230**
	skipped question		**17**

2. Please rate how the importance of each of the questions:							
	Extremely Important	**Very Important**	**Mildly Important**	**Neutral**	**Mildly Unimportant**	**Very Unimportant**	**Extremely Unimportant**
How important is the venue in your decision to attend the annual meeting?	19.3% (46)	**42.9% (102)**	21.4% (51)	8.0% (19)	3.4% (8)	2.5% (6)	2.5% (6)
How important is ease of air travel to the destination (need for connections to smaller cities) to you?	27.1% (65)	**38.8% (93)**	23.8% (57)	5.4% (13)	1.7% (4)	1.7% (4)	1.7% (4)
How important is the room rate or charge ($350-$450 versus current range of $250-$350 per night) in deciding to attend the meeting?	19.4% (46)	**32.5% (77)**	22.8% (54)	14.3% (34)	5.1% (12)	3.0% (7)	3.0% (7)
How important is the location on influencing your willingness to pay increased room rates and charges?	18.4% (45)	**35.7% (87)**	25.8% (63)	12.7% (31)	3.7% (9)	2.5% (6)	1.2% (3)
How important is it to have easy access to Disney properties when the meeting is in Orlando?	7.5% (18)	14.2% (34)	17.1% (41)	17.9% (43)	7.9% (19)	15.8% (38)	**19.6% (47)**
How important is on site golf?	2.9% (7)	6.3% (15)	10.0% (24)	13.0% (31)	7.9% (19)	19.2% (46)	**40.6% (97)**
How important are family friendly activities?	10.9% (26)	15.5% (37)	**19.2% (46)**	17.2% (41)	9.6% (23)	12.1% (29)	15.5% (37)
							Other (please specify)
							answered question
							skipped question

Subject: Re: Possible 2012 DSPN Annual Meeting Hotels
Date: Thursday, October 2, 2008 8:43 AM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Groff, MD Michael mgroff@bidmc.harvard.edu

As the size of the section continues to grow, the costs of attending meetings rises, and the demands of clinical practice increase, meeting location and venue selection are important in terms of providing a quality experience outside of the scientific sessions. Traditionally, the section has alternated between southwest and southeast locations and has been held at resort type conference centers with extracurricular activities (golf, tennis, Disney) readily available. The increased size of our meeting limits returning to some venues and we are also faced with increasing costs from those venues that are loarge enough to house us. We seek input from our membership regarding the location and type of venue selected for the annual meeting.

Exit this survey >>

Spine Section Annual Meeting Location Survey 2008

Dear Spine and Peripheral Nerve Section Member:

The 25th Annual Meeting of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves will be held in Phoenix, Arizona from March 11-14, 2009.

As the size of the section continues to grow, the costs of attending meetings rises and the demands of clinical practice increase, meeting location and venue selection are important in terms of providing a quality experience outside of the scientific sessions. Traditionally, the section has alternated between southwest and southeast locations and has been held at resort type conference centers with extracurricular activities (golf, tennis, Disney) readily available. The increased size of our meeting limits returning to some venues and we are also faced with increasing costs from those venues that are large enough to house us.

We seek input from our membership regarding the location and type of venue selected for the annual meeting.

Did you plan to attend the meeting in 2009?

Yes

No

Please rate how the importance of each of the questions:

	Extremely Important	Very Important	Mildly Important	Neutral	Mildly Unimportant	Very Unimportant	Extremely Unimportant
How important is the venue in your decision to attend the annual meeting?							
How important is ease of air travel to the destination (need for connections to smaller cities) to							

you?
If room
charges
were $350-
450 versus
$250-350
per night,
how would
that
influence
your choice
to attend
the
meeting?
How does
location
influence
your
willingness
to pay
increased
room
charges?
How
important
is it to
have easy
access to

access to Disney properties when the meetng is in Orlando?
How important is on site golf?
How important are family friendly activities?

Other (please specify)

Thanks for you help!

Done >>

RESEARCH AND AWARDS COMMITTEE REPORT

Spine Section Executive Committee Meeting
March 11, 2009
Phoenix, AZ

2009 Awards Recipients

Mayfield Basic Science Award Winner:
Daniel L Master; Thomas Cowan; Sreenath Narayan; Robert Kirsch; Harry Hoyen
"Involuntary, Electrically Excitable Nerve Transfer for Denervation: Results from an Animal Model"

Mayfield Clinical Science Award Winners:
Matthew B. Maserati; Bradley Stephens; Zohny Zohny; Joon Y. Lee; Adam S. Kanter; Richard M. Spiro; David O. Okonkwo
"Occipital Condyle Fractures: Clinical Decision Rule and Surgical Management"

Ronald Apfelbaum Research Award:
Mohammed Shamji, MD
Ottawa Hospital
"Translation of Thermally-Responsive Anticytokine Drug Depots to Treat Lumbar Radiculopathy"

David Kline Research Award:
Wilson Ray, MD
Washington University
"Role of T-helper Cell Differentiation in Promoting Nerve Allograft Survival"

Sanford Larson Research Award:
Justin Brown, MD
Washington University
"Objective Quantification of Postural Correlates of Multilevel Nerve Compression"

Subject: Fw: DSPN Award/Fellowship Reimbursement Question
Date: Thursday, January 15, 2009 10:54 PM
From: mummanenip@neurosurg.ucsf.edu
Reply-To: <mummanenip@neurosurg.ucsf.edu>
To: Groff, MD Michael mgroff@bidmc.harvard.edu

Groffie. For exec agenda. Pm
Sent from my Verizon Wireless BlackBerry

-----Original Message-----
From: "Resnick \(Daniel\)" <resnick@neurosurg.wisc.edu>

Date: Thu, 15 Jan 2009 21:26:47
To: <CIS8Z@hscmail.mcc.virginia.edu>; <MummaneniP@neurosurg.ucsf.edu>; <gerspc@UPMC.EDU>; <jmb@1CNS.ORG>; <cis8z@virginia.edu>
Subject: Re: DSPN Award/Fellowship Reimbursement Question

It is a great idea but not doable this year- it requires a budget that needs to be voted on by the exec committee- praveen- put it on as an action item for march

----- Original Message -----
From: Shaffrey, Chris I *HS <CIS8Z@hscmail.mcc.virginia.edu>
To: 'MummaneniP@neurosurg.ucsf.edu' <MummaneniP@neurosurg.ucsf.edu>; 'gerspc@UPMC.EDU' <gerspc@UPMC.EDU>; 'jmb@1CNS.ORG' <jmb@1CNS.ORG>; Resnick (Daniel); 'cis8z@virginia.edu' <cis8z@virginia.edu>
Sent: Thu Jan 15 18:57:15 2009
Subject: Re: DSPN Award/Fellowship Reimbursement Question

I like the idea of 1K and free meeting. Dan. Will this work?

----- Original Message -----
From: Mummaneni, Praveen <MummaneniP@neurosurg.ucsf.edu>
To: Shaffrey, Chris I *HS; Gerszten, Peter <gerspc@UPMC.EDU>; Jacqueline M. Bellan <jmb@1CNS.ORG>; Resnick <resnick@neurosurg.wisc.edu>; cis8z@virginia.edu <cis8z@virginia.edu>
Sent: Thu Jan 15 19:46:52 2009
Subject: RE: DSPN Award/Fellowship Reimbursement Question

International fellowship awards are only 5k,
If we pay for the meeting hotel and domestic flights, that will severely

cut into this amount.

Just an fyi.

Dan, your call.

Tks
Praveen

-----Original Message-----
From: Shaffrey, Chris I *HS [mailto:CIS8Z@hscmail.mcc.virginia.edu]
Sent: Thursday, January 15, 2009 4:34 PM
To: Mummaneni, Praveen; Gerszten, Peter; 'Jacqueline M. Bellan';
Resnick; cis8z@virginia.edu
Subject: RE: DSPN Award/Fellowship Reimbursement Question

Dan should be able to give the answer on this. From my recollection,
part of the support included the statement that this this
included/supported the attendenc at the meeting. We may need to look,
but this support is likely in addition to what is already committed. I
do not have a problem waiving the meeting fee but I am not sure we have
budgeted an additional 1 K for each of the fellows. Dan do you have
insight on this matter?
Christopher I Shaffrey, MD, FACS
Harrison Distinguished Professor
Neurological and Orthopaedic Surgery
University of Virginia
Phone: (434) 243-9714

_____
From: mummanenip@neurosurg.ucsf.edu [mummanenip@neurosurg.ucsf.edu]
Sent: Thursday, January 15, 2009 3:36 PM
To: Gerszten, Peter; 'Jacqueline M. Bellan'; Resnick; cis8z@virginia.edu
Subject: Re: DSPN Award/Fellowship Reimbursement Question

I think we should let award winning fellows and residents come to the
annual mtg for free and pay their hotel and airfare up to a max of 1k.

We can't pay for international airfare due to cost but 1k would take care of hotel and meals.

The cns does this for their meeting. It is part of our goals to encourage our trainees.

I am ccing dan resnick and chris shaffrey (current and incoming section chairs). Dan and chris, can we reimburse our resident and fellow award winners to attend our meeting (separate from their awards funds)?

Praveen

Sent from my Verizon Wireless BlackBerry

From: "Gerszten, Peter"
Date: Thu, 15 Jan 2009 14:37:31 -0500
To: 'Jacqueline M. Bellan'<jmb@1CNS.ORG>;
<mummanenip@neurosurg.ucsf.edu>
Subject: RE: DSPN Award/Fellowship Reimbursement Question

I don't believe that they do.

Peter

From: Jacqueline M. Bellan [mailto:jmb@1CNS.ORG]
Sent: Thursday, January 15, 2009 12:08 PM
To: Gerszten, Peter; mummanenip@neurosurg.ucsf.edu
Subject: DSPN Award/Fellowship Reimbursement Question

Drs.,

All notifications have been sent to the award and fellowship winners. One question that I am getting is "do the winners get reimbursed for their travel and hotel accommodations if they choose to attend the meeting?" I don't recall the CNS processing these refunds last year -

do you know if the AANS handle the refunds?

I appreciate your assistance in this matter so that I can direct the winners accordingly.

Jackie Bellan
Senior Meeting Services Coordinator

Congress of Neurological Surgeons
10 North Martingale Road
Suite 190
Schaumburg, IL 60173
Phone: 847-240-2500
Fax: 847-240-0804
Mail to: jmb@1cns.org<mailto:jmb@1cns.org>
Visit us on line at:
www.cns.org<file:///C:/Documents%20and%20Settings/jmb/Application%20Data/Microsoft/Signatures/www.cns.org>
Mark your calendar now for the 2009 CNS Annual Meeting, October 24-29, 2008 in New Orleans, Louisiana!

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AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons

Education and Innovation

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m.mclaughlin@princetonbrainandspine.com

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trost@neurosurg.wisc.edu

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zagere@uphs.upenn.edu

December 23, 2008

Michael Y. Wang, MD
University of Miami
Department of Neurosurgery
1095 NW 14th Terrace
Miami, FL 33136

Dear Dr. Wang:

As the American Association of Neurological Surgeons/Congress of Neurological Surgeons Section on Disorders of the Spine and Peripheral Nerves Education Chairman, the Accreditation Council for Continuing Medical Education (ACCME) requires that all potential Conflicts of Interest at the Annual Meeting be resolved prior to the start of the educational activity. Enclosed you will find Conflict of Interest Forms for the upcoming 2009 AANS/CNS Disorders of the Spine and Peripheral Nerves Annual Meeting for your review.

As you review the forms, please sign each one and note any with potential conflict of interest issues. We ask that you return all of the forms to us no later than January 10.
Upon receipt we will then forward any forms that you have identified with potential conflicts for further review and resolution to Dr. Paul G. Matz, Scientific Program Chair. There are several options available to address specific conflict scenarios.

Please let us know if you have any questions regarding this process as required by ACCME.

Thank you.

Sincerely,

Regina Shupak, CMP
Director of Meeting Services

Cc: Paul G. Matz, Scientific Program Chair
Charles Kuntz, IV, Annual Meeting Chair

Education and Innovation

RESOLUTION OF CONFLICT OF INTEREST FORM
For CNS CME Activities

The *Resolution of Conflict of Interest Form* is designed to assist CNS staff and volunteer physician leaders responsible for the development of CME activities in 1) determining if a conflict of interest exists; and 2) documenting the actions undertaken to resolve all potential conflicts of interest with any individual in a position to influence and/or control the content of CME activities. **This form must be completed for all individuals returning a disclosure listing financial relationships with commercial interests.**

PLEASE COMPLETE THE FOLLOWING:

NAME OF INDIVIDUAL WITH THE EDUCATIONAL ASSIGNMENT:
Joseph T. Alexander

NATURE OF THE EDUCATIONAL ASSIGNMENT:
2009 AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting Faculty (March 11 – 14, 2009)
(eg, CME planning group member, author, faculty, etc)

NAME OF THE CME ACTIVITY (DATES/LOCATION IF APPLICABLE):
FRI-16: Luncheon Symposium II - Critical Review and Analysis of the SPORT Trials: Implications for your Practice; *SAT-08*: *David Cahill Memorial Controversies - Spine and Peripheral Nerve*

DISCLOSURE AND RELATIONSHIPS OR AFFILIATIONS:
Stryker Spine: *Consultant*

NAME OF INDIVIDUAL SUBMITTING THIS FORM:
Michael Y. Wang, MD, Education Chairperson

DATE: _____ SIGNATURE: _____

☐ **Upon review of the disclosure form it was determined that the financial relationship does not relate to the educational assignment. IF SO, YOUR FORM IS NOW COMPLETE. IF NOT, PLEASE PROCEED.**

Upon review of the disclosure form, it was determined that a potential conflict may exist and the following mechanism(s) were used to resolve that potential conflict of interest:

☐ **Based on prior knowledge of the contents of this educational presentation, the Committee can attest that no commercial bias exists. The presentation has been viewed and/or evaluated in the past and no commercial bias was detected.**

☐ **The Committee used a peer review process* for enduring material CME, journal CME, etc.** (Process by which materials are peer reviewed or judged to ensure the data supports the conclusions before they are accepted for presentation or publication). Peer review bodies either directly revised or required revisions by faculty prior to final acceptance.

☐ **The Committee conducted a peer review of the individual's content prior to the live or online CME activity (e.g., review of handouts and/or slides). Faculty was required to revise content based on recommendations from the peer review, if applicable.**

Changes made: _____

☐ **The Committee altered the control over the content by:**

- ☐ Choosing someone else to control that part of the content.
- ☐ Changing the focus of the CME activity so that is does not relate to the products or services of the commercial interest.
- ☐ Changing the content/topic of the individual's educational assignment so that it does not relate to the products or services of the commercial interest.
- ☐ Limiting the individual's content to a report without practice recommendations (if individual was funded by a commercial company to perform research, the individual's presentation may be limited to research data and results).
- ☐ Limiting the role of the individual to reporting practice recommendations based on formal structured review of the literature with the inclusion and exclusion criteria stated (evidence-based).
- ☐ Enhancing podium disclosure of potential conflicts by Moderator.
- ☐ Other (please describe).

☐ **The individual was able to document the 'best available evidence' to support his/her recommendations.**

☐ **The individual changed his/her relationship with the commercial interest, eliminating the financial relationship and thus, any potential for conflict of interest. A new disclosure form and conflict of interest form will be filed.**

☐ **The Committee has chosen not to use the individual and identified a replacement.**

☐ **Other (please describe).**

_____

*Peer review must ensure that 1) all practice recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for indications and contraindications in the care of patients; and 2) all scientific research referred to, reported or used in the CME activity in support or justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.

NOTES:

Lectureship Policies for AANS/CNS Joint Sections
At the AANS Annual Meeting

Section Responsibilities:

The Section will be responsible for securing any sponsorship money to be used to support the lectureship. All funds paid to the lecturer will be paid out of Section funds, including any travel reimbursement, honoraria, and certificate/scroll expenses. The AANS will not waive or comp registration for lecturers or speakers for any Section Session. If the Section chooses to cover registration expenses, they will be paid out of Section funds. The Section is responsible for notifying the AANS of any new lectureships and the Section's policies regarding that lectureship. Names for all lectureships are to be provided upon request each year by meetings department staff (currently Kristi Conley).

AANS Responsibilities:

The AANS will see that funds secured by the Section in support of lectureships are deposited into the Section checking account and credited to that Section. The AANS will provide checks cut from the Section funds to the lecturer for honoraria and/or expenses. These checks will be mailed to the recipient after the AANS Annual Meeting. The AANS will not waive or comp registration for lecturers or speakers for any Section Session. If the Section chooses to cover registration expenses, they will be paid out of Section funds. The AANS will have the certificate/scroll made per instructions to be provided by the Section. AANS will bring these certificates/scrolls to the Section's meeting room at the Annual Meeting. The AANS will not pay for any honoraria, expenses, or certificate/scrolls from AANS funds. On file at the AANS is a listing of certificates/scrolls currently issued and can be provided upon request.

Individual Responsibilities:

The selected lecturer will provide timely expense reports, including receipts for all expenses, for any lectureship for which the Section provides travel reimbursement from Section funds. If asked, the individual will be responsible for supplying the AANS with their social security number or tax id number for income tax reporting purposes.

AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerve
Guidelines Committee Report
March 2009

1. Update of Lumbar Fusion Guidelines
    a. Project allocated to the Lumbar Fusion Task Force
        i. Collaborative effort with Orthopedics
        ii. Mike Kaiser/Chris Bono
        iii. Literature search currently underway with assistance of NASS

2. CSM Guidelines
    a. Approved by the JGC
    b. Awaiting acceptance to JNS:Spine
        i. Chapters re-submitted to in February 2009 after requested revisions completed

3. Metastatic Spine Guidelines
    a. Guidelines committee established
    b. Topic list completed – 14 topics to date
    c. Topic assignments made
    d. Anticipated first meeting in Chicago or Denver - April 2009
    e. No funds dispersed to date

4. Thoracolumbar Trauma Guidelines
    a. Guidelines committee established
    b. Currently formulating topic list
    c. Anticipated first meeting in Chicago – Summer 2009
    d. No funds dispersed to date

5. Cervical Spine Trauma Guidelines
    a. Anticipated update of current guidelines in 2009
    b. Will be submitted to NGC once completed

Subject: RE: Guidelines finally all accepted
Date: Thursday, March 5, 2009 9:07 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: paul matz matzpg@yahoo.com, Paul Anderson anderson@orthorehab.wisc.edu, tanvir choudri tanvir.choudhri@msnyuhealth.org, Michael Groff, MD mgroff@bidmc.harvard.edu, Bob Heary heary@umdnj.edu, Langston Holly lholly@mednet.ucla.edu, Michael Kaiser Mgk7@columbia.edu, Praveen Mummaneni vmum@aol.com, Timothy Ryken timothy-ryken@uiowa.edu, Ed Vresilovic ekajv2000@aol.com

Congratulations Paul, a job well done!
Daniel K. Resnick MD, MS
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

_____

From: paul matz [matzpg@yahoo.com]
Sent: Thursday, March 05, 2009 7:58 PM
To: Paul Anderson; tanvir choudri; Mike Groff; Robert Heary; Langston Holly; mike kaiser; praveen mummaneni; Resnick (Daniel); Tim Ryken; Ed Vresilovic
Subject: Guidelines finally all accepted

Gentlemen,

The Cervical guidelines have officially all been accepted. I have not received a publication date. However, I wanted to thank all of your for your efforts. I think the chapter represent a seminal systematic review and critical analysis of a complex subject. When this started 3y ago, the S&P 500 was at 1150, banks were solvent, retirement was an option, and the word "real estate" did not strike fear into the hearts of millions; also, I think the Golden State was in the black. Hopefully, 3y from now, we will be able to say the same is true.

Warmest regards and thanks for a job well done.

Paul Matz

Paul G. Matz, MD
Associate Professor of Surgery (Neurosurgery)

University of Alabama, Birmingham
510 20th Street South
Birmingham, AL 35294
Phone: 205-975-8872; Fax: 205 975-8337
email: matzpg@yahoo.com

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Subject: Re: Posterior Cervical Talk
Date: Thursday, September 25, 2008 7:23 AM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Michael Kaiser Mgk7@columbia.edu
Cc: 'mgroff@bidmc.harvard.edu' mgroff@bidmc.harvard.edu, 'pmatz@uabmc.edu' pmatz@uabmc.edu

Hi Mike,
In terms of the trauma designees, please touch base with Shelly Timmons- I spoke with her last night and she (trauma section chair) did not know who chose these participants. I would suggest involving Patricia Raskin as she is the main trauma person on the JGC. I would strongly suggest that completion of the JGC training module be a prerequisite for participation. Thanks for getting this together. BTW, the tumor section approved 15K for the mets project (which seemed reasonable to me- they put up 50K for the cranial project which is ongoing and don't have a bankroll like ours).
Dan

----- Original Message -----
From: Michael Kaiser <mgk7@columbia.edu>
To: Resnick (Daniel)
Cc: Mike Groff <mgroff@bidmc.harvard.edu>; pmatz@uabmc.edu <pmatz@uabmc.edu>
Sent: Sat Sep 20 16:18:40 2008
Subject: Re: Posterior Cervical Talk

Dan/MIke

Sorry I never forward any update regarding the Guidelines committee. The following are current issues:

1. Tim recently e-mailed me questioning the funding for the Metastatic Tumor Guidelines:

I am going to be sending you a followup request for funding prior to the section meeting – the tumor section agreed to fund half of the metastatic spine guidelines project – so somehow I have to get this all formalized – I think it would be easiest to get the funds in one place but not sure how to do that quite yet - tcr

My impression was that we had agreed to fund half the project along with the tumor section. In order to make things easier for Tim, could the funding be funneled through one organization, either the tumor section or the spine section write a check to the other section?

2. Paul has finalized the CSM guidelines and plans on submitting the JNS:Spine shortly after the CNS meeting.

3. Thoracolumbar Trauma guidelines

I hope to finalize the list of participants and develop a topic list over the next couple of months with the intention of having our first meeting early in 2009.

The tentative list includes (Dan do want to be included or are you busy enough):

Paul Matz, MD - University of Alabama, AL - Co-Chair

Christopher Ames, MD – University of California – San Francisco, CA
Roger Hartl – Cornell, NYC
Patrick R. Pritchard - University of Alabama, AL
Mike Groff - Beth Isreal Deaconess Medical Center, MA
Charlie Kuntz – University of Cincinnati, OH
Tim Ryken – University of Iowa, IA
Devanand A. Dominique (Trauma) – Temple University, PA
Craig Rabb – University of Colorado, CO (Trauma)
Paul Arnold (Trauma) – University of Kansas, KS
Kurt Eichholz – Vanderbilt University, TN
John O'Toole – Rush University, IL

I am not sure if everyone is committed at this point and I need to get a couple of Orthopods on the panel. I would appreciate any suggestions. The members of the trauma section were provided (I never received a direct request to participate except for Devanand) so I am not sure how committed to the project they will be. I am going to send a formal request to all listed shortly.

Let me know if you have any questions.

Mike

Michael Kaiser, MD, FACS
Department of Neurosurgery
Columbia University
212 305-0378
mgk7@columbia.edu

On Sep 20, 2008, at 8:39 AM, Resnick (Daniel) wrote:

Got it-
If you get a chance and haven't already given Groff an update, can you drop me an email about the guidelines committee and any progress on the next projects?
Daniel K. Resnick MD, MS

Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Michael Kaiser [mgk7@columbia.edu]
Sent: Friday, September 19, 2008 4:00 PM
To: Resnick (Daniel)
Subject: Posterior Cervical Talk

Dan

Not going to make the meeting. I've attached my talk for Saturday's conference and will send my Sunday talk later tonight. I know the posterior cervical talk is too long and I'm sorry I had to divide it into six parts, but I was planning on editing the slides tonight. There should be enough to use if anyone wants to use it. Let me know if you get it.

Sorry

Mike

Subject: RE: Follow up to phone tag
Date: Wednesday, January 14, 2009 2:20 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Adrienne Lea alea@thejns.org
Cc: Christopher Wolfla CWolfla@mcw.edu, Groff, MD Michael mgroff@bidmc.harvard.edu, matzpg@yahoo.com

Hi Adrienne,
Per our conversation earlier today, as long as the JNS can guarantee free access to the guidelines (no membership or subscribership requirements for downloads), the spine section, CNS, AANS and their designees (NASS for example with permission) can provide direct links to the documents without intervening web pages, and the requirements for inclusion in the NGC are fulfilled, then housing the documents on the JNS website should be acceptable.
Thanks for your patience and perserverance.
Dan

Daniel K. Resnick MD, MS
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

_____
From: Adrienne Lea [alea@thejns.org]
Sent: Wednesday, January 14, 2009 12:13 PM
To: Resnick (Daniel)
Cc: Wolfla Chris (cwolfla@mcw.edu); Michael Groff
Subject: Re: Follow up to phone tag

We will allow linking to the spine section site, but not posting or unrestricted distribution. However, I have spoken with Dr. Jane and we are happy to make the articles (if accepted) freely available on our site. That would be in perpetuity, for subscribers or non subscribers.
If you have questions please feel free to contact me at 434 982 1206.
Thanks-
Adrienne

On Jan 14, 2009, at 1:00 PM, Resnick (Daniel) wrote:

> Hi Adrienne,
> If you can provide a letter to Chris Wolfla, secretary of the CNS
> and Mike Groff, secretary of the spine section that JNSG will allow

> posting and distribution of the guidelines without restriction then
> I'm OK with signing the copyright forms. We will post the pdf's on
> the section website for easier access by non JNSG subscribers.
> Dan
>
> Daniel K. Resnick MD, MS
> Associate Professor and Vice Chairman
> Department of Neurological Surgery
> University of Wisconsin, Madison
> Chair, AANS/CNS Joint Section on Disorders of the Spine
> _____
> From: Adrienne Lea [alea@thejns.org]
> Sent: Tuesday, January 13, 2009 4:59 PM
> To: Resnick (Daniel)
> Subject: RE: Follow up to phone tag
>
> We can provide them links to the material.
> Thanks-
> Adrienne
>
>> It also needs to be freely available to the CNS and spine section for
>> posting on their websites without a portal through JNS.
>> Daniel K. Resnick MD, MS
>> Associate Professor and Vice Chairman
>> Department of Neurological Surgery
>> University of Wisconsin, Madison
>> Chair, AANS/CNS Joint Section on Disorders of the Spine
>>
>> _____
>> From: Adrienne Lea [alea@thejns.org]
>> Sent: Tuesday, January 13, 2009 2:22 PM
>> To: Resnick (Daniel)
>> Subject: Follow up to phone tag
>>
>> Dear Dr. Resnick:
>> I called your office and missed you so maybe we can "converse" via
>> e-mail.
>> Regarding the correspondence below, we just want to make sure we
>> are on

>> the same page. If the guidelines articles are published, the
>> Journal of
>> Neurosurgery Publishing Group will retain copyright but we will
>> make the
>> material available for the Clearinghouse to link to per my message
>> below.
>> Please feel free to call me if you have any questions regarding
>> this -- my
>> number is 434 982 1206.
>> Thanks-
>> Adrienne
>>
>>
>>
>> Begin forwarded message:
>> From: Adrienne Lea <alea@thejns.org<mailto:alea@thejns.org>>
>> Date: October 23, 2008 1:04:24 PM EDT
>> To: resnick@neurosurg.wisc.edu<mailto:resnick@neurosurg.wisc.edu>
>> Subject: Your question re copyright
>>
>> Dear Dr. Resnick:
>> Dr. Jane and I have discussed this and I left a message at your
>> office.
>> I'm happy to discuss this with you -- I will be in the office today
>> (434
>> 982 1206), out tomorrow but available via cell phone (434 987
>> 0946). I've
>> checked their site and there should be no problem with making the
>> material
>> available via the Clearinghouse, we will just provide the links the
>> Clearinghouse needs to the information on the journal site.
>> Look forward to talking with you.
>> Adrienne Lea
>>
>> Adrienne Lea
>> Director of Publications
>> The Journal of Neurosurgery Publishing Group
>> 1224 Jefferson Park Avenue, Suite 450
>> Charlottesville, VA 22903

>> 434 982 1206 (phone)
>> 434 924 5782 (fax)
>> alea@thejns.org<mailto:alea@thejns.org>
>>
>>
>>
>>
>>
>>
>> Hi Margie,
>> The CNS and AANS need to retain the copyright so we can re-assign
>> it to
>> the National Guidelines Clearinghouse and allow free distribution
>> of the
>> guidelines to anyone who wants to read/copy/print them. We (Me, Doug
>> Kondziolka and Don Quest) have already made an agreement with the
>> NGC that
>> all guidelines produced by the section are available to the NGC now
>> and in
>> the future. This is the same deal we used for the Lumbar Fusion
>> Guidelines with JNSG and the Cervical Trauma Guidelines with
>> Neurosurgery.
>> Dr. Jane agreed to this last time as well (obviously, as the Lumbar
>> Fusion
>> Guidelines were published!).
>> Email me if there are any issues that I can help resolve.
>> Thanks!
>> Dan
>>
>> Daniel K. Resnick MD, MS
>> Associate Professor and Vice Chairman
>> Department of Neurological Surgery
>> University of Wisconsin, Madison
>> Chair, AANS/CNS Joint Section on Disorders of the Spine
>>
>>
>>

Outcomes Committee Report
Spine Section Executive Committee Meeting
Wednesday, March 11, 2009 – Spine Section Meeting - Phoenix

Committee Members:

Zoher Ghogawala zoher.ghogawala@yale.edu
Mike Kaiser mgk7@columbia.edu
Subu Magge subu.n.magge@lahey.org
Peter Angevine pda9@columbia.edu
Jean Coumans jcoumans@partners.org

Potential New Members:

John O'Toole John_Otoole@rush.edu

A. Clinical Trials Proposal Awards $ 500

1. We received 6 clinical trial proposals from 6 different institutions that met all the requirements. All trial proposals were de-identified to ensure a fair and blinded review. All trial proposals were reviewed by at least 2 reviewers from the committee and NIH scoring criteria were followed. Proposals were reviewed according to:

   a) significance
   b) design and approach
   c) innovation
   d) overall potential to have impact on clinical care

   The scores of both reviewers were averaged.

2. Three winners were selected – all had priority scores under 200. Each winner was given the comments of both reviewers in order to prepare a revised application, which will be due April 15, 2009.

   The winners are:

   Richard Lebow, MD (resident) – Joseph Cheng, MD (faculty sponsor)
   Vanderbilt (institution)
   "The effect of a continuous perioperative dexmedetomidine infusion on time-to-discharge in patients undergoing multi-level spinal fusion: a double-blinded, placebo controlled study."
   Design – RCT, 100 patients (4 sites)
   Outcome – Length of Stay, VAS, SF36, cytokine serum levels

Scientific Principle – Controlling the inflammatory response might affect healing and improve pain control after fusion surgery

Marjorie Wang, MD (faculty)
Medical College of Wisconsin (institution)
"Cervical Spondylotic Myelopathy: Can outcome be predicted by diffusion tensor imaging?"
Design: Prospective Single Center Study to evaluate novel technology
Outcome: SF-36 Physical Component Summary Score, mJOA, Neck Disability Index
Scientific Principle – Non-invasive imaging of spinal cord tissue integrity and architecture might help stratify patients with cervical spondylosis and help predict outcome.

Deb Bhowmick, MD (resident) William Welch,MD (faculty sponsor)
University of Pennsylvania (institution)
"Hypertonic saline therapy for the treatment of acute spinal cord injury"
Design: RCT, 68 pts (2 sites)
Outcome: Death, complication, ASIA scores
Scientific Principle – Hypertonic saline might result in the osmotic removal of extra cellular fluid in the CNS and possibly increase blood flow to damaged spinal cord resulting in better outcome after acute spinal cord injury.

B. Clinical Trials Award – $ 50,000

1. The Outcomes will review all three revised proposals and score each of them. The committee will consult senior members of the executive committee to help select a winner if there is uncertainty as to the best overall application. The award will be given in 2 parts: $ 25,000 initially. The second $ 25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal.

2. We have obtained another $ 50,000 dollars from the Wallace Foundation. This money has already been submitted to AANS. We have $ 100,000 dollars to support 2 more awards over the next 2 years.

3. We are awaiting a progress report from our first Clinical Trials Award Winner:

   Khalid Abbed, MD, Yale University, Assistant Professor
   Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.
   Design: pilot study - 100 pts, 3 sites, non-randomized.
   Outcome Instruments: SF-36 PCS and ODI

C. Spine Section Web Site

In addition, we are keeping the section website current with a section on all active clinical trials registered with the NIH site clinicaltrials.gov that relate to spinal diseases. There are currently 56 clinical trials relating to spinal disorders registered with ClinicalTrials.gov – all are listed on our section website.

Appendix – E-blast (sent out by AANS in July, 2008)

2009 AANS/ CNS Spine Section Clinical Trial Awards

Spine Clinical Trial Proposal - $ 500
Spine Clinical Fellowship Award - $ 50,000

The AANS/CNS Spine Section is pleased to announce the continuation of a clinical trials fellowship award to promote well-designed neurosurgical clinical research. Neurosurgical residents/ fellows/clinical instructors/ and assistant professors are eligible to apply for the Clinical Trial Proposal. Applications for the Clinical Fellowship Award will only be accepted from junior faculty members of an accredited neurosurgical department. The objective of this award is to create an infrastructure necessary for executing well-designed multi-center studies, to promote the advancement of evidence-based neurosurgical practices, with an emphasis on spine. **DEADLINE FOR SUBMISSION is December 1, 2008.** The application process can be found on the section website and is summarized below:

Step 1. Clinical Trials Proposal Award - $ 500

This award would be presented annually by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves to no more than three neurosurgical residents or BC/BE neurosurgeons/ fellows in North America who submit an outstanding clinical trials proposal (5 pages maximum) that demonstrates clinical relevance, sound methodological design, and feasibility. Preference would be given to a team that designs a multi-center trial. Winners would be given an honorarium of $ 500 plus reimbursement to attend the annual AANS/CNS Spine Section Meeting (presenter only).

Step 2. Clinical Trials Fellowship Award - $ 50,000

All submitted proposals sponsored by junior faculty will be considered for the Clinical Trials Fellowship Award. Those individuals whose proposals are meritorious would be formally critiqued by the Joint Section Outcomes Committee and invited to submit a revised proposal for the one year $ 50,000 Clinical Trials Fellowship Award. This grant is intended to support a pilot study based on the submitted proposal. The recipient will receive $ 25,000 at the onset of the research project. Involvement of an independent biostatistician for epidemiological support is required. A written progress report within 6 months of receiving the award, including a comprehensive data analysis submitted by the biostatistician, is mandatory. Satisfactory completion of the progress report is required in order to receive the second allotment of $ 25,000.

Outcomes Committee Report
Spine Section Executive Committee Meeting
Wednesday, March 11, 2009 – Spine Section Meeting - Phoenix

Committee Members:

Zoher Ghogawala zoher.ghogawala@yale.edu
Mike Kaiser mgk7@columbia.edu
Subu Magge subu.n.magge@lahey.org
Peter Angevine pda9@columbia.edu
Jean Coumans jcoumans@partners.org

Potential New Members:

John O'Toole John_Otoole@rush.edu

A. Clinical Trials Proposal Awards $ 500

1. We received 8 clinical trial proposals from 8 different institutions that met all the requirements. All trial proposals were de-identified to ensure a fair and blinded review. All competitive trial proposals were reviewed by at least 2 reviewers from the committee and NIH scoring criteria were followed. Proposals were reviewed according to:

   a) significance
   b) design and approach
   c) innovation
   d) overall potential to have impact on clinical care

   The scores of both reviewers were averaged.

2. Three winners were selected – all had priority scores under 200. Each winner was given the comments of both reviewers in order to prepare a revised application, which will be due April 15, 2009.

   The winners are:

   Richard Lebow, MD (resident) – Joseph Cheng, MD (faculty sponsor)
   Vanderbilt (institution)
   "The effect of a continuous perioperative dexmedetomidine infusion on time-to-discharge in patients undergoing multi-level spinal fusion: a double-blinded, placebo controlled study."
   Design – RCT, 100 patients (4 sites)
   Outcome – Length of Stay, VAS, SF36, cytokine serum levels

Scientific Principle – Controlling the inflammatory response might affect healing and improve pain control after fusion surgery

Marjorie Wang, MD (faculty)
Medical College of Wisconsin (institution)
"Cervical Spondylotic Myelopathy: Can outcome be predicted by diffusion tensor imaging?"
Design: Prospective Single Center Study to evaluate novel technology
Outcome: SF-36 Physical Component Summary Score, mJOA, Neck Disability Index
Scientific Principle – Non-invasive imaging of spinal cord tissue integrity and architecture might help stratify patients with cervical spondylosis and help predict outcome.

Deb Bhowmick, MD (resident) William Welch,MD (faculty sponsor)
University of Pennsylvania (institution)
"Hypertonic saline therapy for the treatment of acute spinal cord injury"
Design: RCT, 68 pts (2 sites)
Outcome: Death, complication, ASIA scores
Scientific Principle – Hypertonic saline might result in the osmotic removal of extra cellular fluid in the CNS and possibly increase blood flow to damaged spinal cord resulting in better outcome after acute spinal cord injury.

B. Clinical Trials Award – $ 50,000

1. The Outcomes will review all three revised proposals and score each of them. The committee will consult senior members of the executive committee to help select a winner if there is uncertainty as to the best overall application. The award will be given in 2 parts: $ 25,000 initially. The second $ 25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal.

2. We have obtained another $ 50,000 dollars from the Wallace Foundation. This money has already been submitted to AANS. We have $ 100,000 dollars to support 2 more awards over the next 2 years.

3. We are awaiting a progress report from our first Clinical Trials Award Winner:

   Khalid Abbed, MD, Yale University, Assistant Professor
   Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.
   Design: pilot study - 100 pts, 3 sites, non-randomized.
   Outcome Instruments: SF-36 PCS and ODI

C. Spine Section Web Site

In addition, we are keeping the section website current with a section on all active clinical trials registered with the NIH site clinicaltrials.gov that relate to spinal diseases. There are currently 56 clinical trials relating to spinal disorders registered with ClinicalTrials.gov – all are listed on our section website.

Appendix – E-blast (sent out by AANS in July, 2008)

2009 AANS/ CNS Spine Section Clinical Trial Awards

Spine Clinical Trial Proposal - $ 500
Spine Clinical Fellowship Award - $ 50,000

The AANS/CNS Spine Section is pleased to announce the continuation of a clinical trials fellowship award to promote well-designed neurosurgical clinical research. Neurosurgical residents/ fellows/clinical instructors/ and assistant professors are eligible to apply for the Clinical Trial Proposal. Applications for the Clinical Fellowship Award will only be accepted from junior faculty members of an accredited neurosurgical department. The objective of this award is to create an infrastructure necessary for executing well-designed multi-center studies, to promote the advancement of evidence-based neurosurgical practices, with an emphasis on spine. **DEADLINE FOR SUBMISSION is December 1, 2008.** The application process can be found on the section website and is summarized below:

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This award would be presented annually by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves to no more than three neurosurgical residents or BC/BE neurosurgeons/ fellows in North America who submit an outstanding clinical trials proposal (5 pages maximum) that demonstrates clinical relevance, sound methodological design, and feasibility. Preference would be given to a team that designs a multi-center trial. Winners would be given an honorarium of $ 500 plus reimbursement to attend the annual AANS/CNS Spine Section Meeting (presenter only).

Step 2. Clinical Trials Fellowship Award - $ 50,000

All submitted proposals sponsored by junior faculty will be considered for the Clinical Trials Fellowship Award. Those individuals whose proposals are meritorious would be formally critiqued by the Joint Section Outcomes Committee and invited to submit a revised proposal for the one year $ 50,000 Clinical Trials Fellowship Award. This grant is intended to support a pilot study based on the submitted proposal. The recipient will receive $ 25,000 at the onset of the research project. Involvement of an independent biostatistician for epidemiological support is required. A written progress report within 6 months of receiving the award, including a comprehensive data analysis submitted by the biostatistician, is mandatory. Satisfactory completion of the progress report is required in order to receive the second allotment of $ 25,000.

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons

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Dorothy G. Smith
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Integra LifeSciences
315 Enterprise Drive
Plainsboro, NJ 08536
dsmith@integra-LS.com

17 October 2008

Re: AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Annual David Kline Lectureship

Dear Ms. Smith:

Thanks to Integra LifeSciences for your continued support of the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and the Annual David Kline Lectureship.

Per your request of 14 October 2008, the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves formally requests from Integra LifeSciences support in the amount of $5000.00 for the travel, lodging, and honorarium for the 2009 David Kline lecturer at the Section program at 2009 AANS Annual Meeting.

I will have the Section W-9 form sent to you shortly from the AANS home office.

Thank you again for your support of the Section. If you have any questions or require any additional information, please contact me at your convenience.

Sincerely,

Christopher E. Wolfla, MD
Treasurer

Subject: RE: Kline lecture 2009
Date: Tuesday, October 28, 2008 5:44 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Ronald W. Engelbreit rwe@aans.org, Allen Maniker amaniker@chpnet.org, Rebecca Calloway-Blyth rpc@aans.org, Kristi A. Richardson kar@aans.org, 'belzberg@jhu.edu' belzberg@jhu.edu, Robert Spinner spinner.robert@mayo.edu, Christopher Wolfla CWolfla@mcw.edu
Cc: Groff, MD Michael mgroff@bidmc.harvard.edu

Sounds fine. Mike G- please include the emails below in the agneda book for the next section exec meeting under the peripheral nerve task force
Daniel K. Resnick MD, MS
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Ronald W. Engelbreit [rwe@aans.org]
Sent: Tuesday, October 28, 2008 2:49 PM
To: Allen Maniker; Rebecca Calloway-Blyth; Kristi A. Richardson; 'belzberg@jhu.edu'; 'spinner.robert@mayo.edu'; Christopher Wolfla; Resnick (Daniel)
Subject: RE: Kline lecture 2009

After the misunderstanding of the lectureship last year, the AANS staff has been working under the scenario laid out by Dr. Resnick on July 8th in the email below. It was never Rebecca's intent to ask for more money but simply get the ball rolling on receiving the $5,000 from Integra. I am not sure who from the AANS told you the registration would be comp'd but I will take care of it as per below.

Here is what is going to happen this year:

1. Dr. Wolfla has communicated with Integra regarding their $5000 check. We will wait to see if Integra needs more documentation.
2. The $5000 will flow through the Spine Section from Integra to Dr. Richter.
3. I will instruct our meetings department to comp Dr. Richter's registration.
4. The meetings department will include all the necessary information about the lectureship within the program, etc.
5. The AANS meetings department will provide an outline as to the responsibilities (including financial) of the individuals, the section, and the AANS for any future lectureships. The outline will be distributed to all for approval and implementation.

If you have any questions, please let me know.

Ron

Ronald W. Engelbreit
Deputy Executive Director
American Association of Neurological Surgeons
5550 Meadowbrook Dr., Rolling Meadows, IL 60008
847-378-0509

From: Resnick (Daniel) [mailto:resnick@neurosurg.wisc.edu]
Sent: Tuesday, July 08, 2008 12:08 PM
To: Wolfla Chris (cwolfla@mcw.edu); Michael Groff; Chris Shaffrey (CIS8Z@hscmail.mcc.virginia.edu); Traynelis, Vincent; Mike Wang (mwang2@med.miami.edu)
Cc: amaniker@chpnet.org
Subject: Kline lectureship at AANS

Chris, Chris, Mike, Mike, and Allen,

I just got off the phone with Vince Traynelis who is SPC for the AANS this year. We discussed the Kline lectureship and the problems that occurred this year. The AANS has secured funding from Integra to cover the $1500 and the "oops" from this past year. The AANS has secured an agreement from Integra to fund the lectureship for at least the next year at $1500.00. Specialty speakers invited by sections at the AANS meeting are generally funded by the sections (in contradistinction to the CNS). The vascular, tumor, and peds sections do this as well. Now, strategically, it may or may not make sense for the spine section to sponsor a speaker at a competing meeting (The vascular, tumor, and peds guys do not have an independent meeting within 6 weeks of the AANS). At the same time, a Kline lectureship has been established (by Eric and Raj) and it would seem to be petty and perhaps insulting to Dr. Kline to cancel it at this point. Vince has asked us to continue to administer the lectureship on behalf of the AANS with the understanding that funds would simply pass through the section. This would give the section, or more specifically the peripheral nerve task force, the opportunity and responsibility of choosing the speaker and making sure the funding is secure on a year to year basis. I think we should probably go ahead and do this for the coming year, as funding has been secured and the AANS needs to proceed with it's own meeting planning process- Allen being the peripheral nerve task force representative and Mike Wang being the primary interface between the section and the AANS for the overall program. Please weigh in on your thoughts for this coming year- no official action is needed as we already have a precendent from the last two years if we decide to go ahead with this arrangement. Mike G, please put this on the agenda for September, as it has some strategic implications that should be at least aired publically before a longer term committment is

made.

Thanks!

Dan

From: Allen Maniker [mailto:AManiker@chpnet.org]
Sent: Tuesday, October 28, 2008 10:30 AM
To: Rebecca Calloway-Blyth
Cc: Kristi A. Richardson; Ronald W. Engelbreit; 'belzberg@jhu.edu'; 'spinner.robert@mayo.edu'; Christopher Wolfla; Dr. Resnick
Subject: RE: Kline lecture 2009

With all due respect Rebecca the AANS should be aware of how much misinformation is generated by your staff.
I am very meticulous about these things and checked and double checked all the issues surrounding this lecture.
Only now do I find out that the registration is not comped and that it must come from section money. I was told it would be
comped.

Mr. Archibald has been more than generous with Integra's sponsorship and I find it embarrassing to have to return to him once again
for yet more money.

Furthermore Dr. Richter is now retired and while his membership might be currently active it will not be in 2009.

For the amount of money we as members must contribute to running this organization this kind of misinformation
and mis-communication should really be unacceptable both to the membership and to you as the staff running it.

Allen Maniker,M.D.
Chief of Neurosurgery
Beth Israel Medical Center
New York City

>>> Rebecca Calloway-Blyth <rpc@aans.org> 10/28/2008 11:05 AM >>>
Dear Doctors,

Just to clarify regarding the AANS meeting registration for the Kline Lecturer:
The usual policy regarding invited speakers at the AANS meeting is to comp registration only if the speaker is a non-member. Dr. Richter is a member of AANS.
Also, for future reference, AANS does not cover registration for speakers invited by the Sections. It would be the Spine Section's responsibility to cover his registration - either using the sponsorship money from Integra or Spine Section funds.

I will work on drafting a letter for Dr. Archibald at Integra to secure the sponsorship money.

Thanks,
Rebecca

Rebecca Calloway-Blyth
Sections/Budget Accountant
American Association of Neurological Surgeons
rpc@aans.org
(847) 378-0561

From: Kristi A. Richardson
Sent: Friday, October 24, 2008 2:57 PM
To: Ronald W. Engelbreit; Rebecca Calloway-Blyth
Subject: FW: Kline lecture 2009

FYI below on the Kline Lecture

Kristi A.R. Conley
Meeting Services Coordinator

American Association of Neurological Surgeons (AANS)
5550 Meadowbrook Drive
Rolling Meadows, IL 60008

Direct Phone: 847-378-0532 * Direct Fax: 847-378-0632 * kar@aans.org

Mark your calendar now for the 2009 AANS Annual Meeting in San Diego, CA, May 2-6, 2009!

From: Allen Maniker [mailto:AManiker@chpnet.org]
Sent: Friday, October 24, 2008 2:20 PM
To: hp.richter@t-online.de
Cc: Kristi A. Richardson; Allan belzberg; Simon Archibald; Allan Belzberg; Allan Belzberg; Robert Spinner; Christopher Wolfla; Dr. Resnick
Subject: Kline lecture 2009

Hello Hans-Peter

I hope this finds you well.

It gives me great pleasure to tell you that a unanimous vote of our Peripheral Nerve Task Force nominated you to be named the David Kline lecturer at the 2009 American Association of Neurological Surgeons meeting in San Diego California May 2-6.

We do hope you will consider accepting this honor.

Acceptance comes with a $5,000 (five thousand U.S. dollar)
educational grant from the Integra Corporation to help offset your expenses.
The cost of registration for the meeting will be covered by AANS.

We would like your talk to be on a peripheral nerve topic of your choosing.

I look forward to hearing from you about this exciting event.

Allen Maniker,M.D.
President Peripheral Nerve Task Force
AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

Chief of Neurosurgery
Beth Israel Medical Center
New York, New York

Subject: RE: Grant for 2009 Annual Meeting
Date: Wednesday, December 10, 2008 6:13 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Christopher Wolfla CWolfla@mcw.edu
Cc: Groff, MD Michael mgroff@bidmc.harvard.edu

Thanks Chris-
Mike- please include a copy of this in the agenda book in the section for the peripheral nerve task force. Thanks!
dan
Daniel K. Resnick MD, MS
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Wolfla, Christopher [CWolfla@mcw.edu]
Sent: Wednesday, December 10, 2008 4:43 PM
To: DeGuzman, Darlene
Cc: Resnick (Daniel)
Subject: RE: Grant for 2009 Annual Meeting

Dear Darlene:

I received the check and will forward to the AANS office in Illinois. I made scan which will be put in the Section archives (attached)

Thanks again

Sincerely

Chris

Christopher E. Wolfla, MD
Associate Professor of Neurosurgery
The Medical College of Wisconsin
Secretary, The Congress of Neurological Surgeons

Secretary, The Congress of American Neurosurgical Education
Treasurer, AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

Telephone: 414 805 5424
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cwolfla@mcw.edu

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From: DeGuzman, Darlene [mailto:darlene.deguzman@integra-ls.com]
Sent: Monday, December 08, 2008 2:38 PM
To: Wolfla, Christopher
Subject: Grant for 2009 Annual Meeting

Hi Chris,

I am in the process of mailing the check for the 2009 Annual Meeting in San Diego. Can you please verify who the check should go to as well as the mailing address?

