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

Last Approval: 02/12/2025
Next Review Due By: February 2026

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).

Regulatory Status

The FDA approved artificial lumbar disc systems for surgical implantation within the spine for single-level disc replacement, include prodisc-L Total Disc Replacement (Centinel Spine LLC, approved in 2006), and activL Artificial Disc (Aesculap Implant Systems, approved in 2015). Each device has specific labeling information, but in general, the devices are approved for individuals who are skeletally mature with lumbar degenerative disc disease at a single level.

COVERAGE POLICY

Single-level lumbar artificial intervertebral disc replacement may be **considered medically necessary** when ALL the following criteria are met:

1. Member is aged 18-60 years old, with documented evidence of skeletal maturity
2. Symptoms of unremitting back and/or leg pain, resulting in clinically significant functional disability refractory to at least six consecutive months of conservative treatment, including but not limited to physical therapy and/or pharmacotherapy
3. Diagnosis of single-level lumbar degenerative disc disease, defined as discogenic back pain with degeneration of the disc, confirmed by a complex imaging study (e.g., CT, MRI, etc.)
4. No more than Grade I spondylolisthesis at the involved level

5. 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

6. Member is free from ALL the following contraindications:
   a. Active systemic infection or localized infection at the surgical/implantation site
   b. Allergy or sensitivity to implant materials (e.g., calcium phosphate, chromium, cobalt, molybdenum polyethylene, tantalum, titanium)
   c. Chronic radiculopathy
   d. Clinically compromised vertebral bodies at the affected level due to trauma, disease, or prior surgery
   e. Lumbar spinal stenosis or isolated radiculopathy, especially due to disc herniation
   f. Myelopathy or spinal deformities (e.g., scoliosis)
   g. Osteoporosis or osteopenia (defined as DEXA T-score ≤ -1.0)
   h. Pars defect or other significant bony abnormalities affecting stability
   i. Spondylolysis, isthmic or degenerative spondylolisthesis > Grade I, or segmental instability
   j. Vertebral endplate dimension smaller than required for implant placement (e.g., medial-lateral or anterior-posterior restrictions)

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

Randomized Controlled Trials

Radcliff et al. (2021) published the final 7-year outcomes from a randomized controlled investigational device trial comparing two lumbar total disc replacement (LTDR) devices, activL and ProDisc-L, for single-level lumber degenerative disc disease (DDD). The study included 283 patients randomized to activL (n=218) or ProDisc-L (n=65), with data from 206 patients available at the 7-year mark. Results demonstrated that both devices provided significant improvements in pain reduction, measured using the Visual Analog Scale (VAS), disability index, measured using the Oswestry Disability Index (ODI), quality of life, measured using the 36-item Short Form Health Survey, and opioid use over time, with no patients in either group reporting opioid usage at the 7-year follow-up. Adverse reactions included a low overall reoperation rate of 4.6% for both groups, indicating the need for additional surgical intervention following LTDR was minimal over the 7-year period. The incidence of serious adverse events was 57% for ProDisc-L patients and 38% for activL patients, which included device-related complications such as implant loosening or malposition. Other reported events included adjacent segment disease, postoperative infections requiring medical or surgical intervention, and neurological complications such as nerve root irritation or radiculopathy. The 7-year study supports the long-term efficacy of both devices, with activL demonstrating advantages in range of motion and safety. The study received funding and design input from Aesculap Implant Systems, which may have introduced bias.

Systematic Reviews and Meta-Analyses

Wen et al. (2024) performed a systematic review to evaluate mid- to long-term clinical outcomes, reoperation rates, and complications associated with LTDR in patients with lumbar DDD. The review included 22 studies published between 2012 and 2022, including seven randomized controlled trials (RCTs), and a total sample size of 2,284 patients and a mean follow-up duration of 8.30 years. Patient age range was 18-79 years old, with a mean age of 42.34 years. Key clinical outcomes assessed were improvements in the ODI and VAS pain scores, clinical success rates, and patient satisfaction rates using various point-based scales. The mean ODI and VAS pain score improvements were 30.39 ± 5.32 and 50.71 ± 6.91, respectively. Clinical success was achieved in 74.79% ± 7.55% of cases, and patient satisfaction was reported at 86.34% ± 5.64%. The mean rates for complications and reoperations were 18.53% ± 6.33% and 13.56% ± 3.83%, respectively, with no significant differences observed between mid-term and long-term follow-up periods. The study analyzed various LTDR devices, including metal-on-metal and metal-on-polymer designs such as ProDisc, ActiveL, Charité, and Maverick. Among these, the Charité and ProDisc-L devices were most commonly studied, with Charité showing slightly higher clinical success and patient satisfaction rates. Complications included adjacent segment degeneration, implant migration, and device failure. Reoperations were often necessitated

