Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the
Blue Cross Blue Shield Association

Title: Artificial Intervertebral Disc: Lumbar Spine

Related Policy:	▪ *Artificial Intervertebral Disc: Cervical Spine* ▪ *Lumbar Spinal Fusion*

Professional / Institutional
Original Effective Date: August 9, 2005
Latest Review Date: April 14, 2026
Current Effective Date: September 23, 2008

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

Populations	Interventions	Comparators	Outcomes
Individuals: • With degenerative disc disease	Interventions of interest are: • Lumber artificial intervertebral disc	Comparators of interest are: • Conservative therapy • Lumbar spinal fusion	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

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

BACKGROUND

Degenerative disc disease (DDD), 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 it 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 no 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 (eg, 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, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. Spinal fusion alters the spine biomechanics, 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 (TDR) 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 (eg, device fracture, dislocation, or wear), bone-implant interface failure (eg, subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (eg, osteolysis, heterotopic ossification, pseudotumor formation).

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 (Table 1). Production under the name Charité was stopped in 2010 and the device was withdrawn in 2012.

ProDisc-L Total Disc Replacement system

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, now Centinel Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD. DDD 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 ProDisc-L was also limited to patients with disease

at 1 level. In April 2020, the ProDisc-L 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[a]	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 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[b]	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 6 months of conservative treatment prior to implantation of the device.	P050010/ S020	8/25/2006/ 4/10/2020 (supplement)
Charité	Depuy Spine, Inc	The Charité Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with 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 Charité Artificial Disc should have failed at least 6 months of conservative treatment prior to implantation of the device.	P040006	10/26/2004 Withdrawn 1/5/2012

DDD: degenerative disc disease; PMA: premarket approval

[a] As of July 2025, Highridge Medical has licensed the U.S. rights to launch its own activL lumbar disc.[2,]https://highridgemedical.com/highridge-to-introduce-activl-lumbar-disc/

[b] As of December 2017, the prodisc line was acquired by Centinel Spine.[3,]

A number of other artificial lumbar discs are in development or available only outside of the United States (U.S.):

- The Maverick artificial disc (Medtronic) is not marketed in the U.S. 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.

POLICY

Artificial intervertebral discs of the lumbar spine are considered **experimental / investigational**.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through January 15, 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

This review focuses only on artificial discs currently available in the United States.

Clinical Context and Therapy Purpose

The purpose of the lumbar artificial intervertebral disc in individuals with degenerative disc disease is 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 (DDD).

DDD 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 U.S.: ProDisc-L 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 2). 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 12-Item Short Form Health Survey or 36-Item Short Form Health Survey (SF-36), particularly the physical function subscale of SF-36 , are also used.

Table 2. Patient-reported Outcome Measures for Back Pain

Measure	Outcome Evaluated	Description	MDD and MCID
Oswestry Disability Index (ODI) score	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 (VAS) for back pain	Degree of back pain	Patients indicate the degree of pain on a 0-100 scale	MDD: 2 points
VAS 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 take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36 , or VAS 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 nonfused 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 minimal clinically important difference makes it difficult to compare response rates across studies. Nevertheless, clinical trials should prespecify a minimal clinically important difference 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

Systematic Reviews
Multiple systematic reviews have been conducted to assess the efficacy of total disc replacement (TDR) in managing chronic low back pain.[4,5,6,7,] Below are relevant reviews which includes studies on artificial lumbar intervertebral discs currently available in the U.S. (activL, ProDisc-L).

Jacobs et al (2013) conducted a Cochrane review to assess the effect of total TDR for chronic low back pain due to lumbar DDD compared with fusion or other treatment options.[4,] The review included 40 publications, describing 7 unique RCTs (Table 3). Five RCTs (n=1301, published between 2005 and 2011) specifically compared TDR versus fusion for improvement of pain (VAS) and function (ODI) outcomes at 2 years. These studies had risk of bias due to lack of blinding and industry sponsorship; in addition, 2 trials evaluated the now-withdrawn Charité artificial disc. One study compared disc replacement against rehabilitation; and one was excluded because of the high risk of bias due to possible selective reporting of preliminary results. Pooled results from 2 studies (using combination of Charité, ProDisc-L, or Maverick) demonstrated that the mean improvement in VAS back pain at 2 years in the TDR group was 5.2 mm (out of 100) higher than in the fusion group (676 patients; 95% confidence interval (CI), 0.2 to 10.3; p=.04; low-quality of evidence). Leg pain showed no difference from the same studies. There was a statistically, but

