Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Title: Artificial Intervertebral Discs-Lumbar Spine

Description/Background

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling degenerative disc disease.

The most frequent cause of back pain requiring surgery, degenerative disc disease (DDD) 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 DDD, lack of improvement with nonoperative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (e.g., laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of DDD fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. They include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, and pseudotumor formation).

Regulatory Status

While artificial intervertebral discs in the lumbar spine have been used internationally for more than 10 years, only 3 devices (activL®, Charité®, ProDisc ®-L) have been approved through the U.S. Food and Drug Administration (FDA) through the premarket approval process.

Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of post-marketing studies. The activL® (Aesculap Implant Systems), Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level; activL and Charité is approved for use in levels L4–S1, and the ProDisc-L is approved for use in levels L3–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. Production under the name Charité® was stopped in 2010 and the device was withdrawn in 2012.

Initial approval for ProDiscL was also limited to patients with disease at one 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	P050010/ S020	8/25/2006/ 4/10/2020 (supplement)

		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 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, but was canceled without explanation.

FDA product code: MJO.

Medical Policy Statement

The insertion of artificial intervertebral discs in the lumbar spine is established. It may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines

Inclusions:

A. Lumbar disc replacement with an FDA approved lumbar artificial intervertebral prosthesis* is considered established for the treatment of discogenic low back pain related to a degenerated disc at one or two contiguous levels** planned for the same operative session that meets **ALL** the following criteria:

1. MRI evidence of moderate to severe degeneration with Modic changes at level(s) planned for replacement from L3-S1, when compared to other normal or mildly degenerated levels
2. Symptoms have been present for at least one year and interfere with daily activities
3. Presence of chronic pain and functional impairment that has failed to improve with at least 6 months of non-operative treatment, including all of the following:
    a. Physical therapy/rehabilitation
    b. Pain management (e.g., medication, injections)
    c. Cognitive behavior therapy, where indicated
4. Absence of a poorly treated psychiatric disorder
5. Primary complaint of axial pain, with or without lower extremity pain
6. Individual is skeletally mature and between the ages of 18 and 60
7. There is no significant facet joint arthropathy at level planned for surgery
8. Implant will be used according to FDA-approved (on-label) indications and contraindications

*Only implants with FDA approval are considered established:
1. Prodisc L: L3-S1
2. Active-L: L4-S1

**Note: All requests for 2-level lumbar disc replacements will require review on an individual basis.

Exclusions:

A. Lumbar disc replacement is not considered medically appropriate if the above criteria is not met, or if any of the following contraindications are present:
    1. Disease at a level superior to L3.
    2. Planned disc replacement adjacent to a prior fusion or disc replacement will be performed at the same time as lumbar fusion at another level.
    3. Presence of active infection (at surgical site or systemic).
    4. Active malignancy or history of recent malignancy.
    5. Known hypersensitivity to implant materials (e.g., cobalt, chromium, polyethylene, titanium).
    6. Age less than 18 or greater than 60.
    7. Radiographic evidence of moderate or severe facet joint degeneration or disease or pars defect (unilateral or bilateral spondylolysis) at the intended level.
    9. Paget's disease, osteomalacia, or any other metabolic bone disease (excluding osteoporosis which is addressed below).
    10. Taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids, chemotherapy, dialysis).
    11. Osteoporosis or osteopenia (DEXA bone density T-score of less than -1.0).
    12. Rheumatoid arthritis or other autoimmune disease.
    13. Isolated radicular compression syndromes (including central or far-lateral disc herniation).
    14. Traumatic injury at affected level resulting in compromised vertebral bodies.
    16. Presence of an untreated psychiatric disorder that may affect the success of lumbar disc replacement.
    17. Pregnant or interested in becoming pregnant in the next year.
    18. BMI greater than 40.

19. Symptomatic lumbar spinal stenosis.
20. Spondylolisthesis greater than 3mm.
21. Post laminectomy instability (> 3mm spondylolisthesis).
22. Back or leg pain of unknown etiology.
23. More than 2 levels of symptomatic lumbar disc degeneration.
24. Chronic pain disorder (e.g., fibromyalgia, failed lower back surgery syndrome, presence of lumbar spinal cord stimulator (SCS).

