

FEP 7.01.108 Artificial Intervertebral Disc: Cervical Spine

Effective Date: July 15, 2018

Related Policies:
7.01.87 Artificial Intervertebral Disc: Lumbar Spine

Artificial Intervertebral Disc: Cervical Spine

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.

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 (PMA) 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 through 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 one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (eg, pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (eg, magnetic resonance imaging, computed tomography, x-rays): herniated disc and/or osteophyte formation. The FDA required Medtronic (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 to more fully characterize adverse events in a broader patient population.

In 2014, the Prestige® LP artificial cervical disc (Medtronic Sofamor Danek) was approved by the FDA through the PMA process. The Prestige® LP differs from the original Prestige cervical disc regarding 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. In 2016, the Prestige® LP was approved by FDA for 2 adjacent levels. A postapproval study will follow the investigational device exemption (IDE) patients who received the Prestige® LP at two contiguous levels for ten years. Medtronic will also submit to FDA adverse events, device failures, and complaint analysis for ten 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 the FDA through the PMA process in 2007. As with the Prestige® ST Cervical Disc, the FDA approval of ProDisc-C® was made 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 characterize more fully adverse events when the device is used under general conditions of use. Postapproval study reports are to be delivered to FDA annually.

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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 the FDA 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 computed tomography, myelography and computed tomography, and/or magnetic resonance imaging results. Patients receiving the Bryan® Cervical Disc should have failed at least six weeks of nonoperative treatment before implantation. As a condition for device approval, the FDA required Medtronic Sofamor Danek to extend its follow-up of enrolled subjects to ten 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. Also, Medtronic Sofamor Danek must perform a five-year enhanced surveillance study of the disc to characterize more fully adverse events when the device is used in a broader patient population.

More recently, 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 ten-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, other serious device-related complications, and analysis of all explanted discs.

The following have also 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 3-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 3-piece semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for 1- (P110002) or 2-level (P110009) disc replacement.

A number of other devices are in FDA IDE trials in the United States (see Table 1).

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

Prosthesis	Manufacturer	FDA Status
Kineflex/C®	SpinalMotion	FDA IDE trial complete; status unknown
Freedom®	AxioMed	FDA IDE trial recruiting
M6-C	Spinal Kinetics	FDA IDE trial recruiting complete

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption.

Updates on the regulatory status of these devices are available online using FDA product code MJO (available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>).

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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 through C7; and
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 (eg, Mobi-C, Prestige LP).

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
- Anatomic 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).

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RATIONALE

Summary of Evidence

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, the evidence includes randomized controlled trials and meta-analyses of randomized controlled trials. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At two-year follow-up, trials of all artificial cervical discs met noninferiority criteria. Mid-term outcomes have been reported on five devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous-coated motion]). At four to five years, the trial results have been consistent with the 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. 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 ACDF. There have been no safety signals with discs approved by the Food and Drug Administration for single-level AIDA. The evidence is sufficient to determine 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 randomized controlled trials. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At two- and four-year follow-ups, the first artificial cervical disc approved for two levels (Mobi-C) was found to be superior to ACDF for Neck Disability Index scores, Neck Disability Index success rates, reoperation rates, and overall success composite outcome. At five 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 with 2-level ACDF patients. The Food and Drug Administration approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at two years. The increase in overall success rates at two years has been maintained for those patients who have reached the five- and seven-year follow-ups. Based on this evidence, it can be concluded that 2-level AIDA with either of these Food and Drug Administration-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine 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 indicated that⁴²:

“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.”

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National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence issued guidance (2010) on the artificial cervical disc, concluding that⁴³:

“Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures.....

This procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly.

NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include long-term data on preservation of mobility, occurrence of adjacent segment disease and the avoidance of revision surgery.”

American Association of Neurological Surgeons

Guidelines from the American Association of Neurological Surgeons (2009) addressed anterior cervical discectomy and anterior cervical discectomy and fusion for the treatment of cervical degenerative radiculopathy and cervical spondylotic myelopathy.^{44,45} Neither guideline addressed the artificial cervical disc.

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.

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
March 2014	Update Policy	Policy updated with literature review; references 4, 7, 14-15, 24-25, 27-28, 32, 36, 44, 46-47 added and reordered; policy statement unchanged.
September 2015	Update Policy	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.
December 2016	Update Policy	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).
June 2018	Update Policy	Policy updated with literature review through February 5, 2018; no references added. Policy statements unchanged.

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