not clinically, significant difference in improvement in function (4.3 points) in the TDR group compared with the fusion group across 5 studies (207 patients; 95% CI, 1.9 to 6.7; low-quality of evidence). Patients in the TDR group were more likely to have been improved on the ODI scale at 2 years than a predefined level than in the fusion group (1,244 patients; OR 1.45; 95% CI, 1.06 to1.98; p=.02). Choice of control group (circumferential or anterior fusion) did not appear to result in different outcomes. The single study (Hellum et al, 2011; see RCTs section below) comparing ProDisc-L (n=86) with rehabilitation (n=87) found significant difference in improvement on ODI, but not beyond the clinically relevant difference of 10 points (ProDisc-L group was 12.3 mm higher than in the rehabilitation group at 2-years, 152 patients; 95% CI, 3.1 to 21.3 mm).

Lang et al (2021) performed a meta-analysis comparing TDR, anterior stand-alone fusion (ALIF), and circumferential fusion (CFF) in patients with lumbar DDD, focusing on pain (VAS), function (ODI), and complication rates as primary outcomes.[5,]The secondary outcomes included the mean number of complications per case (MNOC) assessed both at surgery and during follow-up, as well as overall MNOC. The review included 6 studies (4 RCTs and 2 cohort studies) with at least 2 years of follow-up (Table 3). Results indicated that TDR provided better pain relief than ALIF (mean difference (MD) -5.82; 95% CI, -10.17 to -1.46; p=.009) and was also slightly superior to CFF (MD -6.60; 95% CI, -12.91 to -0.30; p=.04). ALIF appeared marginally better than CFF for pain (MD -0.67; 95% CI: -5.87 to 4.52; p=.80), but with significant heterogeneity. Regarding complications, CFF had the lowest overall MNOC (0.1), followed by TDR (1.2) and ALIF (1.5).

Wen et al (2024) performed a systematic review evaluating the clinical outcomes, re-operation rates, and complication rates of TDR devices for lumbar DDD, with all included studies providing at least 5-years of post-operative follow-up.[6,]The review included 22 studies (N=2,284 patients), of which 15 were prospective (including 7 RCTs) and 7 were retrospective. The mean follow-up period was 8.3 years, with an average follow-up rate of 87%. The mean VAS and ODI pain score improvements were 51.7 ± 6.9 and 30.4 ± 5.3 respectively. The mean clinical success and patient satisfaction rates were 74.8% ± 7.5% and 86.3% ± 5.6%, respectively. The mean complication and reoperation rates were 18.5% ± 6.3% and 13.6% ± 3.8%, respectively. There was no significant difference when comparing mid-term (defined as 5 years) and long-term (≥10 years) follow-up studies for all clinical outcomes. This review had several limitations based on heterogeneity across studies, including variations in study designs, sample sizes, populations examined, and the types of devices assessed. Definitions for complications and reoperation rates differed across studies, and 3 (of 7) RCTs evaluated non-FDA approved devices (Kineflex, Charité, and Maverick) (Table 3).

Table 3. Comparison of RCTs Included in Systematic Reviews & Meta-analyses

Study[1]	Device	Jacobs et al (2013)[24,]	Lang et al (2021)[5,]	Wen et al (2024)[6,]
Radcliff et al (2021)[8,]	activL, ProDisc-L			●
Gornet et al (2019)[9,]	Maverick		●	
Yue et al (2019)[10,]	activL			●

