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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ⁷²

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.

FDA Information:^{2 72}

The FDA has approved the following artificial lumbar disc systems for surgical implantation within the spine for single-level disc replacement (activL® Artificial Disc [Aesculap Implant Systems], Charite® [DePuy Spine], and ProDisc-L [DePuySynthes]). Each device has specific labeling information but in general the devices are approved for individuals who are skeletally mature with DDD at a single level.⁷¹

The FDA has approved the following artificial cervical disc systems for single-level treatment (includes but is not limited to): The Prestige™ ST Cervical Disc and Prestige LP 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). Each device has specific labeling information but in general the devices are approved for use in a skeletally mature individual for the reconstruction of a cervical disc from C3–C7 following single-level discectomy or intractable radiculopathy and/or myelopathy. The FDA has granted premarket approval to the following 2 artificial cervical

disc systems for multilevel treatment: the Prestige LP Cervical Disc System (Medtronic Inc.) and The Mobi-C Cervical Disc Prosthesis (LDR Spine USA Inc.). These devices have specific labeling information but in general the devices are approved for use in skeletally mature patients for reconstruction of the disc from C3 to C7 following discectomy at 2 contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space. In 2019 the FDA approved the M6-C™ Artificial Cervical Disc that is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3 – C7.

POSITION STATEMENT CRITERIA ^{1-2 3-65 72}

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 one or two continuous vertebral levels between C3-C7, following single or two-level discectomy
 - ☐ Candidate for single or two-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

LIMITATIONS^{2 72}

1. Cervical Disc Replacement: each device has specific contraindications however these generally include, but are not limited to:
 - ☐ chronic or acute renal failure or history of renal disease
 - ☐ clinically significant cervical instability or 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)
 - ☐ more than one cervical level with DDD (except those specifically FDA approved for two level disease)
 - ☐ neck or arm pain of unknown etiology
 - ☐ not skeletally mature
 - ☐ osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture
 - ☐ pregnancy
 - ☐ prior fusion at an adjacent cervical level
 - ☐ prior surgery at treated level
 - ☐ rheumatoid arthritis or other autoimmune disease
 - ☐ severe facet joint pathology or involved vertebral bodies
 - ☐ severe insulin-dependent diabetes
 - ☐ spinal metastases
 - ☐ taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids)
2. Lumbar disc replacement: each device has specific contraindications however these generally include, but are not limited to:
 - ☐ active systemic infection or infection localized to the site of implantation
 - ☐ allergy or sensitivity to implant materials
 - ☐ bony lumbar stenosis
 - ☐ isolated radicular compression syndromes, especially due to disc herniation
 - ☐ osteopenia
 - ☐ osteoporosis
 - ☐ pars defect

SUMMARY OF MEDICAL EVIDENCE

Cervical:³⁻³²

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.

Two Level Cervical Disc Replacement^{11 12 59-65}

The published evidence for two level cervical disc replacement include randomized controlled trials, prospective and retrospective comparative studies, meta-analysis and systematic reviews that compared 2-level artificial cervical TDR with anterior cervical discectomy and fusion (ACDF). These studies reviewed adult patients with cervical DDD involving more than 1 disc who presented with cervical radiculopathy or myelopathy that had been unresponsive to nonsurgical treatment as candidates for 2-level TDR. The effectiveness of 2-level TDR for treatment of cervical DDD was assessed largely based on measures of neck disability, arm and/or neck pain, neurological status, HRQOL, and rates of adverse events. Overall, with regard to effectiveness, 2-level TDR appears to be at least comparable with ACDF. Overall success rates were higher with cervical TDR than with ACDF and in some studies with 5 to 7 years following treatment overall success ranged from 60.8% to 78.6% for TDR patients and 31.2% to 62.7% of ACDF patients.^{60 62} The systematic reviews and meta-analysis concluded that multilevel TDR carries similar or superior clinical outcomes as ACDF and may be associated with lower risk for AEs and that TDR may be a safe and effective alternative to ACDF for multilevel cervical DDD.⁶³⁻⁶⁵

Lumbar:³³⁻⁵⁸

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.

CPT	Description
	Cervical Disc Replacement
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
	Lumbar Disc Replacement
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
HCPCS	Description
	N/A
ICD-10	Description Diagnosis Codes: [For dates of service on or after 10/01/2015]
G95.89	Other specified diseases of spinal cord
G99.2	Myelopathy in diseases classified elsewhere
M50.00	Cervical disc disorder with myelopathy, unspecified cervical region
M50.20	Cervical disc disorder with myelopathy, mid-cervical region, unspecified level
M50.30	Other cervical disc degeneration, unspecified cervical region
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region

RESOURCE REFERENCES

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REVIEW/REVISION HISTORY

06/14/06: Policy created

01/28/09: Policy had minor revisions, no changes to criteria and procedure remains investigational.

12/14/11: Policy reviewed, no new evidence found, procedure remains investigational.

04/2/14: This policy was reviewed and based on new evidence it was revised to include new coverage criteria for the cervical artificial disc in patients who meet very specific criteria. The lumbar disc replacement remains unproven due to insufficient evidence.

12/16/2015: The policy was reviewed and updated to include criteria for lumbar artificial disc replacement based on new evidence.

12/14/16, 6/22/17: Policy reviewed, no changes

9/13/18: Policy reviewed, changes include new criteria for 2 level cervical disc replacement based on new evidence, and updated the following sections: FDA information and contraindications; references and coding tables.

6/19/19: Policy reviewed, no changes to the criteria. Updated coding. The FDA approved one new device called the M6-C™ Artificial Cervical Disc.

4/23/20: Policy reviewed, no changes to criteria. One code deleted [0375T].

2/8/21: Policy reviewed, no changes to criteria. One new guideline found and added as reference #68. Added codes: 0095T and 0098T.