Introduction

The bones that make up the neck are called cervical vertebrae. Between each of the vertebra is a disc, which acts as a shock absorber and prevents the bones from rubbing together. As a person ages, these discs may break down and become thinner because they lose water and the gel-like substance that’s inside each disc. This is known as degenerative disc disease. Studies show that most adults over the age of forty have some degenerative disc disease when x-rays are done. However for many people no treatment is needed because the neck continues to move normally without pain. In some people who have pain and severe degenerative disc disease is present, treatment may be helpful. An artificial disc is one type of treatment. The artificial disc replaces the damaged natural disc, with the goal being to keep the normal space between the bones and preserve the motion of the neck. This treatment may be considered when there is significant pain that has not responded to other types of treatments. This policy describes when an artificial disc replacement in the neck may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medically necessary sites of service:</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
</tr>
</tbody>
</table>

Inpatient hospital/medical center

Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):

- Anesthesia Risk
  - ASA classification III or higher (see definition)
  - Personal history of complication of anesthesia
  - Documentation of alcohol dependence or history of cocaine use
  - Prolonged surgery (>3 hours)
- Cardiovascular Risk
  - Uncompensated chronic heart failure (NYHA class III or IV)
  - Recent history of myocardial infarction (MI) (<3 months)
  - Poorly controlled, resistant hypertension*
  - Recent history of cerebrovascular accident (< 3 months)
<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
|                                               | o Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty < 90 days)  
|                                               | o Symptomatic cardiac arrhythmia despite medication   
|                                               | o Significant valvular heart disease  
| - Liver Risk                                  | • Advance liver disease (MELD Score > 8)** |
| - Pulmonary Risk                              | o Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)  
|                                               | o Poorly controlled asthma (FEV1 <80% despite treatment)  
|                                               | o Moderate to severe obstructive sleep apnea (OSA)*** |
| - Renal Risk                                  | o End stage renal disease (on dialysis)  
| - Other                                       | • Morbid obesity (BMI ≥ 50)  
|                                               | • Pregnancy  
|                                               | • Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP*** does not meet this criteria])  
|                                               | • Anticipated need for transfusion(s) |

* 3 or more drugs to control blood pressure  
*** Moderate-AHI ≥15 and ≤ 30, Severe-AHI ≥30  
****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)  

<p>| Inpatient hospital/medical center | This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met. |</p>
<table>
<thead>
<tr>
<th>Surgery</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artificial cervical intervertebral disc implantation</td>
<td>Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• The device is approved by Food and Drug Administration (FDA):</td>
</tr>
<tr>
<td></td>
<td>o For <strong>one level</strong>:</td>
</tr>
<tr>
<td></td>
<td>▪ Bryan® Cervical Disc (Medtronic)</td>
</tr>
<tr>
<td></td>
<td>▪ M6-C Artificial Cervical Disc (Spinal Kinetics LLC)</td>
</tr>
<tr>
<td></td>
<td>▪ Mobi-C® Cervical Disc (Zimmer Biomet/LDR Medical)</td>
</tr>
<tr>
<td></td>
<td>▪ PCM (porous-coated motion) Cervical Disc® (NuVasive)</td>
</tr>
<tr>
<td></td>
<td>▪ Prestige®ST Cervical Disc System (Medtronic)</td>
</tr>
<tr>
<td></td>
<td>▪ ProDisc-C® Total Disc Replacement (DePuySynthes)</td>
</tr>
<tr>
<td></td>
<td>▪ SECURE-C® Cervical Artificial Disc (Globus Medical)</td>
</tr>
<tr>
<td></td>
<td>o For <strong>two contiguous levels</strong>:</td>
</tr>
<tr>
<td></td>
<td>▪ Mobi-C® Cervical Disc (Zimmer Biomet/LDR Medical)</td>
</tr>
<tr>
<td></td>
<td>▪ Prestige LP Cervical Disc</td>
</tr>
<tr>
<td></td>
<td>• The patient is skeletally mature</td>
</tr>
<tr>
<td></td>
<td>• The patient has intractable cervical radicular pain or myelopathy</td>
</tr>
<tr>
<td></td>
<td>a. Which has failed at least 6 weeks of conservative non-operative treatment including physical therapy and at least one of the following:</td>
</tr>
<tr>
<td></td>
<td>▪ Acupuncture</td>
</tr>
<tr>
<td></td>
<td>▪ Cervical collar</td>
</tr>
<tr>
<td></td>
<td>▪ Corticosteroids</td>
</tr>
<tr>
<td></td>
<td>▪ Exercise program</td>
</tr>
<tr>
<td></td>
<td>▪ Medical treatment with NSAIDs or other analgesics</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>b. The patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment.</td>
</tr>
<tr>
<td></td>
<td>• Degeneration is documented by imaging within the prior 12 months (magnetic resonance imaging, computed tomography or myelography)</td>
</tr>
<tr>
<td></td>
<td>• Cervical degenerative disc disease is from C3 through C7</td>
</tr>
<tr>
<td>Surgery</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Subsequent artificial cervical intervertebral disc implantation</td>
<td>Subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) 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) and the initial cervical artificial disc implantation is fully healed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| Artificial cervical intervertebral disc implantation | Cervical artificial intervertebral disc implantation is considered investigational for all other indications, including the following:  
- Active infection  
- Anatomical deformity (eg, ankylosing spondylitis)  
- Combined use of an artificial cervical disc and fusion (hybrid surgery)  
- Disc implantation at more than 2 levels  
- Malignancy  
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)  
- Presence of facet arthritis  
- Previous fusion at another cervical level  
- Prior surgery at the treated level  
- Rheumatoid arthritis or other autoimmune disease  
- Translational instability |

