Medical Policy

BlueCross BlueShield of Kansas
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Title: Artificial Intervertebral Disc: Lumbar Spine

See also: Artificial Intervertebral Disc: Cervical Spine

Professional
Original Effective Date: August 9, 2005
Revision Date(s): June 14, 2006; January 1, 2007; July 24, 2007; September 25 2007; February 22, 2010; March 10, 2011; March 8, 2013; June 23, 2015; August 4, 2016; May 23, 2018
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Institutional
Original Effective Date: August 9, 2005
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Current Effective Date: September 23, 2008

Populations	Interventions	Comparators	Outcomes
Individuals: • With lumbar degenerative disc disease	Interventions of interest are: • Lumber artificial intervertebral disc	Comparators of interest are: • Conservative therapy • Lumbar spinal fusion	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling degenerative disc disease.

Objective

The objective of this evidence review is to determine whether implantation of a lumbar artificial intervertebral disc improves the net health outcome in patients with degenerative disc disease.

Background

When conservative treatment of degenerative disc disease (DDD) fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. Also, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and normal biomechanics of the adjacent vertebrae.

Potential candidates for artificial disc replacement have chronic low back pain attributed to DDD, lack of improvement with nonoperative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients for whom fusion is indicated. Patients who require procedures in addition to fusion (eg, laminectomy, decompression) are not candidates for the artificial disc.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. They include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, pseudotumor formation).

Regulatory Status

Three artificial lumbar disc devices (activL®, Charité®, ProDisc®-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of postmarketing studies. The activL® (Aesculap Implant Systems), Charité® (DePuy), and ProDisc®-L (Synthes

Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. Production under the name Charité® was stopped in 2010.

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. The INMOTION® is not currently marketed in the United States.
- The Maverick™ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L™ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L, scheduled in 2013, but was canceled without explanation.

FDA product code: MJO.

POLICY

Artificial intervertebral discs of the lumbar spine are considered **experimental / investigational**.

RATIONALE

The most recent literature update was performed through February 5, 2018.

This review was informed by 3 TEC Assessments (2005, 2007, 2013).[1-3]

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality

and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

This review focuses only on artificial discs currently available in the United States.

Artificial Intervertebral Discs

Randomized Controlled Trials

Three RCTs have compared the treatment of degenerative disc disease (DDD) using lumbar fusion with artificial lumbar intervertebral discs currently available in the United States. They include the pivotal trials for the ProDisc-L and activL discs, and a Food and Drug Administration (FDA)–regulated trial of the ProDisc-L for 2-level DDD. A fourth trial compared ProDisc-L with multidisciplinary rehabilitation. The primary outcome in the FDA-regulated trials is a composite measure of success, which incorporates symptom improvement and absence of complications. The composite success end points included improvements in Oswestry Disability Index (ODI) scores (typically 15 points), improvement or maintenance in neurologic status, radiologic measures of range of motion, freedom from additional surgery, and freedom from serious device-related adverse events. Five-year outcomes have been reported from the pivotal trial for the ProDisc-L. Eight-year data have been reported from a comparison of ProDisc II with multidisciplinary rehabilitation.

A key feature all of these trials is the recruitment of patients specifically with degenerative disease of the intervertebral disc. DDD is partly a diagnosis of exclusion where the degenerated disc is believed to be the pain generator. Radiographic evidence of DDD may include a reduction of disc height and Modic changes, a posterior high-intensity zone, or a dark/black nucleus pulposus on T2-weighted images. Patients with common indications for spinal fusion such as scoliosis, spondylolisthesis, instability, or radiculopathy are excluded.

ProDisc-L at a Single Level

The pivotal study for the ProDisc-L was an unblinded noninferiority trial that originally followed patients for 24 months.[4,5] In the per-protocol analysis reported to FDA, ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%, which achieved both non-inferiority and superiority. Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012.[6-8] The definition of success was changed from the analysis requested by FDA and was reported to be higher at 63.5% at 2 years and 53.7% at 5 years. Noninferiority but not superiority of artificial disc replacement was achieved at 5 years. This change in overall success in ProDisc-L patients indicates a possible decrement in response over time with the artificial disc. This decline in response rate was not observed in the standard fusion group and resulted in a between-group convergence of the primary outcome measure over time. Several individual components of the primary outcome measure and secondary outcome measures (ODI, 36-Item Short-Form Health Survey Physical Component Summary, neurologic success, device success) were also statistically better in the ProDisc-L group than in the fusion group at 2 years, but not at 5 years. Post hoc analysis of radiographs found fewer patients with adjacent-level degeneration in the ProDisc-L group than in the control group. However, the adjacent-level reoperations did not differ significantly between groups (1.9% ProDisc-L vs 4% controls).

