FEP 7.01.87 Artificial Intervertebral Disc: Lumbar Spine

Effective Date: July 15, 2017

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, 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 degenerative disc disease (DDD) at 1 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 cancelled without explanation. FDA product code: MJO.

POLICY STATEMENT

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

Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) 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. In addition, 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

International Society for the Advancement of Spine Surgery
In 2015, the International Society for the Advancement of Spine Surgery published a policy statement on the lumbar artificial disc. The goal of the statement was “to educate patients, physicians, medical providers, reviewers, adjustors, case managers, and all others involved or affected by insurance coverage decisions regarding lumbar disc replacement surgery.” Authors of the statement were selected for their expertise and experience with the artificial lumbar disc and included an investigator from the ProDisc-L IDE trial and another from the ActivL IDE trial. Randomized controlled trial and long-term results favorable to the LADR were discussed.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Effective for services performed from May 16 through August 13, 2007, the Centers for Medicare and Medicaid Services (CMS) found that LADR with the Charité lumbar artificial disc was not reasonable and necessary for the Medicare population older than 60 years of age. Therefore, CMS issued a national noncoverage determination for LADR with the Charité lumbar artificial disc for the Medicare population older than 60 years of age.

Similarly, effective for services performed on or after August 14, 2007, CMS found that LADR was not reasonable and necessary for the Medicare population older than 60 years of age; therefore, LADR is noncovered for Medicare beneficiaries older than 60 years of age. For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination (NCD), leaving such determinations to be made by the local contractors.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
The NCD was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charité), to noncoverage for the lumbar artificial disc replacement procedure for the Medicare population older than 60 years of age. CMS provided this explanation, “The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charité™) 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 manufacturer’s implant.”

REFERENCES


POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>New</td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature search. Several references added, others reordered or removed. Policy statement unchanged.</td>
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<tr>
<td>June 2017</td>
<td>Revise Policy</td>
<td>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.</td>
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