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

Last Approval: 08/12/2026
Next Review Due By: August 2027

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 a motion preserving surgical option for adults with chronic, function limiting low back pain caused by lumber degenerative disc disease. The procedure involves removing the diseased intervertebral disc and implanting an artificial disc designed to maintain segmental mobility, restore disc height, and reduce pain. By preserving motion at the treated level, LTDR may help reduce the risk of adjacent segment degeneration compared with fusion. The procedure often requires a multidisciplinary surgical team because of the proximity of major vascular and abdominal structures (Hayes 2022). FDA approved lumbar artificial discs is indicated for one or two contiguous level degenerative disc disease between L3 - S1 in skeletally mature individuals who have not achieved adequate improvement with conservative therapy. When used in appropriately selected patients, LTDR offers a surgical alternative to lumbar fusion with the potential benefit of maintaining physiologic motion at the treated segment (FDA [PMA] database; NASS 2024; NICE 2009).

Regulatory Status

The U.S. Food and Drug administration (FDA) has approved multiple lumbar artificial disc systems for single level disc replacement in adults with lumbar degenerative disc disease. Approved devices include the ProDisc-L Total Disc Replacement (Centinel Spine, 20060) and the activyL Artificial Disc (Aesculap Implant System, 2015). FDA approved lumbar artificial discs are indicated for skeletally mature individuals with symptomatic single level lumbar degenerative disc disease who have not responded to conservative treatment. In 2020, the FDA expanded the indications for the ProDisc-L Total Disc Replacement to include treatment of two adjacent levels of the lumbar spine. Each device carries specific labeling regarding eligible vertebrae levels, indications, and contraindications.

COVERAGE POLICY

Lumbar artificial intervertebral disc replacement may be **considered medically necessary** for the treatment of low back pain when ALL the following criteria are met:

1. Member is age 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 (e.g., physical therapy, pharmacotherapy, activity modification)
3. Diagnosis of lumbar degenerative disc disease at one or two contiguous levels, defined as discogenic back pain with degeneration of the disc, confirmed by a complex imaging study (e.g., CT, MRI)
4. No more than Grade I spondylolisthesis at the involved level(s)

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

5. The planned implant will be used in the reconstruction of lumbar discs in one or two contiguous vertebral levels between L-3 to S-1, following 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. Any bony abnormality resulting in segmental instability
   i. 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

Daher et al. (2024) conducted a meta-analysis evaluating lumbar disc replacement (LDR) compared with inter body fusion (IBF) for the treatment of lumbar degenerative disc disease. The review included 10 comparative studies a mix of randomized controlled trials and observational cohorts, with a total of 1,720 patients, of whom 1,034 underwent LDR and 686 underwent fusion. Follow up durations across studies range from one to five years. Across pooled analysis, LDR and IBF demonstrated no significant differences in operative time, estimated blood loss, length of stay, complication rates, reoperation rates, disability scores or leg pain. The only consistent difference between procedures was in back pain improvement, where LDR showed a statistically significant advantage. Patients treated with LDR reported 6.95 points lower back pain scores on average compared with fusion (mean difference -6.95; 95% CI -13.50 to -0.40; p= 0.04). However, when back pain outcomes were analyzed by specific follow up time points, the difference was no longer statistically significant, suggesting that the pooled effect may be influenced by follow-up duration or patient characteristics. Overall, the authors concluded that both LDR and fusion are effective surgical options, with LDR offering a potential, but not consistently time dependent advantage and back pain reduction. The main limitations of the study were the absence of postoperative sagittal radiographic parameters and the lack of a cost analysis. A sub-analysis by type of interbody fusion was also not feasible due to the small number of studies using comparable fusion

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

approaches. Despite these constraints, the review incorporated an extensive literature base included a substantial number of studies. Future studies should incorporate standardized radio graphic parameters, compare specific fusion techniques, and include longer term follow-up to clarify whether LDR's back pain benefit persists. Cost effectiveness analysis are also needed to better understand the economic implications of LDR versus fusion.

