Artificial Intervertebral Disc: Cervical Spine

Summary
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.

FDA REGULATORY STATUS
In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as a class III device. 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 using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least 1 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 (Medtronic) to conduct a 7-year post approval clinical study of the safety and function of the device and a 5-year enhanced surveillance study 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 2 rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige® LP was approved by FDA for 2 adjacent levels. A post approval study will follow the investigational device exemption (IDE) patients who received the Prestige® LP at 2 contiguous levels for 10 years. Medtronic will also submit to FDA adverse events, device failures, and complaint analysis for 10 years. This includes subsequent surgeries, heterotopic ossification, device malfunction, and other serious device-related complications.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) was approved by FDA through the premarket approval process in 2007. As with the Prestige® ST Cervical Disc, FDA approval of ProDisc-C® is conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial (discussed in Rationale section), 7-year follow-up of 99 continued-access subjects, and a 5-year enhanced surveillance study to more fully characterize AEs when the device is used under general conditions of use. Postapproval study reports are to be delivered to FDA annually.

The Bryan® Cervical Disc (Medtronic Sofamor Danek) consists of 2 titanium-alloy shells encasing a polyurethane nucleus and has been available outside of the United States since 2002. In 2009, the
Bryan® Cervical Disc was approved by FDA for treatment using an anterior approach of single-level cervical degenerative disc disease 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 1 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 6 weeks of nonoperative treatment before implantation. As a condition for device approval, FDA has 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 IDE study arm, as well as the patients who received the device as part of the continued-access study arm. In addition, Medtronic Sofamor Danek must perform a 5-year enhanced surveillance study of the disc to more fully characterize AEs when the device is used in a broader patient population.

More recently, continued FDA approval requires completion of 2 postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 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, 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 2 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 3-piece semi-constrained device with 2 metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is 3-piece semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for 1-level (P110002) or 2-level (P110009) disc replacement.

**POLICY STATEMENT**

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

1. The device is approved by the Food and Drug Administration (FDA)
2. The patient is skeletally mature
3. The patient has intractable cervical radicular pain or myelopathy
   a. which has failed at least 6 weeks of conservative nonoperative treatment, including an 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, computed tomography, or myelography
5. Cervical degenerative disc disease is from C3-C7
6. The patient is free from contraindication to cervical artificial intervertebral disc implantation

Simultaneous cervical artificial intervertebral disc implantation at a second contiguous level may be considered **medically necessary** if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (ie, Mobi-C, Prestige LP).
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Subsequent cervical artificial intervertebral disc implantation at an adjacent level may be considered medically necessary when all of the following are met: 1. Criteria 1 to 6 above are met; AND

2. The device is FDA-approved for 2 levels; AND

3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; AND

4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

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

- Disc implantation at more than 2 levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Translational instability
- Anatomical deformity (eg, ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)
- Malignancy.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**Summary of Evidence**

For individuals who have cervical radicular pain or myelopathy who receive single-level artificial intervertebral disc arthroplasty (AIDA) of the cervical spine, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbidity events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index (NDI) and overall success composite outcome. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At 4 to 5 years, the trial results are consistent with continued noninferiority of AIDA for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige and ProDisc-C pivotal trials continues to show lower secondary surgery rates, although this is not a consistent finding in other reports. Longer term results for other discs are expected, given the U.S. Food and Drug Administration (FDA) requirement for 7-year postapproval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to more fully characterize adverse events in a broader patient population. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs, but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of anterior cervical discectomy and
fusion (ACDF). There have been no safety signals with discs that have been approved by the FDA for single-level AIDA. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for NDI scores, NDI success rates, reoperation rates, and overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level AIDA for clinical outcomes and lower cumulative reoperation rates. Adjacent segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared to 2-level ACDF patients. FDA approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at 2 years. The increase in overall success rates at 2 years has been maintained for those patients who have reached the 5- and 7-year follow-ups. Based on this evidence, it can be concluded that 2-level AIDA with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
North American Spine Society
The 2015 guidelines from the North American Spine Society state that:
“Cervical artificial disc replacement (CADR, also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:
1. Radiculopathy related to nerve root compression from one or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2-level degenerative disc disease from C3-4 to C6-7 with or without neck pain.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES
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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 11, 27-28, 32, 48, and 50 added; clinical input reviewed; considered medically necessary for single level cervical disc replacement.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 19, 2016; Rationale reorganized and references added; some references removed. Considered medically necessary for 2-level cervical disc replacement with a device that is FDA-approved for 2-levels (ie, Mobi-C, Prestige LP).</td>
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