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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, 11/16, 11/17, 11/18	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With cervical radicular pain or myelopathy 	Interventions of interest are: <ul style="list-style-type: none"> • Single-level artificial intervertebral disc arthroplasty of the cervical spine 	Comparators of interest are: <ul style="list-style-type: none"> • Anterior cervical discectomy and fusion 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • With cervical radicular pain or myelopathy 	Interventions of interest are: <ul style="list-style-type: none"> • Two-level artificial intervertebral disc arthroplasty of the cervical spine 	Comparators of interest are: <ul style="list-style-type: none"> • Anterior cervical discectomy and fusion 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity

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.

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 (RCTs) and meta-analyses of RCTs. 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 evi-

dence 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 FDA 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 two-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. The Food and Drug Administration approval for the Prestige LP was based on superiority to two-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. 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 (NDI) scores, NDI success rates, reoperation rates, and overall success composite outcome. At five years, trial results were consistent with the continued superiority of two-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 two-level ACDF patients. Based on this evidence, it can be concluded that two-level AIDA with either of these FDA 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.

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 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 six 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 two levels (i.e., 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 one to six above are met; AND
2. The device is FDA-approved for two 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 two 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 (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

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 the 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.

Treatment

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 within six weeks, or if symptoms 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.

ACDF has historically been 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 placement of a PEEK (polyetheretherketone) or titanium interbody cage plus 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. Although there may be slight differences between autograft and allograft

sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%-100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

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 an interbody cage and/or bone. An anterior plate is not used to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. AIDA was designed to 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 reason driving device development and use. Disc arthroplasty and ACDF 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 or spondylolisthesis.

Outcome Measures

The NDI is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life.¹ It is a modification of the Oswestry Disability Index, based on responses to 10 questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Response options to each question range from one to five, with a lower numeric score representing a better pain and disability status for that variable. A total NDI score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, NDI scores range from 0% to 100%, with a lower percentage indicating less pain and disability. Neurologic status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge whether patients are within normative parameters for those categories based on physiologic measurement. The anterior functional spinal unit height is a radiographic measure of interdiscal space. Comparison of the immediate postoperative functional spinal unit height with the six-week postoperative value shows whether the disc space has decreased, which indicates that graft or device subsidence has occurred. Other outcome measures may include the 36-Item Short-Form Health Survey Mental and Physical Component Summary scores, 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.

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 (e.g., pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (e.g., 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 the FDA for two adjacent

levels. A postapproval study will follow the investigational device exemption (IDE) patients who received the Prestige® LP at two 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 the FDA through the PMA process in 2007. As with the Prestige® ST Cervical Disc, FDA approval of ProDisc-C® was made conditional on seven-year follow-up of the 209 subjects included in the noninferiority trial, seven-year follow-up of 99 continued-access subjects, and a five-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 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. 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 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. 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 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, 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 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 semi-constrained 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 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>).

RELATED PROTOCOL

Artificial Intervertebral Disc: Lumbar Spine

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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