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

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

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
Marnay et al. (2025) conducted a retrospective single center cohort study to evaluate the long-term outcomes in patients who received one or two level LTDR between 1999 and 2013. The study compared 772 patients with single level LTDR and 415 with two level LTDR. Patients were evaluated preoperatively and then at 3, 6, 12, 18, and 24 months postoperatively, with a total follow-up duration ranging from 7 to 21 years. Objective data analyzed included radiographic, neurological, and physical assessments, as well as complication rates, and reoperation or revision rates. Subjective data analyzed included self-evaluations using the ODI and VAS for back and leg pain. Patients were broken up into four groups: Group 1 (one level/no prior surgery), 52 in Group 2 (one level/prior surgery), 50 in Group 3 (two levels/no prior surgery), and 52 in Group 4 (two levels/prior surgery). From preoperative evaluation to the last follow up, the point improvement in the ODI was 26 points in Groups 1, 2, and 3 and 24 points in Group 4. From preoperative evaluation to last follow up the percentage of VAS improvement ranged from 50 – 60% across all groups. Of all the 1,187 patients, only 49 underwent revision or reoperation. While limitations exist in this retrospective study, the results support the long-term durability and safety of one and two level LTDR.

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)** (2024) coverage recommendations state that lumbar total disc replacement may be appropriate for carefully selected patients with symptomatic degenerative disc disease involving one or two contiguous lumbar levels between L3 and S1 who have not improved with comprehensive nonoperative management. NASS further notes that LTDR is not appropriate in the presence of symptomatic disease at more than two levels, spinal instability, significant facet arthropathy, osteopenia, infection, tumor, or unmanaged psychiatric conditions.

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.

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*

APPROVAL HISTORY

08/12/2026	Policy revised. Updated coverage to include up to two contiguous vertebral levels.
02/11/2026	Policy reviewed**.** No changes to coverage criteria. Updated Overview, Summary of Medical Evidence and References.
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 revised, retired cervical disc replacement criteria for MCG. 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 revised. 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 revised to include criteria for lumbar artificial disc replacement based on new evidence.
04/02/2014	Policy revised to 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. Daher M, Nassar J, Balmaceno-Criss M, et al. Lumbar disc replacement versus interbody fusion: Meta-analysis of complications and clinical outcomes. Orthop Rev (Pavia). 2024 Apr 30;16:116900. doi: 10.52965/001c.116900. PMID: 38699079; PMCID: PMC11062800.
2. Lang SAJ, Bohn T, Barleben L, et al. 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.
3. Li YZ, Sun P, Chen D, et al. 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.
4. Marnay TP, Geneste GY, Edgard-Rosa GW, Grau-Ortiz MM, Hirsch CC, Negre GG. Clinical Outcomes After 1 and 2-Level Lumbar Total Disc Arthroplasty: 1,187 Patients with 7 to 21-Year Follow-up. J Bone Joint Surg Am. 2025 Jan 1;107(1):53-65. doi: 10.2106/JBJS.23.00735. Epub 2024 Nov 22. PMID: 40100011; PMCID: PMC11665976.
5. 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 January 20, 2026. https://www.nice.org.uk/guidance/ipg306.
6. North American Spine Society (NASS). Coverage policy recommendations: Lumbar artificial disc replacement. Revised August 2024. Accessed January 21, 2026. https://www.spine.org/Coverage
7. Radcliff K, Zigler J, Braxton E, 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.
8. United States Food and Drug Administration (FDA). Pre-market approval (PMA). ACTIVL ARTIFICIAL DISC. Product code MJO. PMA: P120024. Accessed January 16, 2026. https://www.accessdata.fda.gov
9. United States Food and Drug Administration (FDA). Pre-market approval (PMA). PRODISC-L TOTAL DISC REPLACEMENT DEVICE. Product code MJO. PMA: P050010. Accessed January 16, 2026. https://www.accessdata.fda.gov
10. 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.

Molina Healthcare, Inc. ©2026 – *This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare.*