MEDICAL POLICY – 7.01.108
Artificial Intervertebral Disc: Cervical Spine

BCBSA Ref. Policy: 7.01.108
Effective Date: July 1, 2017
Last Revised: June 6, 2017
Replaces: 7.01.537

RELATED MEDICAL POLICIES:
7.01.87  Artificial Intervertebral Disc: Lumbar Spine
7.01.560  Anterior Cervical Spine Decompression and Fusion in Adults

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞  Clicking this icon returns you to the hyperlinks menu above.

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 and covered by the health plan.

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.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artificial cervical intervertebral disc implantation</td>
<td>Implanting an artificial cervical intervertebral disc 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>: Bryan Cervical Disc, Mobi-C Cervical Disc Prosthesis, PCM Cervical Disc System, Prestige Cervical Disc System or ProDisc-C Total Disc Replacement</td>
</tr>
<tr>
<td></td>
<td>o For <strong>two contiguous levels</strong>: Mobi-C Cervical Disc Prosthesis, Prestige LP Cervical Disc</td>
</tr>
<tr>
<td></td>
<td>- The patient is skeletally mature</td>
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<tr>
<td></td>
<td>- The patient has intractable cervical radicular pain or myelopathy</td>
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<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>
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<tr>
<td></td>
<td>▪ Medical treatment with NSAIDs or other analgesics</td>
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<td></td>
<td>▪ Cervical collar</td>
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<tr>
<td></td>
<td>▪ Exercise program</td>
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<tr>
<td></td>
<td>▪ Oral corticosteroids</td>
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<tr>
<td></td>
<td>▪ Acupuncture</td>
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<tr>
<td></td>
<td><strong>OR</strong></td>
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<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>
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<tr>
<td></td>
<td>- Degeneration is documented by imaging within the prior 12 months (magnetic resonance imaging, computed tomography myelography)</td>
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<td></td>
<td>- Cervical degenerative disc disease is from C3 through C7</td>
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<tr>
<td></td>
<td>- The patient is free from contraindication to artificial cervical intervertebral disc implantation</td>
</tr>
<tr>
<td>Simultaneous artificial cervical intervertebral disc</td>
<td>Simultaneous implantation of a second artificial cervical intervertebral disc at an adjacent level may be considered</td>
</tr>
<tr>
<td>Surgery</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Implantation</td>
<td>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).</td>
</tr>
</tbody>
</table>

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

**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.
- 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.
Documentation Requirements

- 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>
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</thead>
<tbody>
<tr>
<td>CPT</td>
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<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 osteophytectomy 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 osteophytectomy 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 osteophytectomy 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>
<tr>
<td>22864</td>
<td>Removal 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).
Definition of Terms

**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.

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

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**Evidence Review**

**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 compresses the spinal cord can result in myelopathy, which is seen as subtle changes in gait or balance. In severe cases, myelopathy can lead to weakness in the arms or legs and numbness of the arms or hands. The prevalence of DDD due 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 show at least 1 degenerative change on 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**

Cervical DDD is initially treated conservatively using noninvasive measures (eg, rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve within 6 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.

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. Additionally, an autograft or allograft of bone is placed 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 would otherwise be needed following ACDF without an anterior plate. Although there may be slight differences in the postoperative rate of union when using autograft versus allograft bone sources, 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 bone. An anterior plate is not used 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 reason 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 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 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria. 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 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 Food and Drug Administration (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. 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 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 that the technology results in a meaningful improvement in the net health outcome.
Ongoing and Unpublished Clinical Trials

