

Medical Policy



Title: Artificial Intervertebral Disc: Cervical Spine

See also: Artificial Intervertebral Disc: Lumbar Spine

Professional

Original Effective Date: September 25, 2007

Revision Date(s): September 23, 2008

Current Effective Date: September 23, 2008

Institutional

Original Effective Date: October 23, 2008

Revision Date(s):

Current Effective Date: October 23, 2008

DESCRIPTION

Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine.

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. 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.

One cervical disc arthroplasty product (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: 1) herniated disc and/or 2) osteophyte formation.

A second disc product (Bryan Cervical Disc, Medtronic) 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.

POLICY

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

RATIONALE

Anterior cervical discectomy and fusion (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.

In artificial intervertebral disc arthroplasty (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. (2) It is hypothesized that AIDA maintains anatomical disk space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels (3). 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. (4-6)

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. 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.

Three primary outcome variables were used in the Prestige trial: the Neck Disability Index (NDI), neurological status, and functional spinal unit height (FSU).

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.

The Prestige disc trial showed equivalent results for anterior cervical fusion vs. artificial cervical disc. Thus, 81% of both groups showed at least a 15-point improvement for the 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. (7, 8) 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.

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

22899	Unlisted procedure, spine
0090T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than decompression), cervical; single interspace
0092T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than 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
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REFERENCES

09-23-2008	In Description section:
	<ul style="list-style-type: none"> ▪ Updated wording
	In Policy section:
	<ul style="list-style-type: none"> ▪ Removed "Removal or revision of artificial disc(s) is a non-covered service."
	In Coding section:
	<ul style="list-style-type: none"> ▪ Removed CPT codes 0096T, 0098T
	Added Rationale section

REFERENCES

1. 2007 TEC Assessments: "Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine"
2. Malloy KM, Hilibrand AS. Autograft versus allograft in degenerative cervical disease. *Clin Orthop Rel Res* 2002; 394:27-38.
3. Galler RM, Sonntag VKH. 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.
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.