Thank you,
Darlene

Darlene C. De Guzman
Clinical Affairs, Speakers Bureau Associate
Integra LifeSciences
315 Enterprise Drive
Plainsboro, NJ 08536
Ph: 609-936-6903
Cell: 609-903-0583
Fax: 609-750-4274
E-mail: darlene.deguzman@integra-ls.com <mailto:darlene.deguzman@integra-ls.com>

Subject: Update on PR committee
Date: Thursday, September 25, 2008 7:33 AM
From: Michael Groff <mgroff@bidmc.harvard.edu>
To: executans mgroff@bidmc.harvard.edu

This is passed along from Mike Steinmetz, PR committee.
Thanks,
michael

1. Article published in CNS Q
2. Article submitted and accepted for publication in NEUROSURGEON
3. Add is being placed in NEJM that states" Low back or neck pain..." and emphasizes theat neurosurgeons spend 60%of their time treating patients for back and neck problems.
4. Jim Bean will be interviewed re: carpal tunnel in Physicians Weekly.
5. At the past AANS meeting-Fehlings article on SCI was featured in many publications such as MSN.com; Washington Post.com, YahooHealth (there were a total of 39 in total), Obesity and back pain was featured in 44 with broadcast in 18 media outlets such as NewsChannel5.com in Nashville TN. Traynelis abstract on Prestige disc was featured in 29.
6. Public Awareness releases are being produced for 2009. The next topic to be released in re: sports related cervical injury. I have proposed lumbar and cervical stenosis another one brought up was cervical TDA.
7. THe AANS released general press release promoting the treatment of low back pain and related conditions. This was picked up by About.com with a circulation of 36.9 million-this has been the most significant pick up to date.
8. The AANS website (neurosurgerytoday.org) is a PR based site. The media use this site frequently for thier coverage. New for 2009 will be minmally invasive spine procedures and spinal cord stimuation.
9.The AANS is willing to pitch press releases re: any artilce published in Journal of Neurosurgery spine. If know one is coming out, we have only approximately 2 weeks to get this to Betsy van Die to submit the press release. She is also keeping her eye out on spine articles.

Spine EC
AANS 2009
PR Committee Report

1. Proposal has been sent to AANS and CNS to add a new FTE in the Washington Committee office specifically for Public Relations. This position would be jointly paid for the AANS and CNS. It appears that both are behind the new position. Our committee could work directly with this new person as our PR outlet.

2. The AANS distributed a press release to lay media on a *Journal of Neurosurgery: Spine* article in late January. This is the second time that the AANS has publicized a *JNS* clinical article. The release has generated major media coverage in more than 150 media outlets including HealthDay, MSN, Yahoo!News, Discovery Health, *Forbes*, *Business Week*, *U.S. News & World Report*, SpineUniverse, Medscape, and Occupational Health & Safety, reaching a potential audience of 169 million and counting. *The continued burden of spine fractures after motor vehicle crashes* by Marjorie C. Wang, MD, MPH, and the accompanying editorial by Charles H. Tator, MD, PhD, are posted online at http://thejns.org/toc/spi/current.

3. The attached ad will be published in the February 19 issue of *New England Journal of Medicine*. Per the request of at least one PR Committee member at our Orlando meeting, the image was changed to an adult spine for this second ad. The first ad ran in the October 30, 2008 issue of *NEJM*.

4. At the 2009 AANS Annual Meeting, there will be 2 spine and 3 peripheral nerve/pain oral abstracts promoted to the media. Several other authors with spine research were invited, but unfortunately did not accept the opportunity to participate.

5. Neurosurgerytoday.org is AANS PR post outlet.
New post added on MIS surgery. Describes MIS spine surgery, pros and cons. It also lists and describes some of the common MIS procedures.

WellPoint, Inc.
Medical Policy Questionnaire

November 25, 2008

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines and on behalf of a national healthcare association (“”Association”) to support their processes for developing and maintaining medical policies.

We are currently reviewing the topic of **Artificial Intervertebral Discs**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We have designed our process to help you avoid duplication of effort in reviewing various entities’ medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic will be shared with non-WellPoint entities, the Association and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 35 million members enrolled in our plans, by even broader audience on behalf of the Association and the many millions of Americans whose health care benefits are provided by its member plans.

Attached are ***two (2) draft versions*** of the policy, **7.01.108 Artificial Intervertebral Disc: Cervical Spine (file name CVDI - 701108 - ArtDisc-Cerv.pdf)** and the second is labeled **SURG.00055 Artificial Intervertebral Discs (file name SURG.00055 WP 10-22-2008 CoDr.doc).** The first policy addresses artificial intervertebral discs of the cervical spine only. The second policy addresses artificial intervertebral discs of the cervical and lumbar spine.

***Your input is being requested on both versions*.** Please use the questionnaire labeled **7.01.108 Artificial Intervertebral Disc: Cervical Spine** to complete your response to the Association draft and the *separate* questionnaire for your response regarding the second policy draft labeled **SURG.00055 Artificial Intervertebral Discs** to correspond to your response.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. Please be sure to:

- **Answer all questions**
- **Complete the conflict of interest section**
- **Complete the demographic information and release statement on the following page**
- **Provide peer-reviewed literature citations when changes to a policy position are suggested**

Thank you for supporting our process to maintain medical necessity determinations consistent with the principles of evidence-based medicine by providing your expertise, guidance and input.

Please complete the information on the following page.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before December 23, 2008.

The following information is needed for this review.

Reviewer Name: *(Note: Include credentials)*	Joseph S. Cheng, MD, MS
Board Certification in: *(Note: BC is required)*	Neurological Surgery
Academic/Hospital Affiliation(s):	Vanderbilt University American Association of Neurological Surgeons (AANS) Congress of Neurological Surgeons (CNS)
Address:	Department of Neurosurgery, T-4224 MCN, Nashville, TN 37232
State(s) of Medical Licensure:	Tennessee, Wisconsin
Phone:	(615) 322-1883
Fax:	(615) 343-8104
Date:	November 28, 2008

Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release any or all of the following points of information to the committee(s) and non-WellPoint entities, including a national Association.

	Yes	No	Comments
Your Board Certification	X		
Name of your Academic/Hospital Affiliation(s)	X		
Your Name	X		

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	Current medical evidence indicates that there is sufficient evidence to conclude that using artificial discs in the cervical spine is equivalent to fusion surgery. This position is supported by the Washington State Health Care Authority during its 2008 health technology assessment in addition to an independent panel, convened to review the assessment for Washington State on October 17, 2008, which voted to cover cervical artificial intervertebral discs. In addition, medical evidence to indicate that the use of cervical artificial intervertebral discs is medically necessary and not considered investigational if supported by the findings and policies of other insurance carriers such as Aetna (Clinical Policy Bulletin: Intervertebral Disc Prostheses. Policy Number: 0591 (Last Review: 05/23/2008)). The available studies had sufficient power for their study design, consistent multicenter protocols, homogeneous investigational and control groups, and the patients enrolled were representative of the intended medical population. As well, the outcomes were validated and included independent radiographic assessments.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	The rationale provided in "7.01.108 Artificial Intervertebral Disc: Cervical Spine" does not accurately reflect the current available medial evidence. The first criticism was that 2 years of follow-up is not adequate to evaluate long-term results, in particular any effect of the device on adjacent-level disc degeneration, device durability, adverse events, and revisability. Although it is preferable to have 50 or 100 years of data over 2 years, there is a reasonable amount of time for follow up that can be expected in clinical studies before a procedure is accepted as non-investigational. Follow up of 2 years is considered the standard in our clinical studies. However, artificial cervical discs have been in reported clinical use for almost 20 years with approximately 23,000 artificial cervical discs implanted so far, with the majority outside of the United States (Pracyk 2005, ECRI 20007). The published results are favorable, such as the Prestige Cervical Disc

	Yes	No	Comments
			(previously known as the Bristol Cummins' artificial cervical joint) which was first implanted 17 years ago (Cummins 1998). At 5 years, they were able to follow-up with 18 of the original 20 patients, and noted that the device was stable and mobile and did not report issues related to disc degeneration, device durability, or adverse events. Robertson in 2004 published four year follow up results, noting that in the 12 patients available from the Prestige I study, the device continued to function and adjacent level disease was not present with clinical improvement in patient function and quality of life. Patel in 2007 repored 5-9 year follow-up for 31 patients who had the Prestige artificial disc placed between 1998 and 2002 and noted that all but one patient maintained motion of the artificial disc with no instances of device failure or adverse events. Delamarter in 2007 reported up to 4 year follow-up on 30 patients from the ProDisc-C U.S. IDE study noting clinical improvement. He also noted that motion was maintained, no evidence of adjacent segment degeneration, and no device-related complications. Bertagnoli in 2008 also reported up to 4 years of follow-up for 73 patients using the ProDisc-C artificial cervical disc noting that range of motion was maintained in over 90% of the patients and that there were no device-related complications or re-operations that were required. The Bryan Cervical Disc has been reported to have been implanted in over 15,000 times worldwide (FDA 2007). Goffin in 2006 reported the 4-year results for 69 single level procedures with the Bryan Cervical Disc noting that 61 of 69 patients had an excellent/good result and that motion was preserved in 83% of the patients and that only 3 of 69 developed some adjacent level degeneration at 4-years. This can be compared to the prior studies indicating a prevalence of 2.9% per year with an overall incidence of 25.6% in cervical fusion patients based on survivorship analysis (Hilibrand 1997, 1999). The second criticism was that the study was not blinded, and that the investigators and patients knew which procedure had been performed, which has potential to bias outcome assessments. Although a bias may be introduced, it would be impractical to

	Yes	No	Comments
			double blind a surgeon regarding an implant that is to be surgically placed. While blinded studies are statistically valid and an ideal goal for pharmaceutical studies, it is not something that can be achieved in device studies. In addition, post-operative care and imaging will allow the patient to become aware of their device as it would not be feasible to blind the radiographic review as the device would be clearly identifiable on x-rays. The third and final criticism was that some experimental patients had increased pain of the neck (6.2% vs. 0.8% at 2 years) and arm (9.4% and 5.8%) after the procedure, and that these findings merit additional investigation for their clinical relevance. This finding is unusual and does not reflect the majority of the other published reports noting that artificial intervertebral disc arthroplasty is a good alternative to anterior cervical fusions in patients with cervical spondylosis and degenerative disc disease (Acosta 2005, Anderson 2007, Smucker 2006, Phillips 2005, Anderson 2004, Pracyk 2005, Bertagnoli 2005). As well, there are a number of smaller studies showing that cervical arthroplasty is safe and at as effective as cervical fusions in those patients who had similar surgical indications to ACDF such as radiculopathy and myelopathy (Brown 2006, McAfee 2004). In the three large randomized clinical trials, there were consistent evidence that artificial cervical discs were statistically noninferior to the standard ACDF, with non-statistically significant improvements in neurologic status and the neck disability index (NDI) in the patients receiving the artificial cervical discs. The authors of the Wellpoint draft policy also noted that the FDA has required the Prestige disc manufacturer to conduct a 7-year post-approval clinical study of the safety and function of the device, and a 5-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population. This statement by the FDA does not indicate any negative concerns related to the device as this statement would seem to indicate, as otherwise the Prestige disc would not have been approved by the FDA, but rather a continued evolution of the FDA process.

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Since the enactment of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, the Center for Devices and Radiological Health (CDRH) has been developing new protocols for postmarket surveillance to monitor the performance of marketed medical devices. As the medical devices today are vastly different from those used 30 years ago, "The postmarket system that we set up 30 years ago is not designed to deal with all of the new things that are happening today in the device industry" as noted by CDRH Director Daniel Schultz, M.D..
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:			
Therapeutic Interventions: • The policy indicates artificial intervertebral discs of the cervical spine are considered **investigational** for treatment of disorders of the cervical spine, including degenerative disc disease. – Do you agree? – If no, please comment and cite literature to support.		X	We do not agree with the policy indicating that artificial intervertebral discs of the cervical spine are considered investigational for treatment of disorders of the cervical spine, including degenerative disc disease. This conclusion is not consistent with the favorable results from the available published literature, nor does it indicate the prevailing clinical opinion among neurosurgeons and orthopedic spine surgeons. On September 8, 2006, our American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), and the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves submitted a letter to the FDA in support of a favorable consideration for cervical disc arthroplasty. In addition to the comments as noted above, the follow references are cited for support from the literature. Aetna Clinical Policy Bulletin: Intervertebral Disc Prostheses. Policy Number: 0591 (Last Review: 05/23/2008) (http://www.aetna.com/cpb/medical/data/500_599/0591.html) Bertagnoli R. Single level ProDisc-C Total Disc Replacment up to four years follow-up, Number 145. North American Spine Society, October 15-18, 2008, Toronto, Canada. Cheng JS, Liu F, Komistek RD, Mahfouz MR, Sharma A, Glaser D. Comparison of Cervical Spine Kinematics Using a Fluoroscopic Model for Adjacent Segment Degeneration. Journal of Neurosurgery - Spine, 7(5):509-

	Yes	No	Comments
			513. Nov 2007. Cummins B, Robertson J and Gill S. Surgical experience with an implanted artificial cervical joint, J Neurosurg 1998, 88: 943-948. Delamarter R, Bradhan B, Kanim L, et al. Cervical disc replacement: over 3-4 prospective randomized clinical outcomes and range of motion follow-up witthe Prodisc-C prosthesis, Number 64. North American Spine Society, October 23-27, 2007, Austin, TX. ECRI Institute, Emerging Technology (TARGET) Evidence Report, Artificial intervertebral disc replacement (AIDR) for symptomatic cervical disc disease, 2007. Food and Drug Administration, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, Office of Surveillance and Biometrics, Design of Condition of Approval Studies and Smith & Nephew Birmingham Hip Resurfacing (BHR) System, P040033, September 8, 2005. Food and Drug Administration, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, Medtronic Sofamor Danek Bryan Cervical Disc, P060023, July 17, 2007. Food and Drug Administration, Center for Devices and Radiologic Health, Division of Post-market Surveillance, Office of Surveillance and Biometrics, Guidance for Industry and FDA staff – Procedures for Handling Post-approval Studies Imposed by PMA Order, August 1, 2007. Food and Drug Administration, Center for Devices and Radiologic Health, Post-approval studies, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm Goffin J, Casey A, Kehr P, Liebig K, et al. Preliminary clinical experience with the Bryan Cervical Disc Prosthesis, Neurosurgery 2002, 51: 840-847. Goffin J, van Loon J, van Calenbergh F. Cervical arthroplasty with the Bryan Disc: 4-

	Yes	No	Comments
			and 6-year results, Cervical Spine Research Society, November 30-December 2, 2006, Palm Beach, FL. Hilibrand AS, Carlson GD, Palumbo MA, et al.: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical athrodesis. J Bone Joint Surg 81-A:519-528, 1999. Lee CK, Langrana NA. A review of spinal fusion for degenerative disc disease: need for alternative treatment approach of disc arthroplasty? Spine J. 2004 Nov-Dec;4(6 Suppl):173S-176S. Liu F, Cheng JS, Komistek RD, Mahfouz MR, Sharma A. In Vivo Evaluation of Dynamic Characteristics of the Normal, Degenerative, Fused, and Disc Replacement Cervical Spines. Spine, 32(23): 2578–2584. Nov 1, 2007. Mummaneni, et al. Journal of Neurosurgery Spine. 2007 Mar; 6(3):198-209. Clinical and Radiographic Analysis of Cervical Disc Arthroplasty Compared with Allograft Fusion: A Randomized Controlled Clinical Trial. Office of the Inspector General, Department of Health and Human Services, Review of the Food and Drug Administration's Handling of Adverse Drug Reaction Reports, A-15-98-50001, December 1999. http://www.oig.hhs.gov/oas/reports/phs/c9850001.pdf Papadopoulos S. The Bryan Cervical Disc System, Neurosurg Clin N Am 2005, 16: 629-36. Patel N, Robertson J, Metcalf N and Gill S. Long-term follow-up of patients treated with the Prestige Artificial Disc at a Single Center, Congress of Neurological Surgeons, September 15-20, 2007, San Diego, CA. Pracyk J and Traynelis V. Treatment of the painful motion segment: Cervical arthroplasty, Spine 2005, 30 (16S): S23-32. Robertson J and Metcalf N. Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study, Neurosurg Focus 2004, 3:

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			E10. Washington State Health Care Authority, Health Technology Assessment, HTA Final Report Artificial Discs Replacement, ADR, September 19, 2008,
• Do you consider artificial intervertebral discs of the cervical spine **medically necessary**? If yes, – Are there any specific criteria which would be useful in selecting appropriate patient populations?	X		We would recommend that the indications for use of cervical disc arthroplasty follow the inclusion criteria from the large scale clinical trials used for FDA approval. That would include the application of this procedure to skeletally mature patients with cervical spine disease at C3-C7 necessitating a single-level decompression via an open anterior approach, and used for patients with intractable pain, radiculopathy, and/or myelopathy associated with radiographic studies showing a herniated cervical disc or cervical spondylosis and osteophytes.
– Are there any specific clinical or patient characteristics for when artificial intervertebral discs of the cervical spine are not appropriate? – Please comment and cite literature to support.	X		We would recommend that clinical or patient characteristics for which the artificial intervertebral disc is not appropriate include patients with cervical instability (sagittal plane translation >3.5mm, sagittal plane angulation >20°), facet joint pathology, osteoporosis, cancer, and infection. The literature supporting this is as indicated in the large scale clinical trials.
• Are there additional indications for artificial intervertebral discs of the cervical spine beyond those discussed in the document? – If yes, please comment and cite literature to support.		X	
• Is there evidence to support one type of artificial disc over another (i.e., ProDisc-C® and Prestige ST Cervical Disc)? – If yes, please comment and cite literature to support.		X	
• Is the use of artificial intervertebral discs of the cervical spine safe and efficacious in the treatment of degenerative disc disease? – If yes, please comment and cite literature to support.	X		The available large multicenter prospective randomized IDE studies have concluded that disc arthroplasty is a safe and reasonable alternative to anterior cervical fusion in the treatment of degenerative disc disease in selected patients as described by the study inclusion criteria over a clinically meaningful time point as defined by the FDA. Mummaneni in 2007 reported statistical noninferiority for disc arthroplasty versus ACDF in all three primary outcome variables (Neck Disability Index (NDI), neurological

	Yes	No	Comments
			status, and functional spinal unit height (FSU)) and for the overall success composite outcome with the neurological status noting statistical superiority. Arthroplasty patients showed preservation of motion with retention of sagittal angular motion of over 7 degrees and also a 2-point greater improvement in the Neck Disability Index (NDI). Although it was not statistically significant, there was an overall success with better SF-36 at 12 and 24 months associated with a greater relief of neck pain and earlier return to work in the arthroplasty group. There were no serious associated adverse events and no cases of implant failure or migration, along with a lower rate of revision surgeries including a lower rate of supplemental fixation and of re-operations at the adjacent segment. Murrey reported a prospective, randomized, controlled trial of 209 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive Prodisc-C or ACDF with plate and allograft with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that Prodisc-C is not inferior to ACDF 2 years after surgery in Overall Success, the study's primary endpoint. Heller reported a prospective, randomized, controlled trial of 463 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive Bryan Cervical Disc or Atlantis Cervical Plate with allograft (ACDF) with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that the cervical disc replacement maintained segmental motion at 24 months after implantation and was associated with improved NDI Success (superiority), improved clinical outcomes, and 13 days faster return to work compared to ACDF patients. Statistical superiority in Overall Success (study's primary endpoint) was demonstrated at 24 months.
***Improved Patient Outcomes*:** • Is there adequate evidence to demonstrate that the use of artificial intervertebral discs of the cervical spine provide significant improvements in clinical outcomes *compared to the available alternatives?*		X	The current studies indicate that cervical disc arthroplasty is a safe and reasonable alternative to anterior cervical fusion with equivalent clinical outcomes. The main impetus for motion preservation is adjacent segment degeneration and disease, and this benefit is gained in the setting of equivalent post-operative improvements in clinical outcomes between cervical disc arthroplasty

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	Yes	**No**	**Comments**
			as compared to the available alternatives (cervical fusion).
• Is there *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of artificial intervertebral discs of the cervical spine? If so, please cite.	X		Yes, and these references are as cited above in the responses to the previous questions.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	
***Conflict of Interest*:** Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with artificial intervertebral discs? If so, please disclose that relationship.		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- not primarily for the convenience of the patient, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The term "investigational" means that the medical policy does not meet the Technology Evaluation Criteria.

This means any procedure, treatment, supply, device, equipment, facility or drug (all services), are determined NOT to:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

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	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	The policy position blends in cervical and lumbar disc arthroplasty, which leads to incorrect assumptions. This would be akin to assuming kidney and heart transplants should be the same in regards to coverage decisions on transplants, when they have significantly different indications and outcomes. The Centers for Medicare and Medicaid Services (CMS) have issued a national non coverage determination for lumbar artificial disc replacement for the Medicare population over sixty years of age, but this does not apply to cervical artificial discs. The Category III codes for the cervical disc arthroplasty is incorrect in the policy, as the Federal Register (November 2008) indicates that CPT 22856/22561/22564 is included with appropriate RVU valuations.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	We do not agree with the rationale by the authors of the Artificial Intervertebral Discs draft policy, Document #SURG.00055 (10/22/2008), and do not feel that it accurately reflects the current available medial evidence. Regarding the Charité Artificial Disc, they noted that although the Charité disc had a higher success rate than the BAK cage in its clinical IDE trial, this difference would not have met traditional criteria for a superiority trial. While hypothetically correct, in that a non-inferiority design (as compared to a superiority trial) could result in the Charite with a d=0.15, i.e. 95% confidence interval, could allow a 15% worse result when compared to BAK and still meet non-inferiority criteria, this has not been shown to be the case. The FDA has requested a 10% difference for a non-inferiority study, and the results were sufficient to allow approval of the Charité Artificial Disc. The authors of the Wellpoint draft policy also note that the randomized controlled trial for the Charité Artificial Disc had several methodological issues that made it difficult to interpret the results. Their first concern was that the analysis showed non-inferiority compared to BAK fusion using the composite measure of success, but did not show statistically significant superiority in most outcome measures. However, it should be

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	Yes	No	Comments
			noted that a non-inferiority trial is a common and accepted study method for device trials, and that superiority trials are not the standard of IDE trials. As well, a non-inferiority trial requires that the reference treatment have an established efficacy or that it is in widespread use. In the referenced study, there was evidence that the efficacy of lumbar artificial discs, as measured by the composite measure of overall clinical success, Oswestry Disability Index (ODI) improvement, pain improvement, neurological success, SF-36 improvement, and patient satisfaction was comparable with anterior lumbar interbody fusion or circumferential fusion up to two years following surgery. The overall clinical success (a composite measure considering most or all of the following: ODI improvement, device failure, complications, neurological change, SF-36 change and radiographic success) was achieved in 56% of patients receiving the Charité Artificial Disc and 48% of those receiving the lumbar fusion. The results suggest that 24 month outcomes for lumbar artificial discs were similar to lumbar fusion for degenerative disc disease. The rationale that utilizing a trial designed and analyzed as a noninferiority trial was done so in order to establish a less stringent standard for demonstrating efficacy than a standard clinical trial and that such trials are often employed when there is some margin of acceptable inferiority of a new technology in its principal outcome indicates a negative bias and misunderstanding of what is reasonably acceptable and feasible in clinical device trials. Issues such as unilateral cross over, ability to blind, among others have led to the use of non-inferiority as the base hypothesis in surgical and device trials and have been shown in other large scale non-device surgical studies such as the SPORT trial looking at lumbar disc herniation and disease. As well, fusion has been associated with a notable success rate in control cases and given the disease process being studies. The fusion success rate would be a difficult endpoint for cervical arthroplasty to exceed supporting the rationale for a non inferiority study design rather than a superiority design. There was also a second concern was that there was a lack of a prespecified analysis

	Yes	No	Comments
			plan, unexplained closure of the data base before all patients reached completion, and lack of intent-to-treat analysis that may cast some doubt on the analysis. Although these were not addressed in the available papers, these variables were not an inherent part of the published peer reviewed work nor integral to the conclusions by the artificial disc study authors. Although we all would agree that additional and more rigorous trials of the outcomes of the use of an artificial disc in the treatment of DDD are needed, this same statement regarding the need for more rigorous trials and outcomes may be made for the majority of medical and surgical care currently available. This would then also apply to the general comments noted by the Wellpoint authors in extrapolating comments from Bertagnoli (2006) in that the authors cautiously recommend the use of artificial disc replacement in the treatment of chronic discogenic low back pain, in the study by Chung (2006) noting that future efforts need to be directed toward the evaluation of a larger number of patients with longer follow-up, and Freeman (2006) in that larger, well designed prospective randomized controlled trials with longer follow-up are needed. These general disclaimers and statements for future work were not meant to indicate that the technology and procedure remains experimental and outside the armamentarium of a general spine surgery practice. As well, it should be noted that cervical disc arthroplasty is quite different than lumbar disc arthroplasty. Concerns were raised in that the PMA was contingent upon a seven year post approval study to evaluate long-term safety and effectiveness of the Prodisc-C and the Prestige cervical disc. This has been addressed in the a preceding question regarding the FDA requests and that this does not indicate a device rejection or experimental status, but rather the changing landscape in the FDA and in the area of medical devices. As well, although the Wellpoint document indicates that studies such as by Nabhan (2007) note that the loss of segmental motion was significantly higher in the ACDF group and that significant pain reduction was observed in the neck and arm postoperatively, it would seem that there

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	Yes	**No**	**Comments**
			were attempts to mitigate these positive results by noting comments such as "the study was small and that larger studies with longer follow up are warranted". The issues raised which was postulated to cloud the conclusions such as the trial was unblinded (double blinding is near impossible to do in a surgical study) and the 4% cohort withdraw rate which is not unexpected in this type of clinical trial. Also, although it was ackowledged that the investigational group reported better neurological success, concern was raised in that the investigators provided no detail how the neurological status was measured and evaluated despite that the same argument was not made regarding the prior negative comments regarding artificial cervical discs and which were accepted. This would seem to indicate a bias to accepting negative data regarding surgical treatment while calling into question the positive outcomes.
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:			
Therapeutic Interventions: • The policy indicates that the use of artificial intervertebral discs is investigational in the treatment of cervical and lumbar degenerative disc disease. Do you agree? – If no, please comment and cite literature to support.		X	We do not agree with the policy indicating that artificial intervertebral discs of the spine are considered investigational for treatment of disorders of the spine, including degenerative disc disease. This conclusion is not consistent with the favorable results from the available published literature, nor does it indicate the prevailing clinical opinion among neurosurgeons and orthopedic spine surgeons. In addition to the comments as noted above, the follow references are cited for support from the literature. Food and Drug Administration (FDA). Clinical review for PMA (P040006) Charité artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004. Food and Drug Administration (FDA). In-depth statistical review for expedited PMA (P040006) Charite artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED). Prosthesis intervertebral disc (report

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	Yes	No	Comments
			on the Internet). Edited, 2004. Food and Drug Administration (FDA). New device approval: PRESTIGE cervical disc system - P060018 [report on the Internet]. Edited, 2007. Food and Drug Administration (FDA). New device approval: ProDisc-C total disc replacement - P070001 [report on the Internet]. Edited, 2007. Food and Drug Adminstration (FDA) Executive Summary, Bryan Cervical Disc. Edited, 2007. Washington State Department of Health, Center for Health Statistics, Comprehensive Hospitalization Abstract Reporting System (2005-2007). Edited. Abd-Alrahman, N.; Dokmak, A. S.; and Abou-Madawi, A.: Anterior cervical discectomy (ACD) versus anterior cervical fusion (ACF), clinical and radiological outcome study. Acta Neurochir (Wien), 141(10): 1089-92, 1999. Amit, A., and Dorward, N.: Bryan cervical disc prosthesis: 12-Month clinical outcome. British Journal of Neurosurgery, 21(5): 478-484, 2007. Anderson, P. A., and Rouleau, J. P.: Intervertebral disc arthroplasty. Spine, 29(23):2779-86, 2004. Bartels, R. H.; Donk, R.; van der Wilt, G. J.; Grotenhuis, J. A.; and Venderink, D.: Design of the PROCON trial: a prospective, randomized multi-center study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty. BMC Musculoskelet Disord, 7: 85, 2006. Bertagnoli, R.; Duggal, N.; Pickett, G. E.; Wigfield, C. C.; Gill, S. S.; Karg, A.; and Voigt, S.: Cervical total disc replacement, part two: clinical results. Orthop Clin North Am, 36(3): 355-62, 2005. Bertagnoli, R., and Kumar, S.: Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. Eur Spine J, 11 Suppl 2:S131-6,

Policy Number: SURG.00055 Policy Title: Artificial Intervertebral Discs Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			2002. Bertagnoli, R. et al.: Lumbar total disc arthroplasty utilizing the ProDisc prosthesis in smokers versus nonsmokers: a prospective study with 2-year minimum follow-up. Spine, 31(9): 992-7, 2006. Bertagnoli, R.; Yue, J. J.; Nanieva, R.; Fenk-Mayer, A.; Husted, D. S.; Shah, R. V.; and Emerson, J. W.: Lumbar total disc arthroplasty in patients older than 60 years of age: a prospective study of the ProDisc prosthesis with 2-year minimum follow-up period. J Neurosurg Spine, 4(2): 85-90, 2006. Bertagnoli, R.; Yue, J. J.; Pfeiffer, F.; Fenk-Mayer, A.; Lawrence, J. P.; Kershaw, T.; and Nanieva, R.: Early results after ProDisc-C cervical disc replacement. J Neurosurg Spine, 2(4): 403-10, 2005. Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.: The treatment of disabling multilevel lumbar discogenic low back pain with total disc arthroplasty utilizing the ProDisc prosthesis: a prospective study with 2-year minimum follow-up. Spine, 30(19): 2192-9, 2005. Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.: The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year minimum follow-up. Spine, 30(19): 2230-6, 2005. Blue Cross Blue Shield Association: Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2007. Blue Cross Blue Shield Association: Artificial vertebral disc replacement [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2005. Blumenthal, S.; McAfee, P. C.; Guyer, R. D.; Hochschuler, S. H.; Geisler, F. H.; Holt, R. T.; Garcia, R., Jr.; Regan, J. J.; and

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Ohnmeiss, D. D.: A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine, 30(14): 1565-75; discussion E387-91, 2005. Brantigan, J. W.; Steffee, A. D.; Lewis, M. L.; Quinn, L. M.; and Persenaire, J. M.: Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial. Spine, 25(11): 1437-46, 2000. Brox, J. I. et al.: Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. Pain, 122(1-2): 145-55, 2006. Brox, J. I. et al.: Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. Spine, 28(17): 1913-21, 2003. Caspi, I.; Levinkopf, M.; and Nerubay, J.: Results of lumbar disk prosthesis after a follow-up period of 48 months. Isr Med Assoc J, 5(1): 9-11, 2003. Chou, W. Y.; Hsu, C. J.; Chang, W. N.; and Wong, C. Y.: Adjacent segment degeneration after lumbar spinal posterolateral fusion with instrumentation in elderly patients. Arch Orthop Trauma Surg, 122(1): 39-43, 2002. Chung, S. S.; Lee, C. S.; and Kang, C. S.: Lumbar total disc replacement using ProDisc II: a prospective study with a 2-year minimum follow-up. J Spinal Disord Tech, 19(6): 411-5, 2006. Chung, S. S.; Lee, C. S.; Kang, C. S.; and Kim, S. H.: The effect of lumbar total disc replacement on the spinopelvic alignment and range of motion of the lumbar spine. J Spinal Disord Tech, 19(5): 307-11, 2006.

	Yes	No	Comments
			Cinotti, G.; David, T.; and Postacchini, F.: Results of disc prosthesis after a minimum follow-up period of 2 years. Spine, 21(8): 995-1000, 1996. Coric, D.; Finger, F.; and Boltes, P.: Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. J Neurosurg Spine, 4(1): 31-5, 2006. Cunningham, B. W. et al.: Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITE artificial disc compared with fusion. J Neurosurg Spine, 8(1): 7-12, 2008. David, T.: Long-term results of one-level lumbar arthroplasty: minimum 10-year followup of the CHARITE artificial disc in 106 patients. Spine, 32(6): 661-6, 2007. 46. de Kleuver, M.; Oner, F. C.; and Jacobs, W. C.: Total disc replacement for chronic low back pain: background and a systematic review of the literature. Eur Spine J, 12(2): 108-16, 2003. Duggal, N.; Pickett, G. E.; Mitsis, D. K.; and Keller, J. L.: Early clinical and biomechanical results following cervical arthroplasty. Neurosurg Focus, 17(3): E9, 2004. Errico, T. J.: Lumbar disc arthroplasty. Clin Orthop Relat Res, (435): 106-17, 2005. Etebar, S., and Cahill, D. W.: Risk factors for adjacent-segment failure following lumbar fixation with rigid instrumentation for degenerative instability. J Neurosurg, 90(2 Suppl): 163-9, 1999. Fairbank, J.; Frost, H.; Wilson-MacDonald, J.; Yu, L. M.; Barker, K.; and Collins, R.: Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. BMJ, 330(7502): 1233, 2005. Fernstrom, U.: Arthroplasty with intercorporal endoprosthesis in herniated disc and in painful disc. Acta Chir Scand Suppl, 357: 154-9, 1966.

Policy Number: SURG.00055 Policy Title: Artificial Intervertebral Discs Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	No	Comments
			Fong, S. Y.; DuPlessis, S. J.; Casha, S.; and Hurlbert, R. J.: Design limitations of Bryan disc arthroplasty. Spine J, 6(3): 233-41, 2006. Fraser, R. D.; Ross, E. R.; Lowery, G. L.; Freeman, B. J.; and Dolan, M.: AcroFlex design and results. Spine J, 4(6 Suppl): 245S-251S, 2004. Frelinghuysen, P.; Huang, R. C.; Girardi, F. P.; and Cammisa, F. P., Jr.: Lumbar total disc replacement part I: rationale, biomechanics, and implant types. Orthop Clin North Am, 36(3): 293-9, 2005. Geisler, F. H.; Blumenthal, S. L.; Guyer, R. D.; McAfee, P. C.; Regan, J. J.; Johnson, J. P.; and Mullin, B.: Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine, 1(2): 143-54, 2004. Ghiselli, G.; Wang, J. C.; Bhatia, N. N.; Hsu, W. K.; and Dawson, E. G.: Adjacent segment degeneration in the lumbar spine. J Bone Joint Surg Am, 86-A(7): 1497-503, 2004. Goffin, J. et al.: Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. Spine, 28(24): 2673-8, 2003. Guyer, R. D.; Geisler, F. H.; Blumenthal, S. L.; McAfee, P. C.; and Mullin, B. B.: Effect of age on clinical and radiographic outcomes and adverse events following 1-level lumbar arthroplasty after a minimum 2-year follow-up. J Neurosurg Spine, 8(2): 101-7, 2008. Guyer RD, T. S., Regan JJ: An economic model of one-level lumbar arthoplasty versus fusion. Spine Journal, 7(5): 558-562, 2007.

	Yes	No	Comments
			Hallab, N.; Link, H. D.; and McAfee, P. C.: Biomaterial optimization in total disc arthroplasty. Spine, 28(20): S139-52, 2003. Heidecke, V.; Burkert, W.; Brucke, M.; and Rainov, N. G.: Intervertebral disc replacement for cervical degenerative disease--clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. Acta Neurochir (Wien), 150(5): 453-9; discussion 459, 2008. Hilibrand, A. S.; Carlson, G. D.; Palumbo, M. A.; Jones, P. K.; and Bohlman, H. H.: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. J Bone Joint Surg Am, 81(4): 519-28, 1999. Hoang, L.; Thongtrangan, I.; and Kim, D.: Historical review of cervical arthroplasty. Edited, 2004. Huang, R. C.; Lim, M. R.; Girardi, F. P.; and Cammisa, F. P., Jr.: The prevalence of contraindications to total disc replacement in a cohort of lumbar surgical patients. Spine, 29(22): 2538-41, 2004. Huang, R. C.; Tropiano, P.; Marnay, T.; Girardi, F. P.; Lim, M. R.; and Cammisa, F. P., Jr.: Range of motion and adjacent level degeneration after lumbar total disc replacement. Spine J, 6(3): 242-7, 2006. Ishihara, H.; Kanamori, M.; Kawaguchi, Y.; Nakamura, H.; and Kimura, T.: Adjacent segment disease after anterior cervical interbody fusion. Spine J, 4(6): 624-8, 2004. Jollenbeck, B.; Hahne, R.; Schubert, A.; and Firsching, R.: Early experiences with cervical disc prostheses. Zentralbl Neurochir, 65(3): 123-7, 2004. Kim, D. H.; Ryu, K. S.; Kim, M. K.; and Park, C. K.: Factors influencing segmental range of motion after lumbar total disc replacement using the ProDisc II prosthesis. J Neurosurg Spine, 7(2): 131-8, 2007. Kim, S. H.; Shin, H. C.; Shin, D. A.; Kim, K. N.; and Yoon do, H.: Early clinical experience

	Yes	No	Comments
			with the mobi-C disc prosthesis. Yonsei Med J, 48(3): 457-64, 2007. Kulkarni, V.; Rajshekhar, V.; and Raghuram, L.: Accelerated spondylotic changes adjacent to the fused segment following central cervical corpectomy: magnetic resonance imaging study evidence. J Neurosurg, 100(1 Suppl Spine): 2-6, 2004. Kumar, M. N.; Jacquot, F.; and Hall, H.: Long-term follow-up of functional outcomes and radiographic changes at adjacent levels following lumbar spine fusion for degenerative disc disease. Eur Spine J, 10(4): 309-13, 2001. Lafuente, J.; Casey, A. T.; Petzold, A.; and Brew, S.: The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis: 46 consecutive cases. J Bone Joint Surg Br, 87(4): 508-12, 2005. Le Huec, J. C.; Mathews, H.; Basso, Y.; Aunoble, S.; Hoste, D.; Bley, B.; and Friesem, T.: Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up. Orthop Clin North Am, 36(3): 315-22, 2005. Leivseth, G.; Braaten, S.; Frobin, W.; and Brinckmann, P.: Mobility of lumbar segments instrumented with a ProDisc II prosthesis: A two-year follow-up study. Spine, 31(15): 1726-1733, 2006. Lemaire, J. P.; Carrier, H.; Sariali el, H.; Skalli, W.; and Lavaste, F.: Clinical and radiological outcomes with the Charite artificial disc: a 10-year minimum follow-up. J Spinal Disord Tech, 18(4): 353-9, 2005. Leung, C.; Casey, A. T.; Goffin, J.; Kehr, P.; Liebig, K.; Lind, B.; Logroscino, C.; and Pointillart, V.: Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. Neurosurgery, 57(4): 759-63; discussion 759-63, 2005. Levin, D. A.; Bendo, J. A.; Quirno, M.; Errico, T.; Goldstein, J.; and Spivak, J.: Comparative charge analysis of one- and two-level lumbar total disc arthroplasty

	Yes	No	Comments
			versus circumferential lumbar fusion. Spine, 32(25): 2905-9, 2007. Levin DA, B. J., Quirno M, Errico T, Goldstein J, Spivak J: Comparative charge analysis of one- and two-level lumbar total disc arthroplasty versus circumferential lumbar fusion. Spine 32(25): 2905-9, 2007. Lin, E. L., and Wang, J. C.: Total disk arthroplasty. J Am Acad Orthop Surg, 14(13): 705-14, 2006. Liu, F.; Cheng, J.; Komistek, R. D.; Mahfouz, M. R.; and Sharma, A.: In vivo evaluation of dynamic characteristics of the normal, fused, and disc replacement cervical spines. Spine, 32(23): 2578-84, 2007. Mayer, H. M.: Total lumbar disc replacement. J Bone Joint Surg Br, 87(8): 1029-37, 2005. Mayer, H. M., and Wiechert, K.: Microsurgical anterior approaches to the lumbar spine for interbody fusion and total disc replacement. Neurosurgery, 51(5 Suppl): S159-65, 2002. McAfee, P. C.: The indications for lumbar and cervical disc replacement. Spine J, 4(6 Suppl): 177S-181S, 2004. McAfee, P. C. et al.: A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. Spine, 30(14): 1576-83; discussion E388-90, 2005. McAfee, P. C. et al.: Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. Spine, 31(11): 1217-26, 2006. McCullen, G. M., and Yuan, H. A.: Artificial disc: current developments in artificial disc replacement. Curr Opin Orthop, 14: 138-143, 2003. Medical Services Advisory Committee

	Yes	No	Comments
			(Australia): Artificial intervertebral disc replacement (Total disc arthroplasty). Edited, Canberra, Commonwealth of Australia, 2006. Mehren, C.; Suchomel, P.; Grochulla, F.; Barsa, P.; Sourkova, P.; Hradil, J.; Korge, A.; and Mayer, H. M.: Heterotopic ossification in total cervical artificial disc replacement. Spine, 31(24): 2802-6, 2006. Mummaneni, P. V.; Burkus, J. K.; Haid, R. W.; Traynelis, V. C.; and Zdeblick, T. A.: Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine, 6(3): 198-209, 2007. Nabhan, A.; Ahlhelm, F.; Pitzen, T.; Steudel, W. I.; Jung, J.; Shariat, K.; Steimer, O.; Bachelier, F.; and Pape, D.: Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. Eur Spine J, 16(3): 423-30, 2007. Nabhan, A.; Ahlhelm, F.; Shariat, K.; Pitzen, T.; Steimer, O.; Steudel, W. I.; and Pape, D.: The ProDisc-C prosthesis: clinical and radiological experience 1 year after surgery. Spine, 32(18): 1935-41, 2007. Peng-Fei, S., and Yu-Hua, J.: Cervical disc prosthesis replacement and interbody fusion: a comparative study. Int Orthop, 32(1): 103-6, 2008. Petersilge, C. A.: Lumbar disc replacement. Semin Musculoskelet Radiol, 10(1): 22-9, 2006. Piaggio, G.; Elbourne, D. R.; Altman, D. G.; Pocock, S. J.; and Evans, S. J.: Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. Jama, 295(10): 1152-60, 2006. Pickett, G. E.; Sekhon, L. H.; Sears, W. R.; and Duggal, N.: Complications with cervical arthroplasty. J Neurosurg Spine, 4(2): 98-105, 2006. Pimenta, L.; McAfee, P. C.; Cappuccino, A.;

	Yes	No	Comments
			Bellera, F. P.; and Link, H. D.: Clinical experience with the new artificial cervical PCM (Cervitech) disc. Spine J, 4(6 Suppl): 315S-321S, 2004. Pointillart, V.: Cervical disc prosthesis in humans: first failure. Spine, 26(5): E90-2, 2001. Porchet, F., and Metcalf, N. H.: Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurg Focus, 17(3): E6, 2004. Punt, I. M.; Visser, V. M.; van Rhijn, L. W.; Kurtz, S. M.; Antonis, J.; Schurink, G. W.; and van Ooij, A.: Complications and reoperations of the SB Charite lumbar disc prosthesis: experience in 75 patients. Eur Spine J, 17(1): 36-43, 2008. Putzier, M.; Funk, J. F.; Schneider, S. V.; Gross, C.; Tohtz, S. W.; Khodadadyan-Klostermann, C.; Perka, C.; and Kandziora, F.: Charite total disc replacement-clinical and radiographical results after an average follow-up of 17 years. Eur Spine J, 15(2): 183-95, 2006. Rabin, D.; Pickett, G. E.; Bisnaire, L.; and Duggal, N.: The kinematics of anterior cervical discectomy and fusion versus artificial cervical disc: a pilot study. Neurosurgery, 61(3 Suppl): 100-4; discussion 104-5, 2007. Regan, J. J.; McAfee, P. C.; Blumenthal, S. L.; Guyer, R. D.; Geisler, F. H.; Garcia, R., Jr.; and Maxwell, J. H.: Evaluation of surgical volume and the early experience with lumbar total disc replacement as part of the investigational device exemption study of the Charite Artificial Disc. Spine, 31(19): 2270-6, 2006. Robertson, J. T., and Metcalf, N. H.: Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. Neurosurg Focus, 17(3): E10, 2004. Robertson, J. T.; Papadopoulos, S. M.; and Traynelis, V. C.: Assessment of adjacent segment disease in patients treated with

	Yes	No	Comments
			cervical fusion or arthroplasty: a prospective 2-year study. J Neurosurg Spine, 3(6): 417-23, 2005. Rodts, M. F.: Total disc replacement arthroplasty. Orthop Nurs, 23(3): 216-9, 2004. SariAli el, H.; Lemaire, J. P.; Pascal-Mousselard, H.; Carrier, H.; and Skalli, W.: In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-14 years follow up evaluation. Eur Spine J, 15(10): 1501-10, 2006. Sasso, R. C.; Foulk, D. M.; and Hahn, M.: Prospective, randomized trial of metal-on metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. Spine, 33(2): 123-31, 2008. Sasso, R. C.; Smucker, J. D.; Hacker, R. J.; and Heller, J. G.: Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. J Spinal Disord Tech, 20(7): 481-91, 2007. Sekhon, L. H.: Cervical arthroplasty in the management of spondylotic myelopathy: 18-month results. Neurosurg Focus, 17(3): E8, 2004. Sekhon, L. H., and Ball, J. R.: Artificial cervical disc replacement: principles, types and techniques. Neurol India, 53(4): 445-50, 2005. Shim, C. S.; Lee, S. H.; Park, H. J.; Kang, H. S.; and Hwang, J. H.: Early clinical and radiologic outcomes of cervical arthroplasty with Bryan Cervical Disc prosthesis. J Spinal Disord Tech, 19(7): 465-70, 2006. Shim, C. S. et al.: CHARITI versus ProDisc: A comparative study of a minimum 3-year follow-up. Spine, 32(9): 1012-1018, 2007. Siepe, C. J.; Mayer, H. M.; Heinz-Leisenheimer, M.; and Korge, A.: Total lumbar disc replacement: different results for different levels. Spine, 32(7): 782-90, 2007. Siepe, C. J.; Wiechert, K.; Khattab, M. F.;

Policy Number: SURG.00055 Policy Title: Artificial Intervertebral Discs Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	No	Comments
			Korge, A.; and Mayer, H. M.: Total lumbar disc replacement in athletes: clinical results, return to sport and athletic performance. Eur Spine J, 16(7): 1001-13, 2007. Singh K, V. A., Albert TJ: Assessing the potential impact of total disc arthroplasty on surgeon practice patterns in North America. Spine Journal, 4(6S): S195-201, 2004. The Medical Advisory Secretariat: Artificial discs for lumbar and cervical degenerative disc disease - update. Edited, Toronto, Ministry of Health and Long Term Care, 2006. Tortolani, P. J.; Cunningham, B. W.; Eng, M.; McAfee, P. C.; Holsapple, G. A.; and Adams, K. A.: Prevalence of heterotopic ossification following total disc replacement. A prospective, randomized study of two hundred and seventy-six patients. J Bone Joint Surg Am, 89(1): 82-8, 2007. Tropiano, P.; Huang, R. C.; Girardi, F. P.; Cammisa, F. P., Jr.; and Marnay, T.: Lumbar total disc replacement. Seven to eleven-year follow-up. J Bone Joint Surg Am, 87(3): 490-6, 2005. Tropiano, P.; Huang, R. C.; Girardi, F. P.; and Marnay, T.: Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. J Spinal Disord Tech, 16(4): 362-8, 2003. Wigfield, C.; Gill, S.; Nelson, R.; Langdon, I.; Metcalf, N.; and Robertson, J.: Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. J Neurosurg, 96(1 Suppl): 17-21, 2002. Wigfield, C. C.; Gill, S. S.; Nelson, R. J.; Metcalf, N. H.; and Robertson, J. T.: The new Frenchay artificial cervical joint: results from a two-year pilot study. Spine, 27(22): 2446-52, 2002. Xu, Y. C.; Liu, S. L.; Huang, D. S.; Shen, H. Y.; Li, C. H.; and Ma, R. F.: Correlated evaluation on the spinal segment motion scope and the alteration of the corresponding parameters after artificial lumbar

Policy Number: SURG.00055 Policy Title: Artificial Intervertebral Discs Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			intervertebral disc replacement. Ch J of Clin Rehab, 8(32): 7294-96, 2004. Yang, S.; Hu, Y.; Zhao, J.; He, X.; Liu, Y.; Xu, W.; Du, J.; and Fu, D.: Follow-up study on the motion range after treatment of degenerative disc disease with the Bryan cervical disc prosthesis. J Huazhong Univ Sci Technolog Med Sci, 27(2): 176-8, 2007. Yoon, D. H.; Yi, S.; Shin, H. C.; Kim, K. N.; and Kim, S. H.: Clinical and radiological results following cervical arthroplasty. Acta Neurochirurgica, 148(9): 943-950, 2006. Zeegers, W. S.; Bohnen, L. M.; Laaper, M.; and Verhaegen, M. J.: Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. Eur Spine J, 8(3): 210-7, 1999. Zigler, J. et al.: Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine, 32(11): 1155-62; discussion 1163, 2007.
• If you consider artificial intervertebral discs medically necessary in the treatment of cervical and lumbar degenerative disc disease: – Are there any specific criteria which would be useful in selecting appropriate patient populations?	X		The indications would be symptoms attributed to cervical or lumbar degenerative disc disease including signs of neurological compression. Artificial disc replacement is a potential alternative to spinal fusion in patients and intended to preserve motion at the involved spinal level to decrease stresses on adjacent segment structures and the risk of adjacent segment disease. This would also be based on the inclusion criteria of the patients enrolled in the clinical IDE studies.
– Are there any specific contraindications which would be useful in identifying patients for whom artificial intervertebral discs is not appropriate?	X		We would recommend that clinical or patient characteristics for which the artificial intervertebral disc is not appropriate include patients with spinal instability (sagittal plane translation >3.5mm, sagittal plane angulation >20°), facet joint pathology, osteoporosis, cancer, and infection. The literature supporting this is as indicated in the large scale clinical trials.
• The FDA approval for these devices is contingent upon 5-7 year follow up studies. o Do you think the current literature is sufficient to support use of artificial intervertebral discs?	X		This statement by the FDA does not indicate any specific negative concerns related to the devices as this question would seem to indicate, as otherwise the artificial cervical and lumbar discs would not have been

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	Yes	**No**	**Comments**
			approved by the FDA. This is a continued evolution of the FDA process with the Center for Devices and Radiological Health (CDRH) developing new protocols for postmarket surveillance to monitor the performance of marketed medical devices.
***Improved Patient Outcomes*:** • Is there adequate evidence to demonstrate that the use of artificial intervertebral discs provide significant improvements in clinical outcomes compared to cervical or lumbar fusion?	X		The rationale for this has been provided in the prior questions.
• Is there *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of artificial intervertebral discs? If so, please cite.	X		The citations for this literature have been provided in the previous questions.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	
***Conflict of Interest*:** Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with artificial intervertebral discs? If so, please disclose that relationship.		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- not primarily for the convenience of the patient, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The term "investigational" means that the medical policy does not meet the Technology Evaluation Criteria.