Study[1]	Device	Jacobs et al (2013)[24,]	Lang et al (2021)[5,]	Wen et al (2024)[6,]
Furunes et al (2017)[11,]	ProDisc-L			●
Guyer et al (2016)[12,]	Kineflex-L, Charité			●
Skold et al (2013)[13,]	Charité, ProDisc-L, Maverick			●
Guyer et al (2012)[14,]	Charité			●
Zigler and Delamarter (2012)[15,]	ProDisc-L			●
Delmarter et al (2011)[16,]	ProDisc-L		●	
Gornet et al (2011)[17,]	Maverick	●		
Hellum et al (2011)[18,]	ProDisc-L	●		
Berg et al (2009)[19,]	Charité, ProDisc-L, or Maverick	●		
Moreno and Boulot (2008)[320,]	Charité	●		
Zigler et al (2007)[21,]	ProDisc-L	●	●	
Blumenthal et al (2005) [22,]	Charité	●	●	

[1] Primary studies across the rows;[2] Systematic reviews/meta-analyses across the columns; [3] Publication in French.

Randomized Controlled Trials

Three RCTs have compared the treatment of DDD using lumbar fusion with artificial lumbar intervertebral discs currently available in the U.S. They include the pivotal trials for the ProDisc-L and activL discs, and a U.S. Food and Drug Administration (FDA) regulated trial of the ProDisc-L for 2-level degenerative disc disease. A fourth trial compared ProDisc-L with multidisciplinary rehabilitation. The composite success endpoint included improvements in 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 ProDisc-L and activL. Eight-year data have been reported from a comparison of ProDisc II with multidisciplinary rehabilitation. These trials were included in the above systematic reviews, and no additional relevant RCTs were identified in the updated literature search.

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.

Characteristics of these trials are summarized in Table 4, results in Table 5, and study relevance, design, and conduct limitations are summarized in Tables 6 and 7.

ProDisc-L at a Single Level Compared to Fusion

The pivotal study for the ProDisc-L was an unblinded noninferiority trial that originally followed patients for 2-years.[23,24,] In the per-protocol analysis reported to FDA, ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%, which achieved both non-inferiority and superiority. Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012.[21,15,25,] 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 5 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, SF-36 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).

Additional study of ProDisc-L in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption trial in patients with single-level chronic symptomatic 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 and thereby reduces the risk of adjacent-level segment degeneration better than fusion, remains subject to debate.

ProDisc-L at 2 Levels Compared to Fusion

The ProDisc-L for 2-level lumbar degenerative disc disease was reported in 2011 from a multicenter, randomized, FDA regulated noninferiority trial.[16,] 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. The ProDisc-L group had faster surgeries (160.2 minutes vs 272.8 minutes), less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital lengths of stay (3.8 days vs 5.0 days) than the arthrodesis group. The composite measure of success demonstrated noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in the percentages of patients who achieved at least a 15-point improvement in ODI scores and greater improvements in the SF-36 scores. A greater percentage of patients in the arthrodesis group required secondary surgical procedures. As noted in an accompanying commentary, the study had a number of limitations.[26,] Comparison with a procedure (open 360° fusion) that is not the criterion standard precludes decisions on the

comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of patients and providers.

ProDisc-L Compared to Conservative Treatment

Hellum et al (2011) reported an RCT that compared the use of the ProDisc-L (ProDisc II) with a multidisciplinary rehabilitation program.[18,] 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 ODI 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 ODI score, and the trial was powered to detect a 10-point difference in ODI 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. Five (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, but the mean difference did not achieve the 10-point difference in ODI score considered clinically significant. There were significantly more patients who achieved a 15-point improvement in ODI 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 group.[27,]

Eight-year follow-up of this trial was reported by Furunes et al (2017).[11,] In both the intention-to-treat and per-protocol analysis there was a statistically significant benefit of surgery as measured by the mean ODI, but these differences did not reach the clinically significant threshold of 10 points (see Table 4). More patients in the surgery group (43/61 [70%]) reached a clinically important difference of 15 ODI points than in the rehabilitation group (26/52 [50%]; p=.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 investigational device exemption trial of the activL artificial intervertebral disc were reported by Garcia et al (2015).[28,] In this patient-blinded noninferiority trial, patients with DDD were randomized to treatment with activL or an FDA approved disc (ProDisc-L or Charité). At 2 years, activL was both noninferior and superior to the control group of patients treated with ProDisc-L or Charité. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls. Range of motion at the index level, measured by an independent core radiographic laboratory, was higher in the activL group than in the controls.

