Molina Clinical Policy
Artificial Intervertebral Disc Replacement (ADR) Surgery (Lumbar and Cervical): Policy No. 011

Last Approval: 2/8/2023
Next Review Due By: February 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Cervical artificial disc replacement or cervical disc arthroplasty (CDA) has been developed as a clinical alternative to anterior cervical discectomy and fusion for the treatment of cervical degenerative disc disease (CDDD). The surgery involves replacing a degenerating cervical disc with an artificial disc. 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 ambulatory to 2 days. (Kothari & Chuang, 2023; CMS, 2022; Chou, 2022).

Lumbar total disc replacement (LTDR) is an alternative to vertebral fusion which 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 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. (CMS, 2021, 2007; Chou, 2022).

FDA Information

FDA approved artificial lumbar disc systems for surgical implantation within the spine for single-level disc replacement, include the Activ-L™ (Aesculap) and ProDisc®-L (Centinel Spine). 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. (FDA, n.d.).

The FDA 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), the PRODISC-C® Total Disc Replacement (Synthes, Inc.), the BRYAN® Cervical Disc (Medtronic Sofamor Danek), Secure®-C Cervical Artificial Disc (Globus Medical), M6-C™ Artificial Cervical Disc (Orthofix, formerly Spinal Kinetics LLC), and PCM® Cervical Disc System (NuVasive, Inc.). 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. (FDA, n.d.).

The FDA granted premarket approval to the following two 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 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 two 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. (FDA, n.d.).

COVERAGE POLICY

1. **Cervical** intervertebral disc replacement **may be considered medically necessary** in skeletally mature individuals when **ALL** of the following criteria are met:
   a. Age 18-60 years old
   b. Device is FDA approved for cervical disc replacement
   c. Diagnosis of cervical degenerative disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
   d. Symptoms of unremitting neck and arm pain, resulting in disability and/or neurological deficit that is refractory to six months or more of standard medical management including **ALL** of the following unless contraindicated:
      - Activity restrictions and/or exercise
      - Analgesics
      - Physical therapy
   e. 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
   f. Candidate for single or two-level anterior cervical decompression and interbody fusion

2. **Lumbar** intervertebral disc replacement **may be considered medically necessary** in skeletally mature individuals when **ALL** of the following criteria are met:
   a. Age 18-60 years old
   b. Device is FDA approved for lumbar disc replacement
   c. Diagnosis of single level lumbar degenerative disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
   d. Symptoms of unremitting back and/or leg pain, resulting in disability and/or neurological deficit that is refractory to six months or more of standard medical management including **ALL** of the following unless contraindicated:
      - Activity restrictions and/or exercise
      - Analgesics
      - Physical therapy
   e. 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
   f. Candidate for single-level lumbar decompression and interbody fusion

Limitations and Exclusions

1. **Cervical Disc Replacement:** Each device has specific contraindications however these generally include, but are not limited to:
   a. Chronic or acute renal failure or history of renal disease
   b. 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)
   c. More than one cervical level with DDD (except those specifically FDA approved for two level disease)
   d. Neck or arm pain of unknown etiology
   e. Not skeletally mature
   f. Osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture

g. Pregnancy
h. Prior fusion at an adjacent cervical level
i. Prior surgery at treated level
j. Rheumatoid arthritis or other autoimmune disease
k. Severe facet joint pathology or involved vertebral bodies
l. Severe insulin-dependent diabetes
m. Spinal metastases
n. 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:
   a. Active systemic infection or infection localized to the site of implantation
   b. Allergy or sensitivity to implant materials
   c. Bony lumbar stenosis
   d. Isolated radicular compression syndromes, especially due to disc herniation
   e. Osteopenia
   f. Osteoporosis
   g. Pars defect

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Single-Level Cervical Artificial Disc Replacement

The published evidence consists of randomized controlled trials, clinical trials, meta-analyses, systematic reviews, and prospective studies with follow-up ranging from 2-10 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 Neck Disability Index (NDI), 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 post-surgery. 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.