This means any procedure, treatment, supply, device, equipment, facility or drug (all services), are determined NOT to:

- have final approval from the appropriate government regulatory body; or

- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

Review and Response to position on AxiaLIF®

Please find below the official comments from the American Association of Neurological Surgeons/Congress of Neurological Surgeons regarding Wellpoint's draft coverage policy for the AxiaLIF procedure (Exhibit 1).

Introduction:
The draft policy stating that AxiaLIF is investigational does not accurately describe the procedure nor does it reflect the breadth of published medical evidence. AxiaLIF is an anatomically valid anterior stabilization and interbody fusion technique via a retroperitoneal access that has safely been performed more than 5500 times across the United States. The procedure has been performed in a variety of settings including large academic medical centers, community hospitals, and the outpatient setting. Positive results reported in the literature have been achieved across practice settings with regularity. AxiaLIF is simply an access variation of the current standard of care fusion procedures much as anterior and posterior lumbar interbody fusion techniques. The body of peer reviewed literature demonstrates that AxiaLIF provides comparable fusion rates to other procedures with similar incidence of iatrogenic complications and clinical outcomes. Wellpoint has published supportive positions of other minimally invasive procedures such as TLIF, XLIF and DLIF having deemed them medically necessary. As such, we disagree with other reviewers in that AxiaLIF, like these other procedures, is simply a variation of classical ALIF (anterior lumbar interbody fusion) and PLIF/TLIF (posterior or transforaminal interbody fusion) at L5-S1.

Technical Description:
Wellpoint's current description of the AxiaLIF procedure is inaccurate. The draft policy states "AxiaLIF is…intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of interbody fusion." The approved FDA labeling for the procedure is as follows: "*TranS1 AxiaLIF System is intended to facilitate spinal fusion by providing axial access to the L5-S1 disc space and axial stabilization of those vertebral bodies. The Trans1 AxiaLIF System is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies*." (please see Appendix 2).

AxiaLIF is an anterior stabilization and interbody fusion technique via a retroperitoneal approach that must be performed as an adjunct to posterior (non-interbody) fusion and/or in combination with legally marketed pedicle or facet screws. The current description inaccurately portrays AxiaLIF as a discectomy or fusion assistance procedure not as a true inerbody fusion procedure as it should. It is often used in combination with posterolateral fusion but it is never used in conjunction with ALIF, TLIF, XLIF, or PLIF at the same level. Furthermore, the nomenclature of the current CPT code of AxiaLIF (0195T) describes the procedure as a presacral arthrodesis. There should be no question that AxiaLIF is an interbody fusion procedure. Historical literature has demonstrated the use of transsacral intrumentation via Rogers or Bohlman fibular struts passed through an equivalent anatomical corridor.

Wellpoint reviewers also questions the ability of the surgeon to adequately perform a discectomy due to visualization of the disc space solely via fluoroscopy. However, it is well documented that other MIS fusion techniques such as MIS TLIF, XLIF and DLIF also have limited visualization of the disc space during the discectomy portion of the procedure and require fluoroscopy as an enabler for visualization. It

would seem from the published fusion rates for the AxiaLIF procedure that an adequate and aggressive discectomy was indeed accomplished at the time of surgery given the radiographic fusion rates seen by various authors which are equivalent to historical TLIF and ALIF literature series.

There is also concern about the total amount of fluoroscopy used during the procedure. Despite wide variation in surgical times, the average total amount of fluoroscopy used during the procedure is approximately 2-3 minutes which is far less radiation exposure than a standard CT scan. In this authors experience, the amount of flouroscopy for AxiaLIF is similar or nearly equivalent to that of other minimally invasive procedures such as XLIF, DLIF and minimally invasive TLIF with pedicle screws.

Evidence:
The two main outcomes of interest when considering the clinical rationale for using AxiaLIF are fusion rates over time and complication rates. AxiaLIF has been widely studied with experiences being reported both in peer reviewed journal articles and via abstracts and posters presented at clinical meetings. Overall, fusion rates have been comparable or better than those experienced by standard of care procedures while complications have been reduced. (A full appendix of citations and selected study summaries follows)

In one published study Aryan et al. reports a 91% fusion rate at 17.5 months. This is comparable or superior to current standard of care fusion procedures. In 1998 Kuslich et al reported fusion rates of 88.3% for ALIF cases and 85.3% for PLIF case at 12 months. At two years these rates were 93% for ALIF and 90.6% for PLIF. This represents a significant improvement demonstrated by AxiaLIF as compared to these predicate procedures. Kuslich also reports an overall spinal fusion complication rate of 19.7% of which 2% were major complications, 8.2% were intraoperative complications, and 9.5% were postoperative complications. In contrast, using AxiaLIF Aryan reported 1 local infection at the incision site and no major complications including bowel or vascular injuries. The significantly reduced rate of complications has been widely reported (see full list of references in Exhibit 3).

In 2008, Anand et al published the first peer-reviewed article regarding MIS fusion techniques, including AxiaLIF, in the adult degenerative scoliosis patient population. Traditionally, this patient population has been difficult to treat given the significant morbidity and mortality associated with open fusion procedures. However, Anand reports no surgical or post-surgical complications from the L5-S1 fusion portion of the procedure, and he reported that no blood transfusions occurred and no patients required an ICU stay. Furthermore, overall hospital stays were significantly reduced when compared to traditional fusion procedures in this population. Complications were significantly reduced using AxiaLIF as compared to ALIF or PLIF.

Tobler et al (in press, publication expected late 2009) prospectively followed his first 26 sequential patients who underwent AxiaLIF at L5-S1 for two years. Tobler reports patients had significant pain and disability reduction as early as 3 weeks post-surgery and continued at 24 months postoperatively. Fusion rates were equal or greater when compared to conventional fusion procedures and no severe complications were reported in this patient group. Furthermore, the Company (TranS1, Inc.) has reported all surgical complications resulting from the AxiaLIF procedure to the FDA as part of the continuing safety surveillance and after more than 5,500 completed procedures, the complication rate has consistently remained at approximately 1% which is on par with that of ALIF, TLIF and other L5-S1 interbody fusion techniques. It is crucial to understand that anterior lumbar interbody procedures (ALIF) carry known documented incidences of vascular, bowel, urogenital, and neurological complications. Whereas nonunions exist for all know types of interbody fusion procedures, published and peer-reviewed presented meeting abstract fusion rates for AxiaLIF are at the very least comparable to current standard of care fusion procedures.

AxiaLIF has demonstrated its utility as a treatment for grade 1 or 2 spondylolisthesis. In a peer-reviewed presentation at the Spine Arthroplasty Society in May 2009, WB Rodgers reported positive results using AxiaLIF to correct spondylolisthesis while allowing surgeons to spare the facet joint and surrounding ligamentous tissues thus providing superior stability to the slipped segment with minimum morbidity to the patient.

Rodgers et al has also studied AxiaLIF in the morbidly obese patient. This patient population is often risked out of traditional fusion procedures due to the high risk of major complications. Rodgers treated 37 patients with BMIs >30 and comorbidities which included smoking (38%), prior spine surgery (35%), diabetes (35%), and CAD (54%). The average hospital stay for these patients was 1.05 days, disk height increased an average of 3.6mm. Slip was 57% in spondylolisthesis patients and the reduction was maintained. There were no transfusions or major infections; one patient required a pedicle screw revision at post-op day 15 and one patient had a local incision infection. Pre-op VAS of 8.9 decreased to 3.5 at 3 months and 2.8 at six months. Even in challenging patients, AxiaLIF proved to be safe, effective, and resulted in far fewer complications that those treated with traditional open fusion.

As demonstrated above, AxiaLIF has particular application in patient populations where traditional fusion procedure outcomes have not been strong. For example, the adult degenerative deformity population represents the most challenging fusion patient populationAnand shows that MIS techniques, including AxiaLIF, significantly reduce morbidity and mortality in this vulnerable population which in turns creates significant cost savings for both the hospital and the payer. Rogers et al report using proper care, a transsacral MIS approach using the AxiaLIF fixation system at L5-S1 for a Grade I or Grade II spondylolisthesis provides a readily reproducible and safe alternative to traditional open interbody procedures at L5-S1

AxiaLIF is contraindicated in patients with previous bowel surgery, irritable bowel surgery, pelvic disease, or peri-rectal abscesses. AxiaLIF is also contraindicated in pregnancy and for those with severe spondylolisthesis (grades III or IV). An MRI to the tip of the coccyx should be performed prior to surgery to rule out any sacral abnormalities that would rule out safe access to the L5/S1 disc space.

Discrepancy in Coverage for Spinal Fusion Procedures

TLIF, XLIF and DLIF are all new and minimally invasive approaches to the lumbar spine and all are considered medically necessary. Except for two papers documenting MIS TLIF patients at 6 months (Deutsch H, Musacchio MJ-Neurosurg Focus 2006;20(3):E10) and 18 months (Schwender et al-J Spinal Disord Tech 2005;18(suppl 1):S1-S6), there are no peer-reviewed published papers on patient outcomes for these procedures. The Deutsch paper followed 20 patients with 6 months of follow-up and Schwender followed 49 patients for 18 months (versus 35 patients with 17+ months of follow-up for Aryan). Mean blood loss was higher for TLIF patients (100ml (Deutsch) and 140ml (Schwender) versus 30ml for AxiaLIF) and the TLIF group experienced 2 intraoperative complications (CSF leaks) versus zero in the AxiaLIF group. Schwender documented four complications in his paper-2 patients experienced malpositioned pedicle screws that required removal and 2 patients developed new post-operative radiculopathies. These patients (radiculopathies) required reoperations to resolve their pain. To date, none of the patient outcomes data for AxiaLIF reports new radiculopathies as a result of surgical technique and no patients have required additional procedures. Both MIS TLIF papers and the published AxiaLIF data show equivalent VAS and ODI scores at 6 months. Given the limited data available for other minimally invasive procedures such as TLIF, XLIF and DLIF, AxiaLIF meets the criteria for medically necessity and has more published peer-reviewed patient outcomes data.

Conclusion

AxiaLIF is a reasonable alternate from of anterior stabilization and interbody fusion technique with a growing compendium of published outcomes data. The procedure is widely performed in a variety of settings with a consistently low complication rate. When compared to standard fusion procedures, AxiaLIF has an incidence of iatrogenic complications, perioperative morbidity, hospital stay, and infection rate that is equivalent to traditionally published ALIF and TLIF series.

From a cost-perspective, AxiaLIF provides a lower cost interbody fusion with improved patient outcomes. Current standard of care fusion procedures have a documented reoperation rate of approximately 4% with AxiaLIF's reoperation rates being similar. Futhermore, AxiaLIF patients report equivalent radiographic fusion rates at 12 months with similar VAS and ODI scores respectively.

Based on this review of the published and presented data on the procedure, the positive impact AxiaLIF has on patient outcomes, and its potential to decrease costs associated with spinal fusion, AxiaLIF should be considered medically necessary by Wellpoint.

EXHIBIT 1: Draft Wellpoint Policy

DRAFT 0.00.00 – Axial Lumbar Interbody Fusion (axiaLIF)
Page: 1 of 3

Description

Axial lumbar interbody fusion (also called trans-sacral or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

The AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level Systems were developed by TranS1® and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5 - S1 or L4 – S1 vertebral bodies. FDA Premarket Notification [510(k)J] summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of interbody fusion. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. The device is not meant to be used in patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with legally marketed facet or pedicle screw systems. (1,2)

The procedure for one level axiaLIF is as follows. Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15-20 mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators is passed along the guide pin and a dilator sheath attached to the last dilator is left in place to serve as a working channel for passage of instruments. A threaded reamer is then passed into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors and the nucleus pulposis is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod designed to distract the vertebral bodies, restore disc height, and neural foramen height is then introduced over the guide pin into the S1 and L5 interbodies.

Bone void filler is injected into the rod and enters the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws completes the procedure.(3)

Policy

Axial lumbar interbody fusion is considered investigational.

Policy Guidelines

Rationale

The published literature reporting patient outcomes for axial lumbar interbody fusion is limited to a technical report with presentation of 2 cases(4) and one retrospective case series with patients who received AxiaLIF at L5-S1. The AxiaLIF 2 level system received premarket notification in April 2008. Aryan and colleagues(5) report on their series of 35 patients with average follow-up of 17.5 months. These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the axiaLIF procedure was followed by percutaneous pedicle screw-rod fixation, 2 patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a stand alone procedure. Two patients had axial LIF as part of a larger construct after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar

fusion. Thirty-two patients had radiographic evidence of stable cage placement and fusion at last followup.
In their 2007 review of minimally invasive techniques for lumbar interbody fusion, Shen, et al note that experience with the technique is limited and complication rates are unknown. Complications may include perforation of the bowel and injury to blood vessels and/or nerves as well as infection. They also voice concerns about the increased need for fluoroscopy and the inability of the surgeon to address intracanal pathology or visualize the discectomy procedure directly.(3)
There is insufficient evidence to determine if axial lumbar interbody fusion is as effective or as safe as other surgical techniques, therefore the technology is considered investigational.

References

1. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. Available at http://www.fda.gov/cdrh/pdf7/K073514.pdf
2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. Available at http://www.fda.gov/cdrh/pdf7/K073643.pdf
3. Shen FH, Samartzis D, Dip EBHC, et al. Minimally invasive techniques for lumbar interbody fusion. Orhtop Clin N Am 2007;38(373-386).
4. Marotta N, Cosar M, Pimenta L, Khoo LT. A novel minimally invasive presacral approach and instrumentation technique for anterior L5-S1 intervertebral discectomy and fusion: technical description and case presentations. Neurosurg Focus 2006;20(1)E9.
5. Aryan HE, Newman CB, Gold JJ, et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. Minim Invasive Neurosurg 2008;51(4):225-30.

Codes Number Description

CPT 0195T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace
0196T Each additional interspace

Policy History

Date Action Reason

EXHIBIT 2- Review of AxiaLIF Publications

TranS1 Publication List: Article Summaries				
Author Title		Journal	Month/Year	Summary
Cragg A, Carl A, Casteneda F, Dickman C, Guterman L, Oliveira C	New Percutaneous Access Method for Minimally Invasive Anterior Lumbosacral Surgery	Journal of Spinal Disorders & Techniques	2/1/2004	This study demonstrates the feasibility of the axial access technique to the anterior lower lumbar spine; The technique preserves integrity of the muscles, ligaments, and annulus at L5-S and may provide biomechanical and physiologic advantages over current MISS access techniques
Ledet E, Tymeson M, Salerno S, Carl A, Cragg A	Biomechanical Evaluation of a Novel Lumbosacral Axial Fixation Device	Journal of Biomechanical Engineering	11/1/2005	The purpose of this study was to evaluate the in vitro biomechanical performance of the axial fixation rod, an anulus sparing, centrally placed interbody fusion implant for motion segment stabilization. The preliminary biomechanical data from this study indicate that the axial fixation rod compares favorably to other devices and may be suitable to reduce pathologic motion at L5-S1, thus promoting bony fusion.
Yuan P, Day T, Albert T, Morrison W, Pimenta L, Cragg A, Weinstein M	Anatomy of the Percutaneous Presacral Space for a Novel Fusion Technique	Journal of Spinal Disorders & Techniques	6/1/2006	The objective was to evaluate the safety of a paracoccygeal approach to the axial lumbosacral spine and determine structures that could potentially be injured. The coronal safe zone was 6.9 and 6.0 cm on MRI and CT, respectively. This safe zone may guide surgeons when utilizing the percutaneous paracoccygeal approach.
Eck J, Hodges S, Humphreys S	Perspectives on Modern Orthopaedics: Minimally Invasive Lumbar Spinal Surgery	Journal of the American Academy of Orthopedic Surgeons	6/6/2007	A review of minimally invasive techniques for lumbar spine fusion developed in an attempt to decrease the complications related to traditional open exposures (eg, infection, wound healing problems).
Akeson B, Wu C, Mehbod A, Transfeldt E	Biomechanical Evaluation of Anterior Transacral Fixation	Journal of Spinal Disorders & Techniques	2/1/2008	The aim of this study is to evaluate the biomechanics of the transsacral rod fixation. Transsacral rod fixation provides strong ligamentotaxis due to intact annulus. Standalone transsacral rod is able to reduce ROM significantly and achieve indirect decompression by distracting L5-S1 disc space. However, additional posterior fixation, such as facet screws or pedicle screws, is required to achieve better construct stability for successful fusion.
Asgarzadie, F; Khoo LT; Cosar, M; Marotta, N; Pimenta, L.	One Year Outcomes of Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior Lumbosacral Intervertebral Discectomy and Fusion	The Spine Journal	9/1/2007	Summary of presentation at the 22nd Annual Meeting of the North American Spine Society
Shen, F; Samartzis, D; Khanna, A; Anderson, DA	Minimally Invasive Techniques for Lumbar Interbody Fusions	Orthopedic Clinics of North America	7/1/2007	This article provides a general review of the history, indications, brief overview, and description of the more common minimally invasive spine surgery techniques used for achieving a lumbar interbody fusion.

Aryan HE, Newman CB, Gold JJ, Acosta FL Jr, Coover C, Ames CP	Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience	Minimally Invasive Neurosurgery	8/1/2008	A review of clinical experience with the technique for L5-S1 interbody fusion. It may provide an alternative route of access to the L5-S1 interspace in those patients who may have unfavorable anatomy for or contraindications to the traditional open anterior approach to this level.
Anand, N; Baron, E; Thayanithan, G; Khalsa, K; Goldstein, T	Minimally Invasive Multilevel Percutaneous Correction and Fusion for Adult Lumbar Degenerative Scoliosis	Journal of Spinal Disorders & Techniques	10/1/2008	This article assessed the feasibility of minimally invasive spine surgery (MIS) techniques in the correction of lumbar degenerative deformity. Multisegment correction can be performed with less blood loss and morbidity than for open correction.
Tobler W, Bohinski R, Basham S, Jamarillo J	Lumbar Interbody Fusion: A Comparative Clinical Assessment of the AxiaLIF System	Neurosurgical Focus	Accepted, not yet published	
Aryan H, Newman C, Acosta F, Coover C, Ames C.	Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience	Journal of Spinal Disorders & Techniques	Accepted, not yet published	

Selected Abstract Summaries		
Author Title		Summary
W. B. Rodgers, M.D., Curtis S. Cox, M.D., Edward J. Gerber, P.A.	SINGLE LEVEL LUMBAR FUSION FOR A GRADE I AND II SPONDYLOLISTHESIS CORRECTION USING THE AXIALIF ROD SYSTEM (Spine Arthroplasty Society, April/May 2009)	Clinical report utlizing the MIS transsacral fusion (AxiaLIF) method with spondylolisthesis correction, which allows surgeons to spare the facet joint and surrounding ligamentous tissues to the spinal column, thus providing superior stability to the slipped segment. The authors found that this approach provides adequate reduction of a Grade I or II spondylolisthesis due to the added contribution in biomechanical stability of the intact surrounding ligamentous tissue and noted that meticulous attention to operative technique is required. The early results demonstrate excellent clinical outcomes with minimal morbidity.
W. B. Rodgers, M.D., Curtis S. Cox, M.D., Edward J. Gerber, P.A.	SINGLE LEVEL LUMBAR FUSION AT L5-S1: A COMPARISON OF MIS TLIF AND AXIALIF (25th Annual Meeting AANS/CNS Section on Disorders of the Spone and Peripheral Nerves, March 2009)	Clinical report comparing experience using two alternatives to fusion at the LS junctions: MIS T/PLIF and AxiaLIF. Surgeons saw fairly equivalent clinical and radiographic outcomes but notably different OR times, blood loss, and length of stay. It was the prevalence of complications in the MIS T/PLIF group that led surgeons to try and then adopt the AxiaLIF as their fusion method of choice at the L5-S1 interval.

Viral Jain, MD William Tobler, MD Robert Bohinski, MD	Axial Lumbar Interbody Fusion: Result of a new minimally invasive lumbosacral fusion technique (American Academy of Orthopaedic Surgeons, Oral Presentation, February 2009)	Retrospective review of author's first 50 consecutive AxiaLIF procedures at 1-year showed statistically significant improvement in patient outcome, comparable fusion rates and very low complication rates
W.B. Rodgers, MD; Curtis Cox, MD; Edward J Gerber, PA	Safety and the Learning Curve of Trans-Sacral Fusion (AxiaLIF) at L5-S1: Complications in the first 100 Surgeries of a Single Surgeon Series	The peri- and post-operative complications associated with the AxiaLIF procedure during the initial adoption phase are reported to demonstrate the feasibility, safety, and effectiveness of the approach. The adoption phase and learning curve for trans-sacral fusion shows very few complications compared to traditional open techniques.

EXHIBIT 3- AxiaLIF Publication, Abstract & Poster List

Original Articles, Scientific Journal & Textbook Publications (Index Medicus)

- Cragg A, Carl A, Casteneda F, Dickman C, Guterman L, Oliveira C: **New Percutaneous Access Method for Minimally Invasive Anterior Lumbosacral Surgery**. J Spinal Disord Tech 17(1):21-28, 2004

- Cragg A, Carl A, Casteneda F, Dickman C, Guterman L, Ledet E, Oliveira C: **Percutaneous Axial Lumbar Spine Surgery (AxiaLIF). An Anatomical Approach to Minimally Invasive Spine Surgery**. Editors Mick Perez Cruet, M.D., Larry Khoo, M.D. and Ricard G. Fessler, M.D., Ph.D. Quality Medical Publishing, St. Louis, MO, April 2006, Chapter 38, pp. 38: 1-17.

- Ledet E, Tymeson M, Salerno S, Carl A, Cragg A: **Biomechanical Evaluation of a Novel Lumbosacral Axial Fixation Device**, Journal of Biomechanical Engineering, November 2005, Volume 127, Issue 6, pp. 929-933

- Khoo L, Marotta N, Cosar M, Pimenta L : **Novel Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior L5-S1 Intervertebral Discectomy and Fusion: Technical Description and Case Presentations**, J Neurosurgery and American Association of Neurological Surgeons: Neurosurgical Focus, Volume 20, January, 2006

- Ledet EH, Carl AL, Cragg A. **Novel Lumbosacral Axial Fixation Techniques**. Expert Review of Medical Devices, 2006; 3(3); 327-34.

- Yuan P, Day T, Albert T, Morrison W, Pimenta L, Cragg A, Weinstein M: **Anatomy of the Percutaneous Presacral Space for a Novel Fusion Technique**, J Spinal Disord Tech, 2006 June; 19 (4):237-241

- Cragg A, Carl A, Ledet E, Diaz R and Pimenta L. **"Percutaneous Axial Lumbar Spine Surgery."** An Anatomical Approach to Minimally Invasive Spine Surgery. St. Louis, MO: Quality Medical, Inc., 2006. 653-670.

- Eck J, Hodges S, Humphreys S. **Perspectives on Modern Orthopaedics: *Minimally Invasive Lumbar Spinal Surgery***. J Am Acad Orthop Surg 2007;15:321-329

- Akeson B, Wu C, Mehbod A, Transfeldt E: **Biomechanical Evaluation of Anterior Transacral Fixation**, J Spinal Disord Tech. 21(1):39-44, February 2008.

- Asgarzadie, F; **Khoo LT**; Cosar, M; Marotta, N; Pimenta, L. **One Year Outcomes of Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior Lumbosacral Intervertebral Discectomy and Fusion.** Proceedings of the 22nd Annual Meeting, The Spine Journal, Volume 7, Number 55, Sept/Oct 2007, Special Interest Paper Presentations 4: Fusion, 26-27S.

- Shen, F; Samartzis, D; Khanna, A; Anderson, DA. **Minimally Invasive Techniques for Lumbar Interbody Fusions**. Orthop Clin N Am 38 (2007) 373–386.

- Coric D; Mummaneni, P: **Nucleus replacement technologies. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2007.** J Neurosurg Spine 8:115–120, 2008.

- Burak M. Ozgur, Marlon Mathews, William Taylor: **Combined XLIF and AxiaLIF Techniques for Minimally-Invasive Surgical Access**. *The Internet Journal of Minimally Invasive Spinal Technology*. 2008. Volume 2 Number 3.

- Diaz R, Pimenta L, Nicola H, Khoo L, Sasso R, Wessman B, Cragg A: ***TranS1® Percutaneous Nucleus Replacement (PNR).*** **Motion Preservation Surgery of the Spine - Advanced Techniques and Controversies: Expert Consult.** Editors James J. Yue, MD, Rudolph Bertagnoli, MD, Paul C. McAfee, MD and Howard S. An, MD. Saunders Publishing, St. Louis, MO, June 2008, Chapter 57, pp: 435-441.

- Aryan HE, Newman CB, Gold JJ, Acosta FL Jr, Coover C, Ames CP. **Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience.** *Minim Invasive Neurosurg.* 2008 Aug, 51(4):225-30.

- Anand, N; Baron, E; Thayanithan, G; Khalsa, K; Goldstein, T. **Minimally Invasive Multilevel Percutaneous Correction and Fusion for Adult Lumbar Degenerative Scoliosis,** J Spinal Disord Tech 2008;21:459–467.

- Tobler W, Bohinski R, Basham S, Jamarillo J. **Lumbar Interbody Fusion: A Comparative Clinical Assessment of the AxiaLIF System**. Neurosurgical Focus. Accepted, not yet published. (26 patient series, prospective, non-randomized, historical fusion controls vs 23/24 fused)

- Aryan H, Newman C, Acosta F, Coover C, Ames C. **Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience.** J Spinal Disord Tech, Accepted for Publication, not yet published. (35 patient series, 24 months, retrospective, non-randomized)

Symposia Presentation

- Pimenta L, Bellera F, Carl A, Ledet E, Cragg A: **New Percutaneous Access Method and Implant for L4-S1 Spinal Fusion Surgery**. Presented at AANS 2004, Session 118 New & Evolving MIS Techniques: Drs. Fessler, Pimenta, Smith & Isaacs,1-6 May 2004, Orlando.

- Albert T, Lieberman I: **Pre-Sacral Approaches & MIS Spine Surgery**, Innovative Techniques in Spine Surgery 2nd Annual Meeting, 20-23 July 2005, Los Cabos, Mexico

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Prospective Clinical Feasibility Study of the Novel Percutaneous Nucleus Replacement (PNR) System. Early Clinical Results**. Presented at the 13th International Meeting on Advanced Spine Techniques (IMAST), 12-15 July 2006, Athens, Greece.

- Aryan, HE; FL Acosta; CP Ames: **Initial Clinical and Radiographic Results of a Minimally Invasive Presacral Approach for L5-S1 Interbody Fusion.** AANS/CNS Section on Disorders of the Spine and Peripheral Nerves (22nd Annual Meeting), Lake Buena Vista, Florida, 2006.

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Early clinical and biomechanical evaluation of the axial lumbar percuatenous nucleus replacement (PNR),** Spine Arthroplasty Society 6: Global Symposium on Motion Preservation Technology. May 9-13, 2006, Montreal, Canada.

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Percutaneous Nucleus Replacement (PNR) L5-S1. A new minimal invasive arthroplasty device. A one year clinical and radiological follow-up.** 2006 Spine Across The Sea; Annual Meeting. July, 2006. Hawaii, USA.

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Minimal Invasive Percutaneous Presacral Axial Lumbar Fusion (AxiaLIF). Prospective clinical and radiographic results after 30 months follow-up.** Section on Disorders of the Spine and Peripheral Nerves, Congress of Neurosurgeons, Chicago, IL, October 7-12, 2006.

- Pimenta L, Guerrero L, Cragg A, Nicola H, Diaz R: **Minimal Invasive Percutaneous Presacral Axial Lumbar Fusion (AxiaLIF). Clinical and Radiographic results after 30 months follow-up**. Session: Spine/Peripheral Nerve, American Association of Neurological Surgeons, Washington, DC, April 14-19, 2007

- Beaubien B, Freeman A, Wessman B, Loughran G: **An in vitro, cadaveric model evaluation of a novel prosthetic nucleus implanted through the pre-sacral approach.** Session: Nucleus Replacement, Spine Arthroplasty Society, Berlin, Germany, May 1-5, 2007.

- Pimenta L, Guerrero L, Cragg A, Nicola H, Diaz R: **Percutaneous Nucleus Replacement (PNR): Initial Clinical Experience.** Session: Innovative Technologies - Mini Papers. Spine Arthroplasty Society, Berlin, Germany, May 1-5, 2007.

- Bradley WD, Rousch T, Hisey M, Ohnmeiss D: **Interbody Fusion Using a Unique Trans-sacral Approach.** Paper #99. International Meeting of Advanced Spinal Techniques, 11-14 July 2007, Paradise Island, Bahamas.

- Asgarzadie, F; **Khoo LT**; Cosar, M; Marotta, N; Pimenta, L. **One Year Outcomes of Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior Lumbosacral Intervertebral Discectomy and Fusion.** Presented at the North American Spine Society, Special Interest Paper Presentations, 22-27 October 2007, Austin, TX.

- Tobler, W; Bohinski, R: **Experience in 150 Cases with the TranS1 Minimally Invasive Fusion Technique at L5-S1.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Pimenta, L; Arias, C: **Two Levels Presacral Axial Lumbar Interbody Fusion (AxiaLIF). A Prospective 12 Months Follow up: Clinical And Radiological Results.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Laughran, G; Beauboin, B: **A Finite Element Study of L5-S1 Spinal Biomechanics Comparing Different Surgical Therapies.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Anand, N; Baron, E; Thaiyananthan, T: **Novel Minimally Invasive Percutaneous Multi-Level 360 Degree Fusion for Lumbar Degenerative Scoliosis - Feasibility, Technique and Early Results.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Zeilstra, D. **Transaxial fixation of the lumbosacral segment as a stand-alone procedure.** Oral paper presentation at EuroSpine/SPINEWEEK, May 26-31, 2008, Geneva, Switzerland.

- Pimenta, L; Arias, C: **Two levels presacral axial lumbar interbody fusion (Axialif). A prospective 18 month follow up: clinical and radiological results.** Oral paper presentation at EuroSpine/SPINEWEEK, May 26-31, 2008, Geneva, Switzerland.

- Anand, N; Baron, E; Thaiyananthan, T: **Minimally Invasive Percutaneous Multilevel 360 degree fusion for Lumbar Degenerative Scoliosis: Radiologic and Clinical Follow-up**. Paper #89. International Meeting of Advanced Spinal Techniques, 8-11 July 2008, Hong Kong, China.

- Tobler, W; Bohinski, R: **Axial lumbar interbody fusion) a new, minimally invasive technique at L5-S1: clinical outcomes, complications, and fusion rates in 50 patients at 1-year follow up.** ABSTRACT NO: 65, Section on Disorders of the Spine and Peripheral Nerves Select Abstract Session. Congress of Neurological Surgeons, 20-25 September 2008, Orlando, FL.

- Jain, T; Tobler, W; Bohinski, R: **Axial Lumbar Interbody Fusion: Result of a new minimally invasive lumbosacral fusion technique**. American Academy of Orthopaedic Surgeons, Oral Presentation, February 25, 2009, Las Vegas, NV.

- Rodgers, WB; Cox, C; Gerber, E: **SINGLE LEVEL LUMBAR FUSION AT L5-S1: A COMPARISON OF MIS TLIF AND AXIALIF.** 25th Annual Meeting AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. March 11 – March 14, 2009, Phoenix, AZ.

- Rodgers, WB; Cox, C; Gerber, E: **SINGLE LEVEL LUMBAR FUSION AT L5-S1: A COMPARISON OF MIS TLIF AND AXIALIF.** Spine Arthroplasty Society 9 London, April 28 - May 1, 2009, London, UK.

- Anand, N; Baron, E; Thaiyananthan, T: **Minimally Invasive AxiaLIF L5-S1 Interbody Fusion for Anterior Column Support at the End of a Long Segment Fusion: 1 Year Clinical and Functional Outcome.** Spine Arthroplasty Society 9 London, April 28 - May 1, 2009, London, UK.

Scientific Posters

- Cragg A, Carl A, Castaneda F, Dickman C, Guterman L, Oliveira C: **New Percutaneous Access Method for Minimally Invasive Anterior Lumbosacral Surgery**. World Spine, Chicago, IL August 2003

- Cragg A, Carl A, Casteneda F, Dickman, C, Guterman L, Oliveira C: **Percutaneous Axial Lumbar Fusion: A feasibility study**. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, San Diego, CA March 16-19, 2004

- Yuan PS, Albert TJ, Pimenta L, Cragg A: **Anatomy of the Percutaneous Presacral Approach to the Lumbosacral Spine: Relevance for a Novel Fusion Technique**. Presented as IMAST 2004 e-poster, 1-3 July 2004, Southampton Bermuda

- Oliveira C, Carl A, Dickman C, Guterman L, Cragg A: **New Percutaneous Approach For Axial Lumbar Interbody Fusion**. Presented as IMAST 2004 Scientific Poster, 1-3 July 2004, Southampton Bermuda

- Pimenta L, Bellera F, Carl A, Ledet E, Cragg A: **New Percutaneous Access Method and Implant for L4-S1 Spinal Fusion Surgery**. Presented at the IMAST 2004 Scientific Poster, 1-3 July 2004, Southampton Bermuda

- Pimenta L, Diaz R, Cragg A: **Percutaneous Access, Fusion Results & Method and Implant for L4-S1 Spinal Fusion Surgery**. Presented at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 9-12 March 2005, Phoenix, AZ

- Pimenta L, Guerrero L, Cragg A, Diaz R: **360 degrees minimal invasive axial percutaneuos L5-S1 fusion (AxiaLIF). 2 years clinical and radiological follow-up**. Presented at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 15-18 March 2006, Lake Buena Vista, FL

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Feasibility Study of Percutaneous Axial Lumbar fusion: Interim Results**. Presented at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 15-18 March 2006, Lake Buena Vista, FL

- Pimenta L, Guerrero L, Cragg A, Diaz R: **Percutaneous Presacral AxiaLIF. A 360 degree minimal invasive fusion to treatment degenerative lumbosacral spine disease. Results at 30 months follow-up.** Presented at the 13th International Meeting on Advanced Spine Techniques (IMAST), 12-15 July 2006, Athens, Greece.

- Pimenta L, Guerrero L, Cragg A, Diaz R: **A Prospective 30 months study of a minimal invasive percutaneous axial lumbar fusion (AxiaLIF). Clinical and radiographic follow-up results**. Presented at the 13th International Meeting on Advanced Spine Techniques (IMAST), 12-15 July 2006, Athens, Greece.

- Acosta, FL; HE Aryan; CP Ames: **Initial Results of a Percutaneous Presacral Approach for L5-S1 Interbody Fusion.** American Association of Neurological Surgeons (74th Annual Meeting), San Francisco, California, 2006.

- Aryan, HE; FL Acosta; CP Ames: **Percutaneous Pre-Sacral Interbody Fusion for Degeneration of the L5-S1 Disc Space.** 13th Annual Meeting International Meeting on Advanced Spine Techniques (IMAST), 12-15 July 2006, Athens, Greece.

- Kitchel, S**: Stand Alone Axial ALIF with TranS1,** 13th Annual Meeting International Meeting on Advanced Spine Techniques (IMAST), 12-15 July 2006, Athens, Greece.

- Asgarzadie, F; Khoo LT; Cosar, M; Marotta, N; Pimenta, L. **One Year Outcomes of Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior Lumbosacral Intervertebral Discectomy and Fusion.** Presented at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 6-10 March 2007, Scottsdale, AZ.

- Bradley WD, Rousch T, Hisey M, Ohnmeiss D: **Interbody Fusion Using a Unique Trans-sacral Approach.** Minimally Invasive Spine Society, 16-17 November 2007, San Diego, CA.

- Madera M, Tobler W: **Outpatient Fusion at L5-S1 with the TranS1 Technique.** Minimally Invasive Spine Society, 16-17 November 2007, San Diego, CA.

- Pimenta, L; Arias, C: **Two Levels Presacral Axial Lumbar Interbody Fusion (AxiaLIF). A Prospective 12 Months Follow up: Clinical And Radiological Results.** Presented at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Feb 27 – March 1, 2008, Orlando, FL.

- Anand N, Wupperman R, Rosemann R, Baron E: **Minimally Invasive AxiALIF L5-S1 Interbody Fusion For Anterior Column Support at The End Of A Long Segment Fusion: Early Results.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Bradley, WD, Roush, T, Ohnmeiss, D: **Minimally Invasive Trans-sacral Approach to L5-S1 Interbody Fusion: Technique and Clinical Results.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Aryan H, Newman C, Acosta F, Coover C, Ames C. **Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience.** Global Symposium on Motion Preservation Technology 8th Annual Meeting from May 6-9, 2008, Miami, Florida.

- Anand, N; Baron, E; Thaiyananthan, T: **Minimally invasive AxiaLIF L5-S1 interbody fusion for anterior column support at the end of a long segment fusion.** E-Poster ID: 363. International Meeting of Advanced Spinal Techniques, 8-11 July 2008, Hong Kong, China.

- Tobler, W; Bohinski, R: **Axial lumbar interbody fusion) a new, minimally invasive technique at L5-S1: clinical outcomes, complications, and fusion rates in 50 patients at 1-year follow up.** ABSTRACT NO: 65, Section on Disorders of the Spine and Peripheral Nerves Select Abstract Session. Congress of Neurological Surgeons, 20-25 September 2008, Orlando, FL.

- Rodgers, WB; Cox, C; Gerber, E: **SINGLE LEVEL LUMBAR FUSION FOR A GRADE I AND II SPONDYLOLISTHESIS CORRECTION USING THE AXIALIF ROD SYSTEM.** Poster Number 28. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Rodgers, WB; Cox, C; Gerber, E: **SINGLE LEVEL LUMBAR FUSION AT L5-S1: A COMPARISON OF MIS TLIF AND AXIALIF.** Poster Number 30. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Rodgers, WB; Cox, C; Gerber, E: **THE MORAL IMPERATIVE OF MINIMALLY INVASIVE SURGERY: A COMPARISON OF TRADITIONAL AND MINIMALLY INVASIVE LUMBAR FUSION IN OCTOGENARIANS.** Poster Number 43. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Rodgers, WB; Cox, C; Gerber, E: **SAFETY AND THE LEARNING CURVE OF TRANS-SACRAL FUSION (AXIALIF) AT L5-S1: COMPLICATIONS IN THE FIRST 100 SURGERIES OF A SINGLE SURGEON SERIES.** Poster Number 29. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Rodgers, WB; Cox, C; Gerber, E: **TRANSSACRAL INTERBODY FUSION (AXIALIF) IN OBESE PATIENTS.** Poster Number 26. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Ferrara, L; Nasca, R; Myers, M; Lhamby, J: **A CLINICAL STUDY OF THE SAFETY AND EFFECTIVENESS OF THE AXIALIF 2L SYSTEM FOR LUMBAR INTERVERTEBRAL FUSION.** Poster Number 50. 2008 Annual Meeting of the Society for Minimally Invasive Spine Surgery, November 14, 2008, Henderson, NV.

- Ferrara, L: **A Clinical Study of the Safety and Effectiveness of the AxiaLIF 2L System for Lumbar Intervertebral Fusion.** Spine Arthroplasty Society 9 London, April 28 - May 1, 2009, London, UK.

- Rodgers, WB; Cox, C; Gerber, E: **AxiaLIF in the treatment of Grades 1 and 2, L5-S1 Spondylolisthesis correction in the Obese Patient.** E-Poster Number: 1511. AANS Annual Meeting, San Diego, CA, May 2-6, 2009.

Instructional Learning Courses

- Lieberman, I.H.: **TranS1 AxLIF Technique, Biomechanics and Discectomy Validation**. Presented at the IMAST 2004 training session, 1-3 July 2004, Southampton Bermuda

- Pimenta L, Bellera F, Carl A, Ledet E, Cragg A: **New Percutaneous Access Method and Implant for L4-S1 Spinal Fusion Surgery**. Presented at the IMAST 2004 Instructional Learning Course, 1-3 July 2004, Southampton Bermuda

- Khoo L, Pimenta L: AxiaLIF: **The Least Invasive Technique of Interbody Fusion**, The American Association of Neurological Surgeons, 73rd Annual Meeting, Practical Course Instruction, 16-21 April 2005, New Orleans, LA

- Lieberman I, Khoo L, Pimenta, L: **Least Invasive Access for L5-S1 Lumbar Fusion**, Presented at the IMAST 2005 Instructional Learning Course, 7-9 July 2005, Banff, Canada

- Tobler W: AxiaLIF: **Less Invasive Technique of L5-S1 Interbody Fusion**, The American Association of Neurological Surgeons, 74th Annual Meeting, Practical Course Instruction, 22-27 April 2006, San Francisco, CA

- Lieberman I, Ames C, Pimenta, L: **AxiaLIF Clinical Results at One Year for L5-S1 Lumbar Fusion**, Presented at the IMAST 2006 Instructional Learning Course, 12-15 July 2006, Athens, Greece

- Tobler W: AxiaLIF: **One Year Clinical Results of L5-S1 Interbody Fusion**, The American Association of Neurological Surgeons, 75th Annual Meeting, Practical Course Instruction, 14-19 April 2007, Washington, DC

- Bradley W, Anand N, Pimenta, L: **AxiaLIF: Advanced Techniques and Indications in Complex Lumbar Spine**, Presented at the IMAST 2007 Instructional Learning Course, 11-14 July 2007, Paradise Island, Bahamas

- Rodgers WB: **Initial 50 Case Experience in DDD and Instability with AxiaLIF L4-S1**, Presented at the IMAST 2008 Instructional Learning Course, 8-11 July 2008, Hong Kong, China

- Anand N, Rong LM: **Experience in DDD, Instability and Deformity with AxiaLIF L4-S1**, Presented at the IMAST 2008 Instructional Learning Course, 8-11 July 2008, Hong Kong, China

Peer Reviewed Clinical Papers Submitted, Not Yet Accepted for Publication

- Pimenta L, Díaz R, Nicola H, Cragg A. **Minimal Invasive Percutaneous Presacral Axial Lumbar Fusion (AxiaLIF). A Prospective 30 Months Study: Clinical and Radiological Follow-Up Results.** J Spine Arthroplasty Society. Submitted, not yet accepted. (26 patient series, prospective, non-randomized, historical fusion controls)

- Tobler, W, Bohinski, R, Ferrara, L: **Axial Lumbar Interbody Fusion: Clinical Outcomes, Complications and Fusion Rates of a 2-year Follow Up Study**. J Neurosurgery and American Association of Neurological Surgeons: Neurosurgical Focus, Submitted, Not Yet Published.

- Luther, N, Tomasino, A, Parikh, K, Härtl, R: **3D-Neuronavigation for Minimally Invasive Presacral Approach to L5/S1 Fusion with Posterior Stabilization.** J Neurosurgery and American Association of Neurological Surgeons: Neurosurgical Focus, Submitted, Not Yet Published.

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December 31, 2008

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
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Hubert H. Humphrey Building
Room 314-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CAG-00401N – Wrong Surgery Performed on a Patient; CAG-00402N – Surgery on the Wrong Body Part; CAG-00403N – Surgery on the Wrong Patient;

Dear Mr. Weems:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide comments regarding the Centers for Medicare and Medicare Services' (CMS) proposal to develop three new National Coverage Determinations (NCDs) that address Medicare coverage of certain surgical procedures, including Surgery on the Wrong Body Part, Surgery on the Wrong Patient, and Wrong Surgery Performed on a Patient. The AANS and CNS, representing 4,000 practicing neurosurgeons across the United States, are dedicated to ensuring that its members provide the highest quality of care to their patients. Patient safety and high quality outcomes are very high priorities of the AANS and CNS, and both organizations have publicly endorsed the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery, which offer clear, concise solutions to help physicians eliminate preventable surgical errors.

The AANS and CNS believe that serious, truly preventable medical errors are intolerable and that it is not reasonable for Medicare or other payers to reimburse a physician, hospital, or other provider for costs associated with such errors. However, we question whether the Medicare NCD process is the most effective way for CMS to address its concerns about "wrong" surgeries. Medicare NCDs set national policy on whether and under what conditions Medicare will cover an item or service. ***We request that CMS instead consider the value of developing a clear payment policy outlining circumstances under which surgery claims would not be payable by Medicare.***

For example, if a physician failed to use commonly accepted patient safety practices, which resulted in surgery on a wrong body part, a Medicare carrier might deny partial or complete payment for the service or claim. The issue at question is not whether surgical procedures would be covered by the Medicare program, but rather, under what circumstances the payment for covered surgical procedures would be denied or reduced. Payment determinations, unlike the NCD approach, are more sensitive to the nuanced nature of surgical procedures and include appeal mechanisms through which physicians and other providers can petition decisions that they

believe are inappropriate. Under the NCD approach, providers have absolutely no recourse if they believe CMS inaccurately determined that a particular surgery should not be covered.

If CMS proceeds with the NCD approach to "wrong" surgeries, rather than make payment policy changes, it is critical that the NCD language be written in a way that is sensitive to the nuanced nature of surgical procedures. In medicine, but especially in surgery, clinical scenarios are not clear cut and often are not foreseeable. Given this reality, the NCD language must provide flexibility and ensure that those who make a good faith effort to provide high quality of care are not inappropriately penalized. We greatly appreciate that under the proposed NCD language for Surgery on the Wrong Body Part and Wrong Procedure Performed on a Patient, CMS excludes emergent situations that occur in the course of surgery and/or whose exigency preludes obtaining informed consent. This statement is absolutely critical. We also appreciate CMS' statement that the NCDs are "not intended to capture changes in the surgical plan after surgical entry into the patient based on the discovery of unusual physical configuration or pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation." ***We request that CMS modify this statement so that it reflects changes that occur at anytime following anesthesia induction, rather than simply surgical entry. We also request that CMS strengthen this statement by making it an explicit exclusion to the NCD policy.***

The AANS and CNS wholeheartedly agree with CMS that Surgery on the Wrong Body Part, such as operating on the left leg instead of the right leg, is unwarranted and should not be reimbursed by Medicare. However, we are concerned that the proposed NCD language on wrong body part may be too broadly defined. In particular, we are concerned about the inclusion of spine level in the classification of wrong body part. Unlike other events that may fall under this NCD, wrong level surgery in the spine is not completely avoidable, even when using intra-operative imaging. It can be extremely difficult to precisely verify the correct disc level prior to performing lumbar spine surgery on patients with morbid obesity or to correctly identify lower cervical spine levels in patients with large shoulders. These determinations are always going to require some amount of human judgment, which is certainly not error proof. In addition, reinterpretation of preoperative imaging during surgery may result in a correct judgment to extend surgery to alternative or additional spinal levels beyond that planned preoperatively. ***The AANS and CNS strongly urge CMS to either exempt wrong spine levels from its NCD proposal or to include an additional statement that excludes exceptional circumstances from non-coverage determinations, such as situations where patient characteristics can impede identification of the precise location prior to surgical entry into the patient.***

The AANS and CNS commend CMS for attempting to eliminate serious and truly preventable medical errors through its proposed NCDs. We believe this is a much more rational policy proposal than CMS' current hospital-acquired condition (HAC) non-payment policy. As we have expressed in previous comments, the HAC policy erroneously targets conditions that cannot ever be reduced to zero (e.g., surgical site infections); does not recognize patient case-mix or situations where a complication occurs despite strict adherence to evidence-based guidelines (e.g., a percentage of patients will still develop surgical site infections, despite adherence to the most appropriate prophylactic measures); and does little to recognize the value of quality in relation to the cost of compliance. ***The AANS and CNS continue to object to the current HAC policy and other future expansions of this policy for conditions that are not 100% preventable even when physicians and hospitals follow all established procedures to eliminate such conditions.*** We urge CMS to focus its limited resources on more pressing problems, such as

wrong person and wrong site surgeries and other more serious, preventable events, rather than attempt to expand its current HAC policy to other health care settings.

