Medical Policy

Artificial Intervertebral Disc - Cervical Spine

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Policy Number: 585
BCBSA Reference Number: NA

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

Surgical implantation of FDA–approved cervical intervertebral disc (IVD) prosthesis) may be MEDICALLY NECESSARY in a skeletally mature individual when ALL of the following criteria are met:
- Individual has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy
- Unremitting neck and arm pain, resulting in disability and/or neurological deficit, that is refractory to at least six weeks of standard medical and surgical management (e.g., reduced activities, exercise, analgesics, physical therapy)
- Single-level disc degeneration has been confirmed on complex imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI])
- The planned implant will be used in the reconstruction of a cervical disc at C3-C7, following single-level discectomy
- The individual is a candidate for single-level anterior cervical decompression and interbody fusion.

Surgical implantation of cervical intervertebral disc (IVD) prosthesis for ANY of the following is INVESTIGATIONAL:
- The planned procedure includes the combined use of a prosthesis and spinal fusion
- Simultaneous multilevel implantation is planned
- The individual had prior fusion at an adjacent cervical level
- The individual had prior surgery at the treated level
- Osteopenia, osteomalacia, or osteoporosis (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
- Infection, systemic or local
• Rheumatoid arthritis or other autoimmune disease
• Paget’s disease, osteomalacia or any other metabolic bone disease
• There is radiological evidence of ANY of the following:
  o clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3.5
    mm subluxation or > 11 degrees angulation)
  o 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)
  o multilevel degenerative disc
  o spinal metastases.
• Non FDA–approved cervical disc prosthesis.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
Prior authorization is required for inpatient procedures.

Commercial Members: PPO, and Indemnity
Prior authorization is required for inpatient procedures.

Medicare Members: HMO BlueSM
Prior authorization is required for inpatient procedures.

Medicare Members: PPO BlueSM
Prior authorization is required for inpatient procedures.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. 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. A draft of future ICD-10 Coding related to this document, as it might look today, is
included below for your reference.

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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical</td>
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ICD-9 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-9 CM-procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>84.62</td>
<td>Insertion of total spinal disc prosthesis, cervical</td>
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ICD-10 Procedure Codes

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

Surgical decompression of the nerve root or spinal cord by anterior cervical discectomy and fusion, with or without plate fixation, using autologous or allogeneic bone is considered the standard surgical treatment for symptomatic cervical DDD when conservative measures have failed. Adjacent segment degeneration following cervical fusion is a concern however; Hilibrand et al. (1999) estimated that more than 25% of patients will develop adjacent segment disease during the first 10 years following cervical fusion and the risk of repeat operation after a prior fusion in half of all symptomatic patients. In hopes of restoring spinal motion and preventing adjacent segment disease, cervical intervertebral disc prostheses have been developed for use in patients with symptomatic cervical disc disease associated with DDD at a single level between C3 to C7. Cervical disc arthroplasty utilizes the same surgical approach as a fusion; however instead of using bone graft and anterior plate fixation during the arthroplasty, the surgeon secures a prosthetic disc into the intervertebral space. The device is designed to assist in maintaining vertebral height while decompressing the spinal cord or nerve root in the neck.

While the goal of each device is similar, their components and general design varies. Most of these prostheses are in various stages of research and clinical testing; several manufacturers have received investigational device exemptions. Cervical intervertebral disc prostheses that have been approved by the FDA for surgical implantation within the spine, for single-level cervical disc replacement include but are not limited to: The Prestige™ ST Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), the PRODISC-C® Total Disc Replacement (Synthes, Inc., New York, NY), the BRYAN® Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), Secure®-C Cervical Artificial Disc (Globus Medical, Audubon, PA) and PCM® Cervical Disc System (NuVasive, Inc., San Diego, CA).

PRESTIGE™ ST Cervical Disc: The PRESTIGE™ ST Cervical Disc consists of a two-piece articulating metal-on-metal device that is inserted into the intervertebral disc space at a single cervical level using an anterior approach. The components are affixed to the vertebral body by two bone screws through an anterior flange, and locked into place with a lock screw mechanism. This prosthesis is designed to allow the following motions ex-vivo: a minimum of 10 degrees motion off the neutral position in flexion/extension and lateral bending, unconstrained axial rotation, and two millimeters (mm) of anterior/posterior translation. (This device has been modified since its original design, and previous versions have included the Bristol/Cummins disc, the Prestige I and the Prestige II).

U.S. Food and Drug Administration (FDA): In July 2007, the FDA granted a premarket approval for the PRESTIGE™ ST Cervical Disc prosthesis. According to the manufacturer and the FDA premarket approval, this device is indicated for use in a skeletally mature patient for the reconstruction of a cervical disc from C3–C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The intractable radiculopathy and/or myelopathy (i.e., herniated disc, and/or osteophyte formation) should be severe enough to produce symptomatic nerve root and/or spinal cord compression, documented by patient history (e.g., neck and/or arm pain, functional deficit, and/or neurological deficit) and radiographic studies (e.g., CT, MRI, x-rays).

According to the FDA the Prestige Cervical Disc prosthesis is contraindicated in patients with an active infection or with an allergy to stainless steel. In addition, the safety and effectiveness of this device has not been established in patients with the following conditions:

- more than one cervical level with DDD
- not skeletally mature
- clinically significant cervical instability
- prior fusion at an adjacent cervical level
- severe facet joint pathology or involved vertebral bodies
- prior surgery at treated level
- osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture
- spinal metastases
- chronic or acute renal failure or history of renal disease
- taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids)
• pregnant  
• severe insulin-dependent diabetes

The safety and effectiveness of the use of this device has also not been established in patients who have not undergone six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued nonoperative care.

As part of the approval, the FDA is requiring a seven-year post-approval study to evaluate long-term safety and effectiveness of the Prestige ST Cervical Disc. Data will be collected at three, five and seven years postoperatively for all patients. Outcome measures will include Neck Disability Index (NDI) scores, radiograph information and neurological status as well as detailed information regarding adverse events.

**Policy History**

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<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**


x=5&y=11

x=6&y=8

86. van Ooij A, Kurtz SM, Stessels F, Noten H, van Rhijn L. Polyethylene wear debris and long-term clinical


Endnotes

1 Based on expert opinion