by persistent symptoms or device related issues such as polyethylene migration. Limitations of the study included potential publication and selection bias, variations in study methodologies, and limited data on certain devices. The review concluded that LTDR devices provide significant pain relief and functional improvement in patients with lumbar DDD, with outcomes comparable to spinal fusion, the current gold standard. However, long-term studies comparing LTDRs with spinal fusion and examining different implant materials are warranted to establish the optimal treatment approach. The findings support the use of LTDR as a viable option for managing lumbar DDD, emphasizing its potential to maintain clinical benefits for at least 10 years.

Lang et al. (2021) performed a meta-analysis to compare LTDR, anterior lumbar interbody fusion (ALIF), and circumferential fusion (CFF) to treat lumbar DDD. The primary outcomes assessed were pain, measured using VAS, and functional improvement, measured using ODI. Secondary outcomes included the mean number of complications per case at surgery, follow-up, and overall. The meta-analysis included six prospective studies with at least two years of follow-up, with four RCTs and two cohort studies for a total of 1,508 cases, with study sizes ranging from 74 to 577 patients. The results demonstrated that LTDR was superior to ALIF and CFF in reducing pain and improving function, with statistically significant results (a VAS mean difference of -5.82 to -6.60, and an ODI mean difference of -5.06 to -6.77; $p < 0.05$). CFF had the lowest overall mean number of complications per case (0.1), followed by TDR (1.2) and ALIF (1.5). During surgery, ALIF had fewer complications than LTDR, while LTDR slightly outperformed CFF. During follow-up, LTDR was superior to ALIF and comparable to CFF. The findings suggest that LTDR is the most appropriate surgical technique for treating DDD, followed by ALIF and CFF. Potential bias stems from funding by manufacturing companies for some included studies, which led to a reduction in evidence level for those trials. Additionally, the relatively small number of studies and the variability in follow-up durations (two to three years) limit the generalizability of the findings. Future research with consistent methods, longer follow-up, and independently funded studies is recommended to strengthen the evidence.

Li et al. (2020) performed a systematic review and meta-analysis comparing the efficacy and safety of LTDR versus lumbar fusion for treating lumbar DDD. The study included seven RCTs involving 1,706 patients, with 1,150 patients undergoing LTDR and 556 undergoing fusion. Follow-up periods ranged from two to five years. The results demonstrated that LTDR was superior in functional outcomes, as measured by ODI with a standardized mean difference (SMD) of -0.20 ($p=0.007$), and in pain reduction, as assessed by VAS, with an SMD of -0.18 ($p=0.001$). LTDR patients also reported higher satisfaction rates (75.5% versus 64.2%, $p<0.001$), shorter operative times (SMD=-1.16; $p=0.005$), and shorter hospital stays (SMD=-0.95; $p=0.002$). There were no significant differences in blood loss, reoperation rates, or work status between the two groups. Complication rates were lower in the LTDR group, with 15.3% compared to 26.8% in the fusion group ($p<0.001$). However, complications unique to LTDR, such as vascular injuries and ureteral damage due to the anterior surgical approach, were noted. Reoperation rates did not differ significantly between the groups (6.3% for LTDR versus 8.4% for fusion, $p=0.152$). The study acknowledged potential bias, including limitations in blinding and heterogeneity in perioperative data such as operative time and blood loss. The review suggests LTDR offers better functional outcomes, higher patient satisfaction, and fewer complications compared to lumbar fusion, making it a viable alternative treatment for lumbar DDD. However, its adoption may be limited by surgical complexity, cost, and reimbursement barriers. The authors recommend further long-term RCTs to confirm these findings.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2022) published a Health Technology Assessment comparing the effectiveness of LTDR to spinal fusion when performed using FDA approved artificial discs 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 have 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)