Providing and delivering the highest possible patient safety standards is an integral component of improving the nation's healthcare system. We appreciate the opportunity to comment on these proposed NCDs and look forward to continuing a dialogue with CMS on this important matter.

Sincerely,

James R. Bean, MD, President
American Association of Neurological Surgeons

P. David Adelson, MD, President
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cc: Robert E. Harbaugh, MD, Chairman, AANS/CNS Washington Committee
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DRAFT

7.01.108 – Artificial Intervertebral Disc: Cervical Spine

Description

Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis or instability that compress the spinal cord result in myelopathy, which is manifested by subtle changes in gait or balance, weakness in the arms or legs and numbness of the arms or hands, in severe cases. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, some 95% of men and 70% of women have at least one degenerative change evident at radiographic examination. It is estimated that approximately 5 million adults in the U.S. are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Cervical DDD is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve after 6 weeks or more, or if they progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical DDD and no contraindications for the procedure.

Anterior cervical discectomy and fusion (ACDF) is currently considered the definitive surgical treatment for symptomatic single-level DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurological symptoms may be expected in more than 80% to 100% of ACDF patients.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in AIDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis. Patients with advanced spondylosis or hard disc herniations have a separate pathology and require a different surgical approach.

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The Prestige ST Cervical Disc (Medtronic) received U.S. Food and Drug Administration (FDA) premarket application (PMA) approval as a Class III device on July 16, 2007. The Prestige ST Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy. The device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, X-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received U.S. Food and Drug Administration (FDA) premarket application (PMA) approval in December 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C is conditional on 7-year follow-up of the 209 subjects included in the pivotal non-inferiority trial described above, 7-year follow-up on 99 continued access subjects, and a 5-year enhanced surveillance study to more fully characterize adverse events when the device is used under general conditions of use. The post-approval study reports are to be delivered to the FDA annually.

The Bryan Cervical Disc (Medtronic Sofamor Danek) has been available outside of the U.S. since 2002. The Bryan Cervical Disc was deemed "approvable" by an FDA advisory committee on July 17, 2007, for treatment using an anterior approach of single-level cervical DDD defined as any combination of the following: disc herniation with radiculopathy; spondylotic radiculopathy; disc herniation with myelopathy, or spondylotic myelopathy. The device has not received final approval from the FDA as of October 2008.

Several other devices are under study in FDA Investigational Device Exemption (IDE) trials in the U.S., but final approval of those is not expected for several years.

Note: Artificial intervertebral discs for treating the lumbar spine are considered separately in policy No. 7.01.87.

Policy

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7.01.108 – Artificial Intervertebral Disc: Cervical Spine

Artificial intervertebral discs are considered **investigational** for treatment of disorders of the cervical spine, including degenerative disc disease.

Policy Guidelines

Effective 1/1/09, there are CPT category I codes for a single interspace:

22856 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22861 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864 Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

There are add-on CPT category III codes for implantation in additional interspaces:

0092T: Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical (List separately in addition to code for primary procedure)
0095T: Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical (List separately in addition to code for primary procedure)
0098T: Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical (List separately in addition to code for primary procedure)

Between 1/1/07 and 12/31/08, the following CPT category III codes were used for this procedure:

0090T: Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than decompression), cervical; single interspace
0092T: each additional interspace (List separately in addition to code for primary procedure)
0093T: Removal of total disc arthroplasty, anterior approach, cervical; single interspace
0095T: each additional interspace (List separately in addition to code for primary procedure)

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0096T: Revision of total disc arthroplasty, anterior approach, cervical; single interspace
0098T: each additional interspace (List separately in addition to code for primary procedure)

Rationale

In 2007, this policy was extensively revised based on the results of a TEC Assessment. (1)

ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and emplacement of either autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate.

The choice of bone material for interbody fusion in ACDF has important clinical implications. Allograft bone has several drawbacks, including a small (albeit, unproven) risk of infectious disease transmission; possible immunological reaction to the allograft; and, possible limited commercial availability of appropriate graft material. (2) In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. (3) These include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and, increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies demonstrate similar rates of postoperative fusion (90–100%) and satisfactory outcomes for single-level, anterior-plated ACDF, using either bone source. (4-7) Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material. This is usually left to the patient, based on thorough explanation and discussion of the relative risks and benefits with the surgeon.

In AIDA, an artificial disc device is secured in the prepared intervertebral space rather than bone. An anterior plate is not placed to stabilize the adjacent vertebrae and a post-surgical external orthosis is usually not required. The surgical procedure and perioperative complications of AIDA are nearly identical to those of anterior fusion. (8) It is hypothesized that AIDA maintains anatomical disk space height,

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normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels (8). This has been proposed to reduce the risk of adjacent-level DDD above or below a fusion site, and has been the major rationale driving device development and use. However, while biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD, the clinical relevance of these changes has not been established. (10-12)

Although the Prestige disc has received FDA marketing approval, there is limited published information about the impact of cervical arthroplasty devices on clinical outcomes. One clinical report has been published on the pivotal randomized trial for the Prestige ST disc. (13) Information on the Prestige cervical disc is also available from Medtronic's PMA application to the FDA. (14) These documents report on a randomized study of anterior cervical fusion (with allograft bone and plate stabilization) versus the artificial cervical disc for patients with non-axial pain and other symptoms secondary to radiculopathy or myelopathy that did not improve with a minimum 6 weeks of conservative therapy. The study was designed as a randomized, nonblinded noninferiority trial with a noninferiority margin of 10%. Results for 137 investigational and 148 control patients who were evaluated at 2 years post-surgery were presented to the FDA in the PMA application. This represented about half of the total population (276 and 265, respectively), while the peer-reviewed paper reported on about 75% of cases.

Three primary outcome variables were used in the Prestige trial: the Neck Disability Index (NDI), neurological status, and functional spinal unit height (FSU). The NDI is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life. (15) It is a modification of the Oswestry Low Back Pain Index, based on the response to 10 questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. The response to each question ranges from 1 to 5, with a lower numeric score representing a better pain and disability status for that variable. A total NDI score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, NDI scores range from 0% to 100%, with a lower percentage indicating less pain and disability. The neurological status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge if patients are within normal parameters for those categories based on physiological measurement. Neurological success in the Prestige trial was based on postoperative maintenance or improvement of condition as compared to preoperative status for each component. The anterior FSU height is a radiographic measure of interdiscal space. Comparison of the immediate

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postoperative FSU height with the 6-week postoperative value shows whether or not the disc space has decreased, which indicates graft or device subsidence has occurred.

Secondary outcome measures include the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) mental (MCS) and physical (PCS) component summaries, neck and arm pain status, patient satisfaction, patient global perceived effect, gait assessment, foraminal compression test, adjacent level stability and measurements, return to work, and physician's perception.

Both data sources for the Prestige disc trial showed equivalent results. Thus, 81% of both groups showed at least a 15-point improvement for the Neck Disability Index (NDI), demonstrating noninferiority to fusion, but not superiority. Similarly, the FSU height measure also demonstrated evidence of noninferiority, but not superiority. By contrast, the neurological status showed non-inferiority and statistical superiority for the disc compared to fusion. This contributed to the overall success composite endpoint demonstrating superiority for the disc compared to fusion. The majority of secondary outcome measures for the disc were deemed noninferior to ACDF, but none was statistically superior. Perioperative results and adverse events were similar in both groups, with very few serious complications.

While these results are encouraging, several methodologic and clinical issues need to be considered in analyzing these data. First, given the clinical situation, 2 years of follow-up is not adequate to evaluate long-term results, in particular any effect of the device on adjacent-level disc degeneration, device durability, adverse events, and revisability. (16, 17) Second, the study was not blinded (investigators and patients knew which procedure had been performed), which has potential to bias outcome assessments. Finally, some experimental patients had increased pain of the neck (6.2% vs. 0.8% at 2 years) and arm (9.4% and 5.8%) after the procedure, findings that merit additional investigation for their clinical relevance. In recognition of these caveats, the FDA has required the Prestige disc manufacturer to conduct a 7-year post-approval clinical study of the safety and function of the device, and a 5-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population.

2008 Update
Murrey et al. reported 2-year follow-up of the pivotal FDA randomized non-inferiority trial to determine the safety and efficacy of ProDisc-C in comparison with anterior cervical discectomy and fusion (ACDF). (18)

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In this trial, 103 patients were implanted with the ProDisc-C and 106 were treated with fusion. Follow-up between 6 weeks and 24-months was reported to be 85% in the summary of safety and effectiveness data presented to the FDA. (19) Reasons for the loss to follow-up were not described, but appear to have included 2 patients in the ProDisc-C group who had the implant removed and 5 patients in the fusion group who had undergone additional surgical procedures to modify the original implant. Non-inferiority was achieved for the FDA-defined combined endpoint of neurologic exam, neck disability index, adverse events, and device success, with 72% of ProDisc-C and 68% of fusion patients achieving success in all 4 component endpoints. Clinical outcomes at 24-months follow-up were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88%, respectively), neck disability index (21.4 vs. 20.5 points), reduction in pain scores (e.g., 46 mm vs. 43 mm reduction in neck pain on a visual analog scale), and patient satisfaction (83 mm vs. 80 mm). *Ad-hoc* analysis found superiority using a one-sided statistical test based on a trend towards an increase in the use of muscle relaxants in the fusion group and a greater percentage of revision procedures needed following fusion (8.5%) in comparison with removal of the ProDisc-C implant (1.5%). Limitations of this study are similar to those discussed in a 2008 TEC Assessment of the Prestige ST cervical disc. (1) These include the failure to blind physician outcome assessors and patients, and the reported statistical superiority based on *ad-hoc* analysis that was driven primarily by a single outcome measure (revision of fusion vs. removal of the implant). Most importantly, the 24-month follow-up period does not allow conclusions about long-term device performance, durability, and potential need for and impact of revision surgery. Therefore, the results of this study are insufficient to permit conclusions concerning the effect of this implant on long-term health outcomes.

Nabhan et al. reported 1-year clinical and radiological results of 49 patients who were randomized to receive a ProDisc-C artificial disc or fusion. (20) Measurements taken at 3, 6, 12, 24, and 52 weeks showed a decrease in segmental motion at the index level in both groups over the first 12 weeks after surgery; at 52-weeks segmental translation (xyz axis) was about 1 mm greater in the ProDisc-C group. Clinical results were similar in the two groups, with a 70% reduction in neck pain and 86% reduction in arm pain in the ProDisc-C group and a 68% reduction in neck pain and 83% reduction in arm pain in the ACDF group. As noted by the authors, longer follow-up is needed to determine the effect of this implant on cervical motion and stress at adjacent levels.

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A number of studies have been published from the FDA IDE trial of the Bryan Cervical Disc. Sasso et al. reported a subset of the data from 3 centers with 115 patients randomized to ACDF or the artificial disc in a 1:1 ratio. (21) The average operative time (1.7 hours vs. 1.1 hours for the control group) and the average hospital stay (1 day vs. 0.5 days for the control group) were longer for the Bryan group. Although 12-month follow-up was available for 109 patients (95%), 24-month follow-up was available for only 71 (62%). Given the nearly 40% loss to follow-up, which was not accounted for in the report, these results cannot be interpreted. An independent study by Heidecke and colleagues prospectively evaluated 54 consecutive patients who were treated with a Bryan disc for cervical radiculopathy and/or myelopathy. (22) There were no implant dislocations or migrations in the 2 years after surgery. However, loss of function (range of motion < 3 degrees) was found in 7 (12%) of 59 discs at 2 years after surgery, which was associated with advanced heterotopic ossification (McAffee grades 3-4) in 5 of the 7 patients. Heterotopic ossification grades 1-2 were observed in an additional 12 (20%) segments without loss of function. One patient required disc removal due to radicular neurological symptoms and newly formed dorsal osteophytes at 1 year after surgery. These results reinforce the need for longer-term follow-up.

In summary, evidence to date has not shown a beneficial effect of any cervical disc product on the development of adjacent level disease, whereas long-term complication rates with artificial discs remain unknown. Further, as concluded in the TEC Assessment, given the clinical situation, 2 years of follow-up is not adequate to evaluate long-term results, in particular any effect of the device on adjacent-level disc degeneration, device durability, adverse events, and revisability. Finally, because the performance of each disc type may vary, each disc design will require its own long-term studies to evaluate device-specific performance.

References:

1. TEC Assessments 2007; Tab12.

2. Malloy KM, Hilibrand AS. Autograft versus allograft in degenerative cervical disease. Clin Orthop Rel Res 2002; 394:27-38.

CONFIDENTIAL

3. Galler RM, Sonntag VK. Bone graft harvest. Barrow Quarterly 2003; 19(4):13-9. Available online at http://www.emergemd.com/bniq2/article.asp?article_ref_id=19-4-2. Last accessed November 2007.

4. Fraser JF, Hartl R. Anterior approaches to fusion of the cervical spine: a metaanalysis of fusion rates. J Neurosurg Spine 2007; 6(4):298-303.

5. Samartzis D, Shen FH, Goldberg EJ et al. Is autograft the gold standard in achieving radiographic fusion on one-level anterior cervical discectomy and fusion with rigid anterior plate fixation? Spine 2005; 30(15):1756-61.

6. Yue WM, Brodner W, Highland TR. Long-term results after anterior cervical discectomy and fusion with allograft and plating. Spine 2005; 30(19):2138-44.

7. Suchomel P, Barsa P, Buchvald P et al. Autologous versus allogeneic bone grafts in instrumented anterior cervical discectomy and fusion: a prospective study with respect to bone union pattern. Eur Spine J 2004; 13(6):510-5.

8. Goffin J. Complications of cervical disc arthroplasty. Semin Spine Surg 2006; 18(2):87-98.

9. Sears WR, McCombe PF, Sasso RC. Kinematics of cervical and lumbar disc replacement. Semin Spine Surg 2006; 18(2):117-29.

10. Anderson PA, Sasso RC, Riew KD. Update on cervical artificial disk replacement. AAOS Instr Course Lect 2007; 56:237-46.

11. Phillips FM, Garfin SR. Cervical disc replacement. Spine 2005; 30(17 Suppl):S27-33.

12. Wigfield C, Gill S, Nelson R et al. Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. J Neurosurg 2002; 96(1 Suppl):17-21.

CONFIDENTIAL

13. Mummaneni PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine 2007; 6(3):198-209.

14. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. Report of United States Clinical Study Results (G010188) -- Prestige® Cervical Disc System. Available online at http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4243b1_02.pdf. Last accessed August 2007.

15. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther 1991; 14(7):409-15.

16. Benzel EC. Cervical disc arthroplasty compared with allograft fusion. J Neurosurg Spine 2007; 6(3):197.

17. McAfee PC. Cervical and lumbar disc replacement – the ease of revision. U.S. Orthopedics Review 2006. Available online at http://www.touchbriefings.com/pdf/1680/mcafee.pdf. Last accessed November 2007.

18 Murrey D, Janssen M, Delamarter R et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J 2008; Sep 5. [Epub ahead of print]

19 ProDisc-C Summary of safety and effectiveness data. Available at: http://www.fda.gov/cdrh/pdf7/p070001b.pdf Last viewed September 2008.

20 Nabhan A, Ahlhelm F, Pitzen T et al. Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. Eur Spine J 2007; 16(3):423-30.

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7.01.108 – Artificial Intervertebral Disc: Cervical Spine

21. Sasso RC, Smucker JD, Hacker RJ et al. Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. J Spinal Disord Tech. 2007; 20(7):481-91.

22. Heidecke V, Burkert W, Brucke M et al. Intervertebral disc replacement for cervical degenerative disease—clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. Acta Neurochir (Wien) 2008; 150(5):453-9.

Codes	Number	Description
CPT	22899	Unlisted procedure, spine
	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical (new code 1/1/09)
	22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical (new code 1/1/09)
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical (new code 1/1/09)
	0092T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical (List separately in addition to code for primary procedure) (language revised 1/1/09)
	0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical (List

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		separately in addition to code for primary procedure)
	0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical (List separately in addition to code for primary procedure)
ICD-9 Procedure	84.62	Insertion of total spinal disc prosthesis, cervical
	84.66	Revision or replacement of artificial spinal disc prosthesis, cervical
ICD-9 Diagnosis		Investigational for all codes.

Policy History

Date	Action	Reason
10/10/06	Add to Surgery section	New policy
12/12/06	Replace policy – coding update only	CPT category III codes added.
12/13/07	Replace policy	Policy updated with TEC Assessment. Policy and reference list revised extensively. No change to policy statement.
11/13/08	Replace policy	Policy updated with literature review; references 18-22 added; no change to policy statement. CPT coding updated.

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September 28, 2008

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Mr. Weems:

On behalf of the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), North American Spine Society (NASS), Scoliosis Research Society (SRS), and Spine Arthroplasty Society (SAS), we appreciate the opportunity to comment on the recently released CMS posting of potential National Coverage Determination (NCD) topics. In particular, our comments refer to the following four proposed NCD topics: 1) Bone Morphogenetic Proteins (BMP), 2) lumbar fusion for degenerative disc disease, 3) artificial cervical discs, and 4) vertebroplasty (VP) and percutaneous vertebral augmentation (kyphoplasty) (KP).

The Medicare national coverage determination process is potentially a very powerful tool to define and regulate quality health care. At its best, it can encourage critical analysis of the medical literature and the practice of evidenced based medicine. It can support best treatment options, limit unsubstantiated care and direct and stimulate needed research. At its worst, however, it can restrict individual patient treatment options and decisions based upon physician experience and be applied inappropriately and in unintended ways, especially by non-Medicare insurance carriers.

Three areas of concern need to be highlighted. First, the study population for an NCD must be clearly defined. For example, spinal fusion is a procedure performed for a wide variety of diagnoses ranging from fracture to spinal deformity to disc degeneration. Each sub-group has

different treatment indications and different levels of evidence. An NCD should clearly identify to whom it does and does not apply. The specific recommendation should not be expanded without careful consideration to dissimilar groups of patients with different diagnoses.

Second, an NCD focuses on the Medicare population (over age 65 or patients with permanent disabilities). Modern medicine realizes that individual patient physiology is a better metric than a patient's age for determining care. When NCDs are based on age, (for example, non coverage over the age of 65) there should be a mechanism for individual consideration for atypical cases (For example, the 68 year old marathon runner, or the 22 year old paraplegic).

Finally, when evaluating the literature, many studies do not specifically include or target the Medicare population. Such research should not be summarily dismissed in the NCD process. It does require, however, careful analysis to determine if and when the study conclusions can be extrapolated to the Medicare population. Similarly, studies done primarily in the Medicare population may be applicable to younger, non-Medicare patients.

A task force composed of members of the above societies was convened to review the proposed NCD topics. A list of the task force members, as well as their disclosures, is attached. The medical evidence, as well as some pending publications and some research in progress, was reviewed and summarized for each topic. Each topic was then evaluated using three criteria:

1. Strength of the evidence
2. Relevance to the Medicare population
3. Likelihood that an NCD will improve the quality of spine care

Using these criteria, we have attempted to rank the topics in order of importance to patients. CMS NCD proposed topics in order of importance to Medicare patients:

1. BMP
2. VP/KP
3. Multilevel fusions
4. Cervical TDA

We have also taken the liberty of suggesting additional topics for NCD consideration in the future, which may be beneficial for CMS to consider. Those topics are as follows:

1. pulsed radiofrequency facet rhizotomy
2. moderate sedation
3. spinal orthosis
4. dynamic spinal fixation
5. interspinous distraction
6. intraoperative spinal monitoring

Bone Morphogenetic Protein (BMP)

CMS Proposed Topic-
"Members of the BMP family are potentially useful as therapeutics in areas such as spinal fusion. BMP-2 and BMP-7 have been shown in clinical studies to be beneficial in the treatment of a variety of bone-related conditions including delayed union and non-union. BMP-2 and BMP-7 have received Food and Drug Administration (FDA) approval for human clinical uses. Certain off-label uses in cervical spine fusion may be associated with life-threatening complications. Is the evidence adequate to demonstrate health improvements in the Medicare population?"

Task Force Comments
Since FDA approval of rhBMP-2 (Medtronic) in 2002, BMPs have been widely used during spine fusion. The initial indication for BMP (rhBMP-2), based upon a premarket study by Medtronic Sofamor Danek (Memphis, TN) was as a bone graft substitute for use during anterior lumbar interbody fusion at a single level, L4-S1 performed in conjunction with an interbody titanium cage (LT cage-Medtronic). Its use in anterior lumbar spine surgery has expanded to treat multiple levels of pathology and to include interbody devices from different manufacturers and devices of varying compositions (metal, bone and synthetic substances). Its "off-label" use has also been extended to posterior lumbar spine applications such as posterolateral fusion (PSF) or transforaminal interbody fusion (TLIF), and, to a much lesser extent, cervical spine applications have been reported. We will briefly review the evidence and comment on each of these uses

Anterior Lumbar Spine
Multiple studies, both basic science (1-3) and clinical (4-12), have substantiated the use of rhBMP-2 as a substitute for iliac crest bone graft (ICBG) in anterior lumbar interbody fusion. Equivalent fusion rates for have been demonstrated in a randomized prospective trial comparing anterior interbody fusion with either BMP or ICBG at a single level, L2-S1 in conjunction with titanium interbody cages. Multiple case series have also demonstrated its effectiveness (13-19). BMP has been shown to be safe (20) and eliminates the need for a separate incision to obtain bone graft and its associated morbidity. Despite its high product cost, BMP has also been shown to be cost effective (8-9) through more rapid mobilization, decreased hospital stay and more rapid return to work. The majority of these studies were done in younger patients and do not specifically address the Medicare population. Younger patients with strong, non-osteoporotic bone are required for fixation of the interbody titanium cage. There is no evidence to suggest that the BMP would be less safe or less effective in an older patient. Indeed, bone quality and not age may be a more important factor to consider when pathology permits a choice between anterior or posterior approach to achieve spinal fusion.

REFERENCE LIST- Anterior Lumbar Spine

1. Sandhu HS, Toth JM, Diwan AD, Seim HB III, Kanim LEA, Kabo JM, Turner AS, "Histological evaluation of the efficacy of rhBMP-2 compared with autograft bone in sheep spinal anterior interbody fusion" Spine 27 (6): 567 – 575, 2002.

2. Hecht BP, Fischgrund JS, Herkowitz HN, Penman L, Toth JM, Shirkhoda A "The use of recombinant human bone morphogenetic protein 2 (rhBMP-2) to promote spinal fusion in a nonhuman primate anterior interbody fusion model" Spine 24 (7): 629 – 636, 1999.

3. Boden SD, Martin GJ Jr, Horton WC, Truss TL, Sandhu HS, "Laproscopic anterior spinal arthrodesis with rh BMP-2 in a titanium interbody threaded cage." J Spinal Disord 11: 95-101, 1998.

4. Burkus JK, Sandhu HS, Gornet MF. "Influence of rhBMP-2 on the healing patterns associated with allograft interbody constructs in comparison with autograft." Spine, 31(7):775-81, 2006.

5. Burkus JK, Sandhu HS, Gornet MF, Longley MC "Use of rhBMP-2 in combination with structural cortical allografts: clinical and radiographic outcomes in anterior lumbar spinal surgery" J Bone Jt Surg, 87 (6): 1205-1212, 2005.

6. Burkus JK, Heim SE, Gornet MF, Zdeblick TA "Is INFUSE Bone Graft superior to autograft bone? An integrated analysis of clinical trials using the LT-CAGE lumbar tapered fusion device" J Spinal Disord Tech, 16 (2): 113 – 122, 2003.

7. Burkus JK, Dorchak JD, Sanders DL "Radiographic assessment of interbody fusion using rhBMP-2" Spine, 28 (4): 372 – 377, 2003.

8. Polly DW, Ogilvie JW, Mafilios MS, Ackerman SJ, Wang JC, Heim SE, Shaffrey CI, Stralka SW, Sandhu HS "A cost analysis of bone morphogenetic protein versus autogenous iliac crest bone graft in single-level anterior lumbar fusion" Orthopedics, 26(10): 1027 – 1037, 2003.

9. Ackerman SJ, Mafilios MS, and Polly DW "Economic Evaluation of Bone Morphogenetic Protein Versus Autogenous Iliac Crest Bone Graft in Single-Level Anterior Lumbar Fusion" Spine, 27 (16s): 594-599, 2002.

10. Burkus JK, Transfeldt E, Kitchel SH, Watkins R, Balderston R "Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein-2" Spine, 27 (21): 2396 – 2408, 2002.

11. Burkus JK, Gornet MF, Dickman C, Zdeblick TA "Anterior interbody fusion using rhBMP-2 with tapered interbody cages" J Spinal Disorders, 15 (5): 337 – 349, 2002.

12. Boden SD, Zdeblick TA, Sandhu HS, Heim SE "The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: A preliminary report" Spine, 25 (3): 376 – 381, 2000.

13. Slosar PJ, Josey R, Reynolds J. "Accelerating lumbar fusions by combining rhBMP-2 with allograft bone: a prospective analysis of interbody fusion rates and clinical outcomes." Spine J; 7: 301-307, 2007.

14. Hansen SM, Sasso RC. "Resorptive response of rhBMP2 simulating infection in an anterior lumbar interbody fusion with a femoral ring" J Spinal Disord Tech., Apr; 19 (2):130-4, 2006.

15. Pradhan BB, Bae HW, Dawson EG, Patel VV, Delamarter RB. "Graft resorption with the use of bone morphogenetic protein: lessons from anterior lumbar interbody fusion using femoral ring allografts and recombinant human bone morphogenetic protein-2" Spine, 31:277-84, 2006.

16. Lee JY, Zeiller S, Voltaggio L, Lim MR, Hilibrand AS, Vaccaro AR, Anderson G, Albert T "Histological analysis of a displaced femoral ring allograft spacer filled with a recombinant human bone morphogenetic protein-2 soaked collagen sponge. A case report" J Bone Jt Surg, 87:2318-2322, 2005.

17. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC, Wang J, Walters BC, Hadley MN "Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 16: bone graft extenders and substitutes" J Neurosurg Spine, 2: 733-736, 2005.

18. Schuler TC, Burkus JK, Gornet MF, Subach BR, Zdeblick TA "The correlation between preoperative disc space height and clinical outcomes after anterior lumbar interbody fusion" J Spinal Disord Tech, 18(5): 396-401, 2005.

19. Kleeman TJ, Ahn UM, Talbot-Kleeman A "Laparoscopic anterior lumbar interbody fusion with rhBMP-2: A prospective study of clinical and radiographic outcomes" Spine, 26 (24): 2751 – 2756, 2001.

20. http://www.fda.gov/cdrh/pdf/P000058.html

Posterior Lumbar Spine

While the body of literature evaluating BMPs in posterior spine fusion is somewhat limited by its relatively recent clinical availability, the literature is growing rapidly and includes a number of high quality studies. We have included some discussion of studies still in the editorial review process in order to demonstrate an appropriate response to CMS staff's expressed concern that ongoing critical evidence development should be undertaken once new technologies reach clinical practice. Several general issues are important in the evaluation of this literature. Firstly, variations in the specific BMP used, as well as dose, concentration, and carrier for each BMP may significantly affect risks or benefits. The studies evaluating high dose rhBMP-2 (40 mg, 2.0 mg/ml), lower dose rhBMP-2 (12 mg, 1.5 mg/ml), and rhBMP-7 all contribute to our overall understanding of biologics in lumbar fusion, but cannot necessarily be considered interchangeably. Secondly, the initial experience suggests that risks and benefits may differ based upon site (lumbar versus cervical) and application technique (PSF versus TLIF).

Posterolateral Spine Fusion (PSF)

The most significant available body of evidence examines the use of rhBMP-2 in posterolateral lumbar fusion. In 2002, Boden reported on a pilot study comparing rhBMP-2 (40mg, 2.0 mg/ml)

and iliac crest bone graft (ICBG) which suggested better fusion rates in the rhBMP-2 patients (Boden, S., Spine 2002; 27(21):2396-408). This led to an FDA approved randomized controlled IDE trial for rhBMP-2 and a compression resistant matrix (CRM) versus ICBG in single level posterolateral fusion. Two-year results from two centers participating in the IDE trial for rhBMP-2 (40 mg, 2.0 mg/ml) in single level posterolateral fusion have been reported (Dimar, J., Spine: Vol. 31, Number 22, pp 2534-2539). This subset of the RCT indicates better fusion rates, equivalent clinical outcomes and no increase in complications with rhBMP-2 versus ICBG. It is important to note that the dose/concentration of rhBMP-2 used in this study (40 mg, 2.0 mg/ml) was significantly greater than the dose/concentration (12 mg. 1.5 mg/ml) in the clinically available Infuse Bone Graft™ product (rhBMP-2/ACS). This raises the question of whether similar fusion rates will be achieved with the product in clinical use, but also affords a test of safety for posterolateral fusion, as complications were not seen with the much higher dose IDE protocol. A second published study from the same IDE trial data reports that the use of rhBMP-2 offsets, at least in part, the adverse effect of cigarette smoking on lumbar fusion rate (Glassman, S, Spine: Vol. 32, Number 15, pp 1693-1698). The complete IDE trial data set has been presented at national meetings, but is not yet published.

Several case series reports have been published on the use of clinically available Infuse Bone Graft™ (rhBMP-2 12 mg, 1.5 mg/ml) in an off-label posterolateral fusion application. One study examines the combination of rhBMP-2/ACS and ICBG, reporting better fusion rates at 2 years postoperatively as compared to ICBG alone (Singh, K., J Spinal Disord Tech 2006;19(6):416-423.). Another study reports on rhBMP-2/ACS in combination with several non-ICBG bone graft extenders, including local bone, demineralized bone matrix and bone bank bone (Glassman, S., Spine J 2007; 7:44-9). This study reports fusion rates equal to or better than ICBG in single and multilevel posterolateral fusion cases. Neither study identifies complications related to the use of rhBMP-2/ACS. An additional study examines repeated exposures to rhBMP-2 without evident adverse consequences (Carreon, L., Spine. 2008 Feb 15;33(4):391-3.). An IDE pilot study comparing rhBMP-2 (12 mg, 1.5 mg/ml) combined with a ceramic bulking agent versus iliac crest bone graft in posterolateral lumbar fusion has been undertaken. It has been presented and is in editorial review (Bae H, Spine J 2007:7;IS-163S).

Most recently, a non-industry sponsored RCT comparing Infuse Bone Graft™ (rhBMP-2/ACS) versus ICBG in patients over 60 years of age has been completed. The study examines clinical outcomes, fusion success, and directly measured economic parameters. Initial perioperative cost data from this RCT demonstrated an increased initial cost for the hospital, but a net savings for the payer over a 3-month period with the use of rhBMP-2/ACS (Glassman, S., Spine J., 2008 (8), pp 443-448). The two-year data revealed similar HRQOL outcomes, but better fusion on CT scan, fewer complications, lower revision rate and lower overall cost in the rhBMP-2/ACS group. This two-year RCT data has been presented, and received the Outstanding Paper Award, at the International Meeting for Advanced Spine Techniques (IMAST) in 2008. The study has been accepted for publication in SPINE, but has not yet reached its publication date. Despite this, the CMS staff may want to consider these data because they so directly address the issues raised in the proposed NCD topic question.

The literature assessing rhBMP-7 (OP-1) in posterolateral spine fusion, also suggests safety, and probable efficacy, based on an RCT comparing rhBMP-7 and ICBG in single level fusion for

degenerative spondylolisthesis (Vaccaro, A., Spine 2005; 30:2709-16.). This study resulted in FDA approval of OP-1 putty, through the HDE process, as an alternative to ICBG in compromised patients. An additional small RCT comparing rhBMP-7 and ICBG in instrumented posterolateral fusion revealed equivalent radiographic success, however nonunion was detected at exploration in 4 of 7 patients (Kanayama, M., Spine 2006; 31:1067-74.).

Transforaminal Lumbar Interbody Fusion (TLIF)

A second common off-label application for rhBMP is in Transforaminal Lumbar Interbody Fusion (TLIF). No Level 1 data exist regarding the role of BMP in TLIF surgery. Several case series have been reported with variable findings. Two initial studies reported high fusion rates and minimal complications using rhBMP-2 for open and minimally invasive TLIFs (Schwender, J., J Spinal Disord Tech 2005 Feb;18 Suppl:S1-6., Villavicencio A., J Neurosurg Spine 2005;3(6):436-443.). Subsequently, concerns have been raised regarding the risk of heterotopic bone formation associated with the use of rhBMP-2 in TLIF. Conflicting evidence includes a prospective CT analysis which documented asymptomatic heterotopic bone in 20% of cases (Joeseph, V., Spine 2007 Dec 1;32(25):2885-90.), and a report of 5 patients seen at a referral center with heterotopic bone and radiculopathy (Wong DA, Spine J. 2007 Nov 21. [E-pub ahead of print]). Whether the risk for symptomatic heterotopic bone formation is dependent upon surgical technique, rhBMP-2 dose or any other surgical variable remains undetermined. No data regarding the use of rhBMP-7 in TLIF are available.

Cervical Spine

Notwithstanding its off-label status, the use of bone morphogenic protein in the anterior cervical spine is considered controversial. This status derives primarily from two clinical observations. First, high fusion (bone healing) rates, in the absence of BMP, with stand-alone allograft have been consistently reported in the literature for both anterior discectomy and corpectomy constructs. Thus, the need for an iliac crest autograft substitute or replacement may have a limited role in comparison to the lumbar spine. Second, the use of BMP in the anterior cervical spine has been reported to be associated with higher than usual rates of soft-tissue swelling, dysphagia, and respiratory complications.

There is conflicting evidence regarding the safety and incidence of soft-tissue complications with BMP use in the anterior cervical spine. In a retrospective study of 200 patients who underwent anterior cervical discectomy with a PEEK spacer and low dose BMP, an incidence of dysphagia of 7 percent was reported (1). In contrast, Shields et al (2) reported a 23 percent complication rate among 151 patients who underwent anterior cervical surgery with high-dose BMP. Complications included postoperative hematomas or readmission for swallowing difficulty or airway distress.

In a retrospective comparative study, another group found a significantly higher incidence and severity of dysphagia in twenty-two patients in whom BMP was used compared to twenty-four in whom allograft alone was used to effect an anterior cervical discectomy and fusion (3). Similarly, Smucker et al (4) found a statistically significantly higher rate of so-called “swelling events” with use of BMP in sixty-nine patients compared to 165 non-BMP controls who underwent anterior cervical spine surgery.

Indeed, higher level evidence exists. In a prospective randomized controlled comparison of thirty-three patients who underwent anterior cervical discectomy and fusion with BMP or allograft, Baskin et al (5) reported no device-related complications. In contrast, Butterman (6) performed a non-randomized, prospective comparison of patients undergoing anterior cervical discectomy and fusion with iliac crest autograft or low-dose BMP. He reported a 50 percent rate of dysphagia in the BMP group versus a 14 percent rate in the iliac crest group.

Provided that close observation of a patient's airway is maintained, perhaps with a planned postoperative intubation interval, off-label BMP use in the anterior cervical spine may have some role as a salvage maneuver in complex cases in which the fusion environment is substantially challenged, such as in the treatment of established nonunions, unusually long multi-level defects, or osteomyelitis (7-8). As peri-esophageal and tracheal inflammation is less likely with posterior application, BMP also may have some role in the posterior cervical spinal fusions in highly select cases (9).

In summary, the current limited data suggest that there is persistent controversy regarding the use of BMP in the anterior cervical spine. The data suggest that its routine use for elective anterior cervical spine surgery does not seem to be warranted. While appropriate dosage has been proposed as a primary factor to ensure safety, the current literature is conflicted regarding this issue.

There is an overwhelming paucity of data evaluating the use of BMP in the posterior cervical spine, making any recommendation regarding its routine use difficult.

Summary - BMP

While the indications for the use of BMPs in spinal surgery in the Medicare population are not fully defined, substantial evidence exists supporting the efficacy and cost effectiveness of BMP in the anterior lumbar interbody fusion. Moderate and increasing evidence is being developed for its use in posterolateral fusions compared to ICBG. Posterolateral fusion, in conjunction with decompression for stenosis or deformity correction, in spondylolisthesis, or degenerative scoliosis, is the most common spinal fusion technique performed in the Medicare population. The Professional Society Coalition Task Force believes that BMP is a reasonable and safe alternative to ICBG in anterior interbody lumbar fusion. For posterior spinal fusion, there is moderate and increasing evidence that BMP is also beneficial. We also believe that ongoing additional investigation will contribute to refinements in dose, carriers and site specific applications for these valuable biologic technologies. In the anterior cervical spine, the evidence is limited and there remain unanswered safety concerns and we do not support its broad use except in ongoing research trials.

Recommendations- BMP

1. **Anterior Lumbar Fusions- Recommend coverage in Medicare and non-Medicare patients without severe osteoporosis.**

2. **Posterior/Lateral Lumbar Fusion- Delay decision pending publication of pending literature.**

3. **Posterior Interbody Fusion- Literature is insufficient to make recommendation. Further study should be encouraged.**

4. **Anterior Cervical Spine- The use of BMP should not be covered/approved for routine use in the cervical spine. The use of BMP for complex, revision, or salvage situations may be appropriate in certain cases. Such cases should be considered on an individual basis. Further study should be encouraged.**

5. **Posterior Cervical/Thoracic Spine- Literature is insufficient to make recommendation. Further study should be encouraged.**

Cervical BMP References

1. Tumialan, L.M., et al., *The safety and efficacy of anterior cervical discectomy and fusion with polyetheretherketone spacer and recombinant human bone morphogenetic protein-2: a review of 200 patients.* J Neurosurg Spine, 2008. **8**(6): p. 529-35.
2. Shields, L.B., et al., *Adverse effects associated with high-dose recombinant human bone morphogenetic protein-2 use in anterior cervical spine fusion.* Spine, 2006. **31**(5): p. 542-7.
3. Vaidya, R., et al., *Complications of anterior cervical discectomy and fusion using recombinant human bone morphogenetic protein-2.* Eur Spine J, 2007. **16**(8): p. 1257-65.
4. Smucker, J.D., et al., *Increased swelling complications associated with off-label usage of rhBMP-2 in the anterior cervical spine.* Spine, 2006. **31**(24): p. 2813-9.
5. Baskin, D.S., et al., *A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein-2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate.* Spine, 2003. **28**(12): p. 1219-24; discussion 1225.
6. Buttermann, G.R., *Prospective nonrandomized comparison of an allograft with bone morphogenic protein versus an iliac-crest autograft in anterior cervical discectomy and fusion.* Spine J, 2008. **8**(3): p. 426-35.
7. Aryan, H.E., et al., *Corpectomy followed by the placement of instrumentation with titanium cages and recombinant human bone morphogenetic protein-2 for vertebral osteomyelitis.* J Neurosurg Spine, 2007. **6**(1): p. 23-30.
8. Allen, R.T., et al., *Bone morphogenetic protein-2 (BMP-2) in the treatment of pyogenic vertebral osteomyelitis.* Spine, 2007. **32**(26): p. 2996-3006.
9. Oluigbo, C.O. and G.A. Solanki, *Use of recombinant human bone morphogenetic protein-2 to enhance posterior cervical spine fusion at 2 years of age: technical note.* Pediatr Neurosurg, 2008. **44**(5): p. 393-6.

Vertebroplasty and Kyphoplasty

CMS Proposed Topic-

"Vertebroplasty and kyphoplasty are radiologic procedures for the treatment of the intense pain caused by vertebral compression fracture in patients whose pain has been refractory to medical management or other therapy. Vertebroplasty and kyphoplasty involve the intraosseous injection

of acrylic cement under local anesthesia and fluoroscopic guidance to control the pain of vertebral fractures associated with osteoporosis, tumors, and trauma. Typically, vertebroplasties are performed in an outpatient setting, while kyphoplasty typically requires hospital admission. Is the evidence adequate to demonstrate health benefits from pain reduction in selected patients?"

Task Force Comments

Vertebroplasty (VP) and kyphoplasty (KP) are procedures performed for conditions that are common in the Medicare population, specifically patients over the age of 65. Approximately 35% of women in the US 65 years or older have osteoporosis. Vertebral compression fracture (VCF) is the most common complication of this condition and more than 700,000 new vertebral compression fractures occur every year in the United States alone. These fractures account for more than 100,000 hospital admissions and close to $1.5 billion in annual costs.

Although most patients with VCF are asymptomatic or minimally symptomatic, a significant number of patients have sufficient pain to limit activity, resulting in decreased quality of life and disability. VCF may also lead to progressive spinal deformity, and the incidence of additional fractures is increased in patients with an incident VCF. They may be associated with other systemic conditions, including metastatic disease and chronic steroid use.

Conventional treatment for VCF is designed to alleviate symptoms, and includes analgesic medications, a variety of bracing alternatives, and modification of activity. Some patients do experience improvement in their symptoms over time, with medical treatment. Failure of medical management often results in the option of a percutaneous surgical procedure being offered. However, the severity of a patient's pain and the associated disability are the determining factors for whether a trial of medical management is warranted.

Percutaneous vertebral augmentation (PVA) is a minimal access procedure which restores strength to the fractured vertebra by the injection of polymethylmethacrylate (PMMA). Vertebroplasty (PV) and kyphoplasty (KP), a variation of vertebroplasty, have become increasingly popular as a treatment alternative for VCF. Leading experts from many major insurance carriers have reviewed the body of scientific literature available and concluded that coverage for these procedures is warranted.

The following conditions are considered indications for this procedure, provided the affected vertebra has not been extensively destroyed and the patient's medical condition permits treatment:

1) osteoporotic vertebral compression fractures that have not responded to medical treatment including bracing, rest, analgesics, with incapacitating pain that may preclude mobilization in a previously mobile patient;
2) osteolytic vertebral metastasis or myeloma with severe back pain related to vertebral body destruction without cortical involvement; and
3) painful vertebral hemangioma

Percutaneous vertebroplasty is contraindicated in patients with local infection, spinal cord compression, destruction of the posterior wall of the vertebral body and severe degrees of vertebral body collapse; certain other medical conditions, such as coagulopathies, may preclude the procedure.

Results from the current studies evaluating vertebroplasty and kyphoplasty for treatment of both VCF related to osteoporosis and metastatic disease point to consistent and dramatic reduction in pain, typically within one day of the procedure. Other significant outcomes include decreased analgesic use and improvement in physical function or disability scale scores (Bouza et al 2006).

The most consistently raised issue in recent TEC assessments relates to the nature of studies, specifically the lack of comparative, blinded randomized clinical trials, and the use of subjective measures of pain and activity as outcome measures. The literature has consistently described pain relief, measured by VAS score, in a large percentage of patients treated with PVA (Bouza et al 2006; Eck et al 2008; Hulme et al 2006). Furthermore, pain relief is durable. Similar clinical benefits are noted in both VP and KP (Eck et al 2008).

The majority of the studies published on PVA are in the form of prospective consecutive case series or retrospective studies (Eck et al 2008). The retrospective studies include large numbers of patients whose quality of life is reportedly substantially improved with PVA intervention (Bouza et al 2006; Eck et al 2008; Hulme et al 2006).

The most commonly reported complications following PVA were cement leaks perioperatively or subsequent fractures in the first year post procedure. Cement (PMMA) leaks are commonly quoted at around 9% of treated osteoporotic vertebrae and slightly higher for metastatic fractures. Most leaks involve the disc or perivertebral soft tissues and are most commonly clinically asymptomatic (Hulme et al 2006). New fractures of remote and adjacent vertebrae in most studies occurred in frequency equivalent to the general osteoporotic population that had one previous vertebral fracture (Hulme et at 2006).

Recognizing the limitations of the current literature, and balancing that with the clinical benefits described in large numbers of patients according to the retrospective studies, the following summary comments are provided:

1. PVA is a reasonable treatment option for managing vertebral compression fractures related to osteoporosis or metastatic disease.

2. Multiple studies indicate that both procedures are safe and efficacious in the treatment of osteoporotic and pathological vertebral compression fractures. The most common complication is extravasation of cement, which is of no consequence in most patients.

3. Many prospective consecutive case series indicate that PVA improves pain and function. There are no large long term randomized clinical trials comparing PVA with the natural history of VCF. In fact there exist no quality studies of the natural history of vertebral compression fractures.

4. Both VP and KP have similar clinical results and can be performed on an outpatient basis.

5. Kyphoplasty is significantly more expensive than vertebroplasty without a proven value added benefit.

Despite the lack of randomized clinical trials, the consistency of the findings regarding a large improvement in pain and function indicates that both vertebroplasty and kyphoplasty are effective in the treatment of pain due to vertebral fractures. VP is reasonable and necessary by producing immediate improvement in a patient's quality of life, primarily through the alleviation of pain and rapid return to ambulation. KP is equally as effective, but at a substantially greater cost. NASS encourages CMS to focus on best patient care by continuing coverage for patients with these minimally-invasive treatments that have been safely and successfully performed on thousands of patients across the United States, typically providing patients with immediate relief from pain and an independence from reliance on narcotics.

In summary, the benefits of vertebroplasty and kyphoplasty far outweigh any risks and the risks of conservative therapy, and the success rates are consistently high. These procedures are effective by producing immediate improvement in a patient's quality of life, primarily through the alleviation of pain and rapid return to ambulation. The value added benefit of KP over VP has not been demonstrated.

Recommendations- Vertebroplasty/Kyphoplasty

1. **VP- Recommend coverage in Medicare and non-Medicare patients for osteoporotic VCF**

2. **KP- Recommend coverage in Medicare and non-Medicare patients for osteoporotic VCF**

3. **VP and KP- Recommend coverage in Medicare and non-Medicare patients for osteolytic vertebral metastasis, myeloma and vertebral hemangioma**

4. **There is no added value of KP over VP and CMS hospital and outpatient payment policy should be equivalent for the two procedures.**

Vertebroplasty / Kyphoplasty References

Bouza C, Lopez T, Magro A, Navalpotro L, Amate J. Efficacy and safety of balloon kyphoplasty in the treatment of vertebral compression fractures: a systematic review. Eur Spine J 2006; 15:1050–1067.

Eck J, Nachtigall D, Humphreys S, Hodges S. Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures: a meta-analysis of the literature. Spine J. 2008; 8(3):488-497.

Hulme P, Krebs J, Ferguson S, Berlemann U. Vertebroplasty and Kyphoplasty: A Systematic Review of 69 Clinical Studies. Spine 2006; 31(17):1983–2001.

Multi-level Lumbar Fusion for Degenerative Disc Disease

CMS Proposed Topic-
"For certain patients, a two level spinal fusion may be an effective treatment for debilitating back pain from two degenerated lumbar discs. Multilevel fusion as a primary treatment for low back pain from degenerated discs is a controversial topic in spine medicine. However, lumbar fusion of three or more levels of the low back as a primary treatment for back pain is rarely recommended, and many surgeons recommend against it in all cases of multilevel degenerative disc disease. Is the evidence adequate to specify groups that do and do not benefit from the lumbar fusion procedure?"

Task Force Comments

Our primary concern with regard to the proposed NCD topic on multilevel lumbar fusion revolves around the difficulty in clearly defining the population in question. We agree that there is no high quality or even consistent lower quality evidence indicating that multilevel (3 or more level) fusion is effective as a treatment for isolated back pain without neurological deficit, deformity, or stenosis. Evidence to definitively support or refute the efficacy of such procedures is not likely to be available in a reasonable timeframe because these procedures are uncommonly performed in any patient population. According to MedPar data, a grand total of 688 such multilevel procedures with a primary diagnosis of degenerative disc disease were performed in the United States during 2007 (out of approximately 57,000 fusions performed for degenerative disease). Given difficulties with the fidelity of administrative databases, it is likely that the true incidence is even lower due to failure to code for associated diagnoses. Furthermore, when such procedures are performed, they are more likely performed in an elective fashion on younger patients. These are "boutique" procedures that are not typically performed in the over age 65 Medicare or Medicaid population.

Answerable questions must be used as the basis for reasoned debate when policy decisions are proposed. For example, at the 2006 MCAC meeting on lumbar fusion, the published MCAC question, similarly described as fusion for isolated low back pain in the Medicare population, was not able to be addressed. The majority of data reviewed by the speakers, and much of the panel discussion, addressed the utilization of lumbar fusion in completely different patient populations. Nonetheless, the panel was required by procedure to vote on the atypical use of fusion for low back pain in the Medicare population, as this was the specific MCAC question. As there was no evidence relevant to the Medicare or Medicaid population, the panel was forced to conclude that such procedures were not supported by high quality evidence. This conclusion, supported by a draft Tech Report, has been published and used to inappropriately limit access to lumbar fusion in other populations.

