Molina Clinical Policy
Lumbar Artificial Intervertebral Disc Replacement
Policy No. 011

Last Approval: 2/14/2024
Next Review Due By: February 2025

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

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 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 2007, 2021; Chou 2023).

FDA Information

The FDA approved artificial lumbar disc systems for surgical implantation within the spine for single-level disc replacement, include the Activ-LTM (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 2022).

COVERAGE POLICY

1. **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. **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

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 one-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 one-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 lumbar DDD in a meta-analysis of 14 randomized controlled trials. The analysis showed that TDR resulted in significantly improved ODI ($p < 0.0001$), VAS ($p = 0.001$), SF-36 ($p < 0.0001$), patient satisfaction ($p < 0.0001$), overall success ($p = 0.001$), reoperation rate ($p = 0.047$), length of hospital stay ($p < 0.00001$), and postsurgical complication rate ($p < 0.0001$). 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 lumbar DDD that have failed conservative measures.

Hayes (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 one-level symptomatic lumbar DDD. Twenty-one studies were included in the assessment and the evidence was considered moderate quality. The investigation concluded that single-level LTDR is at least comparable with spinal fusion up to five years post-surgery in patients who have failed conservation treatment. Evidence available was not sufficient to evaluate the effectiveness of two-level LTDR as an alternative to spinal fusion.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** (2009) published guidelines 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 lumbar 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) 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 lumbar DDD, presence of spinal instability, osteopenia, presence of infection or tumor, and presence of a poorly managed psychiatric disorder.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	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

2/14/2024	Policy reviewed; no changes to criteria. Policy name changed to 'Lumbar Artificial Disc Replacement'. Updated references and summary of medical evidence. Reviewed by a practicing physician board certified in orthopedic surgery, spine surgery.
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. Reviewed by a practicing physician board certified in orthopedic surgery, spine surgery.
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 reviewed, no changes to criteria and procedure remains investigational.
6/14/2006	New policy.

REFERENCES

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2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National coverage determination (NCD) – Lumbar artificial disc replacement (LADR) (150.10). Effective August 14, 2007. Accessed December 8, 2023. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=313.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination (LCD) – Lumbar artificial disc replacement (L37826). Effective August May 6, 2019. Revision June 17, 2021. Accessed December 8, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37826&ver=21.
4. Chou R. Subacute and chronic low back pain: Surgical treatment. Updated September 27, 2023. Accessed December 8, 2023. https://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-surgical-treatment.
5. Hayes. Health technology assessment: Comparative effectiveness review of lumbar total disc replacement for degenerative disc disease. Published April 1, 2019. Updated March 24, 2022. Accessed December 8, 2023. https://evidence.hayesinc.com/report/dir.lumb0001.
6. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine. Interventional procedures guidance [IPG306]. Published July 22, 2009. Accessed December 8, 2023. https://www.nice.org.uk/guidance/ipg306.
7. North American Spine Society (NASS). Coverage policy recommendations: Lumbar artificial disc replacement. Revised February 2019. Accessed December 8, 2023. https://www.spine.org/Coverage.
8. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 501(k) premarket notification database: Manual instruments designed for use with total disc replacement devices. Published June 2, 2022. Accessed December 8, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220861.

APPENDIX

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

Washington

For Medicaid requests, in addition to the MCP, clinical reviewers should consider the WA Health Technology Clinical Committee Final Evidence Report for “Artificial Disc Replacement – Re-review" (from 3/17/17).