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.

RELATED PROTOCOL

Artificial Intervertebral Disc: Lumbar Spine

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With cervical radicular pain or myelopathy</td>
<td>Single-level cervical disc arthroplasty</td>
<td>Anterior cervical discectomy and fusion</td>
<td>Symptoms, Morbid events, Functional outcomes, Quality of life, Treatment-related morbidity</td>
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<tr>
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<td>Two-level cervical disc arthroplasty</td>
<td>Anterior cervical discectomy and fusion</td>
<td>Symptoms, Morbid events, Functional outcomes, Quality of life, Treatment-related morbidity</td>
</tr>
</tbody>
</table>

DESCRIPTION

Several prosthetic devices are currently available for cervical disc arthroplasty. Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for patients with symptomatic cervical degenerative disc disease.

SUMMARY OF EVIDENCE

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, 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 non-inferiority criteria compared to anterior cervical discectomy.
and fusion. 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 non-inferiority of cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige, ProDisc-C, and Mobi-C pivotal trials continue 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. There have been no safety signals with discs approved by the U.S. Food and Drug Administration (FDA) for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. FDA approval for the Prestige LP was based on superiority to 2-level anterior cervical discectomy and fusion 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 10-year follow-up. At 2 and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to anterior cervical discectomy and fusion for Neck Disability Index scores, Neck Disability Index success rates, reoperation rates, and the overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty 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 anterior cervical discectomy and fusion patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty 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 an 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 is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical degenerative disc disease 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 degenerative disc disease secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical degenerative disc disease. By age 65, 95% of men and 70% of women have at least 1 degenerative change evident at the radiographic examination. It is estimated that approximately 5 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

Anterior cervical discectomy and fusion has historically been considered the definitive surgical treatment for symptomatic degenerative disc disease of the cervical spine. The goals of anterior cervical discectomy and fusion 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 anterior cervical
discectomy and fusion patients. Anterior cervical discectomy and fusion 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 anterior cervical discectomy and fusion 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% to 100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level degenerative disc disease and the need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for patients with symptomatic cervical degenerative disc disease. In cervical disc arthroplasty, 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 cervical disc arthroplasty 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 degenerative disc disease above or below a fusion site has been the major reason driving device development and use. Disc arthroplasty and anterior cervical discectomy and fusion have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in cervical disc arthroplasty candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis or spondylolisthesis.

REGULATORY STATUS

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 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 (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 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 in a broader patient population.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine), was approved by the FDA through the premarket approval process in 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C was made conditional on the 7 year follow-up of the 209 subjects included in the non-inferiority 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. The ProDisc-C Vivo is currently marketed by Centinal Spine.

More recently, continued FDA approval requires the completion of 2 postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10 year enhanced surveillance of adverse event data. Continued approval is contingent on the 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.
Devices with FDA approval for use in the United States are described in Table 1. These devices are for 1 site or 2 contiguous sites, there are no devices approved for non-contiguous sites. FDA Product Code: MJO

Table 1. Cervical Disc Prostheses Approved for use in the United States

<table>
<thead>
<tr>
<th>Prosthesis</th>
<th>Manufacturer</th>
<th>Characteristics</th>
<th>FDA Approval</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige® ST</td>
<td>Medtronic</td>
<td>Stainless Steel.</td>
<td>P060018</td>
<td>2007</td>
</tr>
<tr>
<td>ProDisc-C®</td>
<td>Centinal Spine</td>
<td>2 metal (cobalt-chromium alloy) endplates and a polyethylene insert.</td>
<td>P070001</td>
<td>2007</td>
</tr>
<tr>
<td>Bryan® Cervical Disc</td>
<td>Medtronic Sofamor Danek</td>
<td>2 titanium-alloy shells encasing a polyurethane nucleus.</td>
<td>P060023</td>
<td>2009</td>
</tr>
<tr>
<td>PCM [porous-coated motion] Cervical Disc®</td>
<td>NuVasive</td>
<td>PCM® is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert.</td>
<td>P100012</td>
<td>2012</td>
</tr>
<tr>
<td>SECURE®-C</td>
<td>Globus Medical</td>
<td>Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert.</td>
<td>P100003</td>
<td>2012</td>
</tr>
<tr>
<td>Mobi-C®</td>
<td>Zimmer Biomet (previously LDR Spine)</td>
<td>Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert.</td>
<td>P110002/ P110009</td>
<td>2013</td>
</tr>
<tr>
<td>Prestige LP™</td>
<td>Medtronic Sofamor Danek</td>
<td>Titanium-ceramic composite with a metal-on-metal bearing. Approved for both 1 and 2- levels.</td>
<td>P090029</td>
<td>2014/2016</td>
</tr>
<tr>
<td>M6®-C</td>
<td>Orthofix (previously Spinal Kinetics)</td>
<td>Ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates.</td>
<td>P170036</td>
<td>2019</td>
</tr>
<tr>
<td>Simplify® Cervical Artificial Disc</td>
<td>NuVasive (previously Simplify Medical)</td>
<td>PEEK endplates and a mobile ceramic core. MRI compatible.</td>
<td>P200022</td>
<td>2020</td>
</tr>
</tbody>
</table>

FDA: U.S. Food and Drug Administration; MRI: magnetic resonance imaging.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


