Artificial Intervertebral Disc: Cervical Spine

Medical Benefit

Effective Date: 10/01/15
Next Review Date: 07/17

Preauthorization

Yes
Review Dates: 06/07, 07/08, 05/09, 05/10, 03/11, 03/12, 03/13, 03/14, 03/15, 07/15, 07/16

Preauthorization is required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Patients/individuals with:  
  • Cervical radicular pain or myelopathy | Interventions of interest are:  
  • Artificial cervical disc replacement | Comparators of interest are:  
  • Anterior cervical discectomy and fusion | Relevant outcomes include:  
  • Functional outcomes  
  • Treatment-related morbidity  
  • Morbid events  
  • Symptoms |

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).

Summary of Evidence

After two years of follow-up, randomized trials of all the artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index and overall success composite outcome. Mid-term outcomes have been reported on four of the devices (Prestige ST, ProDisc-C, Mobi-C, Bryan discs). The trial results are consistent with continued noninferiority of artificial intervertebral disc arthroplasty for all devices and lower cumulative reoperation rates at four to five years. Longer term results are expected, given the U.S. Food and Drug Administration requirement for seven- to 10-year postapproval studies of the safety and function of the devices, and five- to 10-year enhanced surveillance study of these discs to more fully characterize adverse events in a broader patient population.

Policy

Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met:

1. The device is approved by FDA
2. The patient is skeletally mature
3. The patient has intractable cervical radicular pain or myelopathy
   a. which has failed at least six weeks of conservative nonoperative treatment, including active pain
      management program or protocol, under the direction of a physician, with pharmacotherapy that
      addresses neuropathic pain and other pain sources AND physical therapy; OR
   b. if the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression
      requiring hospitalization or immediate surgical treatment.

4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or
   myelography

5. Cervical degenerative disc disease is limited to a single level from C3-C7

6. The patient is free from contraindication to cervical artificial intervertebral disc implantation

Cervical artificial intervertebral disc implantation is considered investigational for all other indications, including
the following:

- Disc implantation at more than one level
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Multilevel disc disease
- Translational instability
- Anatomical deformity (e.g., ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
- Malignancy

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, 95% of men and 70% of women have at least one
degenerative change evident at radiographic examination. It is estimated that approximately five 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 in 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 disectomy 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, disectomy, 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 anatomic disc 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 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 FDA premarket application (PMA) approval as a class III device in 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., magnetic resonance imaging [MRI], computed tomography [CT], x-rays): herniated disc and/or osteophyte formation. FDA has required the Prestige disc manufacturer to conduct a seven-year postapproval 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 (AEs) in a broader patient population.
The Prestige® LP artificial cervical disc was approved by FDA in 2014. The Prestige® LP differs from the original Prestige cervical disc in terms of material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has two rails that press-fit into holes created during the surgical procedure.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in 2007. As with the Prestige ST Cervical Disc, FDA approval of ProDisc-C is conditional on seven-year follow-up of the 209 subjects included in the noninferiority trial, seven-year follow-up on 99 continued access subjects, and a five-year enhanced surveillance study to more fully characterize AEs when the device is used under general conditions of use. The postapproval study reports are to be delivered to 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 FDA in 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 nonoperative treatment before implantation of the Bryan cervical disc. As a condition for approval of this device, 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 AEs when the device is used in a broader patient population.

In more recent years, continued FDA approval requires completion of two postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to seven years. The second study provides 10-year enhanced surveillance of AE 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 polyethylene 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 (see Table 1).

### Table 1. Cervical Disc Prostheses Under Investigation in the United States

<table>
<thead>
<tr>
<th>Prosthesis (Manufacturer)</th>
<th>Implant Composition</th>
<th>Articulation Design</th>
<th>Bearing Surface</th>
<th>Bearing Constraint</th>
<th>Fixation</th>
<th>FDA Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinflex C® Cervical Artifical Disc Implant (Spinal Motion)</td>
<td>Cobalt-chromium-molybdenum</td>
<td>3-piece, metal core</td>
<td>MoM</td>
<td>Unconstrained</td>
<td>Primary: central keel Secondary: endplate ingrowth</td>
<td>FDA IDE trial complete</td>
</tr>
<tr>
<td>Discover (DePuy)</td>
<td>Titanium-on-polyethylene</td>
<td>3-piece, polyethylene core</td>
<td>MoP</td>
<td>Unconstrained</td>
<td>Primary: spike fixation Secondary: endplate</td>
<td>FDA IDE trial enrollment complete</td>
</tr>
</tbody>
</table>
### Related Protocol

**Artificial Intervertebral Disc: Lumbar Spine**

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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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### References

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


14. Delamarter RB, Murrey D, Janssen ME. Results at 24 months from the prospective, randomized multicenter investigational device exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. SAS Journal. 2010; 4:122-128.