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

0164T* 0165T 22857 22862 22865
22860*

*Note: All requests for 2-level lumbar disc replacements will require review on an individual basis.

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Code(s) 0164T and 22865 may be covered by certain contracts. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of the lumbar artificial intervertebral discs to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with lumbar degenerative disc disease.

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs.

Intervention

The therapy being considered is implantation of a lumbar artificial intervertebral disc.

Two artificial intervertebral discs are currently marketed in the US: ProdiscL and activL.

Comparators

The following therapies are currently being used to make decisions about lumbar artificial intervertebral disc.

Relevant comparators are conservative therapy and lumbar spinal fusion.

Conservative treatment may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms “nonsurgical” and “nonoperative” have also been used to describe conservative treatment. For example, professional societies recommend that surgery for lumbar spinal stenosis should be considered only after a patient fails to respond to conservative treatment, but there is no consensus about what constitutes an adequate treatment course or duration.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Outcome measures for back surgery are relatively well-established (Table 1). These include back and leg visual analog scores to assess pain and the Oswestry Disability Index (ODI) to assess functional limitations related to back pain. Broader functional status indices such as the SF-12 or SF-36, particularly the physical function subscale of SF-36, are also used.

Table 2. Patient-Reported Outcome Measure for Back Pain

Measure	Outcome Evaluated	Description	MDD and MCID
Oswestry Disability Score (ODI)	Functional disability and pain related to back conditions	Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0-100% of maximum score	MDD: 8-10 points MCID varies; often 15 points (30 percentage points).
Visual analog scale for back pain	Degree of back pain	Patients indicate the degree of pain on a 0-100 scale	MDD: 2 points

Visual analog scale for leg pain	Degree of leg pain	Patients indicate the degree of pain on a 0-100 scale	MDD: 5 points

MDD: minimal detectable difference; MCID: Minimal clinically important difference.

Both short-term and long-term outcomes are important in evaluating back treatments. Net benefit should consider immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures. Lumbar artificial disc devices are theorized to reduce the occurrence of adjacent-level degeneration, which has been observed after fusion more often than occurs naturally in non fused segments; some RCTs have reported the occurrence of adjacent level degeneration at 5 years.

Patient preferences are important in decision-making about elective back surgery. In particular, to avoid the morbidity and risk of complications of the surgery, some patients may choose to prolong conservative treatments even if it means they have additional pain and functional limitation. Conversely, some patients will accept long-term outcomes of surgery similar to those of conservative therapy to get faster relief of symptoms and improvement in function. Patient preferences have not been compared in a systematic fashion.

Group means are commonly designated as primary outcome measures in spine studies. Variation in the calculation and definition of MCIDs makes it difficult to compare response rates across studies. Nevertheless, clinical trials should prespecify an MCID for ODI and other measures when used, and report response rates in addition to group means.

The primary outcome in FDA-regulated trials was a composite measure of success, which incorporates symptom improvement and absence of complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Three RCTs have compared the treatment of degenerative disc disease (DDD) using lumbar fusion with artificial lumbar intervertebral discs currently available in the United States. They include the pivotal trials for the ProDisc-L and activL discs, and a Food and Drug Administration (FDA)—regulated trial of the ProDisc-L for 2-level DDD. A fourth trial compared ProDisc-L with multidisciplinary rehabilitation. The primary outcome in the FDA-regulated trials is a composite measure of success, which incorporates symptom improvement and absence of complications. The composite success endpoints included improvements in Oswestry

Disability Index (ODI) scores (typically 15 points), improvement or maintenance in neurologic status, radiologic measures of range of motion, freedom from additional surgery, and freedom from serious device-related adverse events. Five-year outcomes have been reported from the pivotal trials for both the ProDisc-L and activL. Eight-year data have been reported from a comparison of ProDisc-II with multidisciplinary rehabilitation.

A key feature all of these trials is the recruitment of patients specifically with degenerative disease of the intervertebral disc. DDD is partly a diagnosis of exclusion where the degenerated disc is believed to be the pain generator. Radiographic evidence of DDD may include a reduction of disc height and Modic changes, a posterior high-intensity zone, or a dark/black nucleus pulposus on T2-weighted images. Patients with common indications for spinal fusion such as scoliosis, spondylolisthesis, instability, or radiculopathy were excluded.