An updated TEC Assessment (2013) evaluated 5-year follow-up from the ProDisc pivotal trial.[3] The Assessment concluded that:

- Additional study of ProDisc in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption trial in patients with single-level chronic symptomatic DDD unresponsive to conservative management.
- Questions remain about the durability of the disc, in particular, the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue.
- The main claim of the artificial disc—that it maintains range of motion and thereby reduces the risk of adjacent-level segment degeneration better than fusion—remains subject to debate.

Hellum et al (2011) reported an RCT that compared the use of the ProDisc-L with a multidisciplinary rehabilitation program.[9] Patients (N=173) were ages 25 to 55 years, had low back pain for a least a year, received physical therapy or chiropractic treatment for at least 6 months without sufficient effect, had an ODI score of at least 30, and showed degenerative intervertebral changes that included at least 40% reduction of disc height, Modic changes, a high-intensity zone in the disc, and morphologic changes identified as changes in the signal intensity in the disc of grade 3 or 4 (see Table 1). The multidisciplinary rehabilitation included a cognitive approach and supervised physical exercise. The primary outcome was ODI score (see Table 2), and the trial was powered to detect a 10-point difference in ODI score. The analysis was intention-to-treat with the last observation carried forward. There were 13 (15%) dropouts in the surgical arm and 21 (24%) in the rehabilitation arm. Also, 5 (6%) patients crossed over from rehabilitation to surgery. Of the 34 patients lost to follow-up, 26 answered a questionnaire between 2.5 and 5 years after treatment. In the intention-to-treat analysis, there was a statistically significant benefit of surgery, but the mean difference did not achieve the 10-point difference in ODI score considered clinically significant. There were significantly more patients who achieved a 15-point improvement in ODI score in the ProDisc group, with a number needed to treat of 4.4. The radiographic assessment identified a similar level of adjacent segment degeneration in both groups, but an increase in facet arthropathy in the ProDisc II group.[10] Eight-year follow-up of this trial was reported by Furunes et al (2017).[11] In both the intention-to-treat and per-protocol analysis there was a statistically significant benefit of surgery as measured by the mean ODI, but these differences did not reach the clinically significant threshold of 10 points (see Table 2). More patients in the surgery group (43/61 [70%]) reached a clinically important difference of 15 ODI points than in the rehabilitation group (26/52 [50%]; p=0.03). Twenty-one (24%) patients randomized to rehabilitation crossed over to surgery while 12 (14%) patients randomized to surgery had undergone additional back surgery.

Table 1. Summary of Key RCT Characteristics for Discs Available in the United States

Study	Countries	Sites	Follow-Up	Participants	Interventions	
					Active	Control
Zigler et al (2007, 2012)[6-8]	U.S.	17	As-treated	Noninferiority trial of patients with single-level DDD	ProDisc-L (n=161)	Circumferential fusion (n=75)
			2 y		156 (97%)	73 (97%)
			5 y		137 (85%)	56 (75%)
Delamarter et al (2011)[12]	U.S.	16	2 y	Noninferiority trial of patients with DDD at 2 contiguous levels	ProDisc-L at 2 levels (n=158)	Circumferential fusion (n=79)
Garcia et al (2015)[13]			2 y	Patient-blinded noninferiority trial of patients with DDD	activL (n=218)	ProDisc-L or Charité (n=106)
Hellum et al (2011, 2012) and Furunes (2017)[9-11]	Norway	5	2 y	Patients with chronic low back pain, ODI score ≥30, and DDD in 1 or 2 levels	ProDisc II (n=87)	Multidisciplinary rehabilitation (n=86)
			2 y	Patients from RCT assessed for adjacent-level degeneration and facet arthropathy	ProDisc II (n=59)	Multidisciplinary rehabilitation (n=57)
			8 y	Patients from RCT assessed at 8-y follow-up	ProDisc II (n=77)	Multidisciplinary rehabilitation (n=74)

DDD: degenerative disc disease; ODI: Oswestry Disability Index; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Outcomes for Discs Available in the United States