A meta-analysis of published randomized controlled trials (Byvaltsev et al., 2020) investigated mid- to long-term outcomes of cervical disc arthroplasty (CDA) versus ACDF. The review included results from eleven randomized controlled trials with a minimum of 48 months of follow up data. The pooled results of patients who underwent CDA had a significantly greater improvement in Neck Disability Index and Short Form 36 Health Survey physical component than those treated with ACDF. No significant difference in neurological success or in neck and arm pain scores. The rate of secondary surgical procedures was significantly lower in patients who underwent CDA compared to those who underwent ACDF.

Wang et al. (2020) examined the results of 11 randomized controlled trials with 3505 patients in a meta-analysis aimed to evaluate the long-term safety and efficiency of CDA versus ACDF for CDD. Outcome measures included neck disability index, neurological success, patient satisfaction, and patient recommendation rates. Functional outcome measures included the visual analog score neck pain and arm pain, the Short Form-36 physical component score, and the Short Form-36 mental component score. Rates of symptomatic adjacent segment degeneration and need for

secondary surgery were also evaluated. The study provided further evidence that CDA provided better functional outcomes and long-term success rate with fewer secondary surgeries.

Two-Level Cervical Artificial Disc Replacement

The published evidence for two level cervical disc replacement includes randomized controlled trials, prospective and retrospective comparative studies, meta-analyses, 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 one 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, health-related quality of life (HRQOL), and rates of adverse events. Overall, regarding effectiveness of 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. (Lanman et al., 2017; Radcliff & Albert, 2016).

A meta-analysis of six randomized controlled trials (Zou et al., 2019) evaluated clinical outcomes following surgical intervention with ACDF or cervical disc replacement at two contiguous levels. The overall sample size included 650 patients, with 317 in the TDR group and 333 in the ACDF group. The meta-analysis concluded that the cervical disc arthroplasty group had equal, or for some aspects more significant, clinical outcomes than treatment with anterior cervical discectomy and fusion.

Gornet et al. (2019) assessed 10-year outcomes on clinical safety and effectiveness of 2-level cervical disc arthroplasty versus ACDF for the treatment of degenerative CDDD at 2 adjacent levels. A prospective, randomized, controlled, multicenter FDA-approved clinical trial was conducted comparing the Prestige LP Cervical Disc (n = 209) at two levels with ACDF (n = 188). Ten-year follow-up data from the study was available on 148 CDA and 118 ACDF patients. From 2 to 10 years, CDA demonstrated statistical superiority over ACDF in measures of overall success, Neck Disability Index, and neurological success. All other measures were at least noninferior for CDA compared to ACDF.

Hayes ([1] 2022) published a Health Technology Assessment comparing the effectiveness of multilevel artificial disc replacement to ACDF for treatment of cervical DDD examined eight studies (12 publications) meeting inclusion criteria. Findings noted that evidence was limited, however did show that TDR had similar or better efficacy and safety across outcomes for patients undergoing 2-level TDR. TDR was scored higher for overall success, HRQOL, and lower rates of reoperation. There was not sufficient evidence to evaluate outcomes of TDR at more than two levels or as part of hybrid surgery.

Lumbar Artificial Disc Replacement

Published evidence consists of randomized controlled trials (RCTs), clinical trials, Cochrane reviews and uncontrolled studies with follow-up ranging from 7 to 17 years. These studies compared 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 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.

Bai et al. (2019) evaluated the outcomes and safety of LTDR versus lumbar fusion for treatment of LDDD in a meta-analysis of 14 randomized controlled trials meeting inclusion criteria. The analysis showed that TDR resulted in significantly improved ODI, VAS, SF-36, patient satisfaction, overall success, reoperation rate, length of hospital stay, and postsurgical complication rate. There was not a significant difference in blood loss, consumption of analgesics, neurologic success, or device success when compared with lumbar fusion. It was concluded that TDR is recommended for relief of pain and improvement in lumbar function for patients with LDD that has failed conservative measures.