ProDisc-L at a Single Level Compared to Fusion

The pivotal study for the ProDisc®-L was an unblinded noninferiority trial that followed 242 patients for 24 months.[5,6] In the per-protocol analysis reported to the FDA, ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%, which achieved both noninferiority and superiority. Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012.[7-9] The definition of success was changed from the analysis requested by FDA and was reported to be higher at 63.5% at 2 years and 53.7% at 5 years. Noninferiority but not superiority of artificial disc replacement was achieved at five years. This change in overall success in ProDisc-L patients indicates a possible decrement in response over time with the artificial disc. This decline in response rate was not observed in the standard fusion group and resulted in a between-group convergence of the primary outcome measure over time. Several individual components of the primary outcome measure and secondary outcome measures (ODI, 36-Item Short-Form Health Survey Physical Component Summary, neurologic success, device success) were also statistically better in the ProDisc-L group than in the fusion group at 2 years, but not at 5 years. Post hoc analysis of radiographs found fewer patients with adjacent-level degeneration in the ProDisc-L group than in the control group. However, the adjacent-level reoperations did not differ significantly between groups (1.9% ProDisc-L vs. 4% controls).

The 2013 updated TEC Assessment evaluated 5-year follow-up from the ProDisc pivotal trial.[2] The Assessment concluded that:

- Additional study of ProDisc in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption (IDE) trial in patients with single-level chronic symptomatic degenerative disc disease (DDD) unresponsive to conservative management.
- Questions remain about the durability of the disc, in particular the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue.
- The main claim of the artificial disc—that it maintains range of motion (ROM) and thereby reduces the risk of adjacent-level segment degeneration better than fusion—remains subject to debate.

Hur et al (2018) evaluated the long-term safety and therapeutic effectiveness of the lumbar total disc replacement (TDR) using ProDisc-L by analyzing the radiologic changes at the index and adjacent levels in minimum 5-year follow-up.[29] Forty-three patients were followed-up for at

least 60 months. Radiologic changes were assessed by segmental range of motion (ROM) at the index and adjacent levels, global lumbar lordosis, and disc space height (DSH). The magnetic resonance imaging and computed tomographic scans were used to determine the facet arthrosis and intervertebral disc degeneration at the index and adjacent levels. Gradual decrements of DSH restoration were observed until the last follow-up. Mean global and segmental ROM of index segments were significantly reduced (P=0.044, 0.00) at the last visit. There were 21 patients (48.8%) with no motion at index segment (ROM<0.5 degrees) at the last visit. Among the 56 segments operated on, progression of facet arthrosis was observed in 30.3% of index segments and 10.9% of adjacent segments. None of the postoperative radiologic parameters included in the present study presented significant correlation with clinical outcome.

ProDisc-at 2 Levels Compared to Fusion

The ProDisc-L for 2-level lumbar DDD was reported in 2011 from a multicenter, randomized, FDA-regulated non-inferiority trial.[10] All patients had DDD at 2 contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of 6 months of conservative therapy, and a minimum ODI score of 40. A total of 237 patients were treated in a 2:1 ratio with total disc arthroplasty or open circumferential arthrodesis (performed through both anterior and posterior open incisions). The TDR group had faster surgeries (160.2 vs. 272.8 min), less estimated blood loss (398.1 vs. 569.3 mL), and shorter hospital lengths of stay (3.8 vs. 5.0 days). At 24 months, 58.8% patients in the ProDisc-L group and 47.8% patients in the arthrodesis group achieved the criteria for success, demonstrating non-inferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in percentage improvement in the ODI (52.4% vs. 40.9%), a greater percentage of patients who achieved at least a 15-point improvement in ODI scores (73.2% vs. 59.7%) and greater improvement in the SF-36 PCS scores (43.9 vs. 39.2), both respectively. A greater percentage of patients in the arthrodesis group required secondary surgical procedures (8.3% vs. 2.4%).