It is also imperative that multi-level fusion procedures for isolated axial LBP or axial LBP without neural compression are not confused with multilevel fusion procedures that are

performed for the purposes of deformity correction, correction of instability, or following destabilizing decompressive procedures in the elderly. There is substantial evidence indicating that the use of fusion in such situations improves functional outcome. In particular, data from the SPORT study, which has been presented and published since the 2006 MCAC meeting, provide high quality evidence supporting the benefit of lumbar fusion in appropriately selected patients (Weinstein JN, N Engl J Med 2007;356;22:2257-2270). Also, consistent with the CMS call for evidence development surrounding lumbar fusion in the Medicare population (Schafer J, Spine 2007;32(22):2403-2404.), several studies examining the role of single and multilevel fusion in older patients have now been published, or are awaiting publication (Glassman SD, Spine J 2007;7(5):547-551, Okuda S, J Bone Joint Surg Am. 2006 Dec;88-A(12):27142720, Glassman SD, Spine J. E-pub 2008, Bridwell K, SRS 2008, Ghogowala, Benzel, etc).

We welcome any and all opportunities to discuss the appropriate use of multilevel fusion in the Medicare population. We agree that demonstration of benefit for lumbar fusion, or any surgical intervention, limited to simple cases and idealized populations is not ultimately sufficient to predict value in standard clinical practice. We believe that additional and ongoing evidence development is critical to guide appropriate resource utilization in the Medicare population. It is our assertion that identification of the most specific and relevant question for analysis is critical in order to maximize the utility of the subsequent analysis.

Recommendations- Multi-level (3 or more levels) Lumbar Fusion for Degenerative Disc Disease

1. **For DDD without deformity or instability, or iatrogenic instability caused by decompression of nervous elements, (isolated axial LBP or axial LBP without neural compression)- Do not recommend coverage in Medicare and non-Medicare patients**

2. **For DDD with deformity, extensive decompression or instability- Recommend coverage in Medicare and non-Medicare patients**

Artificial Cervical Discs

CMS Proposed Topic-
"Artificial cervical discs are being developed in an effort to treat symptomatic degenerative disc disease more effectively. The goal of this type of technology is to maintain spinal motion following anterior discectomy, to reduce the incidence of degeneration of adjacent disc levels of the spine (adjacent-segment disease), and to permit more rapid return to normal activity. Is the evidence adequate that this procedure results in improved health for the Medicare population?"

Task Force Comments-

Spinal spondylosis and cervical degenerative disease are a common problem in the United States and associated with aging (Emery 2001). This is due to the avascular nature of the spinal disc and as it loses proteoglycans, such as chondroitin sulfate, and moisture it is unable to repair itself

and becomes inelastic with microfissures and associated disc herniations resulting in settling and collapse of the disc space. This change in the disc space results in abnormal spinal motion patterns and further leads to anatomical changes in the formation of osteophytic spurs and can be associated with impingement of nerve roots or the spinal cord. This is a common radiographic finding, with 60% of people over the age of 40 showing evidence of cervical degenerative disc disease and spondylosis, and by age 65, almost 95% of men and 70% of women have such changes. While most radiographic changes are asymptomatic, a significant number (over 5 million) of US adults are disabled by spine-related disorders and a portion of these patients are good candidates for surgery.

The initial treatment for cervical spondylosis and degenerative disease is not surgery. Rather, patients undergo initial management with pharmacological agents such as NSAIDs, analgesics, or muscle relaxants, and supplemented with physical therapies such as traction, strength training, stretching, massage, or manipulation therapies. If symptoms persist or worsen, then additional treatment including biofeedback or cognitive therapies may be added along with interventional procedures such as epidural steroid injections, facet joint radiofrequency denervation, or trigger point injections.

These treatments are not panaceas for this disease process, with over $80 billion dollars a year spent on the pain and symptoms related to the non-surgical management of spinal disorders (Brook 2008). This can be contrasted to the $570 million that CMS paid in professional fees in 2007 for the entire field of neurosurgery (cranial and spinal), which represents less that ¾ of 1% of what has been spent on non-surgical treatment. Non-surgical treatments have resulted in an increase in expenditures of 65% (adjusted for inflation) from 1997 to 2005 (Brook 2008). Unfortunately despite these treatments, patients continue to experience physical function limitation and decrease in the activities of daily living with persistent issues related to their mental health, physical functioning, work, school and social limitations.

This debilitating degeneration disease was first noted by Bailey and Casamajor in 1911 when they first described osteo-arthritis of the cervical spine. Clarke and Robinson in 1956 noted that this was not a static problem, but rather that disease and symptom progression was common, albeit gradual. However, improvement was rare and prognosis was generally poor. Cervical spondylosis and associated myelopathy remains the most common cause of nontraumatic spastic paraparesis and quadriparesis, and represents 23.6% of these severely disabled and medically needy patients (Moore 1997).

This unacceptable natural history of this disease has lead to the development of surgical treatments and techniques. Typically, surgical patients have failed 2-6 months of conservative therapy and are unable to perform their activities of daily living due to pain or neurological symptoms. In these patients, surgery, most commonly anterior cervical diskectomy and fusion (ACDF) with or without plate fixation has resulted in the resolution of symptoms in over 80% of those treated (Xie 2007, Yue 2005). The excellent results have resulted in increased use of surgery for cervical spondylosis, especially as more surgeons are trained in this technique. The frequency of cervical surgeries performed has grown from 26,000 per year in 1988-90 to 124,000 procedures in 1999 (Lee 2004).

Although surgery has improved on the patient's health as compared to their natural history of their disease, it is not without its own drawbacks. Chief amongst these are concerns regarding adjacent segment spondylosis, which has been reported to occur at a rate of 2.9% per year with an overall incidence of 25.6% based on survivorship analysis. This has been felt to be related to variables related to the patient's underlying clinical disease along with iatrogenic and lifestyle choices, but also related to the fusion construct itself as related to the biomechanical alterations of a functioning joint.

This plus a desire to speed recovery and maintain normal neck motion has lead to the advent of artificial intervertebral disc arthroplasty as an alternative to anterior cervical fusions in patients with cervical spondylosis and degenerative disc disease (Acosta 2005, Anderson 2007, Smucker 2006, Phillips 2005, Anderson 2004, Pracyk 2005, Bertagnoli 2005). Additional studies have shown that cervical arthroplasty is safe and at least as effective as cervical fusions in those patients who had similar surgical indications to ACDF such as radiculopathy and myelopathy (Brown 2006; McAfee 2004). There are reports that the patients with cervical arthroplasty have an improved post-operative course possibly due to the absence of an anterior plate or the need for an orthoses, and also have a shorter recovery period due to not using bone grafts (Traynelis 2007, Goffin 2006). As well, cervical disc arthroplasty has been associated with maintaining cervical disc height, along with lordosis and motion at the index and at the adjacent cervical spine levels (Sears 2006). This has been postulated to reduce the risk of adjacent level degeneration (Traynelis 2007) and improve the force/load transfer to the adjacent cervical levels (Phillips & Garfin 2005).

Biomechanical models show that there is altered adjacent segment kinematics in patients or spines with a fusion, but as these are biomechanical studies, they do not portend to establish clinical relevance (Anderson 2007, Phillips 2005, Wigfield 2002). It is only in the recent past that further development of available tools to study cervical spine kinematics in a clinical setting has been developed and this shows that there is preserved adjacent segment kinetics in patients with an arthroplasty (Cheng 2007).

Cervical disc arthroplasty is a technology that has final approval from the appropriate governmental regulatory bodies, with the Prestige ST Cervical Disc receiving FDA marketing approval on July 16, 2007 and the ProDisc™-C Total Disc receiving a premarketing application (PMA) approval on December 17, 2007 and further FDA marketing approval on December 22, 2007. In addition, the Bryan Cervical Disc received an approvable decision by an FDA advisory panel on July 17, 2007 but has not received a final marketing approval.

These devices have similar indications for use in skeletally mature patients with cervical spine disease at C3-C7 necessitating a single-level decompression. The devices are implanted via an open anterior approach, similar to that of an ACDF, and used for symptoms similar to an ACDF for patients with intractable pain, radiculopathy, and/or myelopathy associated with radiographic studies showing a herniated cervical disc or cervical spondylosis and osteophytes.

Three large multicenter prospective randomized IDE studies have been completed comparing cervical disc arthroplasty with anterior cervical diskectomy and fusion (Aetna Policy No. 0591).

They have concluded that disc arthroplasty is a safe and reasonable alternative to anterior cervical fusion.

Mummaneni[14] in 2007 reported statistical noninferiority for disc arthroplasty versus ACDF in all three primary outcome variables (Neck Disability Index (NDI), neurological status, and functional spinal unit height (FSU)) and for the overall success composite outcome. The neurological status was the only primary outcome variable for which statistical superiority was achieved. The arthroplasty patients showed preservation of motion with retention of sagittal angular motion of over 7 degrees and also a 2-point greater improvement in the Neck Disability Index (NDI).

They were unable to show that variables such as functional spinal unit (FSU) height reached predetermined levels, but it should be noted that they had difficulty due to anatomical interference and that alternate determinations were made without the FSU height included. Although it was not statistically significant, there was an overall success with better SF-36 at 12 and 24 months associated with a greater relief of neck pain and earlier return to work in the arthroplasty group. There were no serious associated adverse events and no cases of implant failure or migration, along with a lower rate of revision surgeries ($p = 0.0277$) including a lower rate of supplemental fixation ($p = 0.0031$) and of re-operations at the adjacent segment ($p = 0.0492$).

Murrey[16] reported a prospective, randomized, controlled trial of 209 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive PRODISC-C® or ACDF with plate and allograft with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that Prodisc-C® is "not inferior" to ACDF 2 years after surgery in Overall Success, the study's primary endpoint.

Heller[15] reported a prospective, randomized, controlled trial of 463 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive BRYAN® Cervical Disc or Atlantis ® Cervical Plate with allograft (ACDF) with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that the BRYAN® Cervical Disc maintained segmental motion at 24 months after implantation and was associated with improved NDI Success (superiority), improved clinical outcomes, and 13 days faster return to work compared to ACDF patients. Statistical superiority in Overall Success (study's primary endpoint) was demonstrated at 24 months.

Criticism has been raised regarding the non-inferiority design of these trials, and how such a study design does not provide sufficient evidence insufficient to justify coverage. While the studies do not prove superiority, they consistently demonstrate improvement in pain and function that is equivalent to fusion. Additionally the studies have been criticized (BC/BS TEC Assessment (http://www.bcbs.com/blueresources/tec/tec-assessments.html) due to their non-blinded nature. However, this is confusing the science behind device studies with those from other non-surgical disciplines. It would be physically impossible to double blind a surgeon regarding an implant that is to be surgically placed.

Cervical disc arthroplasty is not frequently used in Medicare age patients, with the average study population being young with patients in their mid-40s. Prior IDE studies included patients only between the ages of 18-60, and along with their exclusion criteria which excluded patients with severe disabilities and comorbidities, do not capture patients within the Medicare population. The study by Mummaneni did include patients with cervical arthroplasty up to age 72, and had fusion control patients up to age 73, this was a very small number of patients and data on this subgroup will not be able to show any statistical significance.

It remains unknown if cervical disc arthroplasty will decrease the incidence of adjacent level disc degeneration. There is some evidence that the early re-operation rate is less for disc arthroplasty than the fusion group, but this is due to psedoarthrosis at the index level in the fusion group and not adjacent level degeneration. Reasonable long term wear characteristics are suggested by biomechanical studies, but clinical data are not available at this time.

Recommendations- Cervical disc arthroplasty

1. For cervical spondylosis and disc herniation in non-Mediciare population- Recommend coverage

2. For cervical spondylosis and disc herniation in the Medicare population- Literature is insufficient to make recommendation. Further study should be encouraged.

References – Cervical disc arthroplasty

1. Aetna Clinical Policy Bulletin: Intervertebral Disc Prostheses. Policy Number: 0591 (Last Review: 05/23/2008) (http://www.aetna.com/cpb/medical/data/500_599/0591.html)
2. Lee CK, Langrana NA. A review of spinal fusion for degenerative disc disease: need for alternative treatment approach of disc arthroplasty? Spine J. 2004 Nov-Dec;4(6 Suppl):173S-176S.
3. Moore AP, Blumhardt LD. A prospective survey of the causes of nontraumatic spastic parapesis and a tetraparapesis in 585 patients. Spinal Cord 1997; 35:361-7.
4. Brook, Deyo, Mirza, et al, "Expenditures and Health Status among Adults with Back and Neck Problems". JAMA. 2008;299(6):656-664.
5. Lees F, Turner JW. Natural history and prognosis of cervical spondylosis. BMJ 1963;2:1607–1610.
6. Clarke E, Robinson PK. Cervical myelopathy: a complication of cervical spondylosis. Brain 1956;79:483–510.
7. Radhakrishnan K, Litchy WH, O'Fallon M, Kurland LT. Epidemiology of cervical radiculopathy—…, 1976 through 1990. Brain 1994;117:325–335.
8. Kadanka Z, Bednarik J, Vohanka S, et al. Conservative treatment versus surgery in spondylotic cervical myelopathy…. Eur Spine J 2000;9:538–544.
9. Sampath P, Bendebba M, Davis JD, Ducker TB. Outcome of patients treated for cervical myelopathy…. Spine 2000;25:670–676.
10. Hilibrand AS, Carlson GD, Palumbo MA, et al.: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical athrodesis. J Bone Joint Surg 81-A:519-528, 1999.

11. Bucy PC, Heimburger RF, Oberhill HR: Compression of the cervical spinal cord by herniated intervertebral discs. J Neurosurg 5:471-492, 1948.
12. Frykholm R: Lower cervical vertebrae and intervertebral discs: surgical anatomy and pathology. Acta Chir Scand 101:345-359, 1951.
13. Hilibrand A, et. Al. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. Journal of Bone & Joint Surgery 1999; 81 (4): 519-528.
14. Wang JC. McDonough PW. Endow KK. Delamarter RB. Increased fusion rates with cervical plating for two-level anterior cervical discectomy and fusion [Journal Article] Spine. 25(1):41-5, 2000 Jan.
15. Ghiselli G. Wang JC. Bhatia NN. Hsu WK. Dawson EG. Adjacent segment degeneration in the lumbar spine. [Journal Article] Journal of Bone & Joint Surgery - American Volume. 86-A(7):1497-503, 2004 Jul.4.
16. Okawa, Shinomiya, Takakuda, et. Al. A cadaveric study on the stability of lumbar segment after partial laminotomy and facetectomy with intact posterior ligaments. J of Spinal Disorders. 9(6):518-26, 1996 Dec.
17. Mummaneni, et al. Journal of Neurosurgery Spine. 2007 Mar; 6(3):198-209. Clinical and Radiographic Analysis of Cervical Disc Arthroplasty Compared with Allograft Fusion: A Randomized Controlled Clinical Trial. [Medtronic Funded, PRESTIGE® Cervical Disc* (Medtronic)]

    This was a prospective, randomized, controlled trial of 541 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive PRESTIGE® Cervical Disc or ATLANTIS® Cervical Plate with allograft (ACDF) and followed up at 3 and 6 weeks, 3, 6, 12 and 24 months. The results noted that the PRESTIGE® Cervical Disc maintained segmental motion at 24 months after implantation and was associated with improved neurological status (superiority), improved clinical outcomes, and a reduced rate of secondary surgeries compared to ACDF. Superiority in overall success (study endpoint) was demonstrated at 24 months in the PRESTIGE® Cervical Disc cohort.

18. Heller, et. Al. Abstract, 2007 North American Spine Society Annual Meeting. Comparison of BRYAN® Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion: Clinical and Radiographic Results of a Randomized Controlled Clinical Trial. [Medtronic Funded, BRYAN® Cervical Disc (Medtronic)]

    This was a prospective, randomized, controlled trial of 463 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive BRYAN® Cervical Disc or Atlantis ® Cervical Plate with allograft (ACDF) with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that the BRYAN® Cervical Disc maintained segmental motion at 24 months after implantation and was associated with improved NDI Success (superiority), improved clinical outcomes, and 13 days faster return to work compared to ACDF patients. Statistical superiority in Overall Success (study's primary endpoint) was demonstrated at 24 months in the BRYAN® Cervical Disc cohort.

19. Murrey, et. Al. Abstract, 2007 Cervical Spine Research Society Annual Meeting. Twenty-four month results from the prospective, randomized, multi-center IDE Trial of PRODISC-C® vs. ACDF. [PRODISC-C®, Synthes Spine]

    This was a prospective, randomized, controlled trial of 209 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive PRODISC-C® or ACDF with plate and allograft with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that Prodisc-C® is "not inferior" to ACDF 2 years after surgery in Overall Success, the study's primary endpoint.

20. Sasso, et. Al. J Spinal Disord Tech. Vol. 20, Number 7, Oct. 2007. Clinical Outcomes of BRYAN® Cervical Disc Arthroplasty: a Prospective, Randomized, Controlled, Multi-Center Trial With 24-month Follow-up. [BRYAN® Cervical Disc, Medtronic]

    This was a prospective, randomized, controlled trial of 115 patients from 3 U.S. IDE study sites for the BRYAN® Cervical Disc IDE Study Subset of 463 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive BRYAN® Cervical Disc or ATLANTIS® Cervical Plate with allograft (ACDF) with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results noted that the BRYAN® Cervical Disc maintained segmental motion at 24 months after implantation and was associated with statistically superior scores in Neck Disability Index, Neck Pain, and SF-36 PCS 24 months after surgery.

21. Porchet, etl al. Neurosurg Focus 2004 Sept; 17:36-43. Clinical Outcomes with the PRESTIGE® II Cervical Disc: Preliminary Results from a Prospective Randomized Clinical Trial. [Medtronic Funded, PRESTIGE® Cervical Disc*, Medtronic]

    This was a prospective, randomized, controlled trial of 55 patients consisting of 27 PRESTIGE® II Cervical Disc with 28 iliac crest autograft fusion and with 2-year follow up with most of the outcome measures tending to favor the PRESTIGE® II Cervical Disc, and with the PRESTIGE® II Cervical Disc maintaining motion at treated level without adjacent segment compromise.

22. Hacker, et al. Journal of Neurosurgery Spine 2005 Dec; 3:424-28. Cervical Disc Arthroplasty: A Controlled Randomized Prospective Study With Intermediate Follow Up Results. [Medtronic Funded, BRYAN® Cervical Disc, Medtronic]

    This was a prospective, randomized, controlled trial of 46 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive BRYAN® Cervical Disc or ATLANTIS® Cervical Plate with allograft with follow up of 3 and 6 weeks, 3,6,12 and 24 months. The results show that all patients reported in this study had reached a minimum of 1-year follow up with no device related complications and with equivalent results in releif of arm and neck pain seen in both study groups. The treatment parameters other than OR time were similar with no serious neurological or systemic complications observed and preserved motion was revealed in all BRYAN® Cervical Disc-treated patients.

23. Coric, et al. Journal of Neurosurgery Spine, 2006 Jan, Vol 4:31-35. Prospective Rrandomized Controlled Study of the BRYAN® Cervical Disc: Early Clinical Results from a Single Investigational Site. [Medtronic Funded, BRYAN® Cervical Disc, Medtronic]

    This was a prospective, randomized, controlled trial of 33 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive BRYAN® Cervical Disc or ATLANTIS® Cervical Plate with allograft and follow up of 3 and 6 weeks, 3, 6, 12, 24 months. The results noted that at mean follow up at time of report of 19 months, there was no device related complications and had similar improvements seen in both study groups. The BRYAN® Cervical Disc patients demonstrated maintenance of motion at treated level.

24. Nabhan, et al. Eur Spine J, 2007 Mar; 16(3):423-30. Disc Replacement Using PRODISC-C® versus Fusion: A Prospective Randomized and Controlled Radiographic and Clinical Study. [PRODISC-C®, Synthes Spine]

    This was a prospective, randomized, controlled trial of 25 patients with cervical disc herniation who were randomized to receive either a PRODISC-C® or ACDF. Radiostereometric analysis was used to quantify intervertebral motion immediately and at 3, 6, 12 and 24 weeks. Clinical results were judged using VAS and neuro examination. Motion decreased in both groups over time; however, the loss of segmental motion was significantly higher in the ACDF group. Significant pain reduction was observed in both groups ($p>0.05$). The cervical spine disc prosthesis preserves cervical spine segmental motion within the first 6 months after surgery. Clinical results were the same as early results of ACDF.

25. Anderson, et al. Journal of Neurosurgery, 2004. Comparison of Simulator-Tested and Retrieved Cervical Disc Prostheses. [BRYAN® Cervical Disc, Medtronic].

    This sudy compared wear/debris of human explanted BRYAN® Cervical Discs and PRESTIGE® Cervical Discs to wear/debris from discs tested on a spine simulator. Simulator predicted adequate wear for prostheses out to 40 years and human explants exhibited less wear than predicted by simulators (5 to 10 fold).

26. Anderson, et al. The Spine Journal, 2004. The BRYAN® Cervical Disc: Wear Properties and Early Clinical Results. [BRYAN® Cervical Disc, Medtronic]

    This was an in vitro study to assess the BRYAN® Cervical Disc's wear properties and clinical results with an in vitro mechanical testing in a caprine animal model and in a prospective European human trial. In vitro wear averaged approximately 1.76% by weight at 10M cycles and 18% by weight at 40 million cycles. Wear debris were present in periprosthetic tissues without inflammatory response in animals. 90% of European trial patients had satisfactory results.

27. Bertagnoli, et al. Journal of Neurosurgery, 2005. Early Results After PRODISC-C® Cervical Disc Replacement [PRODISC-C®, Synthes Spine]

This was a case series with follow up at 3, 6, and 12 months and looking at radiographic examination (ROM), ODI, and VAS. At 12 months 63.6% patients completely satisfied, 36.4% satisfied, and 0% unsatisfied.

28. Bertagnoli, et al. Ortho. Clin N. Am., 2005. Cervical Disc Replacement:Part II Clinical Results. [PRODISC-C®, Synthes]

    This was a case series of 27 patients with follow up at 3 and 6 wks, 3, 6, 12 months looking at NDI, VAS, ROM, and other clinical parameters. At 12 months it was noted that 52% completely satisfied, 36% satisfied, 12% unsatisfied.

29. Cummins, et al. Journal of Neurosurgery, 1998. Surgical Experience with an Implanted Artificial Cervical Joint. [BRISTOL-CUMMINS DISC]

    This is a retrospective cohort study looking at the surgical experience with the implantation of movable stainless-steel joints in 20 patients. Joint motion was determined by measuring the distance between cervical spine segments during flexion/extension. Follow up 3-65 months. No patients required additional motion segment surgery. Radiography did not demonstrate fusion at the treated level in any patient. Adjacent segment joint degeneration was absent. 16 of 20 patients reported improvement in pain relief. Three patients were considered failures because pain persisted or worsened. Complications were attributed to poor screw placement, incompatible screws, one-size-fits-all implants, and manufacturing errors. Stainless steel appears too suitable for this joint replacement design. With appropriate modification of sizes, this joint is shown to be capable of stability and motion and deserves further clinical evaluation.

30. Datta, et al. J Spinal Disord Tech, Vol. 20, Number 1, Feb. 2007. Sagittal Split Fractures in Multilevel Cervical Arthroplasty Using a Keeled Prosthesis [PRODISC-C®, Synthes Spine]

    This is a case report of a 34-year old male with a 2-level cervical spondylosis unresponsive to nonoperative care for 24 months. FDA compassionate use granted for treatment with Prodisc -C® at C5-6 and C6-7 levels The PRODISC-C® was inserted successfully at the C6-7 level. Following that, during use of a keeled osteotome at the C5-6 level, a loss of resistance was felt and radiographic imaging revealed a sagittal split fracture of the C6 vertebral body with no instability or loose fragments observed. Insertion of the PRODISC-C® at C5-6 was performed as planned. Postoperative radiographic evaluation revealed a fracture of the C5 vertebral body that was not detected during surgery. The patient had immediate relief of his preoperative symptoms and eventual relief of neck pain related to the fracture. The author concludes that this adverse event may be attributed to the keeled design of the prosthesis, as well as the need for chisel cutting before and during insertion of the prosthesis.

31. Dmitriev, et al. SPINE, 2005. Adjacent Level Intradiscal Pressure and Segmental Kinematics Following Cervical Arthroplasty. [PCM®, Cervitech, Inc.]

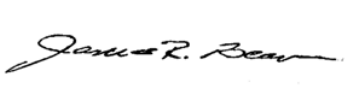
    This is a laboratory study looking at intradiscal pressure at levels adjacent to an arthroplasty. In 10 cadavers, similar adjacent level IDP's were recorded between TDR

and intact spine in all loading conditions ($p<.05$). Segment above both arthrodesis groups had higher intradiscal pressure at adjacent level above ($p<.05$).

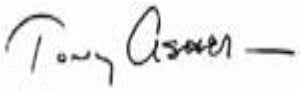
The American Association of Neurological Surgeons, Congress of Neurological Surgeons, North American Spine Society, Scoliosis Research Society, and Spine Arthroplasty Society appreciate the opportunity to offer these comments to CMS regarding potential NCD topics. We look forward to our continued relationship to further improve patient access to quality spine care.

Sincerely,

Thomas Faciszewski, MD
President
North American Spine Society



James R. Bean, MD
President
American Association of
Neurological Surgeons



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SOCIETY COALITION TASK FORCE ON
LUMBAR FUSION

Response to Posting of Potential CMS NCD Topics
September 28, 2008

On behalf of the Professional Society Coalition Task Force on Lumbar Fusion, representing the North American Spine Society, American Association of Neurological Surgeons, American Academy of Orthopaedic Surgeons, Congress of Neurological Surgeons and the Scoliosis Research Society, we appreciate the opportunity to comment regarding the recently released CMS posting of potential national coverage determination (NCD) topics. In particular, our attached comments refer to two of the proposed NCD topics, Bone Morphogenetic Proteins (BMP) and lumbar fusion for degenerative disc disease, which relate to our primary goal of evidence development surrounding lumbar fusion surgery. We hope that, following review of these comments by the Centers for Medicare & Medicaid Services (CMS) staff, we will have a further opportunity to pursue our cooperative effort to optimize both care and resource utilization for Medicare patients needing lumbar fusion surgery.

> ***CMS Proposed NCD Topic-Bone Morphogenetic Protein (BMP)****: Members of the BMP family are potentially useful as therapeutics in areas such as spinal fusion. BMP-2 and BMP-7 have been shown in clinical studies to beneficial in the treatment of a variety of bone-related conditions including delayed union and non-union. BMP-2 and BMP-7 have received Food and Drug Administration (FDA) approval for human clinical uses. Certain off-label uses in cervical spine fusion may be associated with life-threatening complications. Is the evidence adequate to demonstrate health improvements in the Medicare population?*

Since the initial approval of rhBMP-2 for anterior interbody fusion in 2002, BMPs have been widely used for lumbar spine fusion. However, the majority of use has been “off-label” in posterior spine applications such as posterolateral fusion (PSF) or transforaminal interbody fusion (TLIF). To a much lesser extent, cervical spine applications have been reported and, as noted in the proposed topic posting, complications related to anterior cervical applications are a significant concern. Given the primary Task Force mandate regarding evidence surrounding lumbar fusion, these comments do not specifically address cervical applications.

While the body of literature evaluating BMPs in posterior spine fusion is somewhat limited by its relative recent clinical availability, the literature is growing rapidly and includes a number of high quality studies. We have included some discussion of studies still in the editorial review process in order to demonstrate an appropriate response to the CMS staff’s expressed concern that ongoing critical evidence development should be undertaken once new technologies reach clinical practice. Several general issues are important in the evaluation of this literature. Firstly, variations in the specific BMP used, as well as dose, concentration, and carrier for each BMP may significantly affect risks or benefits. The studies evaluating high dose rhBMP-2 (40 mg, 2.0 mg/ml), lower dose rhBMP-2 (12 mg, 1.5 mg/ml), and rhBMP-7 all contribute to our overall understanding of biologics in lumbar fusion, but cannot necessarily be considered interchangeably. Secondly, the initial experience suggests that risks and benefits may differ based upon site (lumbar versus cervical) and application technique (PSF versus TLIF).

Posterolateral Spine Fusion (PSF)

The most significant available body of evidence examines the use of rhBMP-2 in posterolateral lumbar fusion. In 2002, Boden reported on a pilot study comparing rhBMP-2 (40mg, 2.0 mg/ml) and iliac crest bone graft (ICBG) which suggested better fusion rates in the rhBMP-2 patients (Boden S., Spine 2002; 27(21):2396-2408). This led to an FDA approved randomized controlled investigational device exemption (IDE) trial for rhBMP-2 and a compression resistant matrix (CRM) versus ICBG in single level posterolateral fusion. Two-year results from two centers participating in the IDE trial for rhBMP-2 (40 mg, 2.0 mg/ml) in single level posterolateral fusion have been reported (Dimar J., Spine; 31(22):2534-2539). This subset of the randomized controlled trial (RCT) indicates better fusion rates, equivalent clinical outcomes and no increase in complications with rhBMP-2 versus ICBG. It is important to note that the dose/concentration of rhBMP-2 used in this study (40 mg, 2.0 mg/ml) was significantly greater than the dose/concentration (12 mg. 1.5 mg/ml) in the clinically available Infuse Bone Graft™ product (rhBMP-2/ACS). This raises the question of whether similar fusion rates will be achieved with the product in clinical use, but also affords a test of safety for posterolateral fusion, as complications were not seen with the much higher dose IDE protocol. A second published study from the same IDE trial data reports that the use of rhBMP-2 offsets, at least in part, the adverse effect of cigarette smoking on lumbar fusion rate (Glassman S., Spine; 32(15):1693-1698). The complete IDE trial data set has been presented at national meetings, but is not yet published.

Several case series reports have been published on the use of clinically available Infuse Bone Graft™ (rhBMP-2 12 mg, 1.5 mg/ml) in an off-label posterolateral fusion application. One study examines the combination of rhBMP-2/ACS and ICBG, reporting better fusion rates at two years postoperatively as compared to ICBG alone (Singh K., J Spinal Disord Tech 2006;19(6):416-423). Another study reports on rhBMP-2/ACS in combination with several non-ICBG bone graft extenders, including local bone, demineralized bone matrix and bone bank bone (Glassman S., Spine J 2007; 7:44-49). This study reports fusion rates equal to or better than ICBG in single and multilevel posterolateral fusion cases. Neither study identifies complications related to the use of rhBMP-2/ACS. An additional study examines repeated exposures to rhBMP-2 without evident adverse consequences (Carreon L., Spine 2008; 33(4):391-393). An IDE pilot study comparing rhBMP-2 (12 mg, 1.5 mg/ml) combined with a ceramic bulking agent versus iliac crest bone graft in posterolateral lumbar fusion has been undertaken. It has been presented and is in editorial review (Bae H., Spine J 2007;7:IS-163S).

Most recently, a non-industry sponsored RCT comparing Infuse Bone Graft™ (rhBMP-2/ACS) versus ICBG in patients over 60 years of age has been completed. The study examined clinical outcomes, fusion success, and directly measured economic parameters. Initial perioperative cost data from this RCT demonstrated an increased initial cost for the hospital, but a net savings for the payer over a three month period with the use of rhBMP-2/ACS (Glassman S., Spine J 2008; 8:443-448). The two-year data revealed similar health related quality of life outcomes, but better fusion on CT scan, fewer complications, lower revision rate and lower overall cost in the rhBMP-2/ACS group. This two-year RCT data has been presented, and received the Outstanding Paper Award, at the International Meeting for Advanced Spine Techniques (IMAST) in 2008. The study has been accepted for publication in SPINE, but has not yet reached its publication date. Despite this, the CMS staff may want to consider this data because it so directly addresses the issues raised in the proposed NCD topic question.

The literature assessing rhBMP-7 (OP-1) in posterolateral spine fusion is less robust, but also suggests safety, and probable efficacy, based on an RCT comparing rhBMP-7 and ICBG in single level fusion for degenerative spondylolisthesis (Vaccaro A., Spine 2005; 30:2709-2716). This study resulted in FDA approval of OP-1 putty, through the humanitarian device exemption process, as an alternative to ICBG in compromised patients. An additional small RCT comparing rhBMP-7 and ICBG in instrumented posterolateral fusion revealed equivalent radiographic success, however nonunion was detected at exploration in 4 of 7 patients (Kanayama M., Spine 2006; 31:1067-1074.).

Transforaminal Lumbar Interbody Fusion (TLIF)

A second common off-label application for rhBMP is in Transforaminal Lumbar Interbody Fusion (TLIF). No Level 1 data exists regarding the role of BMP in TLIF surgery. Several case series have been reported with variable findings. Two initial studies reported high fusion rates and minimal complications using rhBMP-2 for open and minimally invasive TLIFs (Schwender J., J Spinal Disord Tech 2005; 18 Suppl:S1-6) (Villavicencio A., J Neurosurg Spine 2005;3(6):436-443). Subsequently, concerns have been raised regarding the risk of heterotopic bone formation associated with the use of rhBMP-2 in TLIF. Conflicting evidence includes a prospective CT analysis which documented asymptomatic heterotopic bone in 20% of cases (Joeseph V., Spine 2007; 32(25):2885-2890.) and a report of five patients seen at a referral center with heterotopic bone and radiculopathy (Wong DA, Spine J 2007; Nov 21. [E-pub ahead of print]). Whether or not the risk for symptomatic heterotopic bone formation is dependent upon surgical technique, rhBMP-2 dose or any other surgical variable, remains undetermined. No data regarding the use of rhBMP-7 in TLIF is available.

Summary

In summary, while the indications for the use of BMPs in spinal surgery in the Medicare population are not fully defined, substantial evidence exists supporting the efficacy and cost effectiveness of BMP in posterolateral fusions compared to ICBG. Posterolateral fusion, in conjunction with decompression for stenosis or deformity correction, in spondylolisthesis, or degenerative scoliosis, is the most common spinal fusion technique performed in the Medicare population. The Professional Society Coalition Lumbar Fusion Task Force believes that it would not be appropriate to exclude the use of BMPs in the Medicare population. We also believe that ongoing additional investigation will contribute to refinements in dose, carriers and site specific applications for these valuable biologic technologies.

> ***CMS Proposed NCD Topic-Lumbar Fusion for Degenerative Disc Disease****:For certain patients, a two level spinal fusion may be an effective treatment for debilitating back pain from two degenerated lumbar discs. Multilevel fusion as a primary treatment for low back pain from degenerated discs is a controversial topic in spine medicine. However, lumbar fusion of three or more levels of the low back as a primary treatment for back pain is rarely recommended, and many surgeons recommend against it in all cases of multilevel degenerative disc disease. Is the evidence adequate to specify groups that do and do not benefit from the lumbar fusion procedure?*

Our primary concern with regard to the proposed NCD topic on multilevel lumbar fusion revolves around the difficulty in clearly defining the population in question. It is agreed that there is no high quality or even consistent lower quality evidence indicating that multilevel (three or more level) fusion is effective as a treatment for isolated back pain without neurological deficit, deformity, or stenosis. Evidence to definitively support or refute the efficacy of such procedures is not likely to be available in a reasonable timeframe because these procedures are uncommonly performed in any patient population. According to MedPar data, a grand total of 688 such procedures were performed in the United States during 2007 (out of approximately 57,000 fusions performed for degenerative disease). Given difficulties with the fidelity of administrative databases, it is likely that the true incidence is even lower due to failure to code for associated diagnoses. Furthermore, when such procedures are performed, they are performed in an elective fashion on younger patients. These are “boutique” procedures that are not performed in the Medicare or Medicaid population. Therefore, the interest of the CMS in multilevel fusion for low back pain is somewhat puzzling.

Answerable questions must be used as the basis for reasoned debate when policy decisions are proposed. For example, at the 2006 MCAC meeting on lumbar fusion, the published MCAC

question, similarly described as fusion for isolated low back pain in the Medicare population, was not able to be addressed. The majority of data reviewed by the speakers, and much of the panel discussion, addressed the utilization of lumbar fusion in completely different patient populations. Nonetheless, the panel was required by procedure to vote on the atypical use of fusion for low back pain in the Medicare population, as this was the specific MCAC question. As there was no evidence relevant to the Medicare or Medicaid population, the panel was forced to conclude that such procedures were not supported by high quality evidence. This conclusion, supported by a draft tech report, has been published and used to inappropriately limit access to lumbar fusion in other populations.

It is also imperative that fusion procedures for isolated low back pain are not confused with multilevel fusion procedures that are performed for the purposes of deformity correction, correction of instability, or following destabilizing decompressive procedures in the elderly. There is substantial evidence indicating that the use of fusion in such situations improves functional outcome. In particular, data from the SPORT study, which has been presented and published since the 2006 MCAC meeting, provides high quality evidence supporting the benefit of lumbar fusion in appropriately selected patients (Weinstein JN, N Engl J Med 2007;356(22):2257-2270). Also, consistent with the CMS call for evidence development surrounding lumbar fusion in the Medicare population (Schafer J, Spine 2007;32(22):2403-2404), several studies examining the role of single and multilevel fusion in older patients have now been published, or are awaiting publication (Glassman SD, Spine J 2007;7(5):547-551) (Okuda S, J Bone Joint Surg Am. 2006;88-A(12):2714-2720) (Glassman SD, Spine J. E-pub 2008) (Bridwell K, SRS 2008) (Ghogowala, Benzel, etc).

The Professional Society Coalition Task Force on Lumbar Fusion would welcome any and all opportunity to discuss the appropriate use of multilevel fusion in the Medicare population. We agree that demonstration of benefit for lumbar fusion, or any surgical intervention, limited to simple cases and idealized populations is not ultimately sufficient to predict value in standard clinical practice. We believe that additional and ongoing evidence development is critical to guide appropriate resource utilization in the Medicare population. It is our assertion that identification of the most specific and relevant question for analysis is critical in order to maximize the utility of the subsequent analysis. We do not believe that the proposed NCD topic on multilevel lumbar fusion meets this standard.

Steven D. Glassman, MD
Co-Chair

Daniel K. Resnick, MD
Co-Chair
Professional Society Coalition Task Force on Lumbar Fusion

UPDATE neurosurgery

FOR IMMEDIATE RELEASE
December 2, 2008

Contact: Katie Orrico, Director
American Association of Neurological Surgeons/
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Washington Office
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Neurosurgeons Raise Concerns about Institute of Medicine Resident Work Hour Report

Further Restrictions in Work Hours Will Jeopardize Quality Resident Training and Patient Safety

WASHINGTON, DC – The American Association of Neurological Surgeons (AANS), American Board of Neurological Surgery (ABNS), Congress of Neurological Surgeons (CNS) and Society of Neurological Surgeons (Senior Society), registered serious concerns about the Institute of Medicine's (IOM's) recommendations to further restrict resident work hours and urged the Accreditation Council for Graduate Medical Education (ACGME) to conduct additional research on the current work hour rules before making any changes to the existing policy.

Neurosurgeons, worried about resident fatigue, embraced the current ACGME rules that were implemented in 2003, and have substantially modified the way residents are trained. However, organized neurosurgery is nevertheless concerned that further restrictions in duty hours have the potential to significantly harm patients and increase healthcare costs.

"The IOM committee, in making these recommendations, has failed to adequately consider the key patient safety issues – the considerable risks associated with too many patient handoffs and lack of continuity of care in complex neurosurgical disease or injury cases," remarked AANS President James R. Bean, MD.

H. Hunt Batjer, MD, Marchese Professor and Chair, Department of Neurological Surgery, Northwestern University Feinberg School of Medicine and immediate past chairman of the ABNS, echoed these sentiments by noting that risky patient handoffs have proven to cause medical errors. "Furthermore, patients expect *their* surgeons to take care of them and additional restrictions in duty hours, such as limiting each shift to 16 hours, will erode this fundamental tenet of the doctor-patient relationship." Dr. Batjer went on to warn that, "Patients should be troubled by the prospects of the handoff revolving door."

Additional restrictions in resident work hours will also create a new generation of surgeons with reduced surgical experience and expertise due to less exposure to complex surgical cases and direct patient care. "Unless the residency training period is extended considerably, residents in neurosurgery will receive 25 to 50 percent less training than residents received prior to 2003," stated M. Sean Grady, MD, Charles Harrison Frazier Professor and Chairman, Department of Neurosurgery, University of Pennsylvania and current ABNS chairman. "One could reasonably ask whether any patient would choose to be treated by a neurosurgeon who receives half the training of today's practitioners."

Neurosurgical training is among the lengthiest, requiring a minimum of six years after medical school, and requires residents to master the most complex system in the human body. Neurosurgical residents must acquire extensive knowledge and experience in treating patients with neurosurgical disorders and must develop the judgment and ability to accumulate significant technical experience to perform many demanding operative procedures. Neurosurgical practice is unlike virtually any other physician specialty as neurosurgical procedures are long,

-- MORE --

typically lasting between 4 and 18 hours, and neurosurgeons treat critically ill patients, who often come to the hospital on an urgent or emergency basis.

The IOM committee charged with conducting this study appears to have largely disregarded the recommendations of leaders in medical education, including the ABNS, Senior Society, ACGME, American Board of Medical Specialties (ABMS) and the Association of American Medical Colleges (AAMC). These groups uniformly recommended that the evidence does not support any further restrictions in work hours until additional research is conducted. These organizations also stressed that a single set of work hour rules may not be appropriate given the differences among specialties (medical vs. surgical) and the year of training (first year vs. chief resident).

"Given that the IOM Committee did not include a single practicing representative from a surgical discipline, we are not entirely surprised by the recommendations in this report," noted Robert E. Harbaugh, MD, FACS, FAHA, University Distinguished Professor and Chair, Department of Neurosurgery, Penn State University, M.S. Hershey Medical Center. "It is shockingly simplistic to apply a one-size-fits-all approach to residency training, and the IOM Report appears to gloss over the significant differences among the various specialties which make certain per shift and other duty hour restrictions feasible in some training programs but not others."

As noted in the report, the IOM's recommendations, if implemented, will significantly increase graduate medical education and healthcare delivery costs as hospitals will need to increase the numbers of faculty and mid-level practitioners and lengthen residency training so that residents gain the requisite experience to practice safely. Dr. Batjer predicted that the financial impact would be significant, and for many facilities untenable in this age of declining reimbursement and budget constraints. He went on to note, "We may also need to lengthen residency training, which will significantly delay neurosurgical residents' entry into the workforce. There are only approximately 3,300 actively practicing neurosurgeons serving over 5,000 hospitals in the United States and any further restrictions on neurosurgical workforce will certainly reduce patient access to neurosurgical care."

*The **American Association of Neurological Surgeons** (AANS), founded in 1931, and the **Congress of Neurological Surgeons** (CNS), founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. These groups represent approximately 7,400 neurosurgeons worldwide. The **Society of Neurological Surgeons** (the "Senior Society") is the American society of leaders in neurosurgical residency education, and is the oldest neurosurgical society in the world. Academic department chairman, residency program directors, and other key individuals comprise the active membership of the Society. The **American Board of Neurological Surgery** (ABNS) is the nationally recognized certifying agency for the specialty of neurosurgery and one of the 24 member boards of the American Board of Medical Specialties. The ABNS is responsible for establishing training standards that must be met and for conducting written and oral examinations that must be passed in order to become board certified neurosurgeons. As such it is active in the training and certification of young neurosurgeons, as well as the maintenance of certification.*

Neurological surgery is the medical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the entire nervous system, including the spinal column, spinal cord, brain and peripheral nerves.

-- END --

January 30, 2009

Leah Hole-Curry, JD
Program Director
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

SUBJ: Inquiry Regarding Draft Artificial Disc Replacement Findings and Coverage Decision

Dear Ms. Hole-Curry,

The Multisociety Spine Work Group is writing in regard to the Washington State Health Care Authority Health Technology Assessment Clinical Committee's draft Findings and Coverage Decision for artificial disc replacement. Specifically, the Work Group is seeking clarification regarding the limitations of coverage listed in the 12-11-08 draft findings.

It has come to the Work Group's attention that one of the artificial disc replacement limitations of coverage identified in the document stipulates that "patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency." Upon learning of this limitation contained in the document, the Work Group consulted with several physicians present at the October 17 meeting. These physician attendees have no recollection of a discussion during the meeting regarding the inclusion of such a requirement. To that end, the Work Group is inquiring whether this requirement was inadvertently included due to the fact that both lumbar and cervical ADR were assessed concurrently. While this limitation was included in the lumbar fusion decision and is appropriate for lumbar ADR, a structured pain program for cervical artificial disc replacement would be medically contraindicated given the nature of cervical disc herniation and radiculopathy/myelopathy and is also not supported by the current medical literature.

While we recognize that this inquiry comes after the allotted time for public comment, the extended holiday time and the January 2 comment date did not allow for a thorough vetting by all members who participated in the hearing. The Multisociety Spine Work Group would appreciate the Washington State Health Care Authority's consideration of this inquiry and clarification of the inclusion of this limitation prior to the final coverage policy of artificial disc replacement.

Sincerely,

James R. Bean, MD
American Association of Neurological Surgeons

P. David Adelson, MD
Congress of Neurological Surgeons

Charles Branch, MD
North American Spine Society

Oheneba Boachie-Adjei, MD
Scoliosis Research Society

Karin Büttner-Janz, MD, PhD
Spine Arthroplasty Society

cc. Denise Santoyo

Physician-Industry Cooperation In The Medical Device Industry

When physician-inventors team up with industry, is it collaborative innovation or conflict of interest?

by Aaron K. Chatterji, Kira R. Fabrizio, Will Mitchell, and Kevin A. Schulman

ABSTRACT: Anecdotal evidence suggests that innovative medical devices often arise from physicians' inventive activity, but no studies have documented the extent of such physician-engaged innovation. This paper uses patent data and the American Medical Association Physician Masterfile to provide evidence that physicians contribute to medical device innovation, accounting for almost 20 percent of approximately 26,000 medical device patents filed in the United States during 1990–1996. Moreover, two measures indicate that physician patents had more influence on subsequent inventive activity than nonphysician patents. This finding supports the maintenance of an open environment for physician-industry collaboration in the medical device discovery process. [*Health Affairs* 27, no. 6 (2008): 1532–1543; 10.1377/hlthaff.27.6.1532]

THERE IS CONSIDERABLE CONTROVERSY over relationships between medical device companies and practicing physicians. Media outlets have recently highlighted conflicts of interest that can arise from close collaboration between physicians and medical device companies.[1] In particular, concerns have been raised about physicians' financial conflicts of interest in recruiting patients to clinical trials and in reporting results of clinical testing to the medical community.[2] Critics worry that payments by medical device companies to practicing physicians will influence their decisions about which devices to use and how to document patient outcomes and, in turn, will compromise patients' welfare.

By contrast, device firms and physicians that work with them argue that the corporate relationships are essential to device innovation. In this view, physicians provide essential knowledge of technology and medical practice that become in-

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corporated into new devices. Involvement in activities such as clinical trials and testing is one of the means by which physicians can both learn about new technology and pass information about technology to commercializing companies.

This debate requires data concerning the extent to which physician-industry collaboration contributes to technology invention and development. Anecdotal evidence suggests that physicians often play key innovative roles in medical devices.[3] However, little systematic evidence exists. If, in fact, physicians rarely contribute to device innovation, then policymakers may want to create strict barriers to physician-industry interaction to limit conflicts of interest. Alternatively, if physician-led invention is common, then an approach that supports physician-industry interaction while mitigating concerns about conflicts of interest may be required. This paper helps document the role of physicians in the medical device discovery process.

Managing Medical Device Innovation

The medical device sector is highly research-intensive. Medical device companies spend about 9–11 percent of sales on research and development (R&D), second only to the pharmaceutical sector and four times the average for the manufacturing sector as a whole.[4] Small companies in this industry (those with less than $5 million in revenue), including many start-ups and highly innovative firms, spend 343 percent of revenue on R&D, on average.[5] The leading medical device companies derive the majority of their revenues from products that are less than two years old, as a result of competition from fast imitators.[6] The life cycle for new products in the medical device industry lasts about eighteen months, making new product innovations crucial for firms.[7] Their key challenge is to conceive new ideas, anticipate market demand, manage product development, gain regulatory approval, and encourage adoption of new technologies and new generations of existing technologies.

■ **Physicians' contribution to the invention process.** Firms that develop strategies to detect and acquire knowledge residing outside the firm have the most success in maintaining their innovative edge.[8] In the medical device industry, practicing doctors represent an important source of external knowledge regarding unmet needs, customers' preferences, and potential opportunities for either refining existing products or creating novel products that would be well received by other doctors and medical professionals.[9]

Physicians may contribute directly to the innovation process by inventing medical devices themselves. This kind of "user innovation" has been documented in diverse settings such as scientific instruments, snowboards, and software.[10] In the device industry, famed physician-inventors such as Thomas Fogarty have patented numerous inventions and founded multiple companies. Doctors often have the best knowledge about unmet clinical needs and the clearest sense of the most feasible solution to a particular problem, which provides unique insights about mar-

ket needs, product modifications, and new products. Doctors' knowledge is derived from using the device—they know what is problematic, which improvements are most critical, and which solutions are preferable from the perspective of the end user. The depth of this knowledge is based on the experiences of the doctor and may be difficult to convey to industry researchers without the benefit of close communication and a relationship that develops trust.

■ **Physicians' manufacturing and marketing functions.** Physicians who invent new devices or modify existing devices typically do not manufacture and market the devices themselves.[11] Although there are some examples of physician-inventors who became entrepreneurs and started their own companies to bring their inventions to market, most physicians focus on their job as doctors and lack the business and regulatory knowledge required to manufacture and market a device. Instead, most physicians with innovative medical device ideas transfer their ideas to medical device companies, often after patenting an invention that they then license for development, approval, and marketing. Such licenses often involve continuing engagement with the company, so that the physician's knowledge can continue to help shape the development of the new technology.

