

MEDICAL POLICY – 7.01.589

Artificial Intervertebral Disc: Lumbar Spine

BCBSA Ref. Policy: 7.01.87

Effective Date: Jul. 1, 2025 RELATED MEDICAL POLICIES:

Last Revised: Aug. 14, 2025 7.01.108 Artificial Intervertebral Disc: Cervical Spine

Replaced: 7.01.87 7.01.542 Lumbar Spinal Fusion

7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy,

Laminotomy, Laminectomy

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The bones of the spine are called vertebrae. Between each vertebra is a disc, which acts as a shock absorber and prevents the bones from rubbing together. As a person ages, these often become thinner as they lose water and the gel-like substance that's inside of each disc. This is known as degenerative disc disease. Studies show that most adults over the age of forty have some level of degenerative disc disease. Often, no treatment is needed because the degeneration isn't severe enough to cause pain in the lower back (lumbar spine). When there is pain, the usual first step is to try nonsurgical treatment, which often works. In cases where it doesn't work, surgery may be considered. One type of surgery calls for placing an artificial disc between the vertebrae. The goal is to imitate how a natural disc works in the body. This policy describes when artificial intervertebral discs for the lower back may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Surgery	Medically Necessary	
Artificial intervertebral disc	Artificial intervertebral discs of the lumbar spine may be	
- lumbar spine	Artificial intervertebral discs of the lumbar spine may be considered medically necessary when ALL of the following criteria are met: The device is approved by the Food and Drug Administration (FDA) for a single level: (Examples, list may not be all inclusive) activL Artificial Disc (Aesculap Implant Systems, LLC) ProDisc-L (Centinel Spine) Skeletally mature individuals up to age 60 Individual has symptomatic single level discogenic low back pain with lumbar degenerative disc disease at L3-L4, or L4-L5, or L5-S1 level as evidenced on MRI, CT, or plain radiographs within the prior 12 months. Primary complaint is of axial pain, with a possible secondary complaint of lower extremity pain. Symptoms have been present for at least 6 months and have been unresponsive to 3 months of nonoperative conservative management including: Physical therapy that includes a home exercise program, and ONE or more of the following: Analgesics and/or NSAIDs as appropriate and if not contraindicated Epidural steroid injection if medically appropriate and not contraindicated Acupuncture Chiropractic manipulation Massage therapy Restriction or modification of daily activities Investigational Lumbar artificial intervertebral disc implantation is considered investigational for all other indications, including the	
Surgery	Investigational	
Artificial intervertebral	Lumbar artificial intervertebral disc implantation is considered	
disc-lumbar spine other		
indications	following:	
	Active infection	
	Anatomical deformity (e.g., ankylosing spondylitis)	

- Disc implantation at more than one level is planned
- History of lumbar disc replacement at any lumbar level
- History of rheumatoid arthritis, lupus, or other autoimmune disorder
- Lumbar scoliosis
- Lumbar artificial disc at one level combined simultaneously with lumbar spinal fusion at another level (adjacent or nonadjacent; aka hybrid surgery)
- Malignant tumor
- Metabolic bone disease (e.g., osteoporosis, osteopenia; DEXA bone mineral density T-score less than or equal to -1.0)
- Multilevel degenerative disc disease
- Nerve root compression or spinal stenosis
- Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
- Presence of significant facet arthropathy at the operative level
- Presence of spinal instability with spondylolisthesis greater than Grade 1
- Previous fusion at another lumbar level (adjacent or other level)
- Spinal fracture

Documentation Requirements

The following information must be submitted to ensure an accurate, expeditious, and complete review for artificial intervertebral disc implantation:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes that include a current history and physical exam, including any prior spine surgeries
- Detailed documentation of extent and response to non-operative conservative therapy, if applicable, including outcomes of any procedural interventions, medications used and physical therapy/physiatrist notes
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months.

Coding



Code	Description
СРТ	
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, 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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Artificial intervertebral discs for treating the cervical spine are addressed in a separate medical policy (see **Related Policies**).

Evidence Review

Description

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



Background

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 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. Individuals who require procedures in addition to fusion (e.g., laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of degenerative disc disease (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 an individual'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 individuals. 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 (e.g., device fracture, dislocation, or wear), bone-implant interface failure (e.g., subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (e.g., osteolysis, heterotopic ossification, and pseudotumor formation).