In a prospective cohort, Rasouli et al (2019) evaluated clinical outcomes and sagittal range of motion of operated levels and adjacent lumbar motion segments in multiple-level ProDisc-L constructs after 2-6 years follow-up.[30] A total of 159 patients underwent adjacent 2-level (n=114), 3-level (n=41), or 4-level(n=4) lumbar total disk replacement (TDR). Patients were evaluated with radiographic and clinical outcomes measures preoperatively, at 6 weeks, 3 months, 6 months, and annually for 24-72 months postoperatively. Clinical measures: Oswestry Disability Index and Visual Analog Score of patient satisfaction (VAS-S) and pain (VAS-P) data were collected. Radiographic measures: sagittal motion on preoperative and postoperative lumbar radiographs at each operative segment and adjacent segment. At the motion segment adjacent to the TDR, mean preoperative range of motion (ROM) was 8.20±2.88 degrees, compared with 8.40±2.4 degrees postoperatively at last follow-up (P>0.05). Between the 3 TDR groups, there were no significant differences in ROM at any time point except at L5-S1. Across both groups for TDR motion segments, the mean preoperative ROM was 10.15±2.71 versus 12.30±2.25 degrees postoperatively (P=0.011) at last follow-up. At L5-S1 mean preoperative motion was 7.60±3.90 versus 5.81±3.1 degrees postoperatively (P=0.60). At 24-72 months postoperatively, all patients had significant reductions in Oswestry Disability Index, VAS-P, and VAS-S scores (P<0.05). At up to 72 months of follow-up, no patient underwent adjacent-level surgery but there were 3 cases of index-level revision surgery.

ProDisc®-*L* Compared to Conservative Treatment

Hellum et al (2011) reported an RCT that compared the use of the ProDisc-L with a multidisciplinary rehabilitation program.[12] Patients (N=173) were ages 25 to 55 years, had low back pain for a least a year, received physical therapy or chiropractic treatment for at least 6 months without sufficient effect, had an Oswestry Disability Index score of at least 30, and showed degenerative intervertebral changes that included at least 40% reduction of disc height, Modic changes, a high-intensity zone in the disc, and morphologic changes identified as changes in the signal intensity in the disc of grade 3 or 4. The multidisciplinary rehabilitation included a cognitive approach and supervised physical exercise. The primary outcome was Oswestry Disability Index score, and the trial was powered to detect a 10-point difference in Oswestry Disability Index score. The analysis was intention-to-treat with the last observation carried forward. There were 13 (15%) dropouts in the surgical arm and 21 (24%) in the rehabilitation arm. Also, 5 (6%) patients crossed over from rehabilitation to surgery. Of the 34 patients lost to follow-up, 26 answered a questionnaire between 2.5 and 5 years after treatment. In the intention-to-treat analysis, there was a statistically significant benefit of surgery There were significantly more patients who achieved a 15-point improvement in Oswestry Disability Index score in the ProDisc group, with a number needed to treat of 4.4. The radiographic assessment identified a similar level of adjacent segment degeneration in both groups, but an increase in facet arthropathy in the ProDisc II group.[13]

Eight-year follow-up of this trial was reported by Furunes et al (2017).[14] In both the intention-to-treat and per-protocol analysis there was a statistically significant benefit of surgery as measured by the mean Oswestry Disability Index. More patients in the surgery group (43/61 [70%]) reached a clinically important difference of 15 Oswestry Disability Index points than in the rehabilitation group (26/52 [50%]; p=0.03). Twenty-one (24%) patients randomized to rehabilitation crossed over to surgery while 12 (14%) patients randomized to surgery had undergone additional back surgery.

activL Artificial Disc

There are no RCTs of activL compared to fusion or conservative treatment.

Two-year outcomes from the multicenter IDE trial of the activL artificial intervertebral disc were reported by Garcia et al in 2015.[15] In this patient-blinded non-inferiority trial, patients with DDD at either L4-L5 or L5-S1 were randomized to treatment with activL (n=218) or an FDA-approved disc (n=106, ProDisc-L or Charité). At 2 years, activL was both non-inferior (p<0.001) and superior (p=0.02) to the control group. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls ROM the index level, measured by an independent core radiographic laboratory, was higher in the activL group (59%) than in the ProDisc-L and Charité controls (43%; p<0.01).