A Snapshot Of Physician Innovation

■ **Data sources.** To evaluate the role of physician-inventors in the medical device industry, we used data from the American Medical Association (AMA) Physician Masterfile and the National Bureau of Economic Research (NBER) patent database.[12] Bringing these data sets together, we used an algorithm to match the names of doctors in the AMA data to inventors' names in the patent data, using city and state location information from both files to eliminate potential false matches.[13] This approach allowed us to identify which medical device patents had at least one inventor who was a licensed physician.[14]

The average number of inventors on medical device patents in our sample was 1.98, so the presence of one doctor represents a major contributor to the invention.[15] Note that inventor status on a patent involves legal rights and responsibilities and determines ownership of the patent. Incorrect attribution of patent inventorship may invalidate a patent.[16] Thus, inventorship is likely to represent the actual contributions of inventors to the invention.

Of course, this approach provides only a partial picture of physicians' involvement in device innovation. Many innovations are not patented and so will not appear in the data. Nonetheless, the patenting records provide a meaningful assessment of physician innovation.

■ **Measuring the extent of physician innovation.** To explore the role of physicians' innovation in this context, we sought to answer two questions. First, what is the extent of this innovation in the medical device industry, as measured by patent counts? Second, what is its relative importance? We would have liked to examine the corresponding sales of medical devices invented by doctors, but there is no reli-

"Evidence suggests that doctors are important sources of device innovation and is consistent with other studies of user innovations."

able way to match patents to commercialized products. Instead, we focused on the degree to which later inventions referenced a particular invention as a measure of the focal invention's importance in the stream of technological developments, which in turn will affect both corporate sales and patient welfare.

■ **Measuring the impact of physician innovation.** We used two measures of impact. One measure of the importance of a patented innovation involves counting the number of citations it receives in subsequent patents.[17] Much like an influential academic paper, important patents will generate follow-on inventions. These follow-on inventions are legally required to cite patented prior art on which they are based. Being cited by a large number of follow-on inventions indicates that the original invention has been influential in a large number of technological advances. Consistent with this interpretation of patent citations, for example, Manuel Trajtenberg found that the number of citations received was closely associated with independent measures of the social value of computed tomographic (CT) scanner inventions.[18] Researchers often compare the number of citations received by two patents to evaluate which has been more influential.

A second way to measure the impact of a patented invention is to consider the breadth of technological space that it influences. Patents that influence follow-on technologies across a more diverse set of areas have a broader impact. We captured the breadth of citations received with a generality score developed by Trajtenberg and colleagues.[19] The higher the generality score, the more diverse the range of technologies that build upon the original patent.[20]

To accurately measure both aspects of invention impact, we needed a sampling frame that would allow us to observe a reasonable time period after the technology was patented and during which the follow-on citations could occur. We examined patents granted between 1990 and 1996 to provide an appropriate "post-patent" period (until 2002) over which to assess the impact of the patents.

■ **Number of doctors holding patents.** There were 26,158 patents granted in the nineteen medical device patent classes identified by the U.S. Patent and Trademark Office from 1990 through 1996, which collectively received more than 344,000 citations. Of these medical device patents, 5,051 (19.3 percent) had at least one inventor who was a licensed physician. Hence, nearly one in five of the patented inventions in this field were invented by doctors or with the participation of doctors. Since the patent application process is costly in terms of both time and money, this figure does not include the products of "tinkering" by doctors that never result in patented inventions but do affect medical practice.

These results are the first large-sample evidence of the extent of physician innovation in the medical device industry. This evidence strongly suggests that doctors

are important sources of device innovation and is consistent with other studies of user innovations. For example, Eric von Hippel and colleagues found that 20–80 percent of important innovations in scientific instruments, software, and sports equipment are generated by users.[21] However, in a tightly regulated, R&D-intensive industry such as medical devices, we were surprised to find that users accounted for such a high percentage of innovations.

■ **Employment of physician inventors.** Consistent with the idea that physician-inventors are often practicing physicians, almost 60 percent of physician-inventors with identified affiliations worked either in a group practice, two-physician practice, or solo practice (Exhibit 1). In addition, sizable portions work in more complex institutional settings that include medical practice, including medical schools, nongovernment hospitals, and a range of other hospital venues. The core point is that practicing physicians in a wide range of U.S. medical settings commonly engage in medical device inventive activity.

■ **Patenting activity by physician specialty.** Physicians from seven specialties generated more than 50 percent of the patents: orthopedic surgeons, general surgeons , and cardiologists make up the largest share of the inventions, followed by anesthesiologists, internists, ophthalmologists, and diagnostic radiologists (Exhibit 2). Although these areas clearly represent much of the inventive activity, there is considerable dispersion of inventive activity across many specialties. These differences likely reflect the size of the fields, the number of unmet clinical needs, and the

EXHIBIT 1
Primary Employment For Physician-Inventors Of Medical Devices, 1990–1996

Employment setting	Percent of sample
Group practice	31
Two-physician practice	4
Self-employed solo practice	24
Medical school	8
Nongovernment hospital	8
Other non–patient care	3
City/county/state hospital	2
Federal government hospital (veterans)	1
Other patient care	1
HMO	0.3
Federal government hospital (U.S. PHS)	0.3
City/county/state other	0.2
Federal government hospital (Army)	0.2
Federal government hospital (Navy)	0.1
No classification	16
All other	<1.0

SOURCE: Authors' calculation.
NOTES: HMO is health maintenance organization. PHS is Public Health Service.

EXHIBIT 2
Specialties Of Physician-Inventors, 1990–1996 Medical Device Inventions

Specialty	Number of patents	Percent physician patents	Cumulative percentage
Orthopedic surgery	587	11.6	11.6
General surgery	487	9.6	21.2
Cardiovascular disease	481	9.5	30.7
Anesthesiology	322	6.4	37.1
Internal medicine	284	5.6	42.7
Ophthalmology	278	5.5	48.2
Diagnostic radiology	230	4.6	52.8
Family medicine	153	3.0	55.8
Plastic surgery	141	2.8	58.6
Gastroenterology	120	2.4	61.0
Emergency medicine	113	2.2	63.2
Urology	116	2.3	65.5
Obstetrics/gynecology	110	2.2	67.7
Neurological surgery	107	2.1	69.8
Vascular surgery	107	2.1	71.9
Thoracic surgery	101	2.0	73.9
Otolaryngology	83	1.6	75.5
Other specialty	76	1.5	77.0
Unspecified	73	1.5	78.5
Dermatology	61	1.2	79.7
General practice	59	1.2	80.9
Psychiatry	56	1.1	82.0
Pediatrics	57	1.1	83.1
Gynecology	56	1.1	84.2
Hand surgery	51	1.0	85.2
Pulmonary diseases	48	1.0	86.2
Radiology	48	1.0	87.2
Neurology	41	0.8	88.0
Anatomic/clinical pathology	34	0.7	88.7

SOURCE: Authors' calculation.

NOTES: The exhibit reports sources of 4,480 of the 5,051 doctor patents (88.7 percent of the total); in the interest of space, we omitted specialties with less than 0.7 percent of the total. "Percent physician patents" is the percentage of all physician-invented patents in the sample that fall into each specialty category.

technological opportunities in these specialties.

■ **Patents' importance.** Based on a comparison of the mean number of citations received and the generality of these citations, we found that physician patents both received more citations (15.2 versus 12.7) and had higher generality scores (0.41 versus 0.39) than corporate inventions, with both differences statistically significant at better than the 1 percent level (Exhibit 3).[22] In addition, comparing the mean number of citations from follow-on inventions that were developed by corporations indicates that doctors also received more citations from follow-on industry-generated inventions (12.5 versus 10.5).[23]

EXHIBIT 3
Sample Summary Statistics For Physician And Nonphysician Medical Device Inventions: Means And Test For Difference Of Means

Variable	Full sample	Physician inventions	Nonphysician inventions	Difference (physician: nonphysician)
Number of cites received	13.16	15.23	12.66	2.57***
Number of industry cites received	10.88	12.55	10.47	2.07***
Generality of citations received[a]	0.39	0.41	0.39	0.02***

SOURCE: Authors' calculation.

NOTES: The means of generality for the full sample and nonphysician subsample appear the same because of rounding. N = 26,158 (full sample); n = 5,051 (physician); n = 21,007 (nonphysician).

[a] The higher the generality score, the more diverse the technologies that have built upon the original patent.

***$p < 0.01$

Discussion

Our results provide evidence that physicians play an important role in the medical device innovation process. Physicians contributed to almost 20 percent of the patents in this sample of more than 26,000 patents. Furthermore, physician patents were more highly cited by subsequent patents than nonphysician patents and had higher generality scores representing the breadth of the invention. The main conclusion is that doctor innovations in the medical device industry are important for device innovation in the United States.[24]

■ **Quantifying the value of impact.** It is useful to place the impact results into context. What does an additional citation really signify? Attempts to quantify the value of important inventions, as represented by the number of citations received, provides some indication of the magnitude of our results. In analyses of the relationship between the average number of citations received by a firm's patents and the firm's market value, Bronwyn Hall and colleagues found that one additional citation increased the firm's market value by more than 3 percent.[25] This is consistent with the "million dollar" value per citation suggested by Dietmar Harhoff and colleagues as well as findings in other studies of patent indicators.[26] These findings suggest that a difference of even one citation indicates much difference between inventions. Our findings suggest that physician-generated inventions receive on average 2.5 more citations than other medical device inventions—a major difference in the value of these inventions.

■ **Study limitations.** There are several limitations to this analysis. First, although we constructed a rigorous matching algorithm based on geographic characteristics common to our physician and invention data sets to identify physician-inventors of patents, we could not ensure that the match was fully accurate, especially for common names. Second, our measures of impact of physicians' invention are indirect measures, because we could not be sure which patents were incorporated into mar-

keted products. Finally, it is impossible to know from the patent data if and when patents were licensed. Therefore, we could not evaluate the frequency or performance of physician inventions licensed by medical device companies. Nonetheless, the results provide robust evidence that physicians are active medical device patenters and that their patents are common components of subsequent innovations.

Policy Implications And Recommendations

Patients benefit from progress in medical science through the creation of innovative goods and services that bring advances to the clinical realm. Medical devices are one class of products that can accomplish this goal. The life cycle of device innovation, as for other new products, involves three steps: discovery, development, and dissemination. This study provides evidence that physicians are deeply engaged in the discovery stage, where patenting is most common. Indeed, the results undoubtedly understate physicians' engagement in discovery, because many novel ideas are not patented. The Bayh-Dole Act was enacted in part to stimulate this process by encouraging research in academic settings.[27]

Physicians' engagement in device invention includes both academic and, more frequently, nonacademic settings. Frankly, we were surprised by the degree of innovation among physicians in nonacademic settings. This innovation seems to occur without many of the support structures and incentives available in academic settings. Although this finding merits further research to characterize this innovation, our findings suggest that physicians' involvement in medical device innovation goes well beyond traditional research settings.

■ **Support physician-led discovery outside academe.** One policy recommendation, therefore, is to create initiatives that support physician-led discovery outside traditional academic settings. Such initiatives could include small-scale seed funding for inventive projects in clinical practices and nonteaching hospitals or expanded support for physician-inventors bringing ideas through the "valley of death" between discovery and commercialization. These initiatives, which could be managed by the National Institutes of Health or other institutions, could yield sizable payoffs by expanding the scope of traditional settings for device innovation.

■ **Facilitate physicians' knowledge transfer.** The study also has implications beyond the discovery stage. The literature on the management of innovation has long demonstrated the value of connecting people who are engaged in discovery to subsequent steps of development and dissemination to facilitate knowledge transfer throughout the innovation cycle.[28] By inference, therefore, this study suggests that there are benefits to allowing and encouraging physicians to engage in development and dissemination, which typically involves collaboration with commercializing firms, to facilitate innovative activity that will benefit patients. Some of these commercial collaborations will involve the patenting physicians, and others will involve other physicians with insights that contribute to effective development and usage. In either case, physicians' insights about inventive opportunities often make key

"Policies need to maintain the benefits of facilitating physician innovation while limiting the potential for conflicts of interests."

contributions to commercialization of successful medical device innovations.

■ **Limit potential conflicts of interest.** Nonetheless, with opportunities for physicians to engage in innovation come potential conflicts of interest that can harm patients' welfare by biasing physicians' decisions.[29] That is, the paradigm of advancing science and patient welfare through physician-engaged product innovation raises the potential for conflicts of interest on the part of physicians, their institutions, and their industry sponsors.

Avoid absolute barriers to physician-industry collaboration. One approach to limiting conflicts of interest would be to create barriers to collaboration among physicians and corporations in activities such as product testing and clinical trials. However, by extension, our study suggests that strict limits on collaboration would inhibit the flow of ideas from physician-led discovery through development and into medical practice.

Thus, a second policy implication of the study is that regulations should avoid absolute barriers to physicians' engagement in corporate development activities. Instead, policies should take a more nuanced approach to managing potential conflicts of interest. That is, public policies need to maintain the benefits of facilitating physician innovation while limiting the potential for conflicts of interests on the part of physicians and industry. Industry also needs to be supported in its commitment to continue to engage physicians in these efforts.

Increase the scope of congressional transparency requirements. Bias arising from conflicts of interest will be most pronounced when there is a lack of transparency about the roles that physicians play in a given stage of the innovation cycle. The lack of transparency has been highlighted by reports in the lay and medical press illustrating examples of physicians' serving multiple roles in this process without informing others.[30] Hence, a key element of public policy is to ensure reliable transparency of relationships between physicians and corporate sponsors.

Congress is considering legislation to assure the public of transparency in physicians' relationships with industry. Several proposals for "sunshine" laws would require disclosure of financial relationships between physicians and product manufacturers. These requirements would augment existing financial disclosure requirements that exist in continuing medical education, publication in the peer-reviewed literature, and clinical investigation.[31]

Our findings suggest that physicians are active in medical device innovation as early as the discovery stage. In turn, transparency should apply from the beginning of the innovative life cycle. Hence, a third policy implication of the study is that sunshine requirements should apply to physicians' engagement in commercial activity at the discovery stage, as well as at subsequent development and dis-

semination stages.

Mandate audit mechanisms for financial transparency. Finally, for such disclosure requirements to be effective at any stage of the innovation life cycle, there will need to be audit mechanisms that compare disclosures with company data and highlight discrepancies between physicians and industry (of course, legitimate differences may exist between these sources based on differences in accounting and reporting methods adopted by all parties). To ensure that these provisions include private firms that could have sizable physician investment, the sunshine provisions should relate to all firms that have products approved for marketing by the U.S. Food and Drug Administration or for which there is a provision for payment under Medicare or Medicaid.

EMPIRICAL EVIDENCE SUPPORTS the proposition that physicians are important contributors to medical device innovation. This evidence supports the need to foster the role of physicians in technology discovery and to be mindful of this role as policymakers consider conflict-of-interest policies that affect collaboration between physicians and corporations. An R&D climate that fosters physicians' participation in the discovery process may produce more and better medical devices than a climate that discourages physicians from participating. The public would benefit, however, from efforts to promote reliable transparency in physician-corporate relationships throughout the innovation life cycle.

Kevin Schulman has made available a detailed listing of financial disclosures; it is available online at http://content.healthaffairs.org/cgi/content/full/27/6/1532/DC1.

NOTES

1. R. Abelson, "Financial Ties Are Cited as Issue in Spine Study," *New York Times,* 30 January 2008.
2. Dennis Thompson describes a medical conflict of interest as "a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)." D.F. Thompson, "Understanding Financial Conflicts of Interest," *New England Journal of Medicine* 329, no. 8 (1993): 573–576.
3. E.B. Roberts, "Technological Innovation and Medical Devices," in *New Medical Devices: Invention, Development, and Use*, ed. K.B. Ekelman (Washington: National Academies Press, 1988), 35–51.
4. AdvaMed, *The Medical Technology Industry at a Glance, 2004*, http://www.advamed.org/NR/rdonlyres/0A261055-827C-4CC6-80B6-CC2D8FA04A33/0/ChartbookSept2004.pdf (accessed 1 August 2008); and Centers for Medicare and Medicaid Services, "Health Care Industry Market Update: Medical Devices and Supplies," 5 December 2003, http://www.cms.hhs.gov/CapMarketUpdates/Downloads/hcimu120503.pdf (accessed 1 August 2008).
5. AdvaMed, *The Medical Technology Industry at a Glance.*
6. E.A. Halm and A.C. Gelijns, "An Introduction to the Changing Economics of Technological Innovation in Medicine," in *The Changing Economics of Medical Technology,* ed. A.C. Gelijns and E.A. Halm (Washington: National Academies Press, 1991), 1–18.
7. S. Bell, "Investing in Tomorrow: Gaining a Competitive Edge in Outsourcing Your R&D," *Medical Product Outsourcing,* Jan/Feb 2006, http://www.mpo-mag.com/articles/2006/01/investing-in-tomorrow (accessed 17 September 2008).
8. I. Cockburn and R. Henderson, "Absorptive Capacity, Coauthoring Behavior, and the Organization of Research in Drug Discovery," *Journal of Industrial Economics* 46, no. 2 (1998): 157–182; and W.M. Cohen and D.A.

Levinthal, "Absorptive Capacity: A New Perspective on Learning and Innovation," *Administrative Science Quarterly* 35, no. 1 (1990): 128–152.

9. Studies have long documented the role of physicians in medical product use and diffusion. See, for instance, J.S. Coleman, E. Katz, and H. Menzel, *Medical Innovation: A Diffusion Study* (Indianapolis: Bobbs-Merrill Co., 1966); and Roberts, "Technological Innovation and Medical Devices."
10. E. von Hippel, "The Dominant Role of Users in the Scientific Instrument Innovation Process," *Research Policy* 5, no. 3 (1976): 212–239; E. von Hippel, "Lead Users: A Source of Novel Product Concepts," *Management Science* 32, no. 7 (1986): 791–805; and E. von Hippel, "Economics of Product Development by Users: The Impact of 'Sticky' Local Information," *Management Science* 44, no. 5 (1998): 629–644.
11. J.S. Grossman, *Innovative Doctoring: Solutions Lie within Us* (Self-published, 2006).
12. We focus on the nineteen U.S. Patent and Trademark Office (USPTO) classes that contain medical device innovations, as determined by the USPTO.
13. For further details on the matching process, see A.K. Chatterji and K. Fabrizio, "Professional Users as a Source of Innovation: Physician Innovation in the Medical Device Industry" (Working Paper, Duke University, Durham, North Carolina, 2008).
14. Inventor status on a patent confers an individual with a legal right to exclude others from use. See B.H. Hall and R.H. Ziedonis, "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–95," *RAND Journal of Economics* 32, no. 1 (2001): 101–128; and A. Mossoff, "Rethinking the Development of Patents: An Intellectual History, 1550–1880," *Hastings Law Journal* 52 (2001): 1255–1322. Therefore, patent inventors are not added superfluously.
15. The number of inventors on inventions including at least one physician range from one to twelve. The number of inventors on other patents in the sample range from one to twenty. Of the physician patents, 43 percent include only the physician as a solo inventor, 27 percent include the physician and one other inventor, and 16 percent include three inventors. The great majority (88 percent) of inventions with a physician-inventor include only one physician-inventor, while an additional 9 percent include two physicians, and less than 3 percent include more than two physicians. We examined the possibility that physicians' solo-invented patents might look quite different from those inventions with a physician as part of an inventing team. Controlling for the effect of having at least one physician-inventor on a patent, results suggest no additional difference in the number of citations received (importance) or number of industry citations received for patents on which the physician is a solo inventor or for patents that contain multiple inventors who are all physicians.
16. D.S. Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement* (New York: Bender, 2002), sec. 22.03.
17. This measure of importance has been used numerous times in the economics of innovation literature and has been shown to be positively related to market value. See B.H. Hall, A. Jaffe, and M. Trajtenberg, "Market Value and Patent Citations," *RAND Journal of Economics* 36, no. 1 (2005): 16–38.
18. M. Trajtenberg, "A Penny for Your Quotes: Patent Citations and the Value of Innovations," *RAND Journal of Economics* 21, no. 1 (1990): 172.
19. M. Trajtenberg, R. Henderson, and A. Jaffe, "University versus Corporate Patents: A Window on the Basicness of Invention," *Economics of Innovation and New Technology* 5, no. 1 (1997): 19–50.
20. For further details on how the generality score is calculated, see Chatterji and Fabrizio, "Professional Users as a Source of Innovation."
21. E. von Hippel, *The Sources of Innovation* (Oxford: Oxford University Press, 1988). The measure of innovation differs across studies, including patents, products, and major contributions.
22. Additional analysis found that the differences between physician patents and nonphysician patents are most dramatic among the most highly cited patents. We confirmed these results using regression analysis controlling for year and other patent characteristics, which the authors can provide on request. Send e-mail to ronnie@duke.edu. Chatterji and Fabrizio, "Professional Users as a Source of Innovation," provides further detail concerning these data.
23. In any such comparison, the noted differences might be partly driven by selection. In our context, differing costs (real or opportunity costs) may generate differing hurdles of expected value of the invention that must be overcome to pursue a patent. If, as a result, physicians have a different propensity to patent their inventions relative to corporations or other individual inventors, then the sets of patented inventions might not be truly comparable. We examined this possible bias in two ways. First, we compared inventions with physician-inventors that were assigned to corporations with other corporate-assigned patents,

and similarly compared noncorporate physician and nonphysician patents. That comparison yielded results very similar to those reported here. Second, we made use of the "primary employment" data for the physician-inventors to examine whether or not physicians who we would expect to incur greater (opportunity and real) costs when pursuing a patent application demonstrate the expected bias in the outcome variables. We did not find such a pattern. These robustness tests give us confidence that the basic differences that we found between physician-generated inventions and other inventions are not driven by selection bias generated by a difference in opportunity costs.

24. It might also be useful to link medical device patents to Food and Drug Administration (FDA)–approved products to provide another view of the importance of physicians in the product development process, but there is no systemic documentation of which patents apply to which medical device products.
25. Hall et al., "Market Value and Patent Citations."
26. D. Harhoff et al., "Citation Frequency and the Value of Patented Inventions," *Review of Economics and Statistics* 81, no. 3 (1999): 511–515.
27. *Bayh-Dole Act*, PL 96-517, codified at 35 U.S. Code, secs. 200–212. See also W. Mitchell, "Using Academic Technology: Transfer Methods and Licensing Incidence in the Commercialization of American Diagnostic Imaging Equipment Research, 1954–1988," *Research Policy* 20, no. 20 (1991): 203–216.
28. J. Jewkes, D. Sawers, and R. Stillerman, *The Sources of Invention* (London: MacMillan, 1958); C. Freeman, *The Economics of Industrial Innovation* (Harmondsworth, U.K.: Penguin, 1974); and C. Varmazis, "Ausiello: More Academy-Industry Collaboration Needed," 28 July 2008, http://www.bio-itworld.com/ecliniqua/2008/07/28/ausiello-dia-keynote.html (accessed 1 August 2008).
29. J.S. Klein, "Stark Laws: Conquering Physician Conflicts of Interest?" *Georgetown Law Journal* 87, no. 2 (1998): 499–529.
30. K.P. Weinfurt et al., "Consistency of Financial Interest Disclosures in the Biomedical Literature: The Case of Coronary Stents," *PLoS ONE* 3, no. 5 (2008): e2128.
31. Regarding continuing medical education, see Accreditation Council for Continuing Medical Education, "ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities," http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (accessed 1 August 2008). Regarding peer-reviewed literature, see International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication," October 2007, http://www.icmje.org (accessed 1 August 2008). Regarding clinical investigation, see U.S. Food and Drug Administration, "Guidance: Financial Disclosure by Clinical Investigators," 20 March 2001, http://www.fda.gov/oc/guidance/financialdis.html (accessed 1 August 2008).

Subject: Physician-Industry Conflicts
Date: Monday, November 24, 2008 8:47 AM
From: Katie O. Orrico <korrico@neurosurgery.org>

TO: AANS EC, CNS EC, Spine Section Leaders, Drugs and Devices Committee

See attached article from the November-December, 2008 Issue of the Journal *Health Affairs*, entitled "Physician-Industry Cooperation in the Medical Device Industry." The article takes a positive position on the direct involvement of physicians in developing medical devices. It recommends some very modest approaches to dealing with the conflict of interest issue.

See also below an article from the *BNA Health Care Daily,* November 21, 2008, noting that Medtronic is facing another Department of Justice investigation for possible off-label promotion of Infuse.

Katie

Government Investigating Medtronic For Off-Label Promotions, Company Says

Medtronic Inc.'s Chairman and Chief Executive Officer Bill Hawkins revealed in Nov. 18 earnings call that the medical device company is under investigation by the Department of Justice for possible off-label promotion of its Infuse biologic product.

In addressing investors and the media, Hawkins said the company recently received a DOJ subpoena looking into off-label use of Infuse. "For years, Medtronic has had strict guidelines in place on appropriate promotion of products according to labeled indications," he noted. Hawkins also said the company is complying with DOJ's request.

Hawkins added that the company is working to minimize the impact of the subpoena and other external factors that affected its biologics division in the second quarter of FY 2009, including a Food and Drug Administration public health notice about the cervical use of bone morphogenic protein, several negative press stories, and a recent whistleblower lawsuit filed against several spine surgeons.

Steps the company is taking, he said, include:
• marketing two recently approved smaller kit sizes of Infuse for use in oral maxillofacial indications;
• exploring alternate distribution channels to accelerate growth in other areas;
• investing in the company's global infrastructure to fuel international growth; and
• advancing clinical trials designed to expand indications for Infuse to postero-lateral,

cervical, and multiple level infusions.

Questions Raised by Others.

Infuse, a bone graft replacement technique that uses a protein to replace bone, recently was singled out by Sen. Chuck Grassley (R-Iowa) in a recent letter in which he pressed Medtronic for information about the company's consulting agreements with physicians, including whether Medtronic intends to make the information public (193 HCDR, 10/6/08 <http://news.bna.com/hdln/display/link_res.adp?fedfid=11032931&fname=a0b7e2x5n7&vname=hcenotallissues>).

In the letter, Grassley asked the company to provide the names of all doctors with whom Medtronic has consulting agreements for the Infuse product, as well as copies of all consulting agreements and the total amount of the payments.

The Grassley letter also asked Medtronic for information on a list of all adverse events involving the unapproved or off-label use of the Infuse product. Grassley asked for responses from the company by Oct. 14.

In July, the Food and Drug Administration said, in response to serious adverse events related to the off-label use of these bone growth products for treatment of cervical spine conditions, that doctors should only use approved treatments for such conditions or enroll as investigators in approved clinical studies.

Katie O. Orrico, Director
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Physician-Industry Cooperation In The Medical Device Industry

When physician-inventors team up with industry, is it collaborative innovation or conflict of interest?

by Aaron K. Chatterji, Kira R. Fabrizio, Will Mitchell, and Kevin A. Schulman

ABSTRACT: Anecdotal evidence suggests that innovative medical devices often arise from physicians' inventive activity, but no studies have documented the extent of such physician-engaged innovation. This paper uses patent data and the American Medical Association Physician Masterfile to provide evidence that physicians contribute to medical device innovation, accounting for almost 20 percent of approximately 26,000 medical device patents filed in the United States during 1990–1996. Moreover, two measures indicate that physician patents had more influence on subsequent inventive activity than nonphysician patents. This finding supports the maintenance of an open environment for physician-industry collaboration in the medical device discovery process. [*Health Affairs* 27, no. 6 (2008): 1532–1543; 10.1377/hlthaff.27.6.1532]

THERE IS CONSIDERABLE CONTROVERSY over relationships between medical device companies and practicing physicians. Media outlets have recently highlighted conflicts of interest that can arise from close collaboration between physicians and medical device companies.[1] In particular, concerns have been raised about physicians' financial conflicts of interest in recruiting patients to clinical trials and in reporting results of clinical testing to the medical community.[2] Critics worry that payments by medical device companies to practicing physicians will influence their decisions about which devices to use and how to document patient outcomes and, in turn, will compromise patients' welfare.

By contrast, device firms and physicians that work with them argue that the corporate relationships are essential to device innovation. In this view, physicians provide essential knowledge of technology and medical practice that become in-

Aaron Chatterji (ronnie@duke.edu) and Kira Fabrizio are assistant professors of strategy, Will Mitchell is the J. Rex Fuqua Professor of International Management and a professor of strategy, and Kevin Schulman is a professor of business administration in the Fuqua School of Business at Duke University, in Durham, North Carolina. Schulman is also a professor of medicine in the Duke University School of Medicine.

DOI 10.1377/hlthaff.27.6.1532 ©2008 Project HOPE–The People-to-People Health Foundation, Inc.

From: "Katie O. Orrico" <korrico@neurosurgery.org>
Subject: **Medtronic Is Sued Over Bone Product**
Date: December 3, 2008 8:57:28 AM EST
To: "Groff,Michael (HMFP - Neurosugery)" <mgroff@bidmc.harvard.edu>, <CIS8Z@hscmail.mcc.virginia.edu>, <CWolfla@mcw.edu>, <heary@umdnj.edu>, <jtalexan59@yahoo.com>, <resnick@neurosurg.wisc.edu>

FYI….
DECEMBER 2, 2008, 11:41 P.M. ET

Medtronic Is Sued Over Bone Product

By THOMAS M. BURTON and DAVID ARMSTRONG

The family of a California woman who went into respiratory arrest and died after neck surgery filed a lawsuit blaming her death on the use of a fast-selling bone-growth protein made by Medtronic Inc.

The case of Shirley Nisbet comes amid a Justice Department investigation and a separate U.S. Senate inquiry into use of the bone-growth product -- called Infuse Bone Graft -- for purposes not approved by the Food and Drug Administration.

Use of Infuse in the neck is one of these so-called off-label uses. The only type of spine surgery for which Infuse has been approved is a frontal approach to the lower backbone, known as the lumbar spine.

Though doctors are allowed to use FDA-approved products any way they see fit, companies aren't allowed to promote off-label uses.

The suit filed Tuesday in federal court in Los Angeles is the first to allege that Infuse was responsible for a death.

It echoes certain allegations made in lawsuits filed in 2002 and 2003 by former employees of Medtronic's spinal division.

In its suit, the Nisbet family alleges that a Medtronic salesman urged that Ms. Nisbet's surgeon use Infuse in her neck surgery even though such use wasn't FDA-approved.

The product is placed in the patient during surgery.

Marybeth Thorsgaard, a spokeswoman for Medtronic, said the Minneapolis company couldn't comment on the lawsuit because it hadn't had time to review the suit or contact the relevant employees.

The FDA declined to comment. The Justice Department didn't return a phone call seeking comment.

The lawsuit alleges Ms. Nisbet, of Vista, Calif., underwent the surgery Aug. 21, about seven weeks after the FDA had warned that Infuse in neck surgery had caused "life-threatening complications."

That July 1 advisory also linked Infuse to "compression of the airway," difficulty swallowing or breathing and the need for breathing tubes.

The suit alleges that Ms. Nisbet went in for surgery to treat neck pain, but that afterward she had swelling in the neck, then difficulty swallowing and breathing.

Early in the morning of Aug. 23, the lawsuit alleges, she went into respiratory arrest, degenerating into a vegetative state, and then was "kept alive by artificial means" until she died Aug. 30.

The lawsuit alleges that a Medtronic sales representative was in the operating room and that "prior to and during the surgery, the Medtronic sales representative encouraged and recommended" the use of Infuse to the doctor, who is identified in the lawsuit but isn't a defendant.

Government investigators haven't commented on their investigation of off-label use of Infuse, and Medtronic has declined to disclose the contents of a subpoena it received from the Justice Department last month.

Medtronic may have made an "adverse event" report on the Nisbet case to the FDA.

A report, filed by the company more than three weeks after Ms. Nisbet's death, doesn't identify the patient or location of the incident but, according to a review by The Wall Street Journal, contains details that appear to match the allegations in her case, such as the patient developing swelling and complaining of increasing difficulty swallowing.

The company's report quotes the surgeon as saying he "does not believe that Infuse played a direct role" in the patient's outcome. The report also said the patient was in a coma.

Medtronic, noting that the lawsuit was filed late in the day, said it couldn't provide an immediate comment on the report.

The lawsuit identifies Ms. Nisbet's surgeon as Johannes Bernbeck, at Baldwin Park Medical Center in Baldwin Park, Calif.

A spokesman for the hospital said the facility and the doctor didn't have time to prepare a comment Tuesday night.

Apart from the Justice Department and Senate inquiries, Medtronic has been accused by former employees of paying kickbacks to doctors -- in the form of phony consulting arrangements, free travel to resorts and sham royalty deals -- to get them to use the company's spine products.

Medtronic, which has denied the allegations, has agreed to pay $40 million to settle claims made in two lawsuits filed by former employees in 2002 and 2003.

Write to Thomas M. Burton at tom.burton@wsj.com and David Armstrong at david.armstrong@wsj.com

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Subject: Medtronic to Voluntarily Disclose Payments to U.S. Physicians
Date: Tuesday, February 24, 2009 9:44 PM
From: Katie O. Orrico <korrico@neurosurgery.org>

Many of you may already have seen this… but in case not, FYI

Katie O. Orrico, Director
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Congress of Neurological Surgeons
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Washington, DC 20005
Direct Dial: 202-446-2024
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Cell: 703-362-4637

From: Medtronic Press Releases
Sent: Tuesday, February 24, 2009 7:02 AM
To: Medtronic Press Releases
Subject: Medtronic to Voluntarily Disclose Payments to U.S. Physicians

News Release

Medtronic Media Contacts:
Jeff Warren <http://wwwp.medtronic.com/Newsroom/MediaContactDetails.do?lang=en_US&itemId=1109369075016> , Investor Relations, 763-505-2696
Steven Cragle <http://wwwp.medtronic.com/Newsroom/MediaContactDetails.do?lang=en_US&itemId=1145914670968> , Public Relations, 818-576-4398

Medtronic to Voluntarily Disclose Payments to U.S. Physicians

Company Supports Transparency Legislation for Entire Industry

MINNEAPOLIS – Feb. 24, 2009 – Medtronic (NYSE: MDT) announced today its commitment to voluntarily disclose payments to U.S. physicians. The company will begin capturing payment data for all of its businesses on January 1, 2010 and will publicly report this information annually. The first disclosure will occur in March of 2011 and will address payments made to physicians during

calendar year 2010. The company will commission an annual third party audit to demonstrate its commitment to the accuracy of these postings, and will make a summary of the audit results public.

Medtronic will report the amount paid in consulting fees, royalties or honoraria for physicians who receive payments of $5,000 or more per year from Medtronic. Consulting agreements include counsel for areas such as education and training, clinical trial design and administration, and product design and safety. The company currently plans to report these data on its company website.

“Relationships between industry and doctors are essential to innovation, education and training in our industry.” said Bill Hawkins, chairman and CEO. “Through greater transparency about the nature of these relationships, we will help people better understand how important they are to developing life-saving and enhancing products for patients who need them.”

Medtronic initiated a first step toward greater transparency when it launched its online Donations Registry in August 2008 (available at www.medtronic.com <http://www.medtronic.com/>). The donations registry makes public donations given by Medtronic to U.S. customers or organizations affiliated with customers, including patient groups and medical societies. In addition, the company has supported Senator Charles Grassley and Senator Herb Kohl’s proposed legislation, the Physician Payments Sunshine Act, which proposed that all medical device manufacturers publicly disclose payments made to physicians for their inventions and assistance in product development, research and training. The company continues to support appropriate legislation in this area. Finally, Medtronic, with the Advanced Medical Technology Association, led the creation of an industry code of ethics designed to guide industry day-to-day relationships with healthcare professionals.

“We will work hard with the bill sponsors to get this legislation passed,” said Hawkins. “These efforts will ensure a level playing field and consistency in reporting.”

About Medtronic

Medtronic, Inc. (www.medtronic.com <http://www.medtronic.com/>), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic’s Annual Report on Form 10-K for the year ended April 25, 2008. Actual results may differ materially from anticipated results.

-end-

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SEPTEMBER 25, 2008

Lawsuit Says Medtronic Gave Doctors Array of Perks

By DAVID ARMSTRONG

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A lawsuit brought by a former Medtronic Inc. lawyer alleges the big medical-device maker gave surgeons a variety of incentives to use its products, including regular entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in.

The previously undisclosed allegations involve Medtronic's spinal-devices unit, which has $3 billion in annual revenue. The unit's business relationships with doctors who use its spinal-repair implants are being investigated by Sen. Charles Grassley and have been the focus of lawsuits by other former employees.

Sen. Grassley has been looking into whether inducements for doctors, like those alleged in the lawyer's suit, have led to what surgeons say is widespread off-label use of Medtronic spine products.

The Food and Drug Administration has approved Medtronic's spinal devices to treat certain conditions, and doctors are free to use FDA-approved products as they see fit. But the FDA has warned that surgeons' use of a Medtronic bone graft in ways the agency hasn't approved has led to potentially life-threatening side effects in dozens of patients.

The former Medtronic lawyer's allegations are contained in a 2002 suit filed in U.S. District Court in Memphis against Minneapolis-based Medtronic and 10 doctors. The lawsuit and other filings in the case remain sealed, except for a heavily redacted copy of the complaint, which contains none of the doctors' names nor specifics of the allegations.

Medtronic has refused repeated requests from the Senate Finance Committee's staff for an unredacted version. Sen. Grassley, an Iowa Republican, is the panel's ranking minority member.

Even the identity of the plaintiff has been withheld. But, according to an unredacted copy of the lawsuit reviewed by The Wall Street Journal, she is Ami P. Kelley, a former senior legal counsel for the spine unit.

Medtronic declined to comment on the lawsuit's allegations. It said it has changed many business practices since the suit was filed, and is "committed to reform and transparency in the industry."

Ms. Kelley's lawsuit says kickbacks were "pervasive" and "the culture and way of doing business" at Medtronic. Sales staff, she said, "routinely took physicians" visiting the spine

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unit's Memphis headquarters to the Platinum Plus strip club, and picked up the tab for the dancers' services during "VIP visits." In 2007, Platinum Plus's owner pleaded guilty to charges related to dancers engaging in acts of prostitution, and the club has closed.

Ms. Kelley's lawsuit sought to recoup damages for the federal government, which prohibits companies from giving doctors inducements to use products covered by Medicare or Medicaid.

Her lawsuit and a separate one that also accused the spine unit of paying illegal kickbacks to doctors were the basis for a $40 million settlement deal between Medtronic and the government in 2006, according to the settlement document.

As part of its deal with the company, the government successfully moved to have the federal court dismiss the two lawsuits. But the other plaintiff, Jacqueline Kay Poteet, who formerly managed travel services for the Medtronic unit, has appealed the dismissal of her suit, arguing the settlement was too small. Under federal law, whistleblowers who recover money for the government can receive a share of that money.

Ms. Poteet's appeal puts the settlement deal at risk. Either Medtronic or the government could pull out of the settlement if the appeals court reverses the dismissal order.

It isn't clear what would happen to the Kelley lawsuit if the settlement agreement were voided. Neither the government, Ms. Kelley's attorneys nor Medtronic would comment on the matter.

Nor is it clear why the lawsuit remains under seal. Typically, such suits are unsealed when the government either declines to get involved in the matter or agrees to a settlement of the case.

Ms. Kelley, who now works at another company, alleges she was dismissed by Medtronic after challenging improper payments. She didn't return phone calls.

The Kelley lawsuit names several top spinal surgeons among the 10 doctor defendants and lists several others as receiving inducements. No finding of wrongdoing has been made against any of the doctors, and Medtronic denies that it engaged in any improper behavior.

The suit says surgeon Jeffrey Wang, now director of the University of California at Los Angeles's Comprehensive Spine Center, "liked to be taken" to Platinum Plus and emailed Medtronic sales official Brad Hancock saying he was "looking forward to going" to the club with him.

A UCLA spokeswoman said Dr. Wang, who isn't named as a defendant in the suit, "denies ever being entertained by Medtronic at the Platinum club" and doesn't recall sending any such email. If he did send it, she said, "it would have been done so in jest."

Attempts to contact Mr. Hancock, who is no longer at Medtronic, were unsuccessful.

Ms. Kelley's suit said Medtronic had consulting agreements with more than 100 surgeons that were "nothing more than a vehicle to pay the surgeons" to use Medtronic devices, instead of rivals' products. She alleged that the company paid patent royalties to doctors who didn't contribute novel ideas to products, created Web sites for them to market their practices, hired business consultants that helped doctors boost profits. She also said Medtronic offered twice-a-year seminars in Orlando and Las Vegas where doctors and hospital administrators received free management advice, and supplied physicians with office staff.

Among the surgeons named in the suit is Hallett Mathews, of Richmond, Va., Ms. Kelley said he was paid $450,000 a year under a consulting agreement. In quarterly reports filed with Medtronic, she said, Dr. Mathews would count his surgeries as time spent doing consulting work for Medtronic. The lawsuit also alleges Medtronic provided Dr. Mathews with a Medtronic credit card.

Last year, Dr. Mathews went to work for Medtronic, where he is vice president of medical and clinical affairs. A spokeswoman for the company said he couldn't comment on the allegations because the suit was sealed.

Medtronic says it overhauled its code of conduct in 2004 to include tougher guidelines on relations with physicians.

Ms. Kelley alleges Medtronic sent physicians on lavish trips under the guise of medical

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conferences, but where little work was done. Her complaint claims that on a five-day, all-expenses-paid trip to Alaska in 2001, which was billed as a "think tank," doctors were supposed to present case studies. But, according to the complaint, little discussion of the case studies took place. One doctor scheduled to give a talk stood before the group, "said he was sorry, but he had not prepared anything," and "drinking then commenced in place of discussion," Ms. Kelley said in the suit.

Medtronic picked up the cost of fishing guides and clothing for the doctors, the suit said. It said "women were also provided for the doctors," but didn't elaborate.

Maurice Smith, a neurosurgeon at the Semmes-Murphey Neurologic and Spine Institute in Memphis, organized the Alaska trip and joined the other doctors there, according to the lawsuit, which names him as a defendant. Ms. Kelley alleges Dr. Smith had a consulting contract that was prepaid for 10 years. She alleged that Dr. Smith provided few services to the company other than hosting the annual "think tank." He didn't return calls seeking comment.

When Medtronic discovered that neurosurgeon Patrick Johnson was in line for a promotion at a Los Angeles hospital, it arranged a helicopter skiing trip for him, and sent along former spine-unit president Michael DeMane and former regulatory chief Jon Serbousek, the lawsuit said. Dr. Johnson, now director of education at the Cedars-Sinai Institute for Spinal Disorders, wasn't named as a defendant in the suit. He didn't respond to requests for comment. Mr. Serbousek couldn't be reached. Mr. DeMane said, "As far as I know, Medtronic did not pay" for Dr. Johnson's trip.

At a Medtronic-sponsored "discussion group" in New Orleans, according to the complaint, the company paid $20,000 to $25,000 to get a group of doctors on a Mardi Gras parade float and another $15,000 to supply doctors with Mardi Gras beads.

Medtronic said it has changed its policies regarding trips like those described in the lawsuit, no longer conducts medical training in resort locations and has also prohibited the company's payment for the travel and expenses of doctors' spouses or guests.

Write to David Armstrong at david.armstrong@wsj.com

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Subject: Re: WellPoint Artificial Disc Tech Assessment
Date: Monday, December 1, 2008 10:41 AM
From: Praveen Mummaneni <vmum@aol.com>
Reply-To: <vmum@aol.com>
To: Cheng, Joseph joseph.cheng@Vanderbilt.Edu, Katie O. Orrico korrico@neurosurgery.org, Christopher Wolfla CWolfla@mcw.edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Groff, MD Michael mgroff@bidmc.harvard.edu, Bob Heary heary@umdnj.edu, Joseph Alexander jtalexan59@yahoo.com, Dan Resnick resnick@neurosurg.wisc.edu
Cc: Cathy Hill chill@neurosurgery.org, Robert Harbaugh reh1@mac.com, Greg Przybylski gprzybyl@optonline.net, jbeanlex@aol.com, Regis Haid rhaid@atlantabrainandspine.com

Here is abstract I sent to jt spine section. It has early 3 and 5 year data on a portion of the cohorts. PraveenABSTRACT Objective. To compare ACDF versus arthroplasty with the PRESTIGE device with 3-5 years of follow up. Methods: 541 patients with single-level cervical disc disease with radiculopathy were prospectively randomized and enrolled at 32 sites to 1 of 2 treatment groups: 276 patients underwent ACD and arthroplasty with the PRESTIGE ST cervical disc and 265 patients underwent ACDF. Of the original 541 patients, 247 have now reached 3 years of follow up and 111 have reached 5 years follow-up. Results The NDI and Neck Pain scores were significantly better in the arthroplasty group at 3 years (P<0.01 and P= 0.044 respectively) but were similar at 5 years (P=0.214 and P=0.895 respectively). There was no statistical difference between groups for the SF36 PCS, SF 36 MCS, or VAS Arm Pain Scores at 3 years or 5 years. At latest follow up, the PRESTIGE arthroplasty devices did maintain a mean of 7.1 degrees of motion on flexion and extension X-rays. At latest follow up, there were 7 PRESTIGE arthroplasties removed versus 11 ACDF's removed. Conclusions. The PRESTIGE ST Cervical Disc maintains physiologic segmental motion at up to 5 years after implantation and is associated with improved NDI and Neck Pain scores as well as reduced secondary surgical procedures compared with anterior cervical discectomy and decompression and fusion.

Sent from my Verizon Wireless BlackBerry

From: "Cheng, Joseph"
Date: Mon, 1 Dec 2008 08:06:03 -0600
To: Katie O. Orrico<korrico@neurosurgery.org>; Wolfla, Christopher<CWolfla@mcw.edu>; Shaffrey, Chris I *HS<CIS8Z@hscmail.mcc.virginia.edu>; <vmum@aol.com>; <mgroff@bidmc.harvard.edu>; <heary@umdnj.edu>; <jtalexan59@yahoo.com>; <resnick@neurosurg.wisc.edu>
Subject: RE: WellPoint Artificial Disc Tech Assessment
Thanks Katie. In my opinion, we may have to "chase our tails" for the

time being. The development of national standards will need significant resources from the AANS/CNS offices and staff, and the current economic climate may preclude this for the time being (although Cathy is awesome and does amazing work!). As I have learned from working on these issues and being on hospital committees, the administrators full time job is to be at these meetings and work on these issues, and will always overwhelm the efforts of us volunteer physicians who still have day jobs and other responsibilities (and they always seem to out number us as well...).

Dan: Do we need to ask Michael to circulate to the entire executive committee of the Section before signing, or are you okay with us proceeding with this as it?

Regards,

Joe

_____
Joseph S. Cheng, M.D., M.S.
Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
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From: Katie O. Orrico [mailto:korrico@neurosurgery.org]
Sent: Mon 12/1/2008 7:36 AM
To: Wolfla, Christopher; Cheng, Joseph; Shaffrey, Chris I *HS; vmum@aol.com; mgroff@bidmc.harvard.edu; heary@umdnj.edu; jtalexan59@yahoo.com; Dr. Resnick
Cc: Cathy Hill; Robert Harbaugh; Greg Przybylski; rhaid@atlantabrainandspine..com; jbeanlex@aol.com
Subject: RE: WellPoint Artificial Disc Tech Assessment

All,

The way these letters typically done is that they are put on AANS/CNS Joint Letterhead and then they are signed by the two presidents and the chair of the particular section or committee as is relevant. We will do that from my end. I'm not sure what needs lawyer review, frankly, if you all agree with the substance of the policy from a section standpoint, we then send to the leadership for their review and then we can get it out the door.

As to the national standard, that is something we can talk about, as I agree we always seem to be behind the 8-ball on all of these coverage policy assaults.

Katie

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Congress of Neurological Surgeons
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From: Wolfla, Christopher [mailto:CWolfla@mcw.edu]
Sent: Sunday, November 30, 2008 11:54 AM
To: Cheng, Joseph; Shaffrey, Chris I *HS; vmum@aol.com; Katie O. Orrico; mgroff@bidmc.harvard.edu; heary@umdnj.edu; jtalexan59@yahoo.com; Dr. Resnick
Cc: Cathy Hill; Robert Harbaugh; Greg Przybylski; rhaid@atlantabrainandspine..com; jbeanlex@aol.com
Subject: RE: WellPoint Artificial Disc Tech Assessment

Dear Joe:

This is really nice work and I recommend that we do this or something like it. I wouldn't send this letter until it has been looked at by the legal department of the AANS and CNS.

I am concerned that we may be chasing our tails. It appears that the criteria may have been chosen to facilitate a specific outcome rather than the other way around. Maybe neurosurgery should attempt to develop and promulgate a standard for what we think is an adequate assessment of new technology so that at least the rules stay the same each time.

Sincerely

Chris

Christopher E. Wolfla, MD
Associate Professor of Neurosurgery
The Medical College of Wisconsin
Secretary, The Congress of Neurological Surgeons
Secretary, The Congress of American Neurosurgical Education
Treasurer, AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

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Sent: Saturday, November 29, 2008 11:57 AM
To: Shaffrey, Chris I *HS; vmum@aol.com; Katie O. Orrico; mgroff@bidmc.harvard.edu; Wolfla, Christopher; heary@umdnj.edu; jtalexan59@yahoo.com; Resnick
Cc: Cathy Hill; Robert Harbaugh; Greg Przybylski; rhaid@atlantabrainandspine..com; jbeanlex@aol.com
Subject: RE: WellPoint Artificial Disc Tech Assessment

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Regards,

Joe

Joseph S. Cheng, M.D., M.S.