Some 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>NCT01609374a</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>243</td>
<td>May 2017</td>
</tr>
<tr>
<td>NCT01763619a</td>
<td>Freedom® Cervical Disc Use In The Treatment of Cervical Degenerative Disc Disease</td>
<td>50</td>
<td>Jul 2017</td>
</tr>
<tr>
<td>NCT00637156a</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</td>
</tr>
<tr>
<td>NCT02403453a</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>NCT00637312a</td>
<td>Clinical Trial Comparing the Blackstone Advent™ Cervical Disc to Anterior Cervical Discectomy and Fusion (ACDF) for the Treatment of One Level Degenerative Disc Disease</td>
<td>108</td>
<td>Terminated (revision rate)</td>
</tr>
<tr>
<td>NCT00478088a</td>
<td>A Pivotal, Multi-Center, Randomized, Controlled Trial Evaluating The Safety and Effectiveness of The NeoDisc™ Versus Instrumented Anterior Cervical Discectomy and Fusion (ACDF) in Subjects With Single-Level Cervical Disc Disease</td>
<td>488</td>
<td>Mar 2012 (completed)</td>
</tr>
<tr>
<td>NCT00432159a</td>
<td>A Multi-Center, Prospective, Randomized Controlled Trial Comparing Cervical Arthroplasty to Anterior Cervical Discectomy and Fusion for the Treatment of Cervical Degenerative Disc Disease (DISCOVER™ IDE Study)</td>
<td>500</td>
<td>May 2016 (completed)</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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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 for July 2015. There was agreement that cervical disc replacement may be medically necessary under specified conditions. Input agreed that combined use of an artificial disc and fusion over 2 levels is investigational. Input was mixed regarding the medical necessity of 2-level AIDA.

Practice Guidelines and Position Statements

North American Spine Society

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

National Institute for Health and Care Excellence

The U.K.’s National Institute for Health and Care Excellence (NICE) issued guidance on the artificial cervical disc in 2010. NICE concluded 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. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

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

The 2009 guidelines from the American Association of Neurological Surgeons address anterior cervical discectomy and anterior cervical discectomy and fusion for the treatment of cervical degenerative radiculopathy and cervical spondylotic myelopathy. These guidelines do not address the artificial cervical disc. 44,45

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.46

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 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 [MRI], computed tomography [CT], x-rays): herniated disc and/or osteophyte formation. FDA has required Medtronic (the Prestige disc manufacturer) to conduct a 7-year postapproval 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.

In 2014, the Prestige® LP artificial cervical disc (Medronic Sofamor Danek) was approved by FDA through the PMA process. 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 PMA process in 2007. As with the Prestige® ST Cervical Disc, 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 more fully characterize adverse events when the device is used under general conditions of use. Post-approval 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 results. 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 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. In addition, Medtronic Sofamor Danek must perform a 5-year enhanced surveillance study of the disc to more fully characterize adverse events when the device is used in a broader patient population.
More recently, continued FDA approval requires completion of 2 post-approval 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 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 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 semiconstrained 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 semiconstrained 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 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</td>
</tr>
<tr>
<td>Freedom®</td>
<td>AxioMed</td>
<td>FDA IDE trial recruiting</td>
</tr>
<tr>
<td>M6-C</td>
<td>Spinal Kinetics</td>
<td>FDA IDE trial recruiting complete</td>
</tr>
</tbody>
</table>

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

Updates to the regulatory status of these devices can be viewed online using FDA product code MJO (available at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm) Accessed June 2017).

References


<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 84.63 added.</td>
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<tr>
<td>01/08/16</td>
<td>Minor update. CPT code 0092T, deleted 12/31/14, removed from policy. No other changes.</td>
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<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<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>
</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). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can 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 complaint 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)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

 Lyme (Amharic):

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 ramifications do not affect your health coverage or help you with costs. You have the right to get this information and help in your language at no cost.

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Oromo (Cushite):


Français (French):


Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konèsan aplikasyon w lan oswa konèsan kouvéti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan séten dat limit pou ka kende kouvéti asirans sante w la oswa pou yo ka ede w avèk yans. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou pèye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):


Hmoob (Hmong):


Ilokano (Ilocano):

Daytoy a Pakdaak ket naglai on Itapate nga Impormasion. Daytoy a pakdaak tabungan nga adda ket naglai on itapate nga impormasion maipanggip iti aplikasyon wovon coverge babaen ti Itama Blue Cross. Daytoy ket tabungan dagiti importante a petaa iti daytoy a pakdaak. Tabungan nga adda rumbeng nga aramidenyo nga adda bakaay dagiti partikular a na lituding nga adda alay tapon mapagtalainneyo a coverge ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasagao nga awan ti bayayado. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):


中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要資訊。本通知中可能有重要日期，您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

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Premera Blue Cross.

In some cases, this information may contain important details about your application or coverage. To obtain this information, you may call Premera Blue Cross toll-free at 800-722-1471 (TTY: 800-842-5357).