**Documentation Requirements**

*The following information must be submitted to ensure an accurate, expeditious, and complete review for cervical spinal fusion surgery:*

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes that include a current history and physical exam
Documentation Requirements

- Clinical notes that document the requesting surgeon personally evaluated the individual at least twice before submitting a request for surgery (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms)
- Detailed documentation of extent and response to non-operative conservative therapy, if applicable, including outcomes of any procedural interventions, medications used and physical therapy/physiatrist notes
- Copy of radiologist’s report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist’s report will supersede.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0095T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical</td>
</tr>
<tr>
<td>0098T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical</td>
</tr>
<tr>
<td>0375T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophysectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels</td>
</tr>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophysectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical</td>
</tr>
<tr>
<td>22858</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophysectomy for nerve root or spinal cord decompression and microdissection); second level, cervical</td>
</tr>
<tr>
<td>22861</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Related Information

Definition of Terms

American Society of Anesthesiologists (ASA) Score:
- **ASA 1**: A normal healthy patient.
- **ASA 2**: A patient with mild systemic disease.
- **ASA 3**: A patient with severe systemic disease.
- **ASA 4**: A patient with severe systemic disease that is a constant threat to life.
- **ASA 5**: A moribund patient who is not expected to survive

Cervical myelopathy: Loss of function in the upper and lower extremities due to compression of the spinal cord within the neck.

Cervical radiculopathy: Persistent neck pain that radiates into the shoulder/arm in a dermatomal/single nerve pattern, or progressive weakness caused by irritation or injury near the root of a spinal nerve in the neck. The North American Spine Society describes the most common clinical findings as arm pain, neck pain, scapular or periscapular pain, and paresthesias, numbness and sensory changes, weakness, or abnormal deep tendon reflexes in the arm.

New York Heart Association (NYHA) Classification:
- **Class I**: No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
- **Class II**: Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- **Class III**: Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.
- **Class IV**: Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Subsidence: Sinking or settling in bone, for example from a prosthetic component of an implant.
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.

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 on the radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to some extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Treatment

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

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 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. The 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.

**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, 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 anterior cervical discectomy and fusion (ACDF). There have been no safety signals with discs approved by the 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 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. The FDA 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 5- and 7-year follow-ups. 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 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 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. 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 that the technology results in a meaningful improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01609374*</td>
<td>Prospective, Concurrently Controlled, Multi-Center Study to Evaluate the Safety and Effectiveness of the Spinal Kinetics™ M6-C Artificial Cervical Disc Compared to Anterior Cervical Discectomy and Fusion (ACDF) for the Treatment of Symptomatic Cervical Radiculopathy</td>
<td>258</td>
<td>Jun 2019</td>
</tr>
<tr>
<td>NCT01763619*</td>
<td>Freedom® Cervical Disc Use In The Treatment of Cervical Degenerative Disc Disease</td>
<td>50</td>
<td>Jul 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT00637156*</td>
<td>A Prospective, Randomized, Controlled, Multicenter Pivotal Clinical Trial of the Artificial Cervical Disc-LP at Two Levels for Symptomatic Cervical Disc Disease</td>
<td>397</td>
<td>Mar 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT02403453*</td>
<td>RHINE™ Cervical Disc Clinical Study</td>
<td>166</td>
<td>Jun 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00432159*</td>
<td>A Multi-Center, Prospective, Randomized Controlled Trial Comparing Cervical Arthroplasty to Anterior Cervical</td>
<td>500</td>
<td>May 2016 (completed)</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>Discectomy and Fusion for the Treatment of Cervical Degenerative Disc Disease (DISCOVER™ IDE Study)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial

*a* Denotes industry-sponsored or cosponsored trial

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2015 Input**

In response to requests, input was received from 3 physician specialty societies and 2 academic medical centers while this policy was under review in 2015. There was agreement that cervical disc replacement may be medically necessary under specified conditions. Likewise, there was agreement that combined use of an artificial disc and fusion over 2 levels is investigational. Input was mixed regarding the medical necessity of 2-level artificial intervertebral disc arthroplasty.

