BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.87 Artificial Intervertebral Disc: Lumbar Spine

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2012

Related Policies:

7.01.108 - Artificial Intervertebral Disc: Cervical Spine

Artificial Intervertebral Disc: Lumbar Spine

Description

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether implantation of a lumbar artificial intervertebral disc improves the net health outcome in patients with degenerative disc disease.

POLICY STATEMENT

Artificial intervertebral discs of the lumbar spine are considered **not medically necessary.**

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Three artificial lumbar disc devices (activL, Charit, 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 Production under the name Charit was stopped in 2010 and the device was withdrawn in 2012.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.[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 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 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 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 Charit 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.

FDA product code: MJO.

RATIONALE

Summary of Evidence

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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 the long-term benefits and harms of vertebral 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 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:

1. Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
2. 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
3. Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
4. 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:

1. Any case that does not fulfill ALL of the above criteria
2. Presence of symptomatic degenerative disk disease at more than 1 level
3. Presence of spinal instability with spondylolisthesis greater than Grade I
4. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least 1 year)
5. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
6. Poorly managed psychiatric disorder
7. Significant facet arthropathy at the index level
8. Age greater than 60 years or less than 18 years
9. Presence of infection or tumor
10. Age greater than 60 years or less than 18 years
11. Presence of infection or tumor

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Effective for services performed on or after August 14, 2007, Centers for Medicare & Medicaid Services (CMS) found "that lumbar artificial disc replacement is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, lumbar artificial disc replacement 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 lumbar artificial disc replacement, leaving such determinations to be made by the local contractors."[23,]

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

"The original NCD [national coverage determination] for LADR [lumbar artificial disc replacement] was focused on a specific lumbar artificial disc implant (Charite) because it was the only one with FDA [Food and Drug Administration] 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 [national coverage determination] 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 lumbar artificial disc replacement rather than lumbar artificial disc replacement with a specific manufacture"s implant."[24,]

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 , 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=gAAAABAAAAAA&. 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.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2014	Replace policy	Policy updated with literature search. Several references added, others reordered or removed. Policy statement unchanged.
July 2015	Replace policy	Policy updated with literature review; references 15, 27-28, and 37 added. Policy statement unchanged.
June 2017	Replace policy	Policy updated with literature review through February 23, 2017; references 4, 16, 22, 27, 32, and 39-40 added. Discussion of artificial discs not available in the United States was removed. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; references 9 -11, and 16 added. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; reference 18 added with updated NASS coverage guidance. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through March 2, 2020; references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through March 10, 2021; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through March 7, 2022; reference added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through March 6, 2023; no references added. Policy statement unchanged.
June 2024	Replace policy	Policy updated with literature review through March 28, 2024; no references added. Policy statement unchanged.