FEP 7.01.87 Artificial Intervertebral Disc: Lumbar Spine

Effective Policy Date: July 1, 2020

Original Policy Date: June 2012

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.

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.

POLICY STATEMENT

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

POLICY GUIDELINES

None
BENEFIT APPLICATION

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

FDA REGULATORY STATUS

Three artificial lumbar disc devices (activL, Charit, 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 Production under the name Charit was stopped in 2010 and the device was withdrawn in 2012.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), Charit (DePuy), and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease at 1 level. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>PMA Number</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>activL</td>
<td>Aesculap Implant Systems, LLC</td>
<td>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 six months of nonoperative treatment prior to implantation of the device.</td>
<td>P120024</td>
<td>06/11/2015</td>
</tr>
<tr>
<td>ProDisc-L</td>
<td>Synthes Spine</td>
<td>The PRODISC-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level 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.</td>
<td>P050010</td>
<td>08/25/2006</td>
</tr>
<tr>
<td>Charite</td>
<td>Depuy Spine, Inc</td>
<td>The CHARITE Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-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 3mm of spondylolisthesis at the involved level. Patients receiving the CHARITE Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the CHARITE Artificial Disc.</td>
<td>P040006</td>
<td>10/26/2004</td>
</tr>
</tbody>
</table>

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 Charit 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.

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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.

**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) of artificial discs vs fusion 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 compared to spinal fusion. 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. No RCTs compared activL to spinal fusion or conservative care. RCTs were limited by a lack of blinding, insufficient followup to evaluate potential harms, and lack of comparison to the criterion standard for treatment of degenerative disc disease. 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**

In 2019, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement. The following recommendation was made:

Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria

1. Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level

2. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs

3. Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention

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

Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:

1. Any case that does not fulfill ALL of the above criteria

2. Presence of symptomatic degenerative disk disease at more than one level

3. Presence of spinal instability with spondylolisthesis greater than Grade I

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4. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)

5. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0

6. Poorly managed psychiatric disorder

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

8. Age greater than 60 years or less than 18 years

9. Presence of infection or tumor

**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 vertebra disc replacement. The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center. 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." 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 lumbar artificial disc replacement is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, lumbar artificial disc replacement 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 lumbar artificial disc replacement, leaving such determinations to be made by the local contractors."

The national coverage determination was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charit), 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 [national coverage determination] for LADR [lumbar artificial disc replacement] 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 [national coverage determination] on LADR. After reviewing the evidence, CMS is convinced that

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indicators for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of lumbar artificial disc replacement rather than lumbar artificial disc replacement with a specific manufacture's implant.²⁵

### REFERENCES

10. 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


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL
POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
<td>Policy updated with literature search. Several references added, others reordered or removed. Policy statement unchanged.</td>
</tr>
<tr>
<td>July 2015</td>
<td>Replace 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>
</tr>
<tr>
<td>June 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2018; references 9 -11, and 16 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2019; reference 18 added with updated NASS coverage guidance. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 2, 2020; references added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

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