Summary of Evidence

For individuals with 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 two but not at five years in this unblinded trial. The potential benefits of the artificial disc (e.g., 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 outcomes.

However, because lumbar fusion may be associated with potential consequences such as pseudoarthrosis, adjacent segment degeneration, and complications at the bone donor site, along with loss of range of motion, lumbar artificial intervertebral disc replacement may be an alternative to fusion as it restores disc height, may spare the individual with loss of mobility, and have potentially reduced rates of reoperation. And, even though the lumbar artificial intervertebral disc replacement may be more technically challenging, there have been high rates of success compared with lumbar fusion procedures.²⁴ The North American Spine Society issued coverage recommendations for this procedure at a single level. Therefore, the Plan will consider their recommendations and allow a lumbar artificial intervertebral disc replacement at a single level medically necessary when the recommended criteria are met.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in February 2025 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.



2008 Input

In response to requests, input was received from one physician specialty society and three academic medical centers while this policy was under review in 2008. The four reviewers disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational.

After considering the clinical input in 2008, it was concluded that, due to limitations of the available randomized controlled trials (described above), combined with the marginal benefit compared with fusion, evidence was insufficient to determine whether artificial lumber discs are beneficial in the short term. Also, serious questions remain about potential long-term complications with these implants.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Pain Society

In 2009, the American Pain Society's practice guidelines concluded there was "insufficient evidence" to adequately evaluate long-term benefits and harms of intervertebral disc replacement. The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center. The rationale for the recommendation was that, although artificial disc replacement has been associated with similar outcomes similar to fusion, the trial results were only applicable to a narrowly defined subset of patients with single-level degenerative disease, and the type of fusion surgery in the trials is no longer widely used due to frequent poor outcomes. Also, all trials had been industry-funded, and data on long-term (> 2 years) benefits and harms following artificial disc replacement were limited.



National Institute for Health and Care Excellence

In 2009, the National Institute for Health and Care Excellence updated its guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine with studies reporting 13-year follow-up, but with most of the "evidence from studies with shorter durations of follow-up."²⁰ The Institute concluded that evidence was "adequate to support the use of this procedure."

North American Spine Society

In 2024, the North American Spine Society issued revised coverage recommendations for lumbar artificial disc replacement.²¹ The following recommendations were made:

"Lumbar artificial disc replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria:

- Pain arising from 1- or 2-level disc disruption involving L3-L4, L4-L5, or L5-S1 segments
- Presence of symptoms for at least 6 months or greater and that are not responsive to multimodal nonoperative treatment over that period, which should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:

- Any case that does not fulfill ALL of the above criteria
- Presence of symptomatic degenerative disk disease at more than two levels
- Significant facet arthropathy at the index level
- Presence of spinal instability with spondylolisthesis greater than Grade I
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)
- Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0

- Poorly managed psychiatric disorder (any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized before surgical intervention).
- Age greater than 60 years or less than 18 years
- Presence of infection or tumor

Medicare National Coverage

Effective for services performed on or after August 14, 2007, Centers for Medicare & Medicaid Services (CMS) found "that LADR [lumbar artificial disc replacement] is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries older than 60 years of age." "For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to be made by the local contractors."²²

The national coverage determination (NCD) was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charité), to noncoverage for the LADR procedure for the Medicare population older than 60 years of age. CMS provided this explanation:

The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charité) because it was the only one with FDA approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc-L, received FDA approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacturer's implant.²³

Regulatory Status

Three artificial lumbar disc devices (activL, Charité, ProDisc-L) have been approved by the US Food and Drug Administration (FDA) through the premarket approval process listed in **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 one level. Initial approval for ProDiscL was also limited to patients with disease at one level. In April 2020, the ProDisc-L indication was expanded to include patients with disease at up to two consecutive levels.¹

Table 1. US 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 six 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 DDD at 1 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	P050010 S020	8/25/2006 4/10/2020 (supplement)

Device	Manufacturer	Indication	PMA Number	Approval Date
		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 DDD at one 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 3mm of spondylolisthesis at the involved level. Patients receiving the CHARITE Artificial Disc should have failed at least six 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 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, was cancelled without explanation.

FDA product code: MJO

References

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History

Date	Comments
08/12/03	Add to Surgery Section - New policy. Hold for notification, effective date December 15, 2003.
01/01/04	Replace policy - CPT code updates only.
05/10/05	Replace policy - Policy updated with February 2005 TEC Assessment; references added; policy statement unchanged.
04/21/06	Codes Updated - No other changes
07/11/06	Replace policy - Policy updated with Medicare noncoverage decision; policy statement unchanged; reference added.
09/12/06	Replace policy - Updated Description and Benefit Application sections to include information on FDA approval of ProDisk L. No other changes.