Five-year results from this trial were reported in Yue et al (2019).[10,] 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=.007). 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.[8,]

Because this study compared activL to other fusion devices, it provides only indirect evidence of effectiveness compared to fusion or conservative care. The study was not powered to detect differences by different control devices, and the control group included patients who received a device that is no longer available in the U.S. (Charité). Additional limitations were a high loss to follow-up at 5 and 7 years, unblinded outcome assessment, and no blinding of patients at the 5-year and 7-year assessments.

Table 4. 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
	[21,]			2 y	2-year results	n=156	n=73
	[15,]			5y	5-year results	n=137	n=56
	[25,]			5 y	5-year adjacent level degeneration results	n=123	n=43
ProDisc-L IDE Study NCT00295009	Delamarter et al (2011)[16,]	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)[28,]	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)[10,]			5y	5-y follow-up (open label)	n=176	n=85

Study	Publications	Countries	Sites	Follow-Up	Study Design and Participants	Interventions Number Analyzed	
ProDisc II vs Conservative Treatment NCT00394732	Hellum et al (2011) [18,]	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)[27,]			2 y	Adjacent-level degeneration and facet arthropathy results	ProDisc II n=59	Multidisciplinary rehabilitation n=57
	Furunes et al (2017)[11,]			8 y	8-year follow-up	ProDisc II n=77	Multidisciplinary rehabilitation n=74

IDE: Investigational Device Exemption; DDD: degenerative disc disease; ODI: Oswestry Disability Index; RCT: randomized controlled trial.

Table 5. 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)[21,15,25,]										
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	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%)

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
						(43.8)				
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)[16],										
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)[28], Yue et al (2019)[10],										
Number analyzed			324	324						
activ-L	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 75.2% Mean	% with ≥15 point improvement 82.7%	Improvement from baseline 74%	Decrease from baseline (mm) -64	≥15% improvement: 88%	≥15% improvement: 87%	1%	5%

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
			improvement: 67%							
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) [18,27,11,]										
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%	MD=-6.9 (-11.7		MD=6.1 (1.2 to 11.0)		MD=9.9				

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
	CI 2.6 to 14.5)	to -2.1)				(0.6-19.2)				

CI: confidence interval; MD: mean difference; NNT: number needed to treat; MD: mean difference; NNT: number needed to treat; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; Rehab: multidisciplinary rehabilitation; SD: standard deviation; SF-36: 36-Item Short Form Health Surve; VAS: visual analog score.

Study Limitations

Tables 6 and 7 summarize the relevance, design, and conduct limitations of the RCTs of artificial discs available in the U.S. The most serious limitations included a lack of blinding, insufficient follow-up to evaluate potential harms, and comparators that are not relevant to current practice.

Table 6. Study Relevance Limitations for RCTs of Artificial Intervertebral Discs Available in the United States

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
ProDisc-L IDE Study Zigler et al (2007, 2012)				Outcome changed from protocol	
ProDisc-L 2-level Delamarter et al (2011)	4. Patients with DDD at 2 levels		2. Comparator not criterion standard		1,2. insufficient follow-up to assess benefits and harms
activL IDE study Garcia et al (2015) Yue et al (2019)			2. no comparison to fusion or conservative care; control group includes patients who received a device not currently available in the US		2. 5-year follow-up not sufficient to assess potential harms
ProDisc II vs conservative care Hellum et al (2011)	4. 33% of surgery patients underwent 2-level surgery		4. 24% of patients randomized to rehabilitation crossed over to surgery		

DDD: degenerative disk disease.
The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations for RCTs of Artificial Intervertebral Discs Available in the United States

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
ProDisc-L IDE Study Zigler et al (2007, 2012)		1, 2. Not blinded		1. High and differential loss to follow-up at 5 years (25% (fusion vs 15% artificial disc)		
ProDisc-L 2-level Delamarter et al (2011)		1, 2. Not blinded				
activL IDE study Garcia et al (2015) Yue et al (2019)		1, 2. Outcome assessment not blinded, patients blinded at 2 y but not 5 y		1. high loss to follow-up at 5 years		
ProDisc II vs conservative care Hellum et al (2011)				1. high and differential loss to follow-up		

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis

(per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

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.