In another systematic review and meta-analysis, Li et al. (2020) reviewed seven randomized controlled trials (1706 patients) and found higher satisfaction post-surgery in patients who underwent LTDR versus lumbar fusion in terms of Oswestry disability index, visual analog scale score, and complication rate. The TDR group showed greater clinical success, short operative time, and reduced hospital stay. There was no significant difference regarding blood loss, work status, and reoperation rate between the two groups.

Hayes ([2] 2022) published a Health Technology Assessment comparing the effectiveness of LTDR to spinal fusion when performed using FDA approved artificial disc in select adult patients with refractory 1-level symptomatic DDD. The investigation concluded that single-level LTDR is at least comparable with spinal fusion up to five years post-surgery. Evidence available was not sufficient to evaluate the effectiveness of 2-level LTDR as an alternative to spinal fusion.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** (2010) published interventional procedures guidance for *Prosthetic Intervertebral Disc Replacement in the Cervical Spine*. The guidance states that current evidence shows that cervical disc replacement is at least as effective as fusion in short-term outcomes and may reduce need for revision surgery in the long term. The procedure does not rise any safety concerns above those already known in relation to fusion surgery. The procedure should take place in settings experienced in surgery of the cervical spine.

Additional guidance was also published by **NICE** (2009) for *Prosthetic Intervertebral Disc Replacement in the Lumbar Spine.* The guidance states that the current evidence on the safety and efficacy of LTDR is sufficient to support use of the procedure. It is recommended that a multidisciplinary team with specialist expertise in the treatment of DDD be involved in careful patient selection for the procedure. The procedure is only indicated in patients for whom conservative therapy has failed.

The **North American Spine Society (NASS)** (2019 & 2015) recommends coverage for lumbar artificial disc replacement in carefully selected patients with symptomatic single level lumbar disc disease that has failed to respond to multi-modal nonoperative treatment. Notable exclusions include multi-level symptomatic DDD, presence of spinal instability, osteopenia, presence of infection or tumor, and presence of a poorly managed psychiatric disorder.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

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 osteophytectomy 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 osteophytectomy 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
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
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

2/8/2023	Policy reviewed, no changes to criteria.
2/9/2022	Policy reviewed, updated overview, summary of evidence, and references.
8/11/2021	Policy reviewed, no changes, updated coding (added 0095T and 0098T).
4/23/2020	Policy reviewed; no changes to criteria; deleted one code (0375T).
6/19/2019	Policy reviewed; no changes to the criteria; updated coding; included a new FDA approved device (M6-C Artificial Cervical Disc).
9/13/2018	Policy reviewed; changes include new criteria for two level cervical disc replacement based on new evidence; updated with FDA information and contraindications; References and Coding updated.
6/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed; updated to include criteria for lumbar artificial disc replacement based on new evidence.
4/2/2014	Policy reviewed; revised include new coverage criteria for the cervical artificial disc in patients who meet criteria; lumbar disc replacement remains unproven.
12/14/2011	Policy reviewed, no new evidence found, procedure remains investigational.
1/28/2009	Policy had minor revisions, no changes to criteria and procedure remains investigational.
6/14/2006	New policy.

REFERENCES

Government Agencies

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2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination (LCD) – Cervical disc replacement (L38033). Available from CMS. Effective Original August October 28, 2019. Revision Effective July 21, 2022.
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4. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 501(k) premarket notification database (search device name for "artificial disc"). Available from FDA. Accessed January 26, 2023.

Evidence Based Reviews and Publications

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Peer Reviewed Publications

1. Bai DY, Liang, L, et al. Total disc replacement versus fusion for lumbar degenerative diseases – a meta-analysis of randomized controlled trials. Medicine (Baltimore). 2019 Jul;98(29):e16460. doi: 10.1097/MD.0000000000016460. PMID: 31335704. PMCID: PMC6709089.
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National and Specialty Organizations

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*