**2009 Input**

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. Input did not support the conclusion that artificial intervertebral disc arthroplasty is investigational.
Practice Guidelines and Position Statements

**North American Spine Society**

The guidelines from the North American Spine Society (2015) indicate 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.”

**National Institute for Health and Care Excellence**

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

Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is at 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.\textsuperscript{41,42} Neither guideline addressed the artificial cervical disc.

\section*{Medicare National Coverage}

A search of the Medicare National Database identified a national coverage determination on artificial intervertebral discs for the lumbar spine, but not for the cervical spine.\textsuperscript{43}

\section*{Regulatory Status}

In 2007, the Prestige\textsuperscript{®} 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\textsuperscript{®} 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 1 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\textsuperscript{®} LP artificial cervical disc (Medtronic Sofamor Danek) was approved by the FDA through the PMA process. The Prestige\textsuperscript{®} 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\textsuperscript{®} LP was approved by the FDA for 2 adjacent levels. A postapproval study will follow the investigational device exemption (IDE) patients who received the Prestige\textsuperscript{®} LP at two contiguous levels for ten years. Medtronic will also submit to the 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\textsuperscript{®} (Synthes Spine), was approved by the FDA through the PMA process in 2007. As with the Prestige\textsuperscript{®} ST Cervical Disc, the FDA approval of ProDisc-C\textsuperscript{®} was made conditional on 7-year follow-up of the 209 subjects included in the
noninferiority trial, 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 the 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 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 post-approval 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 the FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received the 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 1-level (P110002) or 2-level (P110009) disc replacement.

• The M6-C Artificial Cervical Disc (Spinal Kinetics LLC) received Premarket approval (PMA) (P170036) in February 2019. Product Code MJO. It is approved for single level. It incorporates an artificial nucleus made from polycarbonate urethane and a woven fiber annulus made from polyethylene. The M6-C has 2 titanium outer plates with keels for anchoring the disc into the bone of the vertebral body. It is implanted via an anterior approach. Patients should have failed at least 6 weeks of conservative treatment.

A number of other devices are in FDA IDE trials in the United States (see Table 2).

Table 2. Cervical Disc Prostheses Under Investigation in the United States

<table>
<thead>
<tr>
<th>Prosthesis</th>
<th>Manufacturer</th>
<th>FDA Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kineflex/C®</td>
<td>Spinal Motion</td>
<td>FDA IDE trial complete; status unknown</td>
</tr>
<tr>
<td>Freedom®</td>
<td>AxioMed</td>
<td>FDA IDE trial recruiting</td>
</tr>
</tbody>
</table>

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


References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/11/15</td>
<td>New Policy. Replaces policy 7.01.537. Also added definitions of cervical myelopathy and cervical radiculopathy. ICD-9 procedure code 84.61 added.</td>
</tr>
<tr>
<td>01/08/16</td>
<td>Minor update. CPT code 0092T, deleted 12/31/14, removed from policy. No other changes.</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Annual Review, approved September 13, 2016. New policy statement added that 2-level cervical disc replacement may be considered medically necessary when criteria are met. Policy updated with literature review through June 2016; references added, updated and/or removed. Policy statement added as noted.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; Rationale revised, some references removed. Policy statements unchanged.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.</td>
</tr>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 12, 2018. Policy updated with literature review through February 2018; no references added. Medical necessity policy statement revised to include subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) when criteria are met.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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</tr>
<tr>
<td>02/01/19</td>
<td>Investigational statements prior artificial disc placement and replacement at another cervical level removed. Prior artificial disc placement at another cervical level changed.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Minor update, updated title of related policy 7.01.560.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Minor update, clarified Site of Service requirements.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. M6-C Artificial Cervical Disc was added to the list of single level FDA approved devices. Otherwise, policy statements unchanged. Removed CPT code 22864.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

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Toll free 855-332-4535, Fax 425-918-5992. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights compliant with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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