Marnay et al (2025) performed a retrospective, single-center study in France to compare outcomes of 1-level versus 2-level lumbar TDR using the ProDisc-L device, and to determine whether previous surgery at the affected level(s) influenced clinical outcomes.[29,] Between 1999 and 2013, 1,187 patients with chronic lumbar DDD underwent TDR; of these, 772 had a 1-level procedure and 415 had a 2-level procedure. Prior surgery at the index level(s) was present in 373 patients (31%). Evaluations were conducted before surgery; at 3, 6, 12, 18, and 24 months after surgery; and then annually. Follow-up ranged from 7 to 21 years, with a mean duration of 11 years and 8 months. Data collected included radiographic, neurological, and physical assessments, as well as patient-reported outcomes using the ODI and VAS for back and leg pain. The study also recorded perioperative details, complications, and rates of reoperation or revision.

Patients were grouped as follows: 1-level TDR without prior surgery (Group 1), 1-level TDR with prior surgery (Group 2), 2-level TDR without prior surgery (Group 3), and 2-level TDR with prior surgery (Group 4). All groups saw reductions in ODI scores at 3-months, maintaining these improvements over time. While all groups improved, Group 1 had the fastest reduction in ODI, and Group 4 had the slowest. At 3 months, ODI reductions were 45% for Group 1, 38% for Group 2, 36% for Group 3, and 31% for Group 4. VAS pain scores decreased more slowly in patients with previous surgeries, but by 2-years there was no significant difference in pain relief among the groups. Forty-nine patients (4%) needed further surgery, either at a new spinal level or as a revision/reoperation at the original site: 10 patients needed posterior decompression, and 9 required reoperation for hematoma or wound issues; 8 patients (0.67%) had implant revision at the index level, mostly early in Group 1; and 22 patients (1.85%) underwent new surgery at the adjacent level by last follow-up. A total of 890 patients (75%) were monitored at mean follow-up of 11 years and 8 months, while 14 patients (1.2%) were followed for up to 21 years. Over the 7-to-21-year follow-up, revision rates for TDR and new adjacent-level surgeries remained low, at 0.67% and 1.85%, respectively. Patients with a history of prior surgery (Groups 2 and 4) experienced a higher incidence of adjacent-level degeneration requiring surgical intervention compared to those without previous surgery (Groups 1 and 3).

Guyer et al (2024) conducted a retrospective, multi-site spine specialty practice study in the U.S. to determine the frequency and causes of lumbar TDR removal or revision with a mean follow-up of 6 years.[30,]The publication does not specify which device was used in the study; however, the study was supported in part from Aesculap Implant Systems, the manufacturer of activL device. Out of 2,141 patients, 27 (1.26%) required either device removal or revision, with 24 removals (1.12%) and three revisions (0.14%). The primary reasons for removal included migration and/or loosening (12 cases), post-traumatic complications (three cases), lymphocytic reactions to device materials (two cases), ongoing pain (two cases), and single cases of oversized TDR, vertebral

fracture due to osteoporosis, lytic lesion, device subsidence with facet arthrosis, and infection linked to a chest infection 12 years after implantation. The three revisions addressed technique errors, device displacement, and core wear or failure. Thirty-seven percent of procedures occurred within one month of implantation, and 41% happened within the first 25 cases by individual surgeons. One vascular complication was reported, in a trauma-related removal. Study limitations included lack of complete data-sets for some patients (deceased, could not be located, declined to participate) and great variation in the follow-up duration.

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

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

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.[31,] The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center.[32,] 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.

North American Spine Society

In 2019, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement.[33,]The recommendation was that lumbar TDR is indicated for patients with symptomatic single level lumbar disc disease who meet all of the specified criteria.