Associate Professor of Neurological Surgery

Director, Neurosurgery Spine Program

Vanderbilt University Medical Center

T-4224 Medical Center North

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(615) 322-1883

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Katie

Katie O. Orrico, Director
Washington Office
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
725 15th Street, NW
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Office: 202-628-2072
Fax: 202-628-5264
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Sent: Tuesday, November 25, 2008 4:04 PM
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Subject: AANS input on Art Discs - nophi

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Thank you,
Barbara J. Brown

Data Analyst, Office of Medical Policy & Tech Assessment
WellPoint, Inc.
4553 La Tienda Drive
Thousand Oaks, California 91362
(805) 557-5367 (phone)
(805) 557-4155 (fax)

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Subject: RE: WellPoint Artificial Disc Tech Assessment
Date: Monday, December 1, 2008 9:51 AM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Cheng, Joseph joseph.cheng@Vanderbilt.Edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Praveen Mummaneni vmum@aol.com, Katie O. Orrico korrico@neurosurgery.org, Groff, MD Michael mgroff@bidmc.harvard.edu, Christopher Wolfla CWolfla@mcw.edu, Bob Heary heary@umdnj.edu, Joseph Alexander jtalexan59@yahoo.com
Cc: Cathy Hill chill@neurosurgery.org, Robert Harbaugh reh1@mac.com, Greg Przybylski gprzybyl@optonline.net, rhaid@atlantabrainandspine..com, jbeanlex@aol.com

Hi Joe,
Thank you for Yeoman's work on this issue. I have a few comments regarding your response. They follow below. I think we need to be VERY careful with how we present our case- we need to be absolutely correct regarding any statements of "superiority" of arthroplasty given the current evidence as there is simply no good evidence to make that statement (sorry praveen) and the Wellpoint reviewers know it. The data does indicate that for selected patients, as described by the inclusion criteria for the Prestige, ProDisc, and bryan studies, outcomes are at least as good as ACDF and arthroplasty is a clinically reasonable alternative for those patients. We'll let the insurance companies and device manufacturer's fight it out as to whether they are cost effective or not (perhaps the manufacturer's will lower the prices of the devices to make them competitive with ACDF). We need to acknowledge that ACDF is still better in many patients (older, arthritic, etc) and that further follow-up is needed and ongoing.

Item 1 Paragraph 1: There is no evidence of superiority and if we continue to cling to such statements we'll be killed. Stick to the real evidence of non-inferiority.

Item 2 paragraph 1: The criticism regarding blinding is valid- do not risk insulting the wellpoint reviewers. It is fine to say that blinding of the surgeons was impossible and that blinding of the patients was impractical given access of patients to their own medical records. There almost certainly was a bias introduced by the lack of blinding in all of the studies (euphoria bias) and this should be acknowledged and discussed, not denied.

Item 2 Paragraph 3: Avoid claims of superiority- we will hang ourselves in front of any statistically savvy jury. In terms of the delayed neck and arm pain, I would simply state that these reports are unusual based on the literature available, are uncommon overall, and bear further investigation as experience grows with the more widespread use of the devices.

"medically Necessary" and specific criteria- the indications for arthroplasty DO NOT

mirror those for ACDF- the indications mirror the inclusion criteria for the RCT's and should be limited therein. The studies specifically excluded many patients who are now candidates for ACDF.

"Safe and Effective" in selected patients as described by the study inclusion criteria over a clinically meaningful timepoint as defined by the FDA.

Daniel K. Resnick MD, MS
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

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To: jbeanlex@aol.com, william.couldwell@hsc.utah.edu, ttippett2@aol.com
Cc: Katie O. Orrico korrico@neurosurgery.org, Dan Resnick resnick@neurosurg.wisc.edu, Groff, MD Michael mgroff@bidmc.harvard.edu

I have recently had discussions with the leadership of Depuy, Synthes, Medtronic and Biomet about their thoughts on potentially supporting a outcomes registry (through the Joint Section) to help to provide less biased data on several spinal procedures. I was hoping that establishing registry would be my principle contribution for my term as chair of the Joint Section. Each of the companies seemed very enthusiastic about contibuting to establish such a database/registry (pending the details). I am in the process of putting together a proposal for the next Joint Section BOD meeting.

After attenting the AANS BOD meeting, it seems that the outcomes initiative starting with the AANS might serve the purpose and have the advantange of the organizational structure of the AANS. Outcomes data on spinal procedures is desperately needed to counter questions about the effectiveness of much of what we do. I am happy to contribute in any way I can (either through the Joint Section or helping the AANS as it moves forward). If the leadership of the AANS feels that the Joint Section is the best organization to proceed with a registry, I am happy to move forward. If it is thought better through the AANS, I am happy to contribute in any way I can.

From: Robert Harbaugh [mailto:reh1@mac.com]
Sent: Thursday, November 27, 2008 1:16 PM
To: Shaffrey, Chris I *HS
Cc: 'vmum@aol.com'; Katie O. Orrico; mgroff@bidmc.harvard.edu; CWolfla@mcw.edu; heary@umdnj.edu; jtalexan59@yahoo.com; Resnick; Cathy Hill; Greg Przybylski; joseph.cheng@vanderbilt.edu; jbeanlex@aol.com
Subject: Re: WellPoint Artificial Disc Tech Assessment

Chris,

I agree completely on all points. This is just one example of a situation in which an industry sponsored, but AANS/CNS conducted, registry would be of great value to patients, neurosurgeons and industry.

Bob

On Nov 27, 2008, at 1:10 PM, Shaffrey, Chris I *HS wrote:

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Sent: Wednesday, November 26, 2008 9:05 PM
To: Katie O. Orrico; mgroff@bidmc.harvard.edu; Shaffrey, Chris I *HS; CWolfla@mcw.edu; heary@umdnj.edu; jtalexan59@yahoo.com; Resnick
Cc: Cathy Hill; Robert Harbaugh; Greg Przybylski; joseph.cheng@vanderbilt.edu; rhaid@atlantabrainandspine..com
Subject: Re: WellPoint Artificial Disc Tech Assessment

I have 3yr and 5 year data on 100 prestige pts that I am planning to present at the joint section mtg. Should I get that abstract to you? Will it help this cause?

Praveen

Sent from my Verizon Wireless BlackBerry

From: "Katie O. Orrico" <korrico@neurosurgery.org>
Date: Wed, 26 Nov 2008 10:02:33 -0500
To: <vmum@aol.com>; <mgroff@bidmc.harvard.edu>; <CIS8Z@hscmail.mcc.virginia.edu>; <CWolfla@mcw.edu>; <heary@umdnj.edu>; <jtalexan59@yahoo.com>; <resnick@neurosurg.wisc.edu>
CC: Cathy Hill<chill@neurosurgery.org>; Robert Harbaugh<reh1@mac.com>; Greg Przybylski<gprzybyl@optonline.net>; <joseph.cheng@vanderbilt.edu>
Subject: WellPoint Artificial Disc Tech Assessment

Dear Spine Section Leaders:

See below and attached tech assessment on artificial disc and with luck our past documents to CMS, etc. will help us craft a quick response. The bottom-line:

"In summary, evidence to date has not shown a beneficial effect of any cervical disc product on the development of adjacent level disease, whereas long-term complication rates with artificial discs remain unknown. Further, as concluded in the TEC Assessment, given the clinical situation, 2 years of follow-up is not adequate to evaluate long-term results, in particular any effect of the device on adjacent -level disc degeneration, device durability, adverse events, and revisability. Finally, because the performance of each disc type may vary, each disc design will require its own long-term studies to evaluate device specific performance."

"Artificial intervertebral discs are considered **investigational and not medically necessary."**

The Coding and Reimbursement team is on this, but clearly will need Spine Section input.

Katie

Katie O. Orrico, Director

Washington Office

American Association of Neurological Surgeons/

Congress of Neurological Surgeons

725 15th Street, NW

Suite 500

Washington, DC 20005

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From: Technology-Compendium-Wellpoint(Shared Mailbox) [mailto:Technology-Compendium@wellpoint.com]
Sent: Tuesday, November 25, 2008 4:04 PM
To: Katie O. Orrico
Cc: Diny, Jean; Jones, Lynn S.-VA
Subject: AANS input on Art Discs - nophi

To: Katie O. Orrico, Director Washington Office, American Association of

Neurological Surgeons/Congress of Neurological Surgeons

The WellPoint Office of Medical Policy & Technology Assessment (OMPTA) is currently seeking input on the topic of **Artificial Intervertebral Discs**. We would like to give board-certified physicians from your organization the opportunity to provide feedback regarding this topic for the draft policy for a national healthcare association ("Association") and WellPoint. **The Association's draft policy (7.01.108 Artificial Intervertebral Disc: Cervical Spine) and WellPoint draft policy (SURG.00055 Artificial Intervertebral Discs) along with a questionnaire for each are attached for your input.**

We would appreciate receiving your review and comments on or before **December 23, 2008**. If a response cannot be submitted by **December 23**, we still want to hear from you. You may contact Barbara Brown at Technology.Compendium@WellPoint.com <mailto:Technology.Compendium@WellPoint.com> to confirm the extension you would like to submit your response.

Thank you for your collaboration in the process. We are committed to taking into account the view of physicians practicing in relevant clinical areas along with other sources, such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies, when developing medical policies. While the various physician specialty societies may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, we understand the input received does not represent an endorsement or position statement by the physician specialty society, unless otherwise noted.

<<CVDI - 701108 - ArtDisc-Cerv.pdf>> <<SURG 00055 WP 10-22-2008 CoDr.doc>> <<7 01 108 SURG 55 Art Disc Cerv 2008-11-24 V1 Lj jc ag jd CoQu AANS.doc>>

Thank you,
Barbara J. Brown
Data Analyst, Office of Medical Policy & Tech Assessment
WellPoint, Inc.
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American Association of Neurological Surgeons
Congress of Neurological Surgeons

Grassroots Action Alert

CMS Slashes Medicare Reimbursement for Stereotactic Radiosurgery for 2009

NEUROSURGEONS SHOULD CONTACT CMS BY DECEMBER 29, 2009 TO URGE ADOPTION OF THE AMA RUC RECOMMENDED VALUES

BACKGROUND

After years of pressure by the Centers for Medicare and Medicaid Services (CMS) and other payers, the AANS and CNS were finally forced to restructure the coding scheme for stereotactic radiosurgery (SRS). Earlier this year, the CPT Editorial Panel approved 7 new SRS codes (see below) to replace CPT Code 61793, which will no longer be available in 2009. Following the adoption of this new code set, the American Medical Association's Relative Value Update Committee (RUC) approved the AANS/CNS proposed relative value units (RVUs) for these new codes and the proposed values were then submitted to CMS for adoption in the 2009 Medicare Physician Fee Schedule (MFS).

CMS REJECTS RUC RECOMMENDED VALUES

On November 19, 2008, CMS published the 2009 MFS, which includes the RVUs for the new SRS codes. Unfortunately, CMS significantly reduced the RUC proposed values for these new codes based on a rationale that is significantly flawed and does not justify the cuts -- CMS rejected the RUC recommendation that these new codes are comparable to open surgical codes, ruling instead that they should be valued as compared to "more equivalent stereotactic radiation treatment" codes.

Below is a list of the new SRS codes, the RUC recommended values, the values assigned by CMS and the estimated national MFS payment amount for 2009. The current national payment rate for 61793 is $1,140.

CPT Code	Description	RUC Proposed Work RVUs	CMS Approved Work RVUs	Total RVUs		2009 Medicare Payment	
				Proposed	Approved	Proposed	Approved
61800	Application of stereotactic headframe for stereotactic radiosurgery	2.25	2.25	3.39	3.39	$141.76	$141.76
61796	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); 1 simple cranial lesion	15.50	10.79	24.99	20.28	$901.39	$731.50
61797	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, simple	3.48	3.48	5.54	5.54	$199.83	$199.83
61798	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); one complex cranial lesion	19.75	10.79	29.24	20.28	$1,054.69	$731.50
61799	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, complex	4.81	4.81	7.66	7.66	$276.30	$276.30
63620	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); one spinal lesion	15.50	10.79	24.99	20.28	$901.39	$731.50
63621	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional spinal lesion	4.00	4.00	6.37	6.37	$229.77	$229.77

TAKE ACTION NOW

The AANS and CNS will be working hard on your behalf to prevail upon CMS to reverse its decision and adopt the RUC recommended values. But we also need ***your help*** to get the RUC recommended values restored. **WE NEED YOU TO:**

1. **Write a letter to CMS and protest this action (*see sample letter below*) *NO LATER THAN DECEMBER 29, 2008.***

   Letters may be sent in the mail or submitted electronically at http://www.regulations.gov. If you submit electronically take the following steps:

   - Go to: http://www.regulations.gov
   - Enter file code: "CMS-1403-FC" in the *Search Documents* box and click on *Go*
   - Click "Rules" under *Document Type* in the left navigation panel
   - Click "Send a Comment or Submission" and the fill out the form and attach your comment per the instructions

2. **Send copies of your CMS letter to your U.S. Senators and Representatives:**

   The Honorable **[Insert first and last name]**
   United States Senate
   Washington, DC 20510

   The Honorable **[Insert first and last name]**
   United States House of Representatives
   Washington, DC 20515

3. **Send a *blind* copy of your letter and any responses you get from your elected officials to:**

   Katie Orrico, Director
   AANS/CNS Washington Office
   725 15th Street, NW, Suite 500
   Washington, DC 20005
   Fax: 202-628-5264

SAMPLE LETTER

[Insert Date]

Mr. Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-8013

RE: CMS-1403-FC -- *Medicare Physician Fee Schedule – Stereotactic Radiosurgery Codes*

Dear Mr. Weems:

Thank you for the opportunity to comment on the above referenced Medicare Physician Fee Schedule (MFS) regulation. I am writing to object to CMS' decision to significantly reduce the relative value units for the new stereotactic radiosurgery (SRS) codes and urge the agency to reverse its decision and adopt the American Medical Association Relative Value Update Committee's (RUC) recommended values for CPT Codes 61796, 61798 and 63620.

I am a practicing neurosurgeon **[insert some brief information about your practice, the types of neurologic disorders that you treat with SRS and how important stereotactic radiosurgery is to your patients]**.

The CMS rationale for reducing the SRS values is fatally flawed and not reasonable for several reasons, including:

1. *CMS states that the deleted CPT Code 61793 described a full course of stereotactic radiosurgery, inclusive of all lesions and anatomic sites.* This is incorrect, as 61793 was valued for a single metastasis to the brain. Additional lesions are unquestionably more work. The new CPT codes recognize that fact.
2. *CMS states that the work involved in providing radiation therapy and radiosurgery is similar and the work relative values should be similar.* This statement is false and gets to the basic misunderstanding of the difference between SRS (which replaces an open craniotomy or laminectomy) and radiotherapy. Stereotactic radiosurgery is a surgical procedure that is done as part of a multi-disciplinary team that includes neurosurgeons, radiation oncologists and medical physicists. The work effort performed by the radiation oncologist (who bills the 70000 series codes) and the neurosurgeon is separate and distinct with no overlap.
3. *CMS objected to the SRS RUC survey because open surgical reference codes were used*. SRS is a surgical procedure and therefore using open surgical codes as comparators for the new SRS codes was perfectly appropriate. In choosing reference codes it is important to use codes with matching global periods and those that are familiar to the physicians being surveyed.

Failure to appropriately reimburse neurosurgeons for our efforts will restrict our ability to provide our patients who have brain and spine disorders with beneficial -- and minimally invasive -- surgical care. I therefore urge you to reverse your decision and take immediate action and adopt the RUC recommended values for CPT Codes 61796, 61798 and 63620.

Thank you for considering my comments.

Sincerely,

[Insert Your Name]

cc: Senator **[Insert first and last name]**
Senator **[Insert first and last name]**
Representative **[Insert first and last name]**

FOR MORE INFORMATION

The entire MFS can be viewed at: http://edocket.access.gpo.gov/2008/pdf/E8-26213.pdf. If you have any questions, please contact Cathy Hill, Senior Manager for Regulatory Affairs, AANS/CNS Washington Office at chill@neurosurgery.org or 202-628-2072.

THANK YOU FOR YOUR HELP!!!

WELLPOINT

Medical Policy

Subject:	Artificial Intervertebral Discs		
Document #:	SURG.00055	**Current Effective Date:**	10/22/2008
Status:	Consultant Draft	**Last Review Date:**	08/28/2008

Description/Scope

This document describes the use of cervical and lumbar artificial intervertebral discs to treat degenerative disc disease of the spine.

Position Statement

Investigational and Not Medically Necessary:

Artificial intervertebral discs are considered **investigational and not medically necessary.**

Rationale

Charité™ implant:
In October 2004, the U.S. Food and Drug Administration (FDA) granted Premarket Application (PMA) approval for the Charité™ Artificial Disc, stating that the device is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at the L4-L5 interspace or the L5-S1 interspace. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The approval was based in part on the results of a trial that randomized 304 patients with degenerative disc of the lumbar spine to undergo either implantation with a Charité™ artificial disc or undergo lumbar fusion using a BAK® Interbody Fusion System. Patients receiving the artificial disc had an overall composite success rate of 63%, and patients receiving the BAK cage had a success rate of 53%. This met the specified non-inferiority criteria with a p-value of .0001. Although the Charité™ disc had a higher success rate than the BAK cage, this difference would not have met traditional criteria for a superiority trial.

This randomized controlled trial has several methodological issues that make it difficult to interpret the results. The first concern is that the analysis showed non-inferiority compared to BAK fusion using the composite measure of success, but did not show statistically significant superiority in most outcome measures. A trial which is designed and analyzed as a noninferiority trial usually establishes a less stringent standard for demonstrating efficacy than a standard clinical trial. Such trials are often employed when there is some margin of acceptable inferiority of a new technology in its principal outcome that is offset by some other advantage, such as less morbidity, less invasiveness, better acceptability to patients, or lower cost. In the case of the Charité™ disc, there are no offsetting advantages that are immediately evident or proven, as it is simply proposed to provide greater relief of back pain. The Charité™ disc might provide greater flexibility than conventional fusion, but there is no firm evidence to show this.

The second concern is that the lack of a prespecified analysis plan, unexplained closure of the data base before all patients reached completion, and lack of intent-to-treat analysis may cast some doubt on the analysis. Lower back pain is a common condition. Given the population affected, additional and more rigorous trials of the outcomes of

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the use of an artificial disc in the treatment of DDD are needed. Since the long-term safety and effectiveness of the Charité™ Artificial Disc is unknown, the FDA approval of the Charité™ disc is contingent upon a post-approval study.

PRODISC Cervical, Lumbar

The PRODISC-L® received FDA premarket approval (PMA) on August 15, 2006. This device, like the Charité™ consists of two metal endplates with a plastic inlay. The FDA labeled indications for the PRODISC®-L device for spinal arthroplasty are for those patients who:

- are skeletally mature;
- have degenerative disc disease (DDD) at one level in the lumbar spine (from L3-S1;)
- have no more than Grade 1 spondylolisthesis at the involved level;
- have had no relief from pain after at least six months of non-surgical treatment.

The PMA is contingent upon a five year post approval study to evaluate long-term safety and effectiveness of the PRODISC-L®.

Bertagnoli and colleagues (2006) reported in a study (n=22) that the use of PRODISC-L® device for lumbar total disc arthroplasty in patients older than 60 years of age reduces chronic low back pain (LBP) and improves clinical functional outcomes, but the judicious use of artificial disc replacement in this age group is recommended. Until further findings are reported, the authors cautiously recommend the use of artificial disc replacement in the treatment of chronic discogenic low back pain in patients older than age 60 years where bone quality is adequate in the absence of circumferential spinal stenosis.

Chung and colleagues (2006) studied the clinical and radiographic outcomes of 36 consecutive patients who underwent lumbar total disc replacement (TDR) using PRODISC-L® and the factors associated with a better clinical outcome after a 2-year minimum follow-up. At the time of the latest follow-up, the success rate was 94% of 36 patients according to the criteria of the U S Food and Drug Administration. They concluded that the PRODISC-L® showed excellent clinical and radiographic outcomes without any significant complication. However, future efforts need to be directed toward the evaluation of a larger number of patients with longer follow-up.

In a longitudinal prospective study (n=41), Leivseth et al (2006) found that the rotational range of motion of segments instrumented with a PRODISC-L® prosthesis was low, especially at L4-L5 and L5-S1. In the majority of cases, it amounted to less than 45% of the normal range and that virtually no improvement occurred between 1 and 2 years after surgery.

Freeman and colleagues (2006), in a systematic review of the published literature for the Charité™ and PRODISC-L® devices, found that to date, no study has shown total disc replacement to be superior to spinal fusion in terms of clinical outcome. Additionally, the long-term benefits of artificial disc replacement in preventing adjacent level disc degeneration have yet to be realized and the complications of artificial disc replacement may not be known for many years. Larger, well designed prospective randomized controlled trials with longer follow-up are required before widespread use of this technology.

PRODISC-C®

The PRODISC-C® is used for disc replacement in the cervical spine and was granted a PMA by the FDA in December 2007. The following are the FDA labeled indications for use of the PRODISC®-C:

- Patients are skeletally mature;
- Patients have intractable symptomatic cervical disc disease (SCDD);
- Patients need reconstruction of the disc from C3-C7 following single-level discectomy;

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- Patients have failed at least six weeks of non-operative treatment prior to implantation;
- PRODISC®-C is implanted via an open anterior approach.

The PMA is contingent upon a seven year post approval study to evaluate long-term safety and effectiveness of the PRODISC-C®.

Nabhan et al (2007), studied anterior cervical discectomy fusion (ACDF) compared to artificial cervical disc prosthesis. 25 patients with refractory symptomatic cervical soft disc herniation were randomized into two treatment groups; one group was treated with ACDF and the other group was treated with a cervical disc prosthesis. Radiostereometric analysis was used to quantify intervertebral motion immediately as well as 3, 6, 12 and 24 weeks postoperatively. Additional clinical results were judged using the visual analogue scale (VAS) and neuro-examination. The study results found that cervical spine segmental motion decreased over time in the presence of disc prosthesis or ACDF. However, the loss of segmental motion is significantly higher in the ACDF group, when looked at 3, 6, 12 and 24 weeks after surgery. Significant pain reduction was observed in the neck and arm postoperatively, without significant difference between both groups ($P > 0.05$) . The authors acknowledged that the study was small and that larger studies with longer follow up are warranted.

PRESTIGE® Cervical Disc System The PRESTIGE® Cervical Disc System was approved by the US Food and Drug Administration (FDA) on July 16, 2007. This device consists of two main metal pieces, superior (upper) and inferior (lower) parts that move with respect to one another by a ball and trough mechanism. It is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The approval is also subject to a 7-year post-approval study to evaluate the long term safety and effectiveness of the PRESTIGE® Cervical Disc.

In a clinical trial, Mummaneni and colleagues (2007) conducted an unblinded randomized controlled study (RCT) of patients with single-level cervical degenerative disc disease (DDD) and radiculopathy. Patients at 32 medical sites were randomly assigned to one of two treatment groups: 276 patients in the investigational group and 265 patients in the control group. The investigational group underwent anterior cervical discectomy and decompression and artificial intervertebral disc arthroplasty (AIDA) with the PRESTIGE ST Cervical Disc System (Medtronic Sofamor Danek). The control group underwent an allograft anterior cervical discectomy and fusion (ACDF). Eighty percent of the arthroplasty-treated patients (n=223) and 75% of the control patients (n=198) completed clinical and radiographic follow-up examinations at routine intervals for 2 years after surgery. The study groups were well matched demographically and appropriate for surgical fusion. Historically, complete fusion has been associated with a 98% success rate in ACDF control cases. The fusion success rate would be a difficult endpoint for cervical arthroplasty to exceed supporting the rationale for a non inferiority study design rather than a superiority design.

Although the trial has positive aspects, some issues may cloud the conclusions:

- The trial was *unblinded,* which could introduce bias. Blinding would also contribute to better assessment of pain.
- The study reported that 4% of the cohort withdrew because they were dissatisfied with their treatment group.
- The investigational group reported better neurological success, however the investigators provided no detail how the neurological status was measured and evaluated.

Overall, the study failed to demonstrate statistically superiority for the neck disability index (NDI), since scores were statistically significant only at the three month follow up. The study provided outcome information for two years, which precludes conclusions about long term device performance and adjacent disc degeneration. A critical issue not addressed in the study was the difficulty in revising a failed implant.

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Background/Overview

Degenerative disc disease (DDD) affects 40-50% of people over the age of 40 and becomes increasingly common with advancing age. Although it can occur at any spinal level, e.g. cervical, it is most common in the lumbar spine (low back). Disc degeneration is a complex biochemical process that occurs with the loss of normal water content within the disc resulting in the deterioration of the mechanical shock absorbing properties of the disc over time. This will lead to bulging and decreased disc height. The cause most often is the natural aging process although various associated factors may accelerate the process. Not all individuals with disc degeneration are symptomatic with pain. Spinal fusion is a common surgical approach for DDD. The procedure removes the damaged areas of the disc and fuses the remaining vertebral segment, eliminating the motion between adjacent vertebral segments, and thus reducing the pain. However, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels. Artificial discs have been developed as an alternative to cervical or lumbar fusion. This approach is intended to maintain motion and the normal biomechanics of the adjacent vertebrae. Currently, 4 intervertebral devices have FDA approval. The Charité™ and PRODISC-L® devices are used for lumbar disc replacement. The PRESTIGE® and the PRODISC-C® devices are used for cervical disc replacement. These devices consist of a sliding plastic or metal core between two metal end plates and are secured in place between the affected vertebrae. The core shifts dynamically within the disc space during spinal motion. The intent of these devices is to restore disc height and physiologic motion as well as preserving adjacent vertebrae.

In July 2007, the Bryan® Cervical Disc received an approvable recommendation from the FDA's Orthopedic and Rehabilitation Devices advisory panel. The FDA has not made a final approval determination. Other intervertebral discs such as the Maverick™ and FlexiCore™ have been developed. At this time, these devices have not received FDA approval.

The Centers for Medicare and Medicaid Services (CMS) issued a national *non coverage* determination for lumbar artificial disc replacement using any type of lumbar artificial disc for the Medicare population over sixty years of age. For those Medicare beneficiaries younger than sixty years of age, CMS did not issue a national coverage determination, leaving such determinations to be made on a local basis.

Definitions

Intervertebral discs: are soft tissues that sit between each vertebra; these discs act as cushions between the vertebrae

Laminectomy: a surgical procedure for treating spinal stenosis by relieving pressure on the spinal cord; the lamina of the vertebra is removed or trimmed to widen the spinal canal and create more space for the spinal nerves.

Neurogenic: originating in the nervous system

Vertebrae: bones that make up the spinal column, which surround and protect the spinal cord

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace
22862	Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar, single interspace
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
0090T	Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than for decompression), cervical; single interspace
0092T	Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than for decompression), cervical; each additional interspace
0093T	Removal of total disc arthroplasty, anterior approach, cervical; single interspace
0095T	Removal of total disc arthroplasty, anterior approach, cervical; each additional interspace
0096T	Revision of total disc arthroplasty, anterior approach, cervical; single interspace
0098T	Revision of total disc arthroplasty, anterior approach cervical; each additional interspace
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace
0164T	Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
0165T	Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace

ICD-9 Procedure

84.60-84.65	Insertion of partial or total spinal disc prosthesis (includes codes 84.60, 84.61, 84.62, 84.63, 84.64, 84.65)
84.66-84.69	Revision or replacement of artificial spinal disc prosthesis (includes codes 84.66, 84.67, 84.68, 84.69)

ICD-9 Diagnosis

All	diagnoses

References

Peer Reviewed Publications:

1. Bertagnoli R, Yue JJ, Nanieva R, et al. Lumbar total disc arthroplasty in patients older than 60 years of age: a prospective study of the ProDisc prosthesis with 2-year minimum follow-up period. J Neurosurg Spine. 2006; 4(2):85-90.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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2. Bertagnoli R, Yue JJ, Fenk-Mayer A, et al. Treatment of symptomatic adjacent-segment degeneration after lumbar fusion with total disc arthroplasty by using the ProDisc prosthesis: a prospective study with 2-year minimum follow up. J Neurosurg Spine. 2006; 4(2):91-97.
3. Blumenthal S, McAfee PC, Guyer RD, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine. 2005; 30(14):1565-1575.
4. Chung SS, Lee CS, Kang CS. Lumbar Total Disc Replacement Using ProDisc II: A Prospective Study With a 2-Year Minimum Follow-up. J Spinal Disord Tech. 2006; 19(6):411-415.
5. Coric D, Finger F, Boltes P. Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. J Neurosurg Spine. 2006; 4(1):31-35.
6. de Kleuver M, Oner FC, Jacobs WC. Total disc replacement for chronic low back pain: background and a systematic review of the literature. Eur Spine J, 2003; 12:108-116.
7. Freeman BJ, Davenport J. Total disc replacement in the lumbar spine: a systematic review of the literature. Eur Spine J. 2006; 15 Suppl 3:S439-447.
8. Geisler FH, Blumenthal SL, Guyer RD et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine, 2004; 1:143-154.
9. Huang RC, Sandhu HS. The current status of lumbar total disc replacement. Orthop Clin North Am. 2004; 35(1):33-42.
10. Leary SP, Regan JJ, Lanman TH, Wagner WH. Revision and explanation strategies involving the CHARITE lumbar artificial disc replacement. Spine. 2007. 20; 32(9):1001-1011.
11. Leivseth G, Braaten S, Frobin W, Brinckmann P. Mobility of lumbar segments instrumented with ProDisc II prosthesis: a two-year follow-up study. Spine. 2006; 31(15):1726-1733.
12. Malloy KM, Hillibrand AS. Autograft versus allograft in degenerative cervical disease. Clin Orthopaed Rel Res. 2002; (394):27-38.
13. McAfee PC, Cunningham B, Holsapple G, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. Spine. 2005; 15; 30(14):1576-1583.
14. Mummaneni PV, Burkus JK, Haid RW, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine. 2007; 6(3):198-209.
15. Nabhan A, Ahlhelm F, Pitzen T, et al. Disc replacement using Pro-Disc C versus fusion: a prospective randomized and controlled radiographic and clinical study. Eur Spine J. 2007; 16(3):423-430.
16. Pocock SJ. The pros and cons of noninferiority trials. Fundamental Clin Pharmacol. 2002; (17):483-490.
17. Siepe CJ, Mayer HM, Heinz-Leisenheimer M, Korge A. Total lumbar disc replacement: different results for different levels. Spine. 2007; 32(7): 782-790.
18. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurg Focus. 2004; 1517(3):E6.
19. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. Spine. 2007; 32(26):2933-2940;
20. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. J Spinal Disord Tech. 2007; 20(7):481-491.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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21. Robertson JT, Metcalf NH. Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. Neurosurg Focus. 2004; 1517(3):E10.
22. Shim CS, Lee SH, Shin HD, et al. CHARITE versus ProDisc: a comparative study of a minimum 3-year follow-up. Spine. 2007; 32(9): 1012-1018.
23. Shuff C, An HS. Artificial disc replacement: the new solution for discogenic low back pain? Am J Orthop. 2005; 34(1):8-12.
24. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine. 2007; 32(11):1155-1162.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Blue Cross Blue Shield Association. Artificial lumbar disc replacement. TEC Assessment, 2007; 22(02).
2. Blue Cross Blue Shield Association. Artificial vertebral disc replacement. TEC Assessment, 2005; 20(01).
3. Blue Cross Blue Shield Association. Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessment, 2008; 22(12).
4. Centers for Medicare and Medicaid Services. National Coverage Determination for Lumbar Artificial Disc Replacement (LADR) NCD #150.10. Effective date July 17, 2007. Available at: http://www.cms.hhs.gov/mcd/index_chapter_list.asp. Accessed on June 19, 2008.
5. National Institute of Neurological Disorders and Stroke (NINDS). Low back pain fact sheet. 2008. Available at: http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm#102233102 . Accessed on June 19, 2008.
6. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). New Device Approval CHARITÉ™ Artificial Disc - P040006. Available at: http://www.fda.gov/cdrh/mda/docs/p040006.html. Accessed on June 19, 2008.
7. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). New Device Approval PRESTIGE® Cervical Disc System - P060018. Available at: http://www.fda.gov/cdrh/pdf6/p060018.html . Accessed on June 19, 2008.
8. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). ProDisc™-C Total Disc Replacement - P070001. Available at: http://www.fda.gov/cdrh/pdf7/P070001.html . Accessed on June 19, 2008.
9. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). New Device Approval PRODISC®-L Total Disc Replacement - P050010. Available at: http://www.fda.gov/cdrh/pdf5/P050010.html . Accessed on June 19, 2008.

Index

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/28/2008	Medical Policy & Technology Assessment Committee (MPTAC) review. Rationale revised to address the FDA approval of the PRODISC-C®. Background/overview and references updated.
	11/29/2007	Rationale and background/overview updated to address the artificial cervical disc. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting. References updated.
Reviewed 08/23/2007		MPTAC review. References updated.
	02/23/2007	Rationale revised. Statement addressing completion of additional studies deleted.
	02/21/2007	Rationale clarified to distinguish between cervical and lumbar devices.
Reviewed 01/01/2007		Updated coding section with 01/01/2007 CPT/HCPCS changes; removed CPT 0091T, 0094T, 0097T deleted 12/31/2006.
Revised	09/14/2006	MPTAC review. Document revised to address only artificial intervertebral discs. References and coding updated.
Revised	06/08/2006	MPTAC review. Criteria statements revised to include intraspinous decompression implants as investigational/not medically necessary. Rationale, background and references updated. CMS Decision Memorandum dated May 16, 2006 added to background section.
Revised	03/23/2006	MPTAC annual review. Updated references and ICD-9 procedure code changes. Results of case studies from CMS Decision Memorandum dated February 15, 2006 added to the rationale section.
Revised 04/28/2005		MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.. Updated coding: Added CPT codes 0090T and 0098T (effective 07/01/2005)

Pre-Merger Organizations	Last Review Date	Number	Title
Anthem, Inc.	09/19/2003	SURG.00055	Artificial Intervertebral Discs
WellPoint Health Networks, Inc.	12/02/2004	3.07.18	Artificial Intervertebral Discs

DRAFT

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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Subject: Washington State Decision on Coverage for Artificial Disc Replacement
Date: Friday, December 12, 2008 2:16 PM
From: Katie O. Orrico <korrico@neurosurgery.org>
To: Praveen Mummaneni vmum@aol.com, Groff, MD Michael mgroff@bidmc.harvard.edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Christopher Wolfla CWolfla@mcw.edu, Bob Heary heary@umdnj.edu, Joseph Alexander jtalexan59@yahoo.com, Dan Resnick resnick@neurosurg.wisc.edu
Cc: Cathy Hill chill@neurosurgery.org, reh1@mac.com
Priority: Highest

Spine Section Guys:

I'm no expert, but this result seems pretty reasonable? See below for all links, etc. to the documents. Additional comments on this can be submitted until January 2, 2009.

Number and Coverage Topic

10172008 - Artificial Disc Replacement

HTCC Coverage Determination

Cervical and Lumbar Artificial Disc Replacement is a **covered benefit** only under criteria identified in the reimbursement determination**.**

HTCC Reimbursement Determination

Limitations of Coverage

1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency.

2) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:

Artificial Disc Replacement FDA general indications:

• Failure of non-operative treatment

• Skeletally mature patient

• Replacement of a single disc for disc disease confirmed by patient history and imaging

Artificial Disc Replacement FDA general contra-indications:

• Active systemic infection or infection localized to site of implantation

• Allergy or sensitivity to implant materials

• Certain bone and spine diseases (e.g. osteoporosis, spondylosis)

3) For lumbar artificial disc replacement, patients must be 60 years or under.

Non-Covered Indications

Non-FDA approved uses

For Lumbar ADR, patients older than 60 years old

Katie O. Orrico, Director
Washington Office
American Association of Neurological Surgeons/
Congress of Neurological Surgeons

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From: Pam Hayden [mailto:phayden@spine.org]
Sent: Friday, December 12, 2008 3:28 PM
To: Charles Branch, MD; Charles Mick, MD; Christopher Bono; Dr. Resnick; David A. Wong, MD, MSc; David W. Polly; Gunnar Andersson, MD; Hansen Yuan, MD; Jack Zigler, MD; Jeffrey Wang, MD; Jens Chapman, MD; Jerome Schofferman, MD; John Devine, MD; Johnn Heller, MD; Joseph Cheng, MD; Marjorie Eskay-Auerbach, MD, JD; Matthew Gornet, MD; Oheneba Boachie, MD; Praveen Mummaneni, MD; Ray Baker, MD; Richard D. Guyer, MD; Richard Wohns, MD; Steve Garfin; Steven Glassman, MD; Thomas Zdeblick; Tom Faciszewski, MD; Tom Faciszewski, MD (home); Wagner; William Watters
Cc: Belinda Duszynski; Cathy Hill; Dawn Brennaman; Eric Muehlbauer; Katie O. Orrico; Kristy Radcliffe; Nick Schilligo; Peggy Wlezien; Rachel Groman; Robert Haralson, MD; Tressa Goulding; Wendy Hess
Subject: FW: HTA Update: ADR Findings & Decision draft AND Oct. 17th HTCC draft public meeting minutes have been published on our HTA website
Importance: High

Dear Washington State Work Group,
Please see the below e-mail. These documents are now both posted. Please let me know if the work group has the desire to comment and if so what those comments would be by **COB Tuesday, December 16.** If the group chooses to comment, it would be my thought to turn this around next week before we start losing people to the holidays.

Best,
Pam

Pamela M. Hayden
Director, Research & Quality Improvement
North American Spine Society
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Fax 815.675.3137

From: Santoyo, Denise [mailto:Denise.Santoyo@HCA.WA.GOV]
Sent: Thursday, December 11, 2008 6:27 PM
Subject: HTA Update: ADR Findings & Decision draft AND Oct. 17th HTCC draft public meeting minutes have been published on our HTA website

Good afternoon everybody,

The HTA program is in the process of publishing two items on our HTA website, these documents will be available online before COB tomorrow:

- Oct. 17, 2008 Draft HTCC Public Meeting Minutes <http://www.hta.hca.wa.gov/past_materials.html>
- Artificial Disc Replacement Draft Findings & Decision <http://www.hta.hca.wa.gov/art_discs.html>

We are accepting public comments on both documents until **Friday, January 2nd, 2009** due to the Holiday Season.

Please let us know if you have any questions. Thank you for your interest and participation!

Have a wonderful evening,
Denise C. Santoyo
Washington State Health Care Authority
Health Technology Assessment
Program Coordinator
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December 8, 2008

Barbara J. Brown
Data Analyst, Office of Medical Policy & Tech Assessment
WellPoint, Inc.
4553 La Tienda Drive
Thousand Oaks, California 91362

Submitted Via Email: **Technology.Compendium@WellPoint.com**

Subject: BCBSA Draft Policy: 7.01.108 Artificial Intervertebral Disc: Cervical Spine
WellPoint Draft Policy: SURG.00055 Artificial Intervertebral Discs

Dear Ms. Brown:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, we appreciate the opportunity to comment on the above referenced draft coverage policies regarding the topic of Artificial Intervertebral Discs for the national Blue Cross and Blue Shield Association (BCBSA) and WellPoint. Submitted by Joseph S. Cheng, MD, MS, a member of the AANS and CNS Coding and Reimbursement Committee, this represents the collective opinion of organized neurosurgery's board-certified physicians.

We have attached our detailed review and comments on the attached questionnaire form, and as you will see, we do not agree with the proposed position statement that artificial intervertebral discs are considered investigational and not medically necessary in the treatment of degenerative disc disease of the spine.

The AANS and CNS appreciate the opportunity to collaborate in this process and offer these comments and we look forward to our continued relationship to further improve patient access to quality medical care. In the meantime, if you have any questions about our response, please contact us.

Sincerely,

James R. Bean

P. David Adelson

James R. Bean, MD, President
American Association of Neurological Surgeons

P. David Adelson, MD, President
Congress of Neurological Surgeons

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Daniel K. Resnick, MD, Chair
AANS/CNS Section on Disorders of the Spine
and Peripheral Nerves

Attachment: WellPoint, Inc., Medical Policy Questionnaire

cc: Joseph S. Cheng, MD, MS, Member, AANS/CNS Coding and Reimbursement Committee
Gregory J. Przybylski, MD, Chairman, AANS/CNS Coding and Reimbursement Committee

AANS/CNS Staff Contact:

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WellPoint, Inc.
Medical Policy Questionnaire

November 25, 2008

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines and on behalf of a national healthcare association (“”Association”) to support their processes for developing and maintaining medical policies.

We are currently reviewing the topic of **Artificial Intervertebral Discs**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We have designed our process to help you avoid duplication of effort in reviewing various entities’ medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic will be shared with non-WellPoint entities, the Association and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 35 million members enrolled in our plans, by even broader audience on behalf of the Association and the many millions of Americans whose health care benefits are provided by its member plans.

Attached are ***two (2) draft versions*** of the policy, **7.01.108 Artificial Intervertebral Disc: Cervical Spine (file name CVDI - 701108 - ArtDisc-Cerv.pdf)** and the second is labeled **SURG.00055 Artificial Intervertebral Discs (file name SURG.00055 WP 10-22-2008 CoDr.doc).** The first policy addresses artificial intervertebral discs of the cervical spine only. The second policy addresses artificial intervertebral discs of the cervical and lumbar spine.

***Your input is being requested on both versions*.** Please use the questionnaire labeled **7.01.108 Artificial Intervertebral Disc: Cervical Spine** to complete your response to the Association draft and the *separate* questionnaire for your response regarding the second policy draft labeled **SURG.00055 Artificial Intervertebral Discs** to correspond to your response.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. Please be sure to:

- **Answer all questions**
- **Complete the conflict of interest section**
- **Complete the demographic information and release statement on the following page**
- **Provide peer-reviewed literature citations when changes to a policy position are suggested**

Thank you for supporting our process to maintain medical necessity determinations consistent with the principles of evidence-based medicine by providing your expertise, guidance and input.

Please complete the information on the following page.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before December 23, 2008.

The following information is needed for this review.

Reviewer Name: *(Note: Include credentials)*	Joseph S. Cheng, MD, MS Member, AANS and CNS Coding and Reimbursement Committee, representing the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves
Board Certification in: *(Note: BC is required)*	Neurological Surgery
Academic/Hospital Affiliation(s):	Vanderbilt University American Association of Neurological Surgeons (AANS) Congress of Neurological Surgeons (CNS)
Address:	Department of Neurosurgery, T-4224 MCN, Nashville, TN 37232
State(s) of Medical Licensure:	Tennessee, Wisconsin
Phone:	(615) 322-1883
Fax:	(615) 343-8104
Date:	November 28, 2008

Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release any or all of the following points of information to the committee(s) and non-WellPoint entities, including a national Association.

	Yes	No	Comments
Your Board Certification	X		
Name of your Academic/Hospital Affiliation(s)	X		
Your Name	X		

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	Current medical evidence indicates that there is sufficient evidence to conclude that using artificial discs in the cervical spine is equivalent to fusion surgery. This position is supported by the Washington State Health Care Authority during its 2008 health technology assessment in addition to an independent panel, convened to review the assessment for Washington State on October 17, 2008, which voted to cover cervical artificial intervertebral discs. In addition, medical evidence to indicate that the use of cervical artificial intervertebral discs is medically necessary and not considered investigational if supported by the findings and policies of other insurance carriers such as Aetna (Clinical Policy Bulletin: Intervertebral Disc Prostheses. Policy Number: 0591 (Last Review: 05/23/2008)). The available studies had sufficient power for their study design, consistent multicenter protocols, homogeneous investigational and control groups, and the patients enrolled were representative of the intended medical population. As well, the outcomes were validated and included independent radiographic assessments.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	The rationale provided in "7.01.108 Artificial Intervertebral Disc: Cervical Spine" does not accurately reflect the current available medial evidence. The first criticism was that 2 years of follow-up is not adequate to evaluate long-term results, in particular any effect of the device on adjacent-level disc degeneration, device durability, adverse events, and revisability. Although it is preferable to have longer periods of data analysis than 2 years, the 2 year period is a reasonable amount of time for follow up in clinical studies before a procedure is accepted as non-investigational. Follow up of 2 years is considered the standard in our clinical studies. However, artificial cervical discs have been in reported clinical use for almost 20 years with approximately 23,000 artificial cervical discs implanted so far, with the majority outside of the United States (Pracyk 2005, ECRI 20007). The published results are favorable, such as the Prestige Cervical Disc

Definitions of Medically Necessary and Investigational included in Exhibit I

	Yes	No	Comments
			(previously known as the Bristol Cummins' artificial cervical joint) which was first implanted 17 years ago (Cummins 1998). At 5 years, they were able to follow-up with 18 of the original 20 patients, and noted that the device was stable and mobile and did not report issues related to disc degeneration, device durability, or adverse events. Robertson in 2004 published four year follow up results, noting that in the 12 patients available from the Prestige I study, the device continued to function and adjacent level disease was not present with clinical improvement in patient function and quality of life. Patel in 2007 reported 5-9 year follow-up for 31 patients who had the Prestige artificial disc placed between 1998 and 2002 and noted that all but one patient maintained motion of the artificial disc with no instances of device failure or adverse events. Delamarter in 2007 reported up to 4 year follow-up on 30 patients from the ProDisc-C U.S. IDE study noting clinical improvement. He also noted that motion was maintained, no evidence of adjacent segment degeneration, and no device-related complications. Bertagnoli in 2008 also reported up to 4 years of follow-up for 73 patients using the ProDisc-C artificial cervical disc noting that range of motion was maintained in over 90% of the patients and that there were no device-related complications or re-operations that were required. The Bryan Cervical Disc has been reported to have been implanted in over 15,000 times worldwide (FDA 2007). Goffin in 2006 reported the 4-year results for 69 single level procedures with the Bryan Cervical Disc noting that 61 of 69 patients had an excellent/good result and that motion was preserved in 83% of the patients and that only 3 of 69 developed some adjacent level degeneration at 4-years. This can be compared to the prior studies indicating a prevalence of 2.9% per year with an overall incidence of 25.6% in cervical fusion patients based on survivorship analysis (Hilibrand 1997, 1999). The second criticism was that the study was not blinded, and that the investigators and patients knew which procedure had been performed, which has potential to bias outcome assessments. Although a bias may be introduced, it would be impractical to

Definitions of Medically Necessary and Investigational included in Exhibit I

	Yes	No	Comments
			double blind a surgeon regarding an implant that is to be surgically placed. While blinded studies are statistically valid and an ideal goal for pharmaceutical studies, it is not something that can be achieved in device studies. In addition, post-operative care and imaging will allow the patient to become aware of their device as it would not be feasible to blind the radiographic review as the device would be clearly identifiable on x-rays. The third and final criticism was that some experimental patients had increased pain of the neck (6.2% vs. 0.8% at 2 years) and arm (9.4% and 5.8%) after the procedure, and that these findings merit additional investigation for their clinical relevance. This finding is unusual and does not reflect the majority of the other published reports noting that artificial intervertebral disc arthroplasty is a good alternative to anterior cervical fusions in patients with cervical spondylosis and degenerative disc disease (Acosta 2005, Anderson 2007, Smucker 2006, Phillips 2005, Anderson 2004, Pracyk 2005, Bertagnoli 2005). As well, there are a number of smaller studies showing that cervical arthroplasty is safe and at as effective as cervical fusions in those patients who had similar surgical indications to ACDF such as radiculopathy and myelopathy (Brown 2006, McAfee 2004). In the three large randomized clinical trials, there were consistent evidence that artificial cervical discs were statistically noninferior to the standard ACDF, with non-statistically significant improvements in neurologic status and the neck disability index (NDI) in the patients receiving the artificial cervical discs. The authors of the Wellpoint draft policy also noted that the FDA has required the Prestige disc manufacturer to conduct a 7-year post-approval clinical study of the safety and function of the device, and a 5-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population. This statement by the FDA does not indicate any negative concerns related to the device as this statement would seem to indicate, as otherwise the Prestige disc would not have been approved by the FDA, but rather a continued evolution of the FDA process.

