Protocol

Artificial Intervertebral Disc: Cervical Spine

(701108)

Medical Benefit		**Effective Date**: 01/01/08	**Next Review Date**: 03/15
Preauthorization	No	**Review Dates**: 06/07, 07/08, 05/09, 05/10, 03/11, 03/12, 03/13, 03/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Several prosthetic devices are currently available for artificial intervertebral disc arthroplasty (AIDA) of the cervical spine. AIDA is proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for patients with symptomatic cervical degenerative disc disease (DDD).

Background

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 can result in myelopathy, which is manifested by subtle changes in gait or balance, and in severe cases leads to weakness in the arms or legs, and numbness of the arms or hands. 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 United States 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 six 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 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 neurologic symptoms may be expected in 80% to 100% of ACDF patients. 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 immunologic reaction to the allograft, and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities

at the harvest site, generally the iliac crest. These morbidities 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. 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. Biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD; however, the clinical relevance of these changes has not been established.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In AIDA, an artificial disc device is secured in the prepared intervertebral space rather than in bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomical disk space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level degenerative disc disease (DDD) above or below a fusion site has been the major rationale driving device development and use.

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 pathologic condition and require a different surgical approach.

Regulatory Status

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 composed of stainless steel and 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 neurologic deficit) and radiographic studies (e.g., computed tomography [CT], magnetic resonance imaging [MRI], x-rays): herniated disc and/or osteophyte formation. The FDA has required the Prestige disc manufacturer to conduct a seven-year post-approval clinical study of the safety and function of the device and a five-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in December 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C is conditional on seven-year follow-up of the 209 subjects included in the noninferiority trial (discussed in Rationale section), seven-year follow-up on 99 continued access subjects, and a five-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) consists of two titanium-alloy shells encasing a polyurethane nucleus and has been available outside of the United States since 2002. The Bryan Cervical Disc was approved by the FDA in May 2009 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 resulting in impaired function and at least one clinical neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using CT, myelography and CT, and/or MRI. Patients receiving the Bryan cervical disc should have failed at least six weeks of non-operative treatment prior to implantation of the Bryan cervical disc. As a condition for approval of

this device, the FDA required the manufacturer to extend its follow-up of enrolled subjects to 10 years after surgery. The study will involve the investigational and control patients from the pivotal investigational device exemption (IDE) study arm, as well as the patients who received the device as part of the continued access study arm. In addition, the manufacturer must perform a five-year enhanced surveillance study of the BRYAN® Cervical Disc to more fully characterize adverse events when the device is used in a broader patient population.

In more recent years, continued FDA approval requires completion of two post-approval studies. One study provides extended follow-up of the pre-market pivotal cohort out to seven years. The second study provides 10-year enhanced surveillance of adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, or other serious device-related complications, and analysis of all explanted discs. The following have received FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of two metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- Secure®-C (Globus Medical) was approved in 2012 (P100003). The Secure®-C is a three piece semi-constrained device with two metal (cobalt chromium molybdenum alloy) endplates and a polyethelene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is three piece semiconstrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for one (P110002) or two level (P110009) disc replacement.

A number of other devices are under study in FDA IDE trials in the United States.

Table 1. Cervical Disc Prostheses Under Investigation in the U.S.

Prosthesis (Manufacturer)	Implant Composition	Articulation Design	Bearing Surface	Bearing Constraint	Fixation	FDA Status
Prestige® LP (Medtronic)	Titanium-ceramic composite	Ellipsoid saucer	MoM	Semi-constrained	Primary: dual rails Secondary: endplate ingrowth	FDA IDE clinical trial enrollment complete
Kineflex C® Cervical Artificial Disc Implant (Spinal Motion)	Cobalt-chromium-molybdenum	3-piece, metal core	MoM	Unconstrained	Primary: central keel Secondary: endplate ingrowth	FDA IDE clinical trial complete
CerviCore™ Intervertebral Disc (Stryker)	Cobalt-chromium-molybdenum	Saddle	MoM	Unconstrained	Primary: dual rails Secondary: endplate ingrowth	Status unknown
Discover (DePuy)	Titanium-on-polyethylene	3-piece, polyethylene core	MoP	Unconstrained	Primary: spike fixation Secondary: endplate ingrowth	FDA IDE clinical trial enrollment complete
NeoDisc™ (NuVasive)						FDA IDE clinical trial complete
Freedom® Cervical Disc (AxioMed)						FDA IDE trial Recruiting
M6-C (Spinal Kinetics)	Titanium endplates and polymer core	7-piece, with endplates and a nucleus, fibrous annulus, and sheath				FDA IDE trial withdrawn prior to enrollment

FDA: Food and Drug Administration; IDE: investigational device exemption; MoM: metal-on-metal; MoP: metal-on-polyethylene.

Updates to the regulatory status of these devices can be viewed at online site: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm using FDA product code "MJO".

Related Protocol

Artificial Intervertebral Disc: Lumbar Spine

Policy (Formerly Corporate Medical Guideline)

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

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references

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