Five-year results from this trial were reported in Yue et al (2019). Of 341 patients enrolled, 261 contributed data at 5 years (76.5%). The primary composite endpoint results were reported graphically only and demonstrated noninferiority at 5 years for activL versus control artificial discs. Sensitivity analyses using various imputation methods for missing data also showed noninferiority of activL, with the exception of the worst-case scenario (missing data counted as failure for activL and success for control). Freedom from serious adverse events through 5 years was 64% with activL and 47% with control artificial discs (P=0.0068). Seven-year results for 206 individuals who received activL or ProDisc-L were reported in Radcliff et al (2021) and showed no increase in serious adverse events between years 5 and 7.[28]

Radcliff et al (2021), in a prospective multicenter RCT, compared 7-year safety and efficacy outcomes of activL and ProDisc-L lumbar total disc replacements in patients with symptomatic, single-level lumbar degenerative disc disease (DDD).[28] The objectives are to report 7-year outcomes of the trial, evaluate the outcomes for patients lost to follow-up, and determine whether early outcomes predict long-term outcomes. At 7 years, the activL group was noninferior to the ProDisc-L group on the primary composite endpoint (P = .0369). Both groups showed significant reductions in back/leg pain severity and improvements in disability index and quality-of-life relative to baseline (P < .0001). In both groups, opioid use was significantly reduced at 7 years (0%) relative to baseline (P <.01), and the overall reoperation rates were low (4.6%). activL patients showed a significantly better range of motion (ROM) for flexion-extension rotation than ProDisc-L patients (P=.0334). A significantly higher proportion of activL patients did not report serious adverse events (activL, 62%; ProDisc-L, 43%; P=.011). Predictive modeling indicated that >70% of patients (depending on outcome) lost to follow-up after 2 years would show clinically significant improvement at 7 years if improvements were achieved at 2 years.

Table 3. Summary of Key RCT Characteristics for Lumbar Artificial Discs Available in the United States

Study	Publications	Countries	Sites	Follow-Up	Study Design and Participants	Interventions Number Analyzed	
						Active	***Control***
ProDisc-L IDE Study		U.S.	17		Noninferiority trial of patients with single-level DDD	ProDisc-L n=161	Circumferential fusion n=75
	[4.]			2 y	2-year results	n=156	n=73
	[5.]			5y	5-year results	n=137	n=56
	[6.]			5 y	5-year adjacent level degeneration results	n=123	n=43
ProDiscL IDE Study NCT00295009	Delamarter et al (2011)[8.]	U.S.	16	2 y	Noninferiority trial of patients with DDD at 2 contiguous levels	ProDisc-L at 2 levels n=158	Circumferential fusion n=79
activL IDE Study NCT00589797	Garcia et al (2015)[13.]	U.S.	17	2 y	Patient-blinded noninferiority trial of patients with DDD	activL n=218	ProDisc-L or Charité n=106
	Yue et al (2019)[14.]			5y	5-y follow-up (open label)	n=176	n=85

ProDisc II vs Conservative Treatment NCT00394732	Hellum et al (2011) [10.]	Norway	5	2 y	Patients with chronic low back pain, ODI score ≥30, and DDD in 1 or 2 levels	ProDisc II n=87	Multidisciplinary rehabilitation n=86
	Hellum et al (2012)[11.]			2 y	Adjacent-level degeneration and facet arthropathy results	ProDisc II n=59	Multidisciplinary rehabilitation n=57
	Furunes et al (2017)[12.]			8 y	8-year follow-up	ProDisc II n=77	Multidisciplinary rehabilitation n=74

DDD: degenerative disc disease; ODI: Oswestry Disability Index; RCT: randomized controlled trials

Table 4. Summary of Key RCT Outcomes for Artificial Intervertebral Discs Available in the United States