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Since the enactment of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, the Center for Devices and Radiological Health (CDRH) has been developing new protocols for postmarket surveillance to monitor the performance of marketed medical devices. As the medical devices today are vastly different from those used 30 years ago, "The postmarket system that we set up 30 years ago is not designed to deal with all of the new things that are happening today in the device industry" as noted by CDRH Director Daniel Schultz, M.D..
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:			
Therapeutic Interventions: • The policy indicates artificial intervertebral discs of the cervical spine are considered **investigational** for treatment of disorders of the cervical spine, including degenerative disc disease. - Do you agree? - If no, please comment and cite literature to support.		X	We do not agree with the policy indicating that artificial intervertebral discs of the cervical spine are considered investigational for treatment of disorders of the cervical spine, including degenerative disc disease. This conclusion is not consistent with the favorable results from the available published literature, nor does it indicate the prevailing clinical opinion among neurosurgeons and orthopedic spine surgeons. On September 8, 2006, our American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), and the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves submitted a letter to the FDA in support of a favorable consideration for cervical disc arthroplasty. In addition to the comments as noted above, the follow references are cited for support from the literature. Aetna Clinical Policy Bulletin: Intervertebral Disc Prostheses. Policy Number: 0591 (Last Review: 05/23/2008) (http://www.aetna.com/cpb/medical/data/500_599/0591.html) Bertagnoli R. Single level ProDisc-C Total Disc Replacment up to four years follow-up, Number 145. North American Spine Society, October 15-18, 2008, Toronto, Canada. Cheng JS, Liu F, Komistek RD, Mahfouz MR, Sharma A, Glaser D. Comparison of Cervical Spine Kinematics Using a Fluoroscopic Model for Adjacent Segment Degeneration. Journal of Neurosurgery - Spine, 7(5):509-

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			513. Nov 2007. Cummins B, Robertson J and Gill S. Surgical experience with an implanted artificial cervical joint, J Neurosurg 1998, 88: 943-948. Delamarter R, Bradhan B, Kanim L, et al. Cervical disc replacement: over 3-4 prospective randomized clinical outcomes and range of motion follow-up with the Prodisc-C prosthesis, Number 64. North American Spine Society, October 23-27, 2007, Austin, TX. ECRI Institute, Emerging Technology (TARGET) Evidence Report, Artificial intervertebral disc replacement (AIDR) for symptomatic cervical disc disease, 2007. Food and Drug Administration, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, Office of Surveillance and Biometrics, Design of Condition of Approval Studies and Smith & Nephew Birmingham Hip Resurfacing (BHR) System, P040033, September 8, 2005. Food and Drug Administration, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, Medtronic Sofamor Danek Bryan Cervical Disc, P060023, July 17, 2007. Food and Drug Administration, Center for Devices and Radiologic Health, Division of Post-market Surveillance, Office of Surveillance and Biometrics, Guidance for Industry and FDA staff – Procedures for Handling Post-approval Studies Imposed by PMA Order, August 1, 2007. Food and Drug Administration, Center for Devices and Radiologic Health, Post-approval studies, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm Goffin J, Casey A, Kehr P, Liebig K, et al. Preliminary clinical experience with the Bryan Cervical Disc Prosthesis, Neurosurgery 2002, 51: 840-847. Goffin J, van Loon J, van Calenbergh F. Cervical arthroplasty with the Bryan Disc: 4-

Policy Number: 7.01.108 Policy Title: Artificial Intervertebral Disc: Cervical Spine			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			and 6-year results, Cervical Spine Research Society, November 30-December 2, 2006, Palm Beach, FL. Hilibrand AS, Carlson GD, Palumbo MA, et al.: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical athrodesis. J Bone Joint Surg 81-A:519-528, 1999. Lee CK, Langrana NA. A review of spinal fusion for degenerative disc disease: need for alternative treatment approach of disc arthroplasty? Spine J. 2004 Nov-Dec;4(6 Suppl):173S-176S. Liu F, Cheng JS, Komistek RD, Mahfouz MR, Sharma A. In Vivo Evaluation of Dynamic Characteristics of the Normal, Degenerative, Fused, and Disc Replacement Cervical Spines. Spine, 32(23): 2578–2584. Nov 1, 2007. Mummaneni, et al. Journal of Neurosurgery Spine. 2007 Mar; 6(3):198-209. Clinical and Radiographic Analysis of Cervical Disc Arthroplasty Compared with Allograft Fusion: A Randomized Controlled Clinical Trial. Office of the Inspector General, Department of Health and Human Services, Review of the Food and Drug Administration's Handling of Adverse Drug Reaction Reports, A-15-98-50001, December 1999. http://www.oig.hhs.gov/oas/reports/phs/c9850001.pdf Papadopoulos S. The Bryan Cervical Disc System, Neurosurg Clin N Am 2005, 16: 629-36. Patel N, Robertson J, Metcalf N and Gill S. Long-term follow-up of patients treated with the Prestige Artificial Disc at a Single Center, Congress of Neurological Surgeons, September 15-20, 2007, San Diego, CA. Pracyk J and Traynelis V. Treatment of the painful motion segment: Cervical arthroplasty, Spine 2005, 30 (16S): S23-32. Robertson J and Metcalf N. Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study, Neurosurg Focus 2004, 3:

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	Yes	**No**	**Comments**
			E10. Washington State Health Care Authority, Health Technology Assessment, HTA Final Report Artificial Discs Replacement, ADR, September 19, 2008,
• Do you consider artificial intervertebral discs of the cervical spine **medically necessary**? If yes, - Are there any specific criteria which would be useful in selecting appropriate patient populations?	X		We would recommend that the indications for use of cervical disc arthroplasty follow the inclusion criteria from the large scale clinical trials used for FDA approval. That would include the application of this procedure to skeletally mature patients with cervical spine disease at C3-C7 necessitating a single-level decompression via an open anterior approach, and used for patients with intractable pain, radiculopathy, and/or myelopathy associated with radiographic studies showing a herniated cervical disc or cervical spondylosis and osteophytes.
- Are there any specific clinical or patient characteristics for when artificial intervertebral discs of the cervical spine are not appropriate? - Please comment and cite literature to support.	X		We would recommend that clinical or patient characteristics for which the artificial intervertebral disc is not appropriate include patients with cervical instability (sagittal plane translation >3.5mm, sagittal plane angulation >20°), facet joint pathology, osteoporosis, cancer, and infection. The literature supporting this is as indicated in the large scale clinical trials.
• Are there additional indications for artificial intervertebral discs of the cervical spine beyond those discussed in the document? - If yes, please comment and cite literature to support.		X	
• Is there evidence to support one type of artificial disc over another (i.e., ProDisc-C® and Prestige ST Cervical Disc)? - If yes, please comment and cite literature to support.		X	
• Is the use of artificial intervertebral discs of the cervical spine safe and efficacious in the treatment of degenerative disc disease? - If yes, please comment and cite literature to support.	X		The available large multicenter prospective randomized IDE studies have concluded that disc arthroplasty is a safe and reasonable alternative to anterior cervical fusion in the treatment of degenerative disc disease in selected patients as described by the study inclusion criteria over a clinically meaningful time point as defined by the FDA. Mummaneni in 2007 reported statistical noninferiority for disc arthroplasty versus ACDF in all three primary outcome variables (Neck Disability Index (NDI), neurological status, and functional spinal unit height (FSU)) and for the overall success composite

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	Yes	No	Comments
			outcome with the neurological status noting statistical superiority. Arthroplasty patients showed preservation of motion with retention of sagittal angular motion of over 7 degrees and also a 2-point greater improvement in the Neck Disability Index (NDI). Although it was not statistically significant, there was an overall success with better SF-36 at 12 and 24 months associated with a greater relief of neck pain and earlier return to work in the arthroplasty group. There were no serious associated adverse events and no cases of implant failure or migration, along with a lower rate of revision surgeries including a lower rate of supplemental fixation and of re-operations at the adjacent segment. Murrey reported a prospective, randomized, controlled trial of 209 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive Prodisc-C or ACDF with plate and allograft with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that Prodisc-C is not inferior to ACDF 2 years after surgery in Overall Success, the study's primary endpoint. Heller reported a prospective, randomized, controlled trial of 463 patients with 1-level DDD with concordant radiculopathy and/or myelopathy randomized 1:1 to receive Bryan Cervical Disc or Atlantis Cervical Plate with allograft (ACDF) with follow-up of 3 and 6 weeks, 3, 6, 12, 24 months. The results showed that the cervical disc replacement maintained segmental motion at 24 months after implantation and was associated with improved NDI Success (superiority), improved clinical outcomes, and 13 days faster return to work compared to ACDF patients. Statistical superiority in Overall Success (study's primary endpoint) was demonstrated at 24 months.
***Improved Patient Outcomes*:** • Is there adequate evidence to demonstrate that the use of artificial intervertebral discs of the cervical spine provide significant improvements in clinical outcomes *compared to the available alternatives?*		X	The current studies indicate that cervical disc arthroplasty is a safe and reasonable alternative to anterior cervical fusion with equivalent clinical outcomes. The main impetus for motion preservation is adjacent segment degeneration and disease, and this benefit is gained in the setting of equivalent post-operative improvements in clinical outcomes between cervical disc arthroplasty as compared to the available alternatives (cervical fusion).

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	Yes	**No**	**Comments**
• Is there *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of artificial intervertebral discs of the cervical spine? If so, please cite.	X		Yes, and these references are as cited above in the responses to the previous questions.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	
***Conflict of Interest*:** Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with artificial intervertebral discs? If so, please disclose that relationship.		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- not primarily for the convenience of the patient, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The term "investigational" means that the medical policy does not meet the Technology Evaluation Criteria.

This means any procedure, treatment, supply, device, equipment, facility or drug (all services), are determined NOT to:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

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	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	The policy position blends in cervical and lumbar disc arthroplasty, which leads to incorrect assumptions. Cervical and lumbar arthroplasty and their investigational studies should not be conflated, as there are substantial anatomic and procedural differences. The Centers for Medicare and Medicaid Services (CMS) have issued a national non coverage determination for lumbar artificial disc replacement for the Medicare population over sixty years of age, but this does not apply to cervical artificial discs. The Category III codes for the cervical disc arthroplasty is incorrect in the policy, as the Federal Register (November 2008) indicates that CPT 22856/22561/22564 is included with appropriate RVU valuations.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	We do not agree with the rationale by the authors of the Artificial Intervertebral Discs draft policy, Document #SURG.00055 (10/22/2008), and do not feel that it accurately reflects the current available medial evidence. Regarding the Charité Artificial Disc, they noted that although the Charité disc had a higher success rate than the BAK cage in its clinical IDE trial, this difference would not have met traditional criteria for a superiority trial. While hypothetically correct, in that a non-inferiority design (as compared to a superiority trial) could result in the Charite with a d=0.15, i.e. 95% confidence interval, could allow a 15% worse result when compared to BAK and still meet non-inferiority criteria, this has not been shown to be the case. The FDA has requested a 10% difference for a non-inferiority study, and the results were sufficient to allow approval of the Charité Artificial Disc. The authors of the Wellpoint draft policy also note that the randomized controlled trial for the Charité Artificial Disc had several methodological issues that made it difficult to interpret the results. Their first concern was that the analysis showed non-inferiority compared to BAK fusion using the composite measure of success, but did not show statistically significant superiority in most outcome measures. However, it should be noted that a non-inferiority trial is a common

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			and accepted study method for device trials, and that superiority trials are not the standard of IDE trials. As well, a non-inferiority trial requires that the reference treatment have an established efficacy or that it is in widespread use. In the referenced study, there was evidence that the efficacy of lumbar artificial discs, as measured by the composite measure of overall clinical success, Oswestry Disability Index (ODI) improvement, pain improvement, neurological success, SF-36 improvement, and patient satisfaction was comparable with anterior lumbar interbody fusion or circumferential fusion up to two years following surgery. The overall clinical success (a composite measure considering most or all of the following: ODI improvement, device failure, complications, neurological change, SF-36 change and radiographic success) was achieved in 56% of patients receiving the Charité Artificial Disc and 48% of those receiving the lumbar fusion. The results suggest that 24 month outcomes for lumbar artificial discs were similar to lumbar fusion for degenerative disc disease. The rationale that utilizing a trial designed and analyzed as a noninferiority trial was done so in order to establish a less stringent standard for demonstrating efficacy than a standard clinical trial and that such trials are often employed when there is some margin of acceptable inferiority of a new technology in its principal outcome indicates a negative bias and misunderstanding of what is reasonably acceptable and feasible in clinical device trials. Issues such as unilateral cross over, ability to blind, among others have led to the use of non-inferiority as the base hypothesis in surgical and device trials and have been shown in other large scale non-device surgical studies such as the SPORT trial looking at lumbar disc herniation and disease. As well, fusion has been associated with a notable success rate in control cases and given the disease process being studies. The fusion success rate would be a difficult endpoint for cervical arthroplasty to exceed supporting the rationale for a non inferiority study design rather than a superiority design. There was also a second concern that there was a lack of a prespecified analysis plan, unexplained closure of the data base before

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			all patients reached completion, and lack of intent-to-treat analysis that may cast some doubt on the analysis. Although these were not addressed in the available papers, these variables were not an inherent part of the published peer reviewed work nor integral to the conclusions by the artificial disc study authors. Although additional and more rigorous trials of the outcomes of the use of an artificial disc in the treatment of DDD are needed, this same statement regarding the need for more rigorous trials and outcomes may be made for the majority of medical and surgical care currently available. This would then also apply to the general comments noted by the Wellpoint authors in extrapolating comments from Bertagnoli (2006) in that the authors cautiously recommend the use of artificial disc replacement in the treatment of chronic discogenic low back pain, in the study by Chung (2006) noting that future efforts need to be directed toward the evaluation of a larger number of patients with longer follow-up, and Freeman (2006) in that larger, well designed prospective randomized controlled trials with longer follow-up are needed. These general disclaimers and statements for future work were not meant to indicate that the technology and procedure remains experimental and outside the armamentarium of a general spine surgery practice. As well, it should be noted that cervical disc arthroplasty is quite different than lumbar disc arthroplasty. Concerns were raised in that the PMA was contingent upon a seven year post approval study to evaluate long-term safety and effectiveness of the Prodisc-C and the Prestige cervical disc. This has been addressed in the preceding question regarding the FDA requests and that this does not indicate a device rejection or experimental status, but rather the changing landscape in the FDA and in the area of medical devices. As well, although the Wellpoint document indicates that studies such as by Nabhan (2007) note that the loss of segmental motion was significantly higher in the ACDF group and that significant pain reduction was observed in the neck and arm postoperatively, it would seem that there were attempts to mitigate these positive results by noting comments such as "the

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			study was small and that larger studies with longer follow up are warranted". The issues raised which were postulated to cloud the conclusions such as that the trial was unblinded (double blinding is near impossible to do in a surgical study) and the 4% cohort withdraw rate which is not unexpected in this type of clinical trial. Also, although it was acknowledged that the investigational group reported better neurological success, concern was raised that the investigators provided no detail how the neurological status was measured and evaluated, despite the fact that the same argument was not made regarding the prior negative comments regarding artificial cervical discs and the comments accepted. This would seem to indicate a bias toward accepting negative data regarding surgical treatment while calling into question the positive outcomes.
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:			
Therapeutic Interventions: • The policy indicates that the use of artificial intervertebral discs is investigational in the treatment of cervical and lumbar degenerative disc disease. Do you agree? - If no, please comment and cite literature to support.		X	We do not agree with the policy indicating that artificial intervertebral discs of the spine are considered investigational for treatment of disorders of the spine, including degenerative disc disease. This conclusion is not consistent with the favorable results from the available published literature, nor does it indicate the prevailing clinical opinion among neurosurgeons and orthopedic spine surgeons. In addition to the comments as noted above, the follow references are cited for support from the literature. Food and Drug Administration (FDA). Clinical review for PMA (P040006) Charité artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004. Food and Drug Administration (FDA). In-depth statistical review for expedited PMA (P040006) Charite artificial disc, DePuy Spine Inc (report on the Internet). Edited, United States Department of Health & Human Services, 2004. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED). Prosthesis intervertebral disc (report on the Internet). Edited, 2004.

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Food and Drug Administration (FDA). New device approval: PRESTIGE cervical disc system - P060018 [report on the Internet]. Edited, 2007. Food and Drug Administration (FDA). New device approval: ProDisc-C total disc replacement - P070001 [report on the Internet]. Edited, 2007. Food and Drug Adminstration (FDA) Executive Summary, Bryan Cervical Disc. Edited, 2007. Washington State Department of Health, Center for Health Statistics, Comprehensive Hospitalization Abstract Reporting System (2005-2007). Edited. Abd-Alrahman, N.; Dokmak, A. S.; and Abou-Madawi, A.: Anterior cervical discectomy (ACD) versus anterior cervical fusion (ACF), clinical and radiological outcome study. Acta Neurochir (Wien), 141(10): 1089-92, 1999. Amit, A., and Dorward, N.: Bryan cervical disc prosthesis: 12-Month clinical outcome. British Journal of Neurosurgery, 21(5): 478-484, 2007. Anderson, P. A., and Rouleau, J. P.: Intervertebral disc arthroplasty. Spine, 29(23):2779-86, 2004. Bartels, R. H.; Donk, R.; van der Wilt, G. J.; Grotenhuis, J. A.; and Venderink, D.: Design of the PROCON trial: a prospective, randomized multi-center study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty. BMC Musculoskelet Disord, 7: 85, 2006. Bertagnoli, R.; Duggal, N.; Pickett, G. E.; Wigfield, C. C.; Gill, S. S.; Karg, A.; and Voigt, S.: Cervical total disc replacement, part two: clinical results. Orthop Clin North Am, 36(3): 355-62, 2005. Bertagnoli, R., and Kumar, S.: Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. Eur Spine J, 11 Suppl 2:S131-6, 2002.

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Bertagnoli, R. et al.: Lumbar total disc arthroplasty utilizing the ProDisc prosthesis in smokers versus nonsmokers: a prospective study with 2-year minimum follow-up. Spine, 31(9): 992-7, 2006. Bertagnoli, R.; Yue, J. J.; Nanieva, R.; Fenk-Mayer, A.; Husted, D. S.; Shah, R. V.; and Emerson, J. W.: Lumbar total disc arthroplasty in patients older than 60 years of age: a prospective study of the ProDisc prosthesis with 2-year minimum follow-up period. J Neurosurg Spine, 4(2): 85-90, 2006. Bertagnoli, R.; Yue, J. J.; Pfeiffer, F.; Fenk-Mayer, A.; Lawrence, J. P.; Kershaw, T.; and Nanieva, R.: Early results after ProDisc-C cervical disc replacement. J Neurosurg Spine, 2(4): 403-10, 2005. Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.: The treatment of disabling multilevel lumbar discogenic low back pain with total disc arthroplasty utilizing the ProDisc prosthesis: a prospective study with 2-year minimum follow-up. Spine, 30(19): 2192-9, 2005. Bertagnoli, R.; Yue, J. J.; Shah, R. V.; Nanieva, R.; Pfeiffer, F.; Fenk-Mayer, A.; Kershaw, T.; and Husted, D. S.: The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year minimum follow-up. Spine, 30(19): 2230-6, 2005. Blue Cross Blue Shield Association: Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2007. Blue Cross Blue Shield Association: Artificial vertebral disc replacement [report on the Internet]. Edited, Technology Evaluation Center Assessment Program, 2005. Blumenthal, S.; McAfee, P. C.; Guyer, R. D.; Hochschuler, S. H.; Geisler, F. H.; Holt, R. T.; Garcia, R., Jr.; Regan, J. J.; and Ohnmeiss, D. D.: A prospective, randomized, multicenter Food and Drug

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine, 30(14): 1565-75; discussion E387-91, 2005. Brantigan, J. W.; Steffee, A. D.; Lewis, M. L.; Quinn, L. M.; and Persenaire, J. M.: Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial. Spine, 25(11): 1437-46, 2000. Brox, J. I. et al.: Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. Pain, 122(1-2): 145-55, 2006. Brox, J. I. et al.: Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. Spine, 28(17): 1913-21, 2003. Caspi, I.; Levinkopf, M.; and Nerubay, J.: Results of lumbar disk prosthesis after a follow-up period of 48 months. Isr Med Assoc J, 5(1): 9-11, 2003. Chou, W. Y.; Hsu, C. J.; Chang, W. N.; and Wong, C. Y.: Adjacent segment degeneration after lumbar spinal posterolateral fusion with instrumentation in elderly patients. Arch Orthop Trauma Surg, 122(1): 39-43, 2002. Chung, S. S.; Lee, C. S.; and Kang, C. S.: Lumbar total disc replacement using ProDisc II: a prospective study with a 2-year minimum follow-up. J Spinal Disord Tech, 19(6): 411-5, 2006. Chung, S. S.; Lee, C. S.; Kang, C. S.; and Kim, S. H.: The effect of lumbar total disc replacement on the spinopelvic alignment and range of motion of the lumbar spine. J Spinal Disord Tech, 19(5): 307-11, 2006. Cinotti, G.; David, T.; and Postacchini, F.: Results of disc prosthesis after a minimum

	Yes	No	Comments
			follow-up period of 2 years. Spine, 21(8): 995-1000, 1996. Coric, D.; Finger, F.; and Boltes, P.: Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. J Neurosurg Spine, 4(1): 31-5, 2006. Cunningham, B. W. et al.: Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITE artificial disc compared with fusion. J Neurosurg Spine, 8(1): 7-12, 2008. David, T.: Long-term results of one-level lumbar arthroplasty: minimum 10-year followup of the CHARITE artificial disc in 106 patients. Spine, 32(6): 661-6, 2007. 46. de Kleuver, M.; Oner, F. C.; and Jacobs, W. C.: Total disc replacement for chronic low back pain: background and a systematic review of the literature. Eur Spine J, 12(2): 108-16, 2003. Duggal, N.; Pickett, G. E.; Mitsis, D. K.; and Keller, J. L.: Early clinical and biomechanical results following cervical arthroplasty. Neurosurg Focus, 17(3): E9, 2004. Errico, T. J.: Lumbar disc arthroplasty. Clin Orthop Relat Res, (435): 106-17, 2005. Etebar, S., and Cahill, D. W.: Risk factors for adjacent-segment failure following lumbar fixation with rigid instrumentation for degenerative instability. J Neurosurg, 90(2 Suppl): 163-9, 1999. Fairbank, J.; Frost, H.; Wilson-MacDonald, J.; Yu, L. M.; Barker, K.; and Collins, R.: Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. BMJ, 330(7502): 1233, 2005. Fernstrom, U.: Arthroplasty with intercorporal endoprosthesis in herniated disc and in painful disc. Acta Chir Scand Suppl, 357: 154-9, 1966. Fong, S. Y.; DuPlessis, S. J.; Casha, S.; and Hurlbert, R. J.: Design limitations of

	Yes	No	Comments
			Bryan disc arthroplasty. Spine J, 6(3): 233-41, 2006. Fraser, R. D.; Ross, E. R.; Lowery, G. L.; Freeman, B. J.; and Dolan, M.: AcroFlex design and results. Spine J, 4(6 Suppl): 245S-251S, 2004. Frelinghuysen, P.; Huang, R. C.; Girardi, F. P.; and Cammisa, F. P., Jr.: Lumbar total disc replacement part I: rationale, biomechanics, and implant types. Orthop Clin North Am, 36(3): 293-9, 2005. Geisler, F. H.; Blumenthal, S. L.; Guyer, R. D.; McAfee, P. C.; Regan, J. J.; Johnson, J. P.; and Mullin, B.: Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine, 1(2): 143-54, 2004. Ghiselli, G.; Wang, J. C.; Bhatia, N. N.; Hsu, W. K.; and Dawson, E. G.: Adjacent segment degeneration in the lumbar spine. J Bone Joint Surg Am, 86-A(7): 1497-503, 2004. Goffin, J. et al.: Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. Spine, 28(24): 2673-8, 2003. Guyer, R. D.; Geisler, F. H.; Blumenthal, S. L.; McAfee, P. C.; and Mullin, B. B.: Effect of age on clinical and radiographic outcomes and adverse events following 1-level lumbar arthroplasty after a minimum 2-year follow-up. J Neurosurg Spine, 8(2): 101-7, 2008. Guyer RD, T. S., Regan JJ: An economic model of one-level lumbar arthoplasty versus fusion. Spine Journal, 7(5): 558-562, 2007. Hallab, N.; Link, H. D.; and McAfee, P. C.: Biomaterial optimization in total disc

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			arthroplasty. Spine, 28(20): S139-52, 2003. Heidecke, V.; Burkert, W.; Brucke, M.; and Rainov, N. G.: Intervertebral disc replacement for cervical degenerative disease--clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. Acta Neurochir (Wien), 150(5): 453-9; discussion 459, 2008. Hilibrand, A. S.; Carlson, G. D.; Palumbo, M. A.; Jones, P. K.; and Bohlman, H. H.: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. J Bone Joint Surg Am, 81(4): 519-28, 1999. Hoang, L.; Thongtrangan, I.; and Kim, D.: Historical review of cervical arthroplasty. Edited, 2004. Huang, R. C.; Lim, M. R.; Girardi, F. P.; and Cammisa, F. P., Jr.: The prevalence of contraindications to total disc replacement in a cohort of lumbar surgical patients. Spine, 29(22): 2538-41, 2004. Huang, R. C.; Tropiano, P.; Marnay, T.; Girardi, F. P.; Lim, M. R.; and Cammisa, F. P., Jr.: Range of motion and adjacent level degeneration after lumbar total disc replacement. Spine J, 6(3): 242-7, 2006. Ishihara, H.; Kanamori, M.; Kawaguchi, Y.; Nakamura, H.; and Kimura, T.: Adjacent segment disease after anterior cervical interbody fusion. Spine J, 4(6): 624-8, 2004. Jollenbeck, B.; Hahne, R.; Schubert, A.; and Firsching, R.: Early experiences with cervical disc prostheses. Zentralbl Neurochir, 65(3): 123-7, 2004. Kim, D. H.; Ryu, K. S.; Kim, M. K.; and Park, C. K.: Factors influencing segmental range of motion after lumbar total disc replacement using the ProDisc II prosthesis. J Neurosurg Spine, 7(2): 131-8, 2007. Kim, S. H.; Shin, H. C.; Shin, D. A.; Kim, K. N.; and Yoon do, H.: Early clinical experience with the mobi-C disc prosthesis. Yonsei Med J, 48(3): 457-64, 2007.

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	Yes	**No**	**Comments**
			Kulkarni, V.; Rajshekhar, V.; and Raghuram, L.: Accelerated spondylotic changes adjacent to the fused segment following central cervical corpectomy: magnetic resonance imaging study evidence. J Neurosurg, 100(1 Suppl Spine): 2-6, 2004. Kumar, M. N.; Jacquot, F.; and Hall, H.: Long-term follow-up of functional outcomes and radiographic changes at adjacent levels following lumbar spine fusion for degenerative disc disease. Eur Spine J, 10(4): 309-13, 2001. Lafuente, J.; Casey, A. T.; Petzold, A.; and Brew, S.: The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis: 46 consecutive cases. J Bone Joint Surg Br, 87(4): 508-12, 2005. Le Huec, J. C.; Mathews, H.; Basso, Y.; Aunoble, S.; Hoste, D.; Bley, B.; and Friesem, T.: Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up. Orthop Clin North Am, 36(3): 315-22, 2005. Leivseth, G.; Braaten, S.; Frobin, W.; and Brinckmann, P.: Mobility of lumbar segments instrumented with a ProDisc II prosthesis: A two-year follow-up study. Spine, 31(15): 1726-1733, 2006. Lemaire, J. P.; Carrier, H.; Sariali el, H.; Skalli, W.; and Lavaste, F.: Clinical and radiological outcomes with the Charite artificial disc: a 10-year minimum follow-up. J Spinal Disord Tech, 18(4): 353-9, 2005. Leung, C.; Casey, A. T.; Goffin, J.; Kehr, P.; Liebig, K.; Lind, B.; Logroscino, C.; and Pointillart, V.: Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. Neurosurgery, 57(4): 759-63; discussion 759-63, 2005. Levin, D. A.; Bendo, J. A.; Quirno, M.; Errico, T.; Goldstein, J.; and Spivak, J.: Comparative charge analysis of one- and two-level lumbar total disc arthroplasty versus circumferential lumbar fusion. Spine, 32(25): 2905-9, 2007.

Policy Number: SURG.00055 Policy Title: Artificial Intervertebral Discs			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Levin DA, B. J., Quirno M, Errico T, Goldstein J, Spivak J: Comparative charge analysis of one- and two-level lumbar total disc arthroplasty versus circumferential lumbar fusion. Spine 32(25): 2905-9, 2007. Lin, E. L., and Wang, J. C.: Total disk arthroplasty. J Am Acad Orthop Surg, 14(13): 705-14, 2006. Liu, F.; Cheng, J.; Komistek, R. D.; Mahfouz, M. R.; and Sharma, A.: In vivo evaluation of dynamic characteristics of the normal, fused, and disc replacement cervical spines. Spine, 32(23): 2578-84, 2007. Mayer, H. M.: Total lumbar disc replacement. J Bone Joint Surg Br, 87(8): 1029-37, 2005. Mayer, H. M., and Wiechert, K.: Microsurgical anterior approaches to the lumbar spine for interbody fusion and total disc replacement. Neurosurgery, 51(5 Suppl): S159-65, 2002. McAfee, P. C.: The indications for lumbar and cervical disc replacement. Spine J, 4(6 Suppl): 177S-181S, 2004. McAfee, P. C. et al.: A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. Spine, 30(14): 1576-83; discussion E388-90, 2005. McAfee, P. C. et al.: Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. Spine, 31(11): 1217-26, 2006. McCullen, G. M., and Yuan, H. A.: Artificial disc: current developments in artificial disc replacement. Curr Opin Orthop, 14: 138-143, 2003. Medical Services Advisory Committee (Australia): Artificial intervertebral disc replacement (Total disc arthroplasty). Edited,

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Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			Canberra, Commonwealth of Australia, 2006. Mehren, C.; Suchomel, P.; Grochulla, F.; Barsa, P.; Sourkova, P.; Hradil, J.; Korge, A.; and Mayer, H. M.: Heterotopic ossification in total cervical artificial disc replacement. Spine, 31(24): 2802-6, 2006. Mummaneni, P. V.; Burkus, J. K.; Haid, R. W.; Traynelis, V. C.; and Zdeblick, T. A.: Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine, 6(3): 198-209, 2007. Nabhan, A.; Ahlhelm, F.; Pitzen, T.; Steudel, W. I.; Jung, J.; Shariat, K.; Steimer, O.; Bachelier, F.; and Pape, D.: Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. Eur Spine J, 16(3): 423-30, 2007. Nabhan, A.; Ahlhelm, F.; Shariat, K.; Pitzen, T.; Steimer, O.; Steudel, W. I.; and Pape, D.: The ProDisc-C prosthesis: clinical and radiological experience 1 year after surgery. Spine, 32(18): 1935-41, 2007. Peng-Fei, S., and Yu-Hua, J.: Cervical disc prosthesis replacement and interbody fusion: a comparative study. Int Orthop, 32(1): 103-6, 2008. Petersilge, C. A.: Lumbar disc replacement. Semin Musculoskelet Radiol, 10(1): 22-9, 2006. Piaggio, G.; Elbourne, D. R.; Altman, D. G.; Pocock, S. J.; and Evans, S. J.: Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. Jama, 295(10): 1152-60, 2006. Pickett, G. E.; Sekhon, L. H.; Sears, W. R.; and Duggal, N.: Complications with cervical arthroplasty. J Neurosurg Spine, 4(2): 98-105, 2006. Pimenta, L.; McAfee, P. C.; Cappuccino, A.; Bellera, F. P.; and Link, H. D.: Clinical experience with the new artificial cervical

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			PCM (Cervitech) disc. Spine J, 4(6 Suppl): 315S-321S, 2004. Pointillart, V.: Cervical disc prosthesis in humans: first failure. Spine, 26(5): E90-2, 2001. Porchet, F., and Metcalf, N. H.: Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurg Focus, 17(3): E6, 2004. Punt, I. M.; Visser, V. M.; van Rhijn, L. W.; Kurtz, S. M.; Antonis, J.; Schurink, G. W.; and van Ooij, A.: Complications and reoperations of the SB Charite lumbar disc prosthesis: experience in 75 patients. Eur Spine J, 17(1): 36-43, 2008. Putzier, M.; Funk, J. F.; Schneider, S. V.; Gross, C.; Tohtz, S. W.; Khodadadyan-Klostermann, C.; Perka, C.; and Kandziora, F.: Charite total disc replacement-clinical and radiographical results after an average follow-up of 17 years. Eur Spine J, 15(2): 183-95, 2006. Rabin, D.; Pickett, G. E.; Bisnaire, L.; and Duggal, N.: The kinematics of anterior cervical discectomy and fusion versus artificial cervical disc: a pilot study. Neurosurgery, 61(3 Suppl): 100-4; discussion 104-5, 2007. Regan, J. J.; McAfee, P. C.; Blumenthal, S. L.; Guyer, R. D.; Geisler, F. H.; Garcia, R., Jr.; and Maxwell, J. H.: Evaluation of surgical volume and the early experience with lumbar total disc replacement as part of the investigational device exemption study of the Charite Artificial Disc. Spine, 31(19): 2270-6, 2006. Robertson, J. T., and Metcalf, N. H.: Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. Neurosurg Focus, 17(3): E10, 2004. Robertson, J. T.; Papadopoulos, S. M.; and Traynelis, V. C.: Assessment of adjacent segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study. J Neurosurg Spine, 3(6): 417-

	Yes	No	Comments
			23, 2005. Rodts, M. F.: Total disc replacement arthroplasty. Orthop Nurs, 23(3): 216-9, 2004. SariAli el, H.; Lemaire, J. P.; Pascal-Mousselard, H.; Carrier, H.; and Skalli, W.: In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-14 years follow up evaluation. Eur Spine J, 15(10): 1501-10, 2006. Sasso, R. C.; Foulk, D. M.; and Hahn, M.: Prospective, randomized trial of metal-on metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. Spine, 33(2): 123-31, 2008. Sasso, R. C.; Smucker, J. D.; Hacker, R. J.; and Heller, J. G.: Clinical outcomes of BRYAN cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. J Spinal Disord Tech, 20(7): 481-91, 2007. Sekhon, L. H.: Cervical arthroplasty in the management of spondylotic myelopathy: 18-month results. Neurosurg Focus, 17(3): E8, 2004. Sekhon, L. H., and Ball, J. R.: Artificial cervical disc replacement: principles, types and techniques. Neurol India, 53(4): 445-50, 2005. Shim, C. S.; Lee, S. H.; Park, H. J.; Kang, H. S.; and Hwang, J. H.: Early clinical and radiologic outcomes of cervical arthroplasty with Bryan Cervical Disc prosthesis. J Spinal Disord Tech, 19(7): 465-70, 2006. Shim, C. S. et al.: CHARITI versus ProDisc: A comparative study of a minimum 3-year follow-up. Spine, 32(9): 1012-1018, 2007. Siepe, C. J.; Mayer, H. M.; Heinz-Leisenheimer, M.; and Korge, A.: Total lumbar disc replacement: different results for different levels. Spine, 32(7): 782-90, 2007. Siepe, C. J.; Wiechert, K.; Khattab, M. F.; Korge, A.; and Mayer, H. M.: Total lumbar disc replacement in athletes: clinical results,

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			return to sport and athletic performance. Eur Spine J, 16(7): 1001-13, 2007. Singh K, V. A., Albert TJ: Assessing the potential impact of total disc arthroplasty on surgeon practice patterns in North America. Spine Journal, 4(6S): S195-201, 2004. The Medical Advisory Secretariat: Artificial discs for lumbar and cervical degenerative disc disease - update. Edited, Toronto, Ministry of Health and Long Term Care, 2006. Tortolani, P. J.; Cunningham, B. W.; Eng, M.; McAfee, P. C.; Holsapple, G. A.; and Adams, K. A.: Prevalence of heterotopic ossification following total disc replacement. A prospective, randomized study of two hundred and seventy-six patients. J Bone Joint Surg Am, 89(1): 82-8, 2007. Tropiano, P.; Huang, R. C.; Girardi, F. P.; Cammisa, F. P., Jr.; and Marnay, T.: Lumbar total disc replacement. Seven to eleven-year follow-up. J Bone Joint Surg Am, 87(3): 490-6, 2005. Tropiano, P.; Huang, R. C.; Girardi, F. P.; and Marnay, T.: Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. J Spinal Disord Tech, 16(4): 362-8, 2003. Wigfield, C.; Gill, S.; Nelson, R.; Langdon, I.; Metcalf, N.; and Robertson, J.: Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. J Neurosurg, 96(1 Suppl): 17-21, 2002. Wigfield, C. C.; Gill, S. S.; Nelson, R. J.; Metcalf, N. H.; and Robertson, J. T.: The new Frenchay artificial cervical joint: results from a two-year pilot study. Spine, 27(22): 2446-52, 2002. Xu, Y. C.; Liu, S. L.; Huang, D. S.; Shen, H. Y.; Li, C. H.; and Ma, R. F.: Correlated evaluation on the spinal segment motion scope and the alteration of the corresponding parameters after artificial lumbar intervertebral disc replacement. Ch J of Clin Rehab, 8(32): 7294-96, 2004.

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	Yes	**No**	**Comments**
			Yang, S.; Hu, Y.; Zhao, J.; He, X.; Liu, Y.; Xu, W.; Du, J.; and Fu, D.: Follow-up study on the motion range after treatment of degenerative disc disease with the Bryan cervical disc prosthesis. J Huazhong Univ Sci Technolog Med Sci, 27(2): 176-8, 2007. Yoon, D. H.; Yi, S.; Shin, H. C.; Kim, K. N.; and Kim, S. H.: Clinical and radiological results following cervical arthroplasty. Acta Neurochirurgica, 148(9): 943-950, 2006. Zeegers, W. S.; Bohnen, L. M.; Laaper, M.; and Verhaegen, M. J.: Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. Eur Spine J, 8(3): 210-7, 1999. Zigler, J. et al.: Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine, 32(11): 1155-62; discussion 1163, 2007.
• If you consider artificial intervertebral discs medically necessary in the treatment of cervical and lumbar degenerative disc disease: - Are there any specific criteria which would be useful in selecting appropriate patient populations?	X		The indications would be symptoms attributed to cervical or lumbar degenerative disc disease including signs of neurological compression. Artificial disc replacement is a potential alternative to spinal fusion in patients and intended to preserve motion at the involved spinal level to decrease stresses on adjacent segment structures and the risk of adjacent segment disease. This would also be based on the inclusion criteria of the patients enrolled in the clinical IDE studies.
- Are there any specific contraindications which would be useful in identifying patients for whom artificial intervertebral discs is not appropriate?	X		We would recommend that clinical or patient characteristics for which the artificial intervertebral disc is not appropriate include patients with spinal instability (sagittal plane translation >3.5mm, sagittal plane angulation >20°), facet joint pathology, osteoporosis, cancer, and infection. The literature supporting this is as indicated in the large scale clinical trials.
• The FDA approval for these devices is contingent upon 5-7 year follow up studies. o Do you think the current literature is sufficient to support use of artificial intervertebral discs?	X		This statement by the FDA does not indicate any specific negative concerns related to the devices as this question would seem to indicate, as otherwise the artificial cervical and lumbar discs would not have been approved by the FDA. This is a continued evolution of the FDA process with the Center

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	Yes	**No**	**Comments**
			for Devices and Radiological Health (CDRH) developing new protocols for postmarket surveillance to monitor the performance of marketed medical devices.
***Improved Patient Outcomes*:** • Is there adequate evidence to demonstrate that the use of artificial intervertebral discs provide significant improvements in clinical outcomes compared to cervical or lumbar fusion?	X		The rationale for this has been provided in the prior questions.
• Is there *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of artificial intervertebral discs? If so, please cite.	X		The citations for this literature have been provided in the previous questions.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	
***Conflict of Interest*:** Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with artificial intervertebral discs? If so, please disclose that relationship.		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- not primarily for the convenience of the patient, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The term "investigational" means that the medical policy does not meet the Technology Evaluation Criteria.

This means any procedure, treatment, supply, device, equipment, facility or drug (all services), are determined NOT to:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- improve the net health outcome; or

- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

Sorry Mike--the earlier email got buried in the pile...

Chair--Ziya Gokaslan
Treasurer--John Hurlbert
Member at large--Chris Wolfla

--- On **Sun, 11/16/08, Michael Groff *<mgroff@bidmc.harvard.edu>*** wrote:

> From: Michael Groff <mgroff@bidmc.harvard.edu>
> Subject: Re: Pending Action Items - Spine Exec Comm
> To: "Joseph Alexander" <jtalexan59@yahoo.com>
> Cc: "Dan Resnick" <resnick@neurosurg.wisc.edu>
> Date: Sunday, November 16, 2008, 11:13 PM
>
> Joe,
> Do you have nominations for the Treasurer, President elect, and member at large? I need to get that from you in the next 2 – 3 weeks to allow time to circulate it and then post it 90 days before the annual meeting.
> Thanks,
> mike
>
> On 10/18/08 9:59 AM, "Dan Resnick" <resnick@neurosurg.wisc.edu> wrote:
>
> > The lumbar fusion guidelines will be updated through the Lumbar Fusion task Force (it makes perfect sense given the interaction with MCAC) - I'll touch base with Had about the cervical guidelines.
> > Joe Alexander has a slate that he should have gotten to you- I'll cc him and have him send it to you so you can circulate it for exec committee approval prior to posting on the website
> > Daniel K. Resnick MD, MS
> > Associate Professor and Vice Chairman
> > Department of Neurological Surgery
> > University of Wisconsin, Madison
> > Chair, AANS/CNS Joint Section on Disorders of the Spine
> >
> > ---
> >
> > **From:** Michael Groff [mgroff@bidmc.harvard.edu]
> > **Sent:** Friday, October 17, 2008 3:36 PM
> > **To:** Resnick (Daniel)
> > **Subject:** Pending Action Items - Spine Exec Comm
> >
> > Dan,
> > Action items that are still pending:

- Cervical Trauma update: Hadley or Greg Psybilsky.Dan Sciuba, Matz
- Lumbar fusion guidelines Dan Resnick, Langston, brunner, Matt McGrit
- Nominating comm: We need a treasurer, Presedent elect, member at large. Need 90 days before section meeting. Chris to help Report forthcoming.

Michael

Subject: Re: Neurosurgical Research and Education Foundation
Date: Sunday, October 26, 2008 11:11 AM
From: Ziya Gokaslan <zgokasl1@jhmi.edu>
To: RGrossman@tmhs.org
Cc: Groff, MD Michael mgroff@bidmc.harvard.edu, Angela Melton amelton1@jhmi.edu, Eunice Aikins Eaikins@jhmi.edu, Henry Brem hbrem@jhmi.edu, Dan Resnick resnick@neurosurg.wisc.edu

Dear Dr. Grossman,
Thank you very much for very kind invitation to join the Neurosurgical Research and Education Foundation. I feel very priviliged to have been chosen to be a member of the Scientific Advisory Committee. I will be very delighted to serve in this capacity, and I am looking forward to working with you and the other members of the Committee.
Respectfully yours,
Ziya

Ziya L. Gokaslan, M.D., F.A.C.S.
Donlin M. Long Professor
Professor of Neurosurgery, Oncology, and Orthopaedic Surgery
Vice Chairman - Department of Neurosurgery
Director - Neurosurgical Spine Program
Department of Neurosurgery Spine Center
600 North Wolfe Street
Meyer 7-109
Baltimore, MD 21287
410-955-4424
410-502-3399(FAX)
zgokasl1@jhmi.edu
Assistant: Angela Melton
(443) 287-4934

-----Original Message-----
From: "Grossman, Robert G., M.D." <RGrossman@tmhs.org>
Cc: Michele S. Gregory <msg@aans.org>
To: Ziya Gokaslan <zgokasl1@jhmi.edu>

Sent: 10/24/2008 10:24:35 AM
Subject: Neurosurgical Research and Education Foundation

Dear Ziya,

I am writing to you to invite you to become a member of the Scientific Advisory Committee (SAC) of the Neurosurgical Research and Education Foundation (NREF).

As you know, the NREF supports neurosurgical research by giving grants to residents and young faculty. The SAC receives the grant applications (electronically on a disc) in December and reviews the grant applications on a conference call in February. Each member will review 8 - 10 grants in the area of their expertise. The list of members is attached. We need more depth in the area of spine and the AANS/CNS

Spine Section has recommended you as a member of the SAC, a sentiment with which the SAC and I heartily concur.

I do hope that you can join us. The experience is like being on a NIH study section - it is a certain amount of work but very worthwhile and very important for neurosurgery as a whole.

With best regards - Bob

Robert G. Grossman, M.D.

Chairman, Department of Neurosurgery

Director, The Neurological Institute

The Methodist Hospital

6560 Fannin, Suite 944

Houston, TX 77030

713/441-3810 Office

713/793-1004 Fax

rgrossman@tmhs.org <mailto:rgrossman@tmhs.org>

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Research Fellowship

Applicant Number	Name	Institution	Project Title	Disease Category	App. Type	Years	Avg. Score
9	Michael Koltz	University of Maryland	SUR1-regulated NC(Ca-ATP)channel - a novel therapeutic target in perinatal hypoxia and germinal matrix hemorrhage.	Cerebrovascular Disease	RF	1	1.4625
16	Shahid Nimjee	Duke University Medical Center	Antidote-controlled platelet inhibition using RNA aptamer technology.	Cerebrovascular Disease	RF	1	1.475
24	Michael Sughrue	UCSF	The role of complement activation in glioma proliferation.	Brain Tumor	RF	1	1.55
21	Demitre Serletis	University of Toronto	The neurodynamical complexity underlying noise in the brain: Implications for seizure detection and prediction.	Epilepsy	RF	2	1.563636364
15	Kaveh Asadi-Moghaddam	Ohio State University	The role of microRNA-128 in glioma stem cell self-renewal.	Brain Tumor	RF	1	1.62
11	Yi Lu	Brigham & Women's Hosp./Childre n's Hospital Boston	Study of central nervous system axon regeneration and functional recovery after spinal cord injury with genetic and pharmacologic deletion of PTEN.	Spine Trauma/Motor Disorders	RF	2	1.772727273
6	Raqeeb Haque	Columbia Presbyterian Med. Ctr.	A novel approach for convection enhanced delivery of nerve growth factors in a peripheral nerve bridge model to bypass spinal cord injury.	Spine Trauma	RF	1	1.936363636
2	Joel Bauman	University of Pennsylvania	Motion preservation and dynamic stabilization in post-laminectomy cervical spine: facet joint kinematics & pressures in a human cadaveric model.	Other	RF	1	2.025

Young Clinician Investigator

Applicant Number	Name	Institution	Project Title	Disease Category	App. Type		Avg. Score
32	Michael Lim	Johns Hopkins University	Immune characterization of STAT3 in GBM with a novel transgenic model.	Brain Tumor	YCI		1.64

ACS/AANS-NREF Faculty Career Development

Applicant Number	Name	Institution	Project Title	Disease Category	App. Type		Avg. Score
2	Daniel Lim	UCSF	Gene-therapy based induction of neurogenesis from adult human neural precursor cells.	Epilepsy/Mo-tor Disorders	Faculty Development		1.3125

Subject: RE: Soine section NREF
Date: Thursday, September 25, 2008 6:55 PM
From: Chris Shaffrey <CIS8Z@hscmail.mcc.virginia.edu>
To: Dan Resnick resnick@neurosurg.wisc.edu, 'gharsh@stanford.edu' gharsh@stanford.edu, 'mgroff@bidmc.harvard.edu' mgroff@bidmc.harvard.edu, Charles Branch cbranch@wfubmc.edu
Cc: 'msg@aans.org' msg@aans.org

In addition to the two excellent candidates, I would recommend Dan Resnick, Michael Fehlings, Vince Treynelis and John Hurlbert. I am not sure of their availablilty but they are the best, brightest and most research oriented.

Christopher I Shaffrey, MD, FACS
Harrison Distinguished Professor
Neurological and Orthopaedic Surgery
University of Virginia
Phone: (434) 243-9714

_____
From: Resnick (Daniel) [resnick@neurosurg.wisc.edu]
Sent: Thursday, September 25, 2008 12:34 PM
To: 'gharsh@stanford.edu'; 'mgroff@bidmc.harvard.edu'; 'Cbranch@wfubmc.edu'; Shaffrey, Chris I *HS
Cc: 'msg@aans.org'
Subject: Re: Soine section NREF

Hi Griff,
The section supports the NREF and would welcome the opportunity to have greater representation. Ziya and Eric would be great choices for the SAC. Thank you! In terms of the EC, I'd like to consult with Charlie, Chris Shaffrey, and Joe Alexander to suggest a few nominees to present for your consideration. We appreciate your willingness to incorporate spine surgeons in this important cause.
Dan

----- Original Message -----
From: Griffith Harsh <gharsh@stanford.edu>
To: Resnick (Daniel)
Cc: Michele S. Gregory <msg@aans.org>
Sent: Wed Sep 24 18:07:57 2008
Subject: Soine section NREF

Hi, Dan:

I wanted to bring you up to date on our efforts to increase the representation of the spine section on the NREF EC and SAC. Although Jim Guest is on the SAC and Charlie Branch (not to mention Bob Grossman on both and ex officio EC members Jim Bean and Troy Tippett) is on the EC, we still feel spine is under-represented relative to its importance to NS and the section's generosity in supporting NREF. So, Bob Grossman is asking Zia Ghokasalin (and, if he declines, Eric Zager) to join the SAC, and I have asked both Charlie Branch and you, when you return from the CNS, for two names from which we might choose a second spine expert to take Bob Grubb's place on the EC.

Please let me know your suggestions and any other thoughts you might have.

Thanks, and best regards,

Griff

Subject: Re: Soine section NREF
Date: Thursday, September 25, 2008 12:34 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: 'gharsh@stanford.edu' gharsh@stanford.edu, 'mgroff@bidmc.harvard.edu' mgroff@bidmc.harvard.edu, Charles Branch cbranch@wfubmc.edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu
Cc: 'msg@aans.org' msg@aans.org

Hi Griff,
The section supports the NREF and would welcome the opportunity to have greater representation. Ziya and Eric would be great choices for the SAC. Thank you! In terms of the EC, I'd like to consult with Charlie, Chris Shaffrey, and Joe Alexander to suggest a few nominees to present for your consideration. We appreciate your willingness to incorporate spine surgeons in this important cause.
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Sent: Wed Sep 24 18:07:57 2008
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Please let me know your suggestions and any other thoughts you might have.

Thanks, and best regards,

Griff