Medical Policy

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Title: Artificial Intervertebral Disc: Lumbar Spine

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

Professional / Institutional
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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.

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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, 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 degenerative disc disease, lack of improvement with nonoperative treatment, and no contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (eg, laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of degenerative disc disease 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 degenerative disc disease and in part due to the success of the procedure itself. Also, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger 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 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.

Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of postmarketing studies. The activL (Aesculap Implant Systems) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. The activL device is approved for use at 1 level. Initial approval for ProDiscL was also limited to patients with disease at 1 level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels.[1,]

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Table 1. U.S. Food and Drug Administration-Approved Lumbar Artificial Disc Devices

Device	Manufacturer	Indication	PMA Number	Approval Date
activL	Aesculap Implant Systems, LLC	The activL Artificial Disc (activL) is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL Artificial Disc should have failed at least 6 months of nonoperative treatment prior to implantation of the device.	P120024	06/11/2015
ProDisc-L	Synthes Spine	The PRODISC -L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 or 2 contiguous intervertebral level(s) from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients receiving the PRODISC®-L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the PRODISC®-L Total Disc Replacement.	P050010/ S020	8/25/2006/ 4/10/2020 (supplement)
Charite	Depuy Spine, Inc	The Charite Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level from L4-S I. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. Patients receiving the Charite Artificial Disc should have failed at least 6 months of conservative treatment prior to implantation of the CHARITE Artificial Disc.	P040006	10/26/2004 Withdrawn 1/5/2012

PMA: premarket approval

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A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTIONlumbar artificial disc (DePuy Spine) is a modification of the 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.

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POLICY

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

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RATIONALE

This evidence review was created using the PubMed database. The most recent literature update was performed through February 20, 2025.

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.

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

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

Two artificial intervertebral discs are currently marketed in the U.S.: 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 2). These include back and leg visual analog scores to assess pain and the Oswestry Disability Index 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, particularly the physical function subscale of 36-Item Short Form Health Survey, are also used.

Table 2. Patient-reported Outcome Measures 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 take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the Oswestry Disability Index, 36-Item Short Form Health Survey (SF-36), or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and

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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 Oswestry Disability Index 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 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 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 Oswestry Disability Index 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.

A key feature all of these trials is the recruitment of patients specifically with degenerative disease of the intervertebral disc. Degenerative disc disease is partly a diagnosis of exclusion where the degenerated disc is believed to be the pain generator. Radiographic evidence of

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degenerative disc disease 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 3, results in Table 4, and study relevance, design, and conduct limitations are summarized in Tables 5 and 6.

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 24 months.[2,3,] 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.[4,5,6,] 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 (Oswestry Disability Index, 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).

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 trial in patients with single-level chronic symptomatic degenerative disc disease 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.[7,] All patients had degenerative disc disease 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 Oswestry Disability Index 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 Oswestry Disability Index scores and greater improvements in the SF-36 scores. A greater percentage of patients in the arthrodesis

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group required secondary surgical procedures. As noted in an accompanying commentary, the study had a number of limitations.[8,] 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 with a multidisciplinary rehabilitation program.[9,] 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, but the mean difference did not achieve the 10-point difference in Oswestry Disability Index score considered clinically significant. 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.[10,]

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 Oswestry Disability Index, 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 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 investigational device exemption trial of the activL artificial intervertebral disc were reported by Garcia et al (2015).[12,] In this patient-blinded noninferiority trial, patients with degenerative disc disease 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.

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Five-year results from this trial were reported in Yue et al (2019).[13,] 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=.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.[14,]

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 United States (Charite). 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 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)[7,]	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)[12,]	U.S.	17	2 y	Patient-blinded noninferiority trial of	activL n=218	ProDisc-L or Charité n=106

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Study	Publications	Countries	Sites	Follow-Up	Study Design and Participants	Interventions Number Analyzed	
					patients with DDD		
	Yue et al (2019)[13,]			5y	5-y follow-up (open label)	n=176	n=85
ProDisc II vs Conservative Treatment NCT00394732	Hellum et al (2011) [9,]	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)[10,]			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 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	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%)

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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
						(44.6)				
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)[7,]										
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)[12,] Yue et al (2019)[13,]										
Number analyzed			324	324						
activ-L	NR (grap	NR (graph only)	% with ≥15 point	% with ≥15 point	Improvement from	Decrease from	≥15% improve	≥15% improve	1%	5%

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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
	h only)		improvement: 75.2% Mean improvement: 67%	improvement 82.7%	baseline 74%	baseline (mm) -64	ment: 88%	ment: 87%		
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) [9,10,11]										
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%)

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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
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; 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 5 and 6 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 5. 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]
ProDiscL IDE Study Zigler et al (2007, 2012)				Outcome changed from protocol	
ProDiscL 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			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

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Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Yue et al (2019)					potential harms
ProDisc II vs conservative care Hellum et al	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 6. 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]
ProDiscL 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)		
ProDiscL 2-level Delamarter et al (2011)		1, 2. Not blinded				
ActivL IDE study Garcia et al 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		

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Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
ProDiscL vs conservative care Hellum et al				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 (see Tables 7 and 8).

Siepe et al (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution.[15,] This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review. Oswestry Disability Index and visual analog score pain scores were assessed by investigators not involved in pre- or postoperative decision making. At final follow-up, Oswestry Disability Index and visual analog score pain scores were significantly improved over baseline. Overall satisfaction rates were 89.1% 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.[16,] The authors noted the need for appropriate selection criteria.

Another case series, by Tropiano et al (2005), followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.[17,]

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Table 7. Summary of Prospective Cohort Study Characteristics

Study	Country	Participants, N (% of total treated)	Treatment Delivery	Follow-Up (Range), Years
Siepe et al (2014)[15,]	Germany	181 (90%)	ProDisc-II at 1 or 2 levels	7.4 (5.0-10.8)
Laugesen et al (2017)[16,]	Denmark	57 (84%) with DDD	ProDisc-II at 1 or 2 levels	10.6 (8.1-12.6)

DDD: degenerative disc disease.

Table 8. 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)[15,]	1 or 2 level ProDisc-II	42 (ODI)	22	<0.001	7	3.3	<0.001	• 11.9% 1 level • 27.6% 2 levels
Laugesen et al (2017)[16,]	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.

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

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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.[18,] The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center.[19,] The rationale for the recommendation was that, although artificial disc replacement has been associated with outcomes similar to fusion, the trial results were only applicable to a narrowly defined subset of patients with single-level degenerative disease, and the type of fusion surgery in the trials is no longer widely used due to frequent poor outcomes. Also, all trials had been industry-funded, and data on long-term (>2 years) benefits and harms following artificial disc replacement were limited.

National Institute for Health and Care Excellence
In 2009, the National Institute for Health and Care Excellence updated its guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine with studies reporting 13-year follow-up but with most of the "evidence from studies with shorter durations of follow-up."[20,]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.[21,] The following recommendation was made:

Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria:
1. Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
2. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
3. Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
4. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:
1. Any case that does not fulfill ALL of the above criteria
2. Presence of symptomatic degenerative disk disease at more than 1 level
3. Presence of spinal instability with spondylolisthesis greater than Grade I
4. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least 1 year)
5. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
6. Poorly managed psychiatric disorder

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7. Significant facet arthropathy at the index level
8. Age greater than 60 years or less than 18 years
9. Presence of infection or tumor
10. Age greater than 60 years or less than 18 years
11. Presence of infection or tumor

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

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in February 2025 did not identify any ongoing or unpublished trials that would likely influence this review

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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

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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

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