In 2024, the NASS revised their recommendations in light of new long-term data and the expanded FDA approval of ProDisc-L for 2-level use in 2020. The Coverage Committee highlighted findings from both 2-year and 7-year follow-up studies showing that outcomes for discogenic low back pain treated with TDR are at least comparable to those for spinal fusion in properly selected patients. The review included the Marnay et al. ProDisc-L study results in abstract form presented at the 2021 NASS Annual Meeting, as well as 7-year ProDisc-L/activL data by Radcliff et al. (2021) (both discussed in the Rationale section). The NASS Committee also noted that while most long-term studies focus on the Charité device, which was discontinued by the manufacturer in 2012, there remains limited clinical evidence on activL, which received FDA approval in 2015. Performing TDR is technically demanding, and clinicians must be aware of potential pitfalls; therefore, adequate training is essential.

The following revised recommendations were made:

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

1. Pain arising from 1- or 2-level disc disruption involving L3-4, L4-5, and/or L5-S1 segments.
2. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period which should include a physical therapy/rehabilitation program, and may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.
3. 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 disc disease at more than 2 levels.
3. Significant facet arthropathy at the index level or signs that the source of pain is primarily facet mediated.
4. Presence of spinal instability with spondylolisthesis greater than Grade I.
5. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms, extending over a period of at least one year).
6. Osteopenia as evidenced by a DEXA [dual-energy X-ray absorptiometry] bone mineral density T-score less than or equal to -1.0.
7. Poorly managed psychiatric disorder (any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized before surgical intervention).
8. Age greater than 60 years or less than 18 years.
9. Presence of infection or tumor.

International Society for the Advancement of Spine Surgery
In 2021, the International Society for the Advancement of Spine Surgery (ISASS) position statement on cervical and lumbar disc replacement concluded that lumbar TDR, including multi-level use as approved by the FDA, is a safe and effective treatment alternative to fusion for patients meeting well established selection criteria.[34,] FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use.

National Institute for Health and Care Excellence
In 2009, the 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."[35,] NICE concluded that evidence was "adequate to support the use of this procedure."

In 2020, the NICE updated guidance on low back pain and sciatica assessment and management recommended that physicians do not offer disc replacement in people with low back pain (NICE, 2020).[36,]

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2026 did not identify any ongoing or unpublished trials that would likely influence this review

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22860	Total disc arthroplasty, anterior approach, including discectomy ; second lumbar interspace (Prodisc® L Total Disc Replacement)
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
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 (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

REVISIONS	
09-23-2008	In Description section: ▪ Updated wording
	In Policy section: ▪ Removed "Removal or revision of artificial disc(s) is a non-covered service."
	In Coding section: ▪ Removed CPT codes 0090T, 0092T, 0093T, 0095T, 0096T, 0098T
	Added Rationale section
02-22-2010	In Coding Section: Updated wording for CPT codes: 22857, 22862, 22865, 0163T, 0164T, 0165T
	Rationale and References updated.
03-10-2011	Description section updated
	Rationale section updated
	References updated
03-08-2013	Description section updated
	Rational section updated
	In Coding section: ▪ Coding notations updated.
	References updated