Study	Success Rate at 2 Years	Success Rate at 5 Years	ODI Score at 2 years Mean (SD)% change (SD)	ODI Score at 5 years Mean (SD)% change (SD)	VAS Score at 2 years Mean (SD)% change (SD)	VAS Score at 5 years% change (SD)	SF-36 at 2 years% change (SD)	SF-36 at 5 years% change (SD)	Adjacent-Level Degeneration at 5 Years	Reoperation at 5 years
Zigler et al (2007, 2012)[4,5,6.]										
Number analyzed	219	193	220	177	220	176	217	177	161	193
ProDisc-L	63.5%	53.7%	34.5 (24.5) - 47.4 (34.7)	34.2 (24.3) - 47.5 (34.7)	36.6 (30.1) - 49.9 (41.9)	37.1 (29.3) - 48.7 (44.6)	42.8 (11.1) 39.4 (43.5)	42.0 (11.3) 40.1 (43.9)	9.2% (1.9% required surgery)	6/137 (4.4%)
Fusion	45.1%	50.0%	39.8 (24.3) - 37.8 (36.0)	34.5 (24.5) - 47.4 (34.7)	43.3 (31.6) - 42.4 (42.9)	40.0 (32.1) - 47.5 (43.8)	38.8 (11.3) 29.8 (40.9)	40.1 (13.6) 29.9 (43.7)	28.6% (4.0% required surgery)	5/56 (9.0%)
P inferiority	<0.01	0.024								
P superiority	0.044	0.7438	0.055	0.455	0.134	0.567	0.036	0.168	0.004	NR
Delamarter et al (2011)[8.]										
Number analyzed	203									
ProDisc-L	58.8%	NR	52.4% improvement	NR	-43.3	NR	54.2% (54.6)	NR	NR	NR
Fusion	47.8%	NR	40.9% improvement	NR	-36.7	NR	36.2% (44.9)	NR	NR	NR
P noninferiority	0.0008									
P superiority	0.09		0.03		0.118		0.014		0.047	
Garcia et al (2015)[13.] Yue et al (2019)[14.]										

Number analyzed			324	324						
activ-L	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 75.2% Mean improvement: 67%	% with ≥15 point improvement 82.7%	Improvement from baseline 74%	Decrease from baseline (mm) -64	≥15% improvement: 88%	≥15% improvement: 87%	1%	5%
ProDisc-L or Charité	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 66.0%; Mean improvement: 61%	% with ≥15 point improvement 89.6%	Improvement from baseline 68%	Decrease from baseline (mm) -62	≥15% improvement: 81%	≥15% improvement: 82%	6%	10%
P noninferiority	<0.001	NR; activL noninferior to control group								
P superiority	0.02	NR	0.09	0.10	NR	NR	NR	0.24	*0.01*	0.07
Hellum et al (2011, 2012) and Furunes (2017) [10,11,12]										
Number analyzed	173	151 (8 years)		151 (8 years)		151 (8 years)			8 years	173 (8 years)
ProDisc II	51 (70%)	19.8 (16.7)	20.0 (16.4 to 23.6)		35.4		NR	NR	34%	12/86 (14%)
Rehab	31 (47%)	26.7 (14.5)	14.4 (10.7 to 18.1)		49.7		NR	NR	4%	21/87 (24%)
p	0.006			0.02	0.009	0.04			<0.001	NR
	NNT 4.4 (95% CI 2.6 to 14.5)	MD = -6.9 (-11.7 to -2.1)		MD=6.1 (1.2 to 11.0)		MD=9.9 (0.6-19.2)				

CI: confidence interval; MD: mean difference; NNT: number needed to treat; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; Rehab: multidisciplinary rehabilitation; VAS: visual analog score

Observational Studies

While observational studies do not provide evidence of efficacy or comparative efficacy, they may provide information about the durability of any observed improvements and potential impacts of patient selection factors.

Siepe et al (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution.[17] This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review study. Baseline ODI and VAS pain scores, assessed by investigators who were not involved in pre- or postoperative decision making, were significantly improved over baseline. Overall satisfaction rates were 89% for single-level and 69.0% for 2-level disc replacement.

Laugesen et al (2017) found significant improvements in pain and function with 1- or 2-level ProDisc-II implantation at follow-up of 10.6 years, but pain remained moderate, and about

one-third of patients required revision to fusion.[18] The authors noted the need for appropriate selection criteria.

Another case series, Tropiano et al (2005), identified followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.[19]

Table 5. Summary of Prospective Cohort Study Characteristics

Study	Country	Participants, N (% of total treated)	Treatment Delivery	Follow-up (Range), Years
Siepe et al (2014)		181 (90%)	ProDisc-II at 1 or 2 levels	7.41 (5.0-10.8)
Laugesen et al (2017)	Demark	57 (84%) with DDD	ProDisc-II at 1 or 2 levels	10.6 (8.1-12.6)

