Lumbar Disc Arthroplasty

Medicare Advantage Medical Policy # MA-163
Original Effective Date: 02/01/2026
Current Effective Date: 02/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Cervical Disc Arthroplasty is addressed in medical policy MA-162.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider lumbar disc arthroplasty to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered when **ALL** of the following criteria are met:

- Age between 18 and 60 years; **AND**
- Primary complaint of axial pain determined to be of discogenic origin; **AND**
- Symptoms present for at least six (6) months, which have not responded to a multifaceted program of conservative management over that period of time (see Policy Guidelines section for conservative management requirement); **AND**
- Presence of single or dual (when using 2-level FDA-approved implant) level, advanced disc disease at L3-L4, L4-L5, or L5-Sl, as documented by magnetic resonance imaging (MRI) and plain radiographs demonstrating moderate to severe degeneration of the disc with Modic changes (peridiscal bone signal above and below the disc space in question); **AND**
- At least moderate pain and disability ideally documented by a visual analog scale (VAS) pain score of 40 or higher (out of 100, or 4 out of 10) or with functional limitation of one or more Instrumental Activities of Daily Living (IADLs); **AND**
- Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention; **AND**
- Absence of symptomatic degenerative disc disease at all other lumbar levels, as documented by normal radiographs, and MRI showing no abnormalities or mild degenerative changes; **AND**
- Use of an FDA-approved implant for the intended level; **AND**
- Absence of contraindications listed below.

*Note: This document addresses lumbar disc arthroplasty when performed as an **elective, non-emergent** procedure and not as part of the care of an acute or traumatic event.*

Note: The requirement for a period of conservative treatment as a prerequisite to a surgical procedure is waived when there is evidence of progressive nerve or spinal cord compression resulting in a significant neurologic deficit, or when cauda equine syndrome or conus medullaris syndrome is present, and urgent intervention is indicated.

Note: See Policy Guidelines section for expanded description on ADL's and IADL's.

Contraindications to lumbar disc arthroplasty are:

- Significant facet arthropathy at the index level;
- Disease above L3-L4 or L4-L5 depending on FDA-approved levels;
- Bony lumbar spinal stenosis;
- Pars defect;
- Prior fusion at intended level
- Poorly managed psychiatric disorder
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms persisting a minimum of one year)
- Clinically compromised vertebral bodies at affected level due to current or past trauma;
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1;
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium);
- Presence of infection or tumor;
- Osteopenia or osteoporosis (defined as dual-energy x-ray absorptiometry [**DEXA]** bone density measured T-score less than or equal to -1.0).

When Services Are Considered Not Medically Necessary

The use of lumbar disc arthroplasty when patient selection criteria are not met is considered to be **not medically necessary.****

Based on review of available data, the Company considers lumbar disc arthroplasty to be **not medically necessary****, including but not limited to the following:

- Disc replacement at more than one spinal level (unless FDA approved for more than one level, e.g.; prodisc®‡ L Total Disc Replacement); **OR**
- Prior lumbar fusion; **OR**
- Isolated radicular compression syndromes, especially due to disc herniation; **OR**
- Hybrid lumbar total disc arthroscopy/lumbar fusion (lumbar total disc arthroplasty at one level at the same time as lumbar fusion at a different level); **OR**
- Arthroplasty using devices other than those which are U.S. Food and Drug Administration (FDA) approved, or use of an FDA-approved device in a manner which does not meet FDA requirements.

Policy Guidelines

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND at least ONE** complementary conservative treatment strategy.

Physical therapy requirement includes **ANY** of the following:

- Physical therapy rendered by a qualified provider of physical therapy services; **OR**
- Supervised home treatment program that includes **ALL** of the following:
  - Participation in a patient-specific or tailored program; **AND**
  - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises; **AND**
  - Compliance (documented or by clinician attestation on follow-up evaluation);

OR

- **Exception to the physical therapy requirement** in unusual circumstances (for instance intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record;

AND

Complementary conservative treatment requirement includes **ANY** of the following:

- Anti-inflammatory medications and analgesics; **OR**
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants[1]; **OR**
- Epidural corticosteroid injection(s)[1]; **OR**
- Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable.

[1] In the absence of contraindications.

Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by othermethods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit. Clinical reevaluation must be done in reasonable proximity to the anticipated date of service such that the patient's condition would be unlikely to change by the date of service.

Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care; **AND**
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation; **AND**
- More invasive forms of therapy are being considered.

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Activities of Daily Living (ADLs) – These activities are the basic functions required for self-care of every-day life.

- Eating
- Bathing
- Grooming
- Dressing
- Transferring
- Toileting

Instrumental Activities of Daily Living (IADLs) -- These are the complex skills required to successfully live independently.

- Shopping
- Meal Preparation
- Management of Medications
- Transportation
- Housework
- Using communication devices
- Handling personal finances
- Laundry

Imaging Studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Background/Overview

Lumbar disc arthroplasty, also known as lumbar artificial disc surgery or total disc arthroplasty, was developed as an alternative to lumbar fusion for treatment of back pain due to severe degenerative disc disease.
The procedure is similar to lumbar interbody fusion, in that an anterior approach is required. Unlike fusion, motion at the level of disc replacement is maintained, which would seem to be advantageous in terms of preventing secondary degenerative changes and preserving spine mechanics.

Tobacco cessation – To reduce the risk of pseudoarthrosis, adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to spinal surgery is recommended.

When there are patient-specific modifiable comorbidities that may adversely impact patient-reported outcomes or health status, a shared decision-making discussion that covers these modifiable comorbidities is strongly recommended and should be documented.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 (Table 1). 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 postmarketing studies. The activL (Aesculap Implant Systems) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease. Degenerative disc disease 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 1 level. Initial approval for ProDiscL was also limited to patients with disease at 1 level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels.

Table 1. U.S. Food and Drug Administration-Approved Lumbar Artificial Disc Devices

Device	Manufacturer	Indication	PMA Number	Approval Date
activL	Aesculap Implant Systems, LLC	The activL Artificial Disc (activL) is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL Artificial Disc should have failed at least 6 months of nonoperative treatment prior to implantation of the device.	P120024	06/11/2015
ProDisc®‡-L	Synthes Spine	The PRODISC®‡-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1	P050010/ S020	8/25/2006/ 4/10/2020 (supplement)

		or 2 contiguous intervertebral level(s) from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients receiving the PRODISC®‡-L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the PRODISC®‡-L Total Disc Replacement.		
Charite	Depuy Spine, Inc	The Charite Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level from L4-S I. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. Patients receiving the Charite Artificial Disc should have failed at least 6 months of conservative treatment prior to implantation of the CHARITE Artificial Disc.	P040006	10/26/2004 Withdrawn 1/5/2012

PMA: premarket approval

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

- The INMOTIONlumbar 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 canceled without explanation.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. Carelon Medical Benefits Management, Musculoskeletal Clinical Appropriateness Guidelines, Appropriate Use Criteria: Spine Surgery, Lumbar Disc Arthroplasty, November 15, 2025.
2. 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.
3. Bai DY, Liang L, Zhang BB, et al. Total disc replacement versus fusion for lumbar degenerative diseases- a meta-analysis of randomized controlled trials. Medicine (Baltimore). 2019;98(29):e16460.
4. Ding F, Jia Z, Zhao Z, et al. Total disc replacement versus fusion for lumbar degenerative disc disease: a systematic review of overlapping meta-analyses. Eur Spine J. 2017;26(3):806-15.
5. Jacobs W, Van der Gaag NA, Tuschel A, et al. Total disc replacement for chronic back pain in the presence of disc degeneration. Cochrane Database Systematic Reviews. 2012(9):CD008326.
6. 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.
7. National Institute for Health and Care Excellence, Low back pain and sciatica in over 16s: assessment and management, (2020) London UK.
8. Nie H, Chen G, Wang X, et al. Comparison of Total Disc Replacement with lumbar fusion: a meta-analysis of randomized controlled trials. Journal of the College of Physicians and Surgeons--Pakistan: JCPSP. 2015;25(1):60-7.
9. Skold C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. Eur Spine J. 2013;22(10):2288-95.
7. Katz, S., & Akpom, C. A. (1976). 12. Index of ADL. Medical Care, 14 (5), 116–118.

Policy History

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11/18/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 11/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0164T, 0165T, 22857, 22860, 22862, 22865
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally

recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.
When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening.

If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.