Date	Comments
01/26/07	Codes Updated - No other changes.
02/26/07	Update Codes - No other changes.
03/13/07	Replace policy - Title expanded for clarification with the addition of "Lumbar Spine"; cross reference added.
04/10/07	Cross Reference Update - No other changes.
08/14/07	Replace policy - Policy updated with 2007 TEC Assessment; new reference added. Policy statement unchanged.
02/12/08	Replace policy - Policy updated with literature review; no change in policy statement. References added.
01/13/09	Replace policy - Policy updated with literature search; no change to the policy statement. Rationale section extensively revised references and codes added.
12/08/09	Replace policy - Policy updated with literature search; no change to the policy statement. References added.
09/14/10	Cross Reference Update - No other changes.
12/14/10	Replace policy - Policy updated with literature search through August 2010. References have been added and reordered; the policy statement remains unchanged.
12/16/11	Replace policy – Policy updated with literature search through August 2011; Rationale section revised; references 11 and 14 added and references reordered; policy statement unchanged.
11/27/12	Replace policy - Rationale section revised based on literature review through June 2012. References 12, 14,19,20,23 29 added; others renumbered. Policy statement unchanged.
01/10/13	Coding update. CPT code 22586, effective 1/1/13, added to policy.
04/17/13	Update Related Policies – Add 7.01.542.
09/30/13	Update Related Policies. Change title to 7.01.120.
12/09/13	Replace policy. Rationale section updated. Added references 8,9,11,12,13,23,31,32. No change to policy statement. CPT codes 63030 and 63035 removed from policy; these do not apply.
03/25/14	Replace policy. Policy updated with literature search through October, 2013. References 12, 16, 17 and 24 added; others renumbered/removed. Policy statement unchanged. ICD-9 diagnosis and ICD-10-CM codes removed from the policy; these are not utilized in adjudication.
08/12/14	Update Related Policies. Change title to 7.01.542.
01/08/15	Update Related Policies. Add 7.01.551.
06/09/15	Coding update. ICD-10-PCS codes added to support remediation efforts.
	22 2g apastor 22 10 100 to added to support remodulation enough



Date	Comments	
08/11/15	Annual Review. Policy updated with literature review through November 25, 2014; references 15, 27-28, and 37 added; policy statement unchanged.	
07/01/16	Annual Review, approved June 14, 2016. Policy updated with literature review through February 9, 2016; references 16, 22, 27, 32, and 39-40 added. Removed CPT code 22586. Policy statement unchanged.	
10/28/16	Coding update. Removed ICD-10 codes from coding section.	
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; reference 4 added. Discussion of artificial discs not available in the United States was removed. Policy statement unchanged.	
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 9-11 and 16 added. Policy statement unchanged.	
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; reference 18 added with updated NASS coverage guidance. Policy statement unchanged.	
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.	
06/01/20	Interim Review, approved May 12, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.	
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through March 2020; references added. Policy statement unchanged.	
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 10, 2021; no references added. Policy statement unchanged.	
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 7, 2022; reference added. Policy statement unchanged.	
10/01/22	Update to Related Policies. Removed related policy 7.01.120 Facet Arthroplasty due to archival.	
01/01/23	Coding update. Added new CPT code 22860. Revised code description for CPT code 22857.	
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 6, 2023; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.	
02/01/24	Policy renumbered, approved January 9, 2024, from 7.01.87 to 7.01.589 Artificial Intervertebral Disc: Lumbar Spine. References added. Policy position has changed for artificial intervertebral disc: lumbar spine, single level for degenerative disc disease from investigational to considered medically necessary when criteria are met. CPT code 0163T termed 1/1/23 and removed from policy.	



Date	Comments
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through March 28, 2024; no references added. Policy statement unchanged.
04/25/25	Minor update to the introduction section to reflect the change from investigational to medically necessary.
07/01/25	Annual Review, approved June 23, 2025. Policy updated with literature review through February 20, 2025; no references added. Policy statement unchanged.
08/14/25	Minor update. Added revised NASS revised 2024 coverage guidelines for lumbar artificial disc replacement that were inadvertently missed at the annual review.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

