DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

**Lumbar Artificial Disc**

Lumbar total disc replacement (LTDR) involves replacement of a degenerating lumbar (L3-S1) intervertebral disc with an artificial, or prosthetic, disc. The artificial disc is designed to maintain the physiological range of motion and stability of the natural spine and restore disc height and vertebral alignment, and, as a result, relieve pain and prevent adjacent disc degeneration. Implantation of the artificial lumbar disc is performed under general anesthesia using the retroperitoneal or transperitoneal approach. During the surgery, the neurosurgeon may require assistance of a vascular or general surgeon in order to reduce complications that may occur during exposure and instrumentation due to the presence of vital anatomical structures such as the aorta, iliac vessels, sympathetic plexus, and intraperitoneal structures such as the bowel and ureters. An anterior retroperitoneal approach is used to expose the affected disc. The patient is placed in a supine position, and a complete discectomy is performed, including the removal of the posterior lateral recesses of the disc. The bony end plates are prepared by removing the cartilaginous end plates and any osteophytes, although the surrounding spinal ligaments are saved to maintain the stability of the implant. A trial disc and fluoroscopy may be used to determine the midline of the vertebral body for proper placement of the disc. The trial disc is subsequently removed, and the artificial disc is inserted and secured.

**Cervical Artificial Disc**
Cervical artificial disc replacement has been developed as a clinical alternative to anterior cervical discectomy and fusion. The artificial disc is intended to relieve pain, restore disc height, maintain motion of the natural spine, and prevent degeneration of adjacent discs. Cervical Artificial disc implantation is typically performed by an orthopedic surgeon on an inpatient basis. The surgical procedure to implant the Prestige ST artificial disc takes 90 minutes to 2 hours to perform, and involves a cervical discectomy using a standard anterior approach. The patient is placed in a supine position and a complete discectomy is performed, including removal of the posterior lateral recesses of the disc. The bony end plates are prepared by removing the cartilaginous end plates and any osteophytes. A trial disc and fluoroscopy may be used to determine the midline of the vertebral body for proper placement of the disc. The trial disc is then removed and the artificial disc inserted and secured. Hospital stay ranges from 1 to 2 days, after which the patient can resume normal activities with minimal or no restrictions. Following artificial cervical disc replacement, use of a cervical collar is not necessary.

The FDA has approved the following artificial lumbar disc systems for use in the United States: The Inmotion Lumbar Artificial Disc (formerly the Charité Artificial Disc; DePuy Synthes Inc., a Johnson & Johnson Company) and the ProDisc-L Total Disc Replacement (DePuy Synthes Inc., a Johnson & Johnson Company). The Charité Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level from L4-S1. The ProDisc-L is indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level from L3-S1. Patients should have no more than grade 1 spondylolisthesis at the involved level. For both devices patients should have failed ≥ 6 months of conservative treatment prior to implantation of the artificial disc. ²

The FDA has approved the following five artificial cervical disc systems for single-level treatment: Prestige Cervical Disc System; ProDisc-C Cervical Disc Total Cervical Disc Replacement (Synthes Spine Inc.); Bryan Cervical Disc System (Medtronic Inc.); Secure-C Artificial Cervical Disc (Globus Inc.); and the PCM (porous coated motion) Cervical Disc System (Nuvasive Inc.). All of these devices are indicated for use in skeletally mature patients for reconstruction of the disc from C3 to C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. ²

**RECOMMENDATION**

1. **Cervical** intervertebral disc replacement may be considered medically necessary and authorized in skeletally mature individuals when all of the following criteria is met: [ALL]
   - Age 18-60 years old
   - Device is FDA approved for cervical disc replacement
   - Diagnosis of single level degenerative cervical disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
   - Symptoms of unremitting neck and arm pain, resulting in disability and/or neurological deficit that is refractory to all of the following:
     - Six months or more of standard medical management unless contraindicated: [ALL]
       - activity restrictions and/or;
       - exercise; and
       - analgesics; and
physical therapy

- The planned implant will be used in the reconstruction of a cervical disc in only one vertebral level between C3-C7, following single-level discectomy
- Candidate for single-level anterior cervical decompression and interbody fusion

2. **Lumbar** intervertebral disc replacement may be considered medically necessary and authorized in skeletally mature individuals when all of the following criteria is met:
   - Age 18-60 years old
   - Device is FDA approved for lumbar disc replacement
   - Diagnosis of single level degenerative lumbar disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
   - Symptoms of unremitting back and/or leg pain, resulting in disability and/or neurological deficit that is refractory to all of the following:
     - Six months or more of standard medical management unless contraindicated: [ALL]
       - activity restrictions and/or;
       - exercise; and
       - analgesics; and
       - physical therapy
   - The planned implant will be used in the reconstruction of a lumbar disc in only one vertebral level between L-3 to S-1, following single-level discectomy
   - Candidate for single-level lumbar decompression and interbody fusion