Code	Description
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

02/12/2025	Policy revised. Added functional disability stipulation, Grade 1 spondylolisthesis stipulation, and multiple contraindications to coverage criteria. Clarified "conservative treatment." Removed radiculopathy and myelopathy, and criteria to confirm Member is a candidate for surgery from coverage criteria. IRO reviewed on December 26, 2024, by a practicing physician board certified in orthopedic surgery.
02/14/2024	Policy reviewed, no changes to criteria. Policy name changed to 'Lumbar Artificial Disc Replacement.' Updated references and summary of medical evidence. IRO peer review on January 02, 2024, by a practicing physician board certified in orthopedic surgery, spine surgery.
02/08/2023	Policy reviewed, no changes to criteria.
02/09/2022	Policy reviewed, updated overview, summary of evidence, and references.
08/11/2021	Policy reviewed, no changes, updated coding (added 0095T and 0098T).
04/23/2020	Policy reviewed; no changes to criteria; deleted one code (0375T).
06/19/2019	Policy reviewed; no changes to the criteria; updated coding; included a new FDA approved device (M6-C Artificial Cervical Disc).
09/13/2018	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.
06/22/2017	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.
04/02/2014	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.
01/28/2009	Policy reviewed, no changes to criteria and procedure remains investigational.
06/14/2006	New policy.

REFERENCES

1. 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 9, 2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37826&ver=21
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 9, 2024. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=313
3. Chou R. Subacute and chronic low back pain: Surgical treatment. Updated September 27, 2023. Accessed December 17, 2024. https://www.uptodate.com
4. 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 9, 2024. https://evidence.hayesinc.com
5. Lang SAJ, Bohn T, Barleben L, Pumberger M, Roll S, Büttner-Janz K. Advanced meta-analyses comparing the three surgical techniques total disc replacement, anterior stand-alone fusion and circumferential fusion regarding pain, function and complications up to 3 years to treat lumbar degenerative disc disease. Eur Spine J. 2021 Dec;30(12):3688-3701. doi: 10.1007/s00586-021-06784-6. Epub 2021 Apr 10. PMID: 33837832.
6. Li YZ, Sun P, Chen D, Tang L, Chen CH, Wu AM. Artificial Total Disc Replacement Versus Fusion for Lumbar Degenerative Disc Disease: An Update Systematic Review and Meta-Analysis. Turk Neurosurg. 2020;30(1):1-10. doi: 10.5137/1019-5149.JTN.24799-18.2. PMID: 30984993.
7. 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.
8. North American Spine Society (NASS). Coverage policy recommendations: Lumbar artificial disc replacement. Revised February 2019. Accessed December 8, 2023. https://www.spine.org/Coverage
9. Radcliff K, Zigler J, Braxton E, Buttermann G, Coric D, Derman P et al. Final Long-Term Reporting from a Randomized Controlled IDE Trial for Lumbar Artificial Discs in Single-Level Degenerative Disc Disease: 7-Year Results. Int J Spine Surg. 2021 Aug;15(4):612-632. doi: 10.14444/8083. Epub 2021 Jul 15. Erratum in: Int J Spine Surg. 2023 Oct;17(5):753. doi: 10.14444/8083cxx. PMID: 34266934; PMCID: PMC8375685.
10. United States Food and Drug Administration (FDA). Pre-market approval (PMA). ACTIVL ARTIFICIAL DISC. Product code MJO. PMA: P120024. Accessed December 18, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
11. United States Food and Drug Administration (FDA). Pre-market approval (PMA). PRODISC-L TOTAL DISC REPLACEMENT DEVICE. Product code MJO. PMA: P050010. Accessed December 18, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
12. Wen DJ, Tavakoli J, Tipper JL. Lumbar Total Disc Replacements for Degenerative Disc Disease: A Systematic Review of Outcomes With a Minimum of 5 years Follow-Up. Global Spine J. 2024 Jul;14(6):1827-1837. doi: 10.1177/21925682241228756. Epub 2024 Jan 23. PMID: 38263726; PMCID: PMC11268302.