Medical Policy
Artificial Intervertebral Disc: Cervical Spine

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Policy Number: 585
BCBSA Reference Number: 7.01.108
LCD/NCD: N/A

Related Policies
Artificial Intervertebral Disc: Lumbar Spine, #592

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Prior Authorization Request Form: Artificial Intervertebral Disc: Cervical Spine
This form must be completed and faxed to: Medical and Surgical: 1-888-282-0780; Medicare Advantage: 1-800-447-2994
Click here for Artificial Intervertebral Disc: Cervical Spine Prior Authorization Request Form, #952

Cervical artificial intervertebral disc implantation may be considered MEDICALLY NECESSARY when ALL of the following criteria are met:

1. The device is approved by FDA;
2. The patient is skeletally mature;
3. The patient has intractable cervical radicular pain or myelopathy
   a. which has failed at least 6 weeks of conservative nonoperative treatment, including 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 (MRI), computed tomography (CT), or myelography;
5. Cervical degenerative disc disease is from C3-C7; and
6. The patient is free from contraindication to cervical artificial intervertebral disc implantation.
Simultaneous cervical artificial intervertebral disc implantation at a second contiguous level may be considered **MEDICALLY NECESSARY** if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (ie, Mobi-C, Prestige LP).

Subsequent cervical artificial intervertebral disc implantation at an adjacent level may be considered **MEDICALLY NECESSARY** when all of the following are met:

1. Criteria 1 to 6 above are met; and
2. The device is FDA-approved for 2 levels; and
3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; and
4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

Cervical artificial intervertebral disc implantation is considered **INVESTIGATIONAL** for all other indications, including the following:

- Disc implantation at more than 2 levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Translational instability
- Anatomical deformity (eg, ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection, systemic or local
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia) (T-score of -3.5, or -2.5, with vertebral crush fracture)
- Neck or arm pain of unknown etiology
- Absence of neck and/or arm pain
- Progressive neurological deficit or deterioration
- Paget’s disease, osteomalacia or any other metabolic bone disease
- Malignancy.

There is radiological evidence of ANY of the following:

- Clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3.5 mm subluxation or > 11 degrees angulation)
- Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
- Spinal metastases.
- Non FDA–approved cervical disc prosthesis.

**Prior Authorization Information**

**Inpatient**
- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

**Outpatient**
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Prior authorization is required.*</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is required.*</td>
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<tr>
<td>Medicare HMO Blue℠</td>
<td>Prior authorization is required.*</td>
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<tr>
<td>Medicare PPO Blue℠</td>
<td>Prior authorization is required.*</td>
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</table>
CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<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>
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<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 (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10 PCS-procedure codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0RR30JZ</td>
<td>Replacement of Cervical Vertebral Disc with Synthetic Substitute, Open Approach</td>
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</tbody>
</table>

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>22861</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
</tr>
<tr>
<td>0098T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)</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>
</tbody>
</table>
Description
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 1 degenerative change evident at 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. 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) is currently 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 emplacement of either 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. The choice of bone material for interbody fusion in ACDF has important clinical implications. Allograft bone has several drawbacks, including a small (albeit, unproven) risk of infectious disease transmission, possible immunologic reaction to the allograft, and possible limited commercial availability of appropriate graft material. In contrast, use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. These morbidities include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. 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 for single-level, anterior-plated ACDF, using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest and those specific to use of allograft material. Biomechanical modeling 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. Patients with advanced spondylosis or hard disc herniations have a separate pathologic condition and require a different surgical approach.
Summary
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.

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 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index (NDI) and overall success composite outcome. 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 are consistent with 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.

Longer term results for other discs are expected, given the U.S. Food and Drug Administration (FDA) requirement for 7-year postapproval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to more fully characterize adverse events in a broader patient population. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs, but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of ACDF. There have been no safety signals with discs that have been approved by the FDA for single-level AIDA. The evidence is sufficient to determine qualitatively 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 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>8/2018</td>
<td>Outpatient prior authorization is required. Effective 8/1/2018.</td>
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<tr>
<td>5/2018</td>
<td>Clarified coding information</td>
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<td>7/2017</td>
<td>Clarified coding information</td>
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<tr>
<td>5/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>2/2017</td>
<td>BCBSA National medical policy review. Considered medically necessary for 2-level cervical disc replacement with a device that is FDA-approved for 2-levels (ie, Mobi-C, Prestige LP). Effective 2/1/2017.</td>
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<tr>
<td>1/2015</td>
<td>Clarified coding information</td>
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<td>8/2014</td>
<td>Coding information clarified</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


Endnotes

1 Based on expert opinion