DDD: degenerative disc disease

Table 6. Summary of Key Cohort Study Results

Study	Treatment	Functional Status at Baseline	Score at FU	p	VAS Score at Baseline	VAS at FU	p	Complication Rate
Siepe et al (2014)	1 or 2 level ProDisc-II	42 (ODI)	22	<0.001	7	3.3	<0.001	• 11.9% 1 level • 27.6% 2 levels
Laugensen et al (2017)	1 or 2 level ProDisc-II	63.2 (PDQ)	45.6	<0.001	6.8	3.2	<0.001	33% revised to fusion

FU: follow-up; ODI: Oswestry Disability Index; PDQ: Dallas Pain Questionnaire; VAS: visual analog scale

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 vs. fusion with 5-year outcomes and longer-term case series. 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. Superiority of ProDisc-L with circumferential fusion was achieved at 2 but not 5 years in this unblinded trial. Some randomized trials have concluded that this technology is noninferior to fusion The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

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.

In response to requests, BCBSA received input from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. The 4 reviewers

disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational.

After consideration of the clinical input in 2008, it was concluded that due to limitations of the only 2 available RCTs (described here), combined with the marginal benefit compared to fusion, evidence is insufficient to determine whether artificial lumber discs are beneficial in the short term. In addition, serious questions remain about potential long-term complications with these implants.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Pain Society

In 2009, the American Pain Society's (APS) practice guidelines concluded there was "insufficient evidence" to adequately evaluate long-term benefits and harms of vertebral disc replacement.[20] The guideline was based on a systematic review commissioned by APS and conducted by the Oregon Evidence-Based Practice Center.[21] The rationale for the recommendation was that although artificial disc replacement has been associated with similar outcomes compared 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. In addition, all trials had been industry-funded, and data on long-term (beyond 2 years) benefits and harms following artificial disc replacement were limited.

National Institute for Health and Care Excellence

In 2009, U.K.'s National Institute for Health and Care Excellence (NICE) 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."[22] 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.[23] 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 one 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 one 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

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

Government Regulations

National: NCD: 150.10 Effective 08/14/2007.

Effective for services performed from May 16 through August 13, 2007, the Centers for Medicare and Medicaid Services (CMS) found that lumbar artificial disc replacement (LADR) with the Charité lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, CMS issued a national non-coverage determination for LADR with the Charité lumbar artificial disc for the Medicare population over 60 years of age.[24]

Effective for services performed on or after August 14, 2007, CMS found that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age. For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination, leaving such determinations to be made by the local contractors.

The NCD was revised in 2007 to reflect a change from non-coverage for a specific implant (the Charité), to non-coverage for the lumbar artificial disc replacement procedure for the Medicare population older than 60 years of age.[25] CMS provided this explanation, "The original NCD [national coverage determination] 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 manufacture's implant."[26]

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through April 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/12	10/11/11	11/9/11	Joint policy established. This policy was developed as a result of splitting out a former policy entitled “Artificial Intervertebral Discs” into two separate policies, one called “Artificial Intervertebral Discs-Cervical” and the other “Artificial Intervertebral Discs-Lumbar”
3/1/13	2/19/13	3/4/13	Updated policy with references, no change in policy status
9/1/14	6/17/14	6/23/14	References and rationale updated. Policy status unchanged.
11/1/15	8/24/15	9/14/15	Routine update of experimental/investigational policy. Policy status unchanged.
9/1/16	6/21/16	6/21/16	Routine policy updates of rationale and references. No change in policy status
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine policy maintenance. Updated rationale, added references 9-11 and 16. No change in policy status.
9/1/19	6/18/19		Routine policy maintenance. No change in policy status.
9/1/20	6/16/20		Routine policy maintenance. Updated rationale section, added reference #15. No change in policy status.
9/1/21	6/15/21		Routine policy maintenance. No changes in policy status.
9/1/22	6/21/22		Routine policy maintenance, no change in policy status. Reference #28 added.
9/1/23	6/13/23		Policy status changed to established. Rationale updated, new references added. Code 0163T deleted effective 1/1/23. Code 22860 added as

			established. All previous codes now established. Vendor managed: Turning Point. (ds)
9/1/24	6/17/24		Minor changes to verbiage in inclusion section, additions made to exclusion section. No change in policy status. Vendor managed: Turning Point (ds)

Next Review Date: 2nd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ARTIFICIAL INTERVERTEBRAL DISCS – LUMBAR SPINE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.