PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 7.01.589

Artificial Intervertebral Disc: Lumbar Spine

BCBSA Ref. Policy:	7.01.87
Effective Date:	Feb. 1, 2024
Last Revised:	Jan. 9, 2024
Replaces:	7.01.87

RELATED MEDICAL POLICIES:

7.01.108	Artificial Intervertebral Disc: Cervical Spine
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

Clicking this icon returns you to the hyperlinks menu above.

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. There is not enough medical evidence demonstrating the effectiveness of this procedure for the lower back. Artificial disc replacement in the lower back is considered investigational (unproven).

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.

Policy Coverage Criteria

Surgery	Medically Necessary

Artificial intervertebral disc – 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

Surgery	**Investigational**
Artificial intervertebral disc-lumbar spine other indications	**Lumbar artificial intervertebral disc implantation is considered investigational for all other indications, including the following:** • Active infection • Anatomical deformity (e.g., ankylosing spondylitis)

Surgery	Medically Necessary
	• 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
- 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
CPT	
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

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 which 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.[25] 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 March 2023 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 U.S. professional society, an international society with U.S. 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.[19] The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center.[20] 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."[21] The Institute concluded that evidence was "adequate to support the use of this procedure."

North American Spine Society

In 2019, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement.[22] The following recommendation was made:

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

- Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
- Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that 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
- Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention

- 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 one 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
- Significant facet arthropathy at the index level
- 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."[23]

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.[24] 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.[24]

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 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. 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	P120024	06/11/2015

Device	Manufacturer	Indication	PMA Number	Approval Date
		have failed at least six months of nonoperative treatment prior to implantation of the device.		
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 Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the PRODISC-L Total Disc Replacement.	P050010 S020	8/25/2006 4/10/2020 (supplement)
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

1. 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 May 22, 2023.
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 May 22, 2023.
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 May 22, 2023.
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 6, 2023.

22. North American Spine Society (NASS). NASS coverage policy recommendations: Lumbar Artificial Disc Replacement. 2019; **https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations**. Accessed May 22, 2023.

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=gAAAABAAAAAA&**. Accessed May 22, 2023.

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 May 22, 2023.

25. Salzmann SN, Plais N, Shue J, Girardi FP. Lumbar disc replacement surgery-successes and obstacles to widespread adoption. Curr Rev Musculoskelet Med. 2017a;10(2):153-159.PMID: 28324327.

26. Hayes, Inc. Comparative Effectiveness Review. Lumbar Total Disc Replacement for Degenerative Disc Disease. Lansdale, PA: Hayes, Inc.; April 1, 2019.

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.
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.

Date	Comments
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.
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.

Date	Comments
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.

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.

Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator ─ Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.