Study	Success Rate at 2 Years	Success Rate at 5 Years	ODI Score Improvement	VAS Score	Adjacent-Level Degeneration at 5 Years
			5 Years	5 Years	
Zigler et al (2007, 2012)[6-8]					
ProDisc-L	148 (63.5%)	134 (53.7%)	126 (34.2%)	125 (37.1%)	(9.2%)
Fusion	71 (45.1%)	52 (50.0%)	51 (36.2%)	51 (40.0%)	(28.6%)
P inferiority	<0.01	0.024	0.455	0.567	
P superiority	0.044	*NS*			

Study	Success Rate at 2 Years	Success Rate at 5 Years	ODI Score Improvement	VAS Score	Adjacent-Level Degeneration at 5 Years
		Mean ODI Score (SD) at 2 Years	≥15-Point Improvement at 2 Years	Reduction in VAS Score, mm	Secondary Surgical Procedures
Delamarter et al (2011)[12]					
ProDisc-L	58.8%	30.3 (24.3)	73.2%	43.3	2.4%
Fusion	47.8%	38.7 (24.1)	59.7%	36.7	8.3%
P noninferiority	<0.001				
P superiority	*NS*			*NS*	0.047
			≥15-Point Improvement at 2 Years		Surgical Reintervention
Garcia et al (2015)[13]					
activ-L	NR		75.2%		2.3%
ProDisc-L or Charité	NR		66.0%		1.9%
P noninferiority	<0.001				
P superiority	0.02		0.09		*NS*
	≥15-Point Improvement in ODI Score, n (%)	Mean ODI Score (SD) at 2 Years	Mean Improvement in ODI Score at 8 Years (95% CI)	Mean VAS Score at 2 Years	Facet Arthropathy at 2 Years
Hellum et al (2011, 2012) and Furunes (2017) [9-11]					
ProDisc II	51 (70%)	19.8 (16.7)	20.0 (16.4 to 23.6)	35.4	34%
Rehab	31 (47%)	26.7 (14.5)	14.4 (10.7 to 18.1)	49.7	4%
p	0.006		0.02	0.009	<0.001
NNT (95 CI)	4.4 (2.6 to 14.5)	MD = -6.9 (-11.7 to -2.1)	MD=6.1 (1.2 to 11.0)		

CI: confidence interval; MD: mean difference; NNT: number needed to treat; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; Rehab: multidisciplinary rehabilitation; VAS: visual analog score.

ProDisc-L at 2 Levels

The ProDisc-L for 2-level lumbar DDD was reported in 2011 from a multicenter, randomized, FDA-regulated noninferiority trial.[12] All patients had DDD at 2 contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of 6 months of conservative therapy, and a minimum ODI score of 40. The ProDisc-L group had faster surgeries (160.2 minutes vs 272.8 minutes), less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital lengths of stay (3.8 days vs 5.0 days) than the arthrodesis group. The composite measure of success demonstrated noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in the percentages of patients who achieved at least a 15-point improvement in ODI scores and

greater improvements in the 36-Item Short-Form Health Survey scores. A greater percentage of patients in the arthrodesis group required secondary surgical procedures. As noted in an accompanying commentary, the study had a number of limitations.[14] Comparison with a procedure (open 360° fusion) that is not the criterion standard precludes decisions on the comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of patients and providers.

activL

Two-year outcomes from the multicenter investigational device exemption trial of the activL artificial intervertebral disc were reported by Garcia et al (2015).[13] In this patient-blinded noninferiority trial, patients with DDD were randomized to treatment with activL or an FDA-approved disc (ProDisc-L or Charité). activL was both noninferior and superior to the control group of patients treated with ProDisc-L or Charité. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls. Range of motion at the index level, measured by an independent core radiographic laboratory, was higher in the activL group than in the controls.

Observational Studies

While observational studies do not provide evidence of efficacy or comparative efficacy, they may provide information about the durability of any observed improvements and potential impacts of patient selection factors (see Tables 3-4).

Table 3. Summary of Prospective Cohort Study Characteristics

Study	Country	Participants, N (% of total treated)	Treatment Delivery	Follow-Up (Range), Years
Siepe et al (2014)[15]		181 (90%)	ProDisc-II at 1 or 2 levels	7.4 (5.0-10.8)
Laugesen et al (2017)[16]	Denmark	57 (84%) with DDD	ProDisc-II at 1 or 2 levels	10.6 (8.1-12.6)

DDD: degenerative disc disease.

