

FEP 7.01.87 Artificial Intervertebral Disc: Lumbar Spine

Effective Date: July 15, 2018

Related Policies:

7.01.108 Artificial Intervertebral Disc: Cervical Spine

Artificial Intervertebral Disc: Lumbar Spine

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.

FDA 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. 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), Charité® (DePuy), and ProDisc®-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at one level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. Production under the name Charité® was stopped in 2010.

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

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. The INMOTION® is not currently marketed in the United States.
- The Maverick™ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L™ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L, scheduled in 2013, but was canceled without explanation.

FDA product code: MJO.

POLICY STATEMENT

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

BENEFIT APPLICATION

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

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RATIONALE

Summary of Evidence

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes RCTs with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (2014) issued coverage recommendations for lumbar artificial disc replacement.¹⁸ The following recommendation was made:

“Lumbar artificial disc replacement (LADR) is indicated as an alternative to lumbar fusion for patients with discogenic low back pain who meet all of the following criteria from the Lumbar Fusion Recommendation:

Advanced single-level disease noted on an MRI [magnetic resonance image] and plain radiographs of the lumbar spine at L4-5 or L5-S1, characterized by moderate to severe degeneration of the disc with Modic changes (defined as a peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)

Presence of symptoms for at least one year AND that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs

Absence of active significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment

Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

Age 18 to 60 years old (unique to disc replacement, not fusion)

Absence of significant facet arthropathy at the operative level (unique to disc replacement, not fusion)”

Contraindications included multilevel degeneration, facet arthropathy, and hybrid procedures (ie, in combination with a spinal fusion or other stabilizing-type procedure).

American Pain Society

In 2009, the American Pain Society’s practice guidelines concluded there was “insufficient evidence” to adequately evaluate the long-term benefits and harms of vertebral disc replacement.¹⁹ The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center.²⁰ The rationale for the recommendation was that, although artificial disc

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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

The National Institute for Health and Care Excellence (2009) updated its guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine with studies reporting 13-year follow-up but with most of the “evidence from studies with shorter durations of follow-up.”²¹ The Institute concluded that evidence was “adequate to support the use of this procedure.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Effective for services performed on or after August 14, 2007, Centers for Medicare & Medicaid Services (CMS) found “that LADR [lumbar artificial disc replacement] is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries older than 60 years of age.” “For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to be made by the local contractors.”²²

The national coverage determination (NCD) was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charité), to noncoverage for the LADR procedure for the Medicare population older than 60 years of age.²³ CMS provided this explanation,

“The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charite™) because it was the only one with FDA [Food and Drug Administration] approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc®-L, received FDA approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture’s implant.”²⁴

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
March 2014	Update Policy	Policy updated with literature search. Several references added, others reordered or removed. Policy statement unchanged.
July 2015	Update Policy	Policy updated with literature review; references 15, 27-28, and 37 added. Policy statement unchanged.
June 2017	Update Policy	Policy updated with literature review through February 23, 2017; references 4, 16, 22, 27, 32, and 39-40 added. Discussion of artificial discs not available in the United States was removed. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through February 5, 2018; references 9 -11, and 16 added. Policy statement unchanged.

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