REVISIONS	
06-23-2015	Description section update
	Rationale section updated
	References updated
08-04-2016	Description section update
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
05-23-2018	Description section update
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
07-17-2019	Description section update
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
08-21-2020	Description section update
	Rationale section updated
	References updated
07-01-2021	Description section update
	Rationale section updated
	References updated
07-01-2022	Updated Description Section
	Updated Rationale Section
	Updated References Section
01-03-2023	Updated Coding Section ▪ Added 22860 ▪ Deleted 0163T
05-23-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Diagnoses box
	Updated References Section
05-28-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
06-10-2025	Updated Description Section
	Updated Rationale Section
	Updated Reference Section
04-14-2026	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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 January 20, 2026.
2. Highridge Medical to Introduce activL Lumbar Disc. July 8, 2025.
3. Centinel Spine. ProDisc devices.
4. Jacobs WC, van der Gaag NA, Kruyt MC, et al. Total disc replacement for chronic discogenic low back pain: a Cochrane review. Spine (Phila Pa 1976). Jan 01 2013; 38(1): 24-36. PMID 22996268
5. Lang SAJ, Bohn T, Barleben L, et al. Advanced meta-analyses comparing the three surgical techniques total disc replacement, anterior stand-alone fusion and circumferential fusion regarding pain, function and complications up to 3 years to treat lumbar degenerative disc disease. Eur Spine J. Dec 2021; 30(12): 3688-3701. PMID 33837832
6. Wen DJ, Tavakoli J, Tipper JL. Lumbar Total Disc Replacements for Degenerative Disc Disease: A Systematic Review of Outcomes With a Minimum of 5 years Follow-Up. Global Spine J. Jul 2024; 14(6): 1827-1837. PMID 38263726
7. Zigler J, Gornet MF, Ferko N, et al. Comparison of Lumbar Total Disc Replacement With Surgical Spinal Fusion for the Treatment of Single-Level Degenerative Disc Disease: A Meta-Analysis of 5-Year Outcomes From Randomized Controlled Trials. Global Spine J. Jun 2018; 8(4): 413-423. PMID 29977727
8. 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
9. Gornet MF, Burkus JK, Dryer RF, et al. Lumbar disc arthroplasty versus anterior lumbar interbody fusion: 5-year outcomes for patients in the Maverick disc investigational device exemption study. J Neurosurg Spine. Sep 01 2019; 31(3): 347-356. PMID 31100723
10. 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
11. 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
12. Guyer RD, Pettine K, Roh JS, et al. Five-Year Follow-Up of a Prospective, Randomized Trial Comparing Two Lumbar Total Disc Replacements. Spine (Phila Pa 1976). Jan 2016; 41(1): 3-8. PMID 26335669
13. Sköld C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. Eur Spine J. Oct 2013; 22(10): 2288-95. PMID 23893083
14. Guyer et al. (2012). Outcomes of CHARITE Lumbar Artificial Disk versus Fusion: 5-Year Data. Seminars in Spine Surgery, Volume 24, Issue 1, March 2012, Pages 32-36.
15. 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

16. 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
17. Gornet MF, Burkus JK, Dryer RF, et al. Lumbar disc arthroplasty with Maverick disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial. Spine (Phila Pa 1976). Dec 01 2011; 36(25): E1600-11. PMID 21415812
18. 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
19. Berg S, Tullberg T, Branth B, et al. Total disc replacement compared to lumbar fusion: a randomised controlled trial with 2-year follow-up. Eur Spine J. Oct 2009; 18(10): 1512-9. PMID 19506919
20. Moreno P, Boulot J. [Comparative study of short-term results between total artificial disc prosthesis and anterior lumbar interbody fusion]. Rev Chir Orthop Reparatrice Appar Mot. May 2008; 94(3): 282-8. PMID 18456064
21. 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
22. Blumenthal S, McAfee PC, Guyer RD, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine (Phila Pa 1976). Jul 15 2005; 30(14): 1565-75; discussion E387-91. PMID 16025024
23. 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 January 9, 2026.
24. 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 January 10, 2026.
25. 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
26. 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
27. 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

28. 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
29. Marnay TP, Geneste GY, Edgard-Rosa GW, et al. Clinical Outcomes After 1 and 2-Level Lumbar Total Disc Arthroplasty: 1,187 Patients with 7 to 21-Year Follow-up. J Bone Joint Surg Am. Jan 01 2025; 107(1): 53-65. PMID 40100011
30. Guyer RD, Blumenthal SL, Shellock JL, et al. Lumbar Total Disk Replacement Device Removals and Revisions Performed During a 20-Year Experience with 2141 Patients. Spine (Phila Pa 1976). May 15 2024; 49(10): 671-676. PMID 38282440
31. 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
32. 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
33. North American Spine Society (NASS). NASS coverage policy recommendations: Lumbar Artificial Disc Replacement. 2019; https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations. Accessed January 9, 2026.
34. Schroeder GD, Vaccaro AR, Divi SN, et al. 2021 Position Statement From the International Society for the Advancement of Spine Surgery on Cervical and Lumbar Disc Replacement. Int J Spine Surg. Feb 2021; 15(1): 37-46. PMID 33900955
35. 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 January 8, 2026.
36. National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NICE guideline Reference number: NG59. Published: 30 November 2016 Last updated: 11 December 2020.
37. 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 January 6, 2026.
38. 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 January 5, 2026.