**Coverage Exclusions**

1. The following are contraindications to intervertebral disc replacement according to the FDA and may not be authorized:
   - Active systemic infection or infection at the operating site
   - Allergy to implant materials (cobalt, chromium, molybdenum, titanium, or polyethylene) angulation of the disc space > 11° greater than adjacent segments)
   - Congenital stenosis
   - Marked instability on radiographs (e.g., radiographic signs of subluxation > 3.5 mm or
   - Moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of > 50% of its normal height.
   - Osteopenia or osteoporosis
   - Severe facet joint arthropathy
   - Significant anatomical deformity or compromised vertebral bodies at the index level due
   - Significant kyphotic deformity or significant reversal of lordosis or significant spondylolisthesis
   - Symptoms necessitating surgical treatment at more than one cervical level to systemic disease, previous surgery, or trauma.
2. Presence of any of the following conditions is considered investigational because they have not been proven for intervertebral disc replacement:
   - Active malignancy: A patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless treated with curative intent and there have been no clinical signs or symptoms of the malignancy for > 5 years.
   - Combined use of a prosthesis and spinal fusion is planned
   - Paget’s disease, osteomalacia, or any other metabolic bone disease
   - Pregnancy
   - Prior fusion at an adjacent level
   - Prior surgery at the treated level
   - Rheumatoid arthritis or other autoimmune disease.
   - Severe diabetes mellitus requiring daily insulin management
   - Simultaneous multilevel implantation is planned
   - Systemic disease, including AIDS, HIV, or hepatitis

**SUMMARY OF MEDICAL EVIDENCE**

*Cervical:*\(^{3-31}\)

The published evidence consists of randomized controlled trials, clinical trials, meta-analysis, systematic reviews and prospective studies with sample sizes ranging from 50-1648 and follow-up ranging from 2-7 years. Most RCTs compared total disc replacement (TDR) and anterior cervical discectomy and fusion (ACDF) or TDR, ACDF, and dynamic cervical implant (DCI) in adults with cervical DDD with pain that remained intractable after ≥ 6 weeks of conservative treatment. The most common clinical outcomes assessed were neck disability using the NDI scale, arm and neck pain using a 10-centimeter (cm) or 100-mm VAS scale, QOL using the SF-36 Health Survey (QualityMetric Inc.). Most RCTs reported overall success and significantly favored TDR over ACDF at 1 to 5 years postsurgery. Large improvements (e.g., 40 to 60 points on 100-millimeter [mm] visual analog scale [VAS]) in both arm and neck pain were observed within both TDR and ACDF groups, but between-group differences were generally very small and nonsignificant. QOL improvement was statistically significant following both TDR and ACDF. Study results showed that total disc replacement (TDR) is at least as effective as (ACDF) in improving signs and symptoms associated with degenerative disk disease (DDD) and in improving quality of life (QOL) in the short term.

*Lumbar:*\(^{32-57}\)

The published evidence consists of randomized controlled trials (RCTs), clinical trials, Cochrane reviews and uncontrolled studies with sample sizes ranging from 50 up to a total of 2139 and follow-up ranging from 7 to 17 years. These studies compared lumbar total disc replacement (LTDR) with fusion or conservative nonsurgical rehabilitation treatment in adults with symptomatic lumbar DDD (back pain with or without leg pain) at 1 or 2 vertebral levels (L3-S1) that did not improve with conservative treatment. Most RCTs enrolled patients 18 to 60 years of age. Most studies assessed back pain with the VAS and functional disability with the Oswestry Low Back Pain Disability Questionnaire (ODI). Results from self-reported measures of pain, functional disability, patient satisfaction, postoperative work status, and health-related quality of life (HRQoL) suggest that LTDR is...
comparable to spinal fusion in highly selected patients with 1-level lumbar DDD. At 24 months, most RCTs found a statistically significant and clinically relevant improvement in low back pain (defined as ≥ 15-point improvement in ODI scores at 24 months compared with baseline) for LTDR compared with fusion, but at 5-years follow-up, the difference between the groups was no longer significant. Study results showed that 1-level LTDR has comparable efficacy and safety relative to fusion for the treatment of symptomatic DDD in highly selected patients who have failed conservative treatment.

**CODING INFORMATION**

THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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<tr>
<td><strong>Cervical Disc Replacement</strong></td>
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**ICD-9**

**Description Procedure Codes: [For dates of service prior to 10/01/2015]**

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**ICD-9**

**Description Diagnosis Codes: [For dates of service prior to 10/01/2015]**

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**ICD-10**

**Description Procedure Codes PCS: [For dates of service on or after 10/01/2015]**

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**ICD-10**

**Description Diagnosis Codes CM: [For dates of service on or after 10/01/2015]**

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</table>

**RESOURCE REFERENCES**

**Government Agency**


**Peer Reviewed Publications**

**Cervical**


24. Nabhan A. Segmental kinematics and adjacent level degeneration following disc replacement versus fusion: RCT with three years of follow-up. Long term Eff Medical Implants. 2007;17(3):229-36


**Lumbar**


Professional Society Guidelines


Other Resources