Table 4. Summary of Key Cohort Study Results

Study	Treatment	Functional Status at Baseline	Score at FU	p	VAS Score at Baseline	VAS at FU	p	Complication Rate
Siepe et al (2014)[15]	1 or 2 level ProDisc-II	42 (ODI)	22	<0.001	7	3.3	<0.001	• 11.9% 1 level • 27.6% 2 levels
Laugesen et al (2017)[16]	1 or 2 level ProDisc-II	63.2 (PDQ)	45.6	<0.001	6.8	3.2	<0.001	33% revised to fusion

FU: follow-up; ODI: Oswestry Disability Index; PDQ: Dallas Pain Questionnaire; VAS: visual analog scale.

Siepe et al (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution.[15] This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review. ODI and VAS pain scores were assessed by investigators not involved in pre- or postoperative decision making. At final follow-up, ODI and VAS pain scores were significantly improved over baseline. Overall satisfaction rates were 89.1% for single-level and 69.0% for 2-level disc replacement.

Laugesen et al (2017) found significant improvements in pain and function with 1- or 2-level ProDisc II implantation at follow-up of 10.6 years, but pain remained moderate, and about one-third of patients required revision to fusion.[16] The authors noted the need for appropriate selection criteria.

Another case series, by Tropiano et al (2005), followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.[17]

Summary of Evidence

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes RCTs with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. The 4 reviewers disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational. After considering the clinical input in 2008, it was concluded that, due to limitations of the available randomized controlled trials (described herein), combined with the marginal benefit compared with fusion, evidence was insufficient to determine whether artificial lumbar discs are beneficial in the short term. Also, serious questions remained about potential long-term complications with these implants.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (2014) issued coverage recommendations for lumbar artificial disc replacement.[18] The following recommendation was made:

> "Lumbar artificial disc replacement (LADR) is indicated as an alternative to lumbar fusion for patients with discogenic low back pain who meet all of the following criteria from the Lumbar Fusion Recommendation:
>
> - Advanced single-level disease noted on an MRI [magnetic resonance image] and plain radiographs of the lumbar spine at L4-5 or L5-S1, characterized by moderate to severe

degeneration of the disc with Modic changes (defined as a peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)
- Presence of symptoms for at least one year AND that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
- Absence of active significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain
- Age 18 to 60 years old (unique to disc replacement, not fusion)
- Absence of significant facet arthropathy at the operative level (unique to disc replacement, not fusion)"

Contraindications included multilevel degeneration, facet arthropathy, and hybrid procedures (ie, in combination with a spinal fusion or other stabilizing-type procedure).

American Pain Society

In 2009, the American Pain Society's practice guidelines concluded there was "insufficient evidence" to adequately evaluate the long-term benefits and harms of vertebral disc replacement.[19] The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center.[20] The rationale for the recommendation was that, although artificial disc replacement has been associated with outcomes similar to fusion, the trial results were only applicable to a narrowly defined subset of patients with single-level degenerative disease, and the type of fusion surgery in the trials is no longer widely used due to frequent poor outcomes. Also, all trials had been industry-funded, and data on long-term (>2 years) benefits and harms following artificial disc replacement were limited.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2009) updated its guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine with studies reporting 13-year follow-up but with most of the "evidence from studies with shorter durations of follow-up."[21] The Institute concluded that evidence was "adequate to support the use of this procedure."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02381574	French Lumbar Total Disk Replacement Observational Study (FLTDR Observational Study)	600	Dec 2020

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy 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. 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.

CPT/HCPCS

22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

- There are CPT category I codes specific to total disc arthroplasty when performed at a single lumbar spine interspace: 22857, 22862, 22865.
- When more than 1 interspace is involved, the following CPT category III add-on codes would be used: 0163T, 0164T, 0165T.

DIAGNOSIS

Experimental / investigational for all diagnoses related to this medical policy.

REVISIONS	
09-23-2008	In Description section: ▪ Updated wording
	In Policy section: ▪ Removed "Removal or revision of artificial disc(s) is a non-covered service."

REVISIONS	
	In Coding section: ▪ Removed CPT codes 0090T, 0092T, 0093T, 0095T, 0096T, 0098T
	Added Rationale section
02-22-2010	In Coding Section: Updated wording for CPT codes: 22857, 22862, 22865, 0163T, 0164T, 0165T
	Rationale and References updated.
03-10-2011	Description section updated
	Rationale section updated
	References updated
03-08-2013	Description section updated
	Rational section updated
	In Coding section: ▪ Coding notations updated.
	References updated
06-23-2015	Description section update
	Rationale section updated
	References updated
08-04-2016	Description section update
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
05-23-2018	Description section update
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated

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