



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy Artificial Intervertebral Disc: Lumbar Spine

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 592

BCBSA Reference Number: 7.01.87 (For Plan internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Artificial intervertebral discs of the lumbar spine are considered [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code Description
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
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0164T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar
0165T	Revision including replacement of total disc arthroplasty, anterior approach, each additional interspace, lumbar

Description

Degenerative disc disease, 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 it does not cause symptoms. Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with nonoperative treatment, and no 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 degenerative disc disease 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 degenerative disc disease 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).

Summary

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 leading to disabling symptoms.

For individuals who have lumbar degenerative disc disease 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 degenerative disc disease. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2024	Annual policy review. References updated. Policy statements unchanged.
5/2024	Clarified language above code table.
6/2023	Annual policy review. References updated. Policy statements unchanged.
1/2023	Coding clarified.
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2018	New references added from Annual policy review. Summary clarified.
6/2017	Annual policy review. Discussion of artificial discs not available in the United States was removed. Policy statement unchanged. 6/1/2017
5/2016	Annual policy review. New references added.
3/2015	Annual policy review. New references added.
4/2014	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed - Medical Policy Group – Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
1/2011	Updated - Medical Policy Group – Neurology and Neurosurgery. No changes to policy statements.
10/20/2010	Medical Policy 592 effective 10/20/2010.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. U.S. Food & Drug Administration. The prodisc L Total Disc Replacement P050010/S020. April 10, 2020. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050010S020> Accessed March 27, 2024.
2. 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.

3. 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.
4. 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
5. 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
6. 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
7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial lumbar disc arthroplasty. TEC Assessments. 2013;Volume 28:Tab 7.
8. 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
9. 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
10. 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
11. Hellum C, Berg L, Gjertsen Ø, 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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

20. 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
21. 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 27, 2024.
22. 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.
23. 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?NCDId=313&ncdver=2&CoverageSelection=National&Keyword=lumbar+artificial+disc&KeywordLookUp=Title&KeywordSearchType=And&id=170&bc=gAAAAABAAAA&>. Accessed March 27, 2024.
24. Centers for Medicare & Medicaid Services (CMS). Medicare Learning Network Matters: Lumbar Artificial Disc Replacement (LADR). Change request 5727. 2007; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1340CP.pdf>. Accessed March 27, 2024.