

Medical Coverage Policy | Artificial Intervertebral Disc Insertion Lumbar Spine



EFFECTIVE DATE: 01 | 01 | 2023

POLICY LAST REVIEWED: 04 | 17 | 2024

OVERVIEW

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to spinal fusion in patients with degenerative disc disease (DDD) leading to disabling symptoms.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Artificial intervertebral discs of the lumbar spine are considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For Medicare Advantage Plans, see Related Policies section for the Medicare Advantage Plans National and Local Coverage Determinations policy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND

Degenerative disc disease (DDD), the most frequent cause of back pain requiring surgery, is common with age or trauma. Spine imaging, such as magnetic resonance imaging (MRI), computed tomography, or plain radiography, shows that lumbar disc degeneration is widespread, but for most people does not cause symptoms. Potential candidates for artificial disc replacement have chronic low back pain attributed to DDD, lack of improvement with nonoperative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (eg, laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of DDD fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. Also, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain normal biomechanics of the adjacent vertebrae and motion at the operative level once the damaged disc has been removed.

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They include device failure (eg, device fracture, dislocation, or wear), bone-implant interface failure (eg, subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (eg, osteolysis, heterotopic ossification, pseudotumor formation).

Regulatory Status

Three artificial lumbar disc devices (activL, Charité, ProDisc-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. Production under the name Charité was stopped in 2010 and the device was withdrawn in 2012.

Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of post marketing studies. The activL (Aesculap Implant Systems), and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. The activL device is approved for use at one level. Initial approval for ProDiscL was also limited to patients with disease at one level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels.

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. The INMOTION® is not currently marketed in the United States.
- The Maverick™ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L™ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L™, scheduled in 2013, but was cancelled without explanation.

For individuals who have lumbar DDD who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) of artificial discs versus fusion with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement compared to spinal fusion. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. No RCTs compared activL to spinal fusion or conservative care. In general, RCTs were limited by a lack of blinding, insufficient follow-up to evaluate potential harms, and lack of comparison to the criterion standard for treatment of DDD. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Commercial Products

The following services are considered not medically necessary:

- 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,

- lumbar, single interspace
- 0165T** Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace.
(List separately in addition to code for primary procedure)

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations Policy
Prior Authorization of Spinal Procedures

PUBLISHED

Provider Update, June 2024
Provider Update, June 2023
Provider Update, October/December 2022
Provider Update, June 2021
Provider Update, July 2020

REFERENCES

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Lumbar Artificial Disk Replacement (LADR) (150.10). 2007; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=313&ncdver=2&CoverageSelection=National&Keyword=lumbar+artificial+disc&KeywordLookup=Title&KeywordSearchType=And&id=170&bc=gAAAABAAAA&>. Accessed March 27, 2024.
2. Centers for Medicare & Medicaid Services (CMS). Medicare Learning Network Matters: Lumbar Artificial Disk Replacement (LADR). Change request 5727. 2007; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1340CP.pdf>. Accessed March 27, 2024.
3. U.S. Food & Drug Administration. The prodisc L Total Disc Replacement P050010/S020. April 10, 2020. <https://www.fda.gov/medical-devices/recently-approved-devices/prodisc-l-total-disc-replacement-p050010s020>. Accessed March 27, 2024.
4. U.S. Food and Drug Administration. Draft: PRODISC-L Total Disc Replacement package insert. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010c.pdf. Accessed March 26, 2024.
5. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: PRODISC-L Total Disc Replacement. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010b.pdf. Accessed March 28, 2024.
6. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine (Phila Pa 1976)*. May 15 2007; 32(11): 1155-62; discussion 1163. PMID 17495770
7. Zigler JE, Delamarter RB. Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. *J Neurosurg Spine*. Dec 2012; 17(6): 493-501. PMID 23082846
8. Zigler JE, Glenn J, Delamarter RB. Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. *J Neurosurg Spine*. Dec 2012; 17(6): 504-11. PMID 23082849
9. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial lumbar disc arthroplasty. TEC Assessments.2013; Volume 28:Tab 7.
10. Delamarter R, Zigler JE, Balderston RA, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. *J Bone Joint Surg Am*. Apr 20 2011; 93(8): 705-15. PMID 21398574
11. Schoenfeld AJ. Commentary on an article by Rick Delamarter, MD, et al.: Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level degenerative

- lumbar disc disease. Results at twenty-four months. *J Bone Joint Surg Am.* Apr 20 2011; 93(8): e41. PMID 21398573
12. Hellum C, Johnsen LG, Storheim K, et al. Surgery with disc prosthesis versus rehabilitation in patients with low back pain and degenerative disc: two year follow-up of randomised study. *BMJ.* May 19 2011; 342: d2786. PMID 21596740
 13. Hellum C, Berg L, Gjertsen O, et al. Adjacent level degeneration and facet arthropathy after disc prosthesis surgery or rehabilitation in patients with chronic low back pain and degenerative disc: second report of a randomized study. *Spine (Phila Pa 1976).* Dec 01 2012; 37(25): 2063-73. PMID 22706091
 14. Furunes H, Storheim K, Brox JI, et al. Total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain and degenerative discs: 8-year follow-up of a randomized controlled multicenter trial. *Spine J.* Oct 2017; 17(10): 1480-1488. PMID 28583869
 15. Garcia R, Yue JJ, Blumenthal S, et al. Lumbar Total Disc Replacement for Discogenic Low Back Pain: Two-year Outcomes of the activL Multicenter Randomized Controlled IDE Clinical Trial. *Spine (Phila Pa 1976).* Dec 2015; 40(24): 1873-81. PMID 26630435
 16. Yue JJ, Garcia R, Blumenthal S, et al. Five-year Results of a Randomized Controlled Trial for Lumbar Artificial Discs in Single-level Degenerative Disc Disease. *Spine (Phila Pa 1976).* Dec 15 2019; 44(24): 1685-1696. PMID 31404055
 17. 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.* Aug 2021; 15(4): 612-632. PMID 34266934
 18. Siepe CJ, Heider F, Wiechert K, et al. Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. *Spine J.* Aug 01 2014; 14(8): 1417-31. PMID 24448028
 19. Laugesen LA, Paulsen RT, Carreon L, et al. Patient-reported Outcomes and Revision Rates at a Mean Follow-up of 10 Years After Lumbar Total Disc Replacement. *Spine (Phila Pa 1976).* Nov 01 2017; 42(21): 1657-1663. PMID 28368983
 20. Tropiano P, Huang RC, Girardi FP, et al. Lumbar total disc replacement. Seven to eleven-year follow-up. *J Bone Joint Surg Am.* Mar 2005; 87(3): 490-6. PMID 15741612
 21. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976).* May 01 2009; 34(10): 1066-77. PMID 19363457
 22. Chou R, Baisden J, Carragee EJ, et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. *Spine (Phila Pa 1976).* May 01 2009; 34(10): 1094-109. PMID 19363455
 23. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine [IPG306]. 2009; <https://www.nice.org.uk/guidance/IPG306>. Accessed March 6, 2023.
 24. North American Spine Society (NASS). NASS coverage policy recommendations: Lumbar Artificial Disc Replacement. 2019; <https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations>. Accessed March 27, 2024.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

