MEDICAL POLICY – 7.01.87

Artificial Intervertebral Disc: Lumbar Spine

BCBSA Ref. Policy: 7.01.87

Effective Date: July 1, 2017
Last Revised: June 6, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.108 Artificial Intervertebral Disc: Cervical Spine
7.01.120 Facet Arthroplasty
7.01.542 Lumbar Spinal Fusion
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

The bones of the spine are called vertebrae. Between each of vertebra is a disc, which acts as a shock absorber and prevents the bones from rubbing together. As a person ages, these often become thinner as they lose water and the gel-like substance that’s inside each disc. This is known as degenerative disc disease. Studies show that most adults over the age of forty have some level of degenerative disc disease. Often, no treatment is needed because the degeneration isn’t severe enough to cause pain in the lower back (lumbar spine). When there is pain the usual first step is to try nonsurgical treatment which often works. In cases where it doesn’t work, surgery may be considered. One type of surgery calls for placing an artificial disc between the vertebrae. The idea is to imitate how a natural disc works in the body. There is not enough medical evidence demonstrating the effectiveness of this procedure for the lower back. Artificial disc replacement in the lower back is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Artificial intervertebral discs – lumbar spine</td>
<td>Artificial intervertebral discs of the lumbar spine are considered investigational.</td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0163T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
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<td>0164T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0165T</td>
<td>Revision including replacement of total disc arthroplasty, anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
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<tr>
<td>22857</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar</td>
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<td>22862</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar</td>
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<tr>
<td>22865</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar</td>
</tr>
</tbody>
</table>

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### Related Information

Artificial intervertebral discs for treating the cervical spine are addressed in a separate medical policy (see Related Policies).
**Description**

Replacing a disc in the lumbar spine with an artificial intervertebral disc is proposed as an alternative to fusion in patients with persistent and disabling nonradicular low back pain.

**Background**

When conservative treatment of degenerative disc disease (DDD) fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years. This is 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 rate of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels. This is a particular concern for younger patients. During the past 30 years, a variety of 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 motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae.

Potential candidates for artificial disc replacement have chronic low back pain attributed to DDD, lack of improvement with nonoperative treatment, and none of the contraindications for the procedure. Contraindications include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in whom fusion is indicated. Patients who require procedures in addition to fusion, such as laminectomy and/or decompression, are not candidates for the artificial disc.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. These include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, and pseudotumor formation).
Summary of Evidence

The evidence for placing a lumbar artificial intervertebral disc in individuals who have lumbar degenerative disc disease includes randomized controlled trials with 5-year outcomes and case series with longer-term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 5-year results of the ProDisc-L randomized controlled trial provide evidence that artificial disc replacement does not result in worse outcomes than other treatments. Superiority of ProDisc-L with circumferential fusion was achieved at 2, but not 5 years in this unblinded trial. At this time, the potential benefits of the artificial disc, such as faster recovery or reduced adjacent-level disc degeneration, have not been demonstrated. In addition, considerable uncertainty remains about whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge.

Some randomized trials have concluded that this technology is noninferior to fusion, but 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
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</tr>
<tr>
<td>NCT02381574</td>
<td>French Lumbar Total Disk Replacement Observational Study (FLTDR Observational Study)</td>
<td>600</td>
<td>Dec 2020</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01704677</td>
<td>Lumbar Disc Prosthesis Versus Multidisciplinary Rehabilitation in Chronic Back Pain and Localized Degenerative Disc: Long Term Follow-up of a Randomized Multicentre Trial</td>
<td>151</td>
<td>Nov 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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 consideration of the clinical input in 2008, it was concluded that due to limitations of the only 2 available RCTs (described herein), combined with the marginal benefit compared with fusion, evidence is insufficient to determine whether artificial lumbar discs are beneficial in the short term. In addition, serious questions remain about potential long-term complications with these implants.

Practice Guidelines and Position Statements

North American Spine Society

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

“Lumbar artificial disc replacement 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 multi-level degeneration, facet arthropathy, and hybrid procedures (ie, in combination with a spinal fusion or other stabilizing-type procedure).

**International Society for the Advancement of Spine Surgery**

In 2015, the International Society for the Advancement of Spine Surgery (IASS) published a policy statement on the lumbar artificial disc.\(^19\) The goal of the policy 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.” The authors of the policy statement were selected for their expertise and experience with the artificial lumbar disc and included one of the investigators for the Prodisc-L IDE trial and another for the ActivL IDE trial. RCT and long-term results that were favorable to the LADR were discussed.

**American Pain Society**

In 2009, the American Pain Society’s (APS) practice guidelines provided a recommendation of “insufficient evidence” to adequately evaluate long-term benefits and harms of intervertebral disc replacement.\(^20\) The guideline was based on a systematic review commissioned by APS and conducted by the Oregon Evidence-Based Practice Center.\(^21\) The rationale for the recommendation was that although artificial disc replacement has been associated with similar outcomes compared with 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. In addition, all trials had been industry-funded, and data on long-term (beyond 2 years) benefits and harms following artificial disc replacement were limited.

**National Institute for Health and Clinical Excellence**

In 2009, the UK’s National Institute for Health and Clinical Excellence (NICE) updated the guidance on 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. NICE concluded that evidence appeared adequate to support the use of this procedure, provided that normal arrangements are in place for clinical governance, consent, and audit. Clinicians were encouraged to continue to collect and publish data on longer-term outcomes, including information about patient selection and the need for further surgery.

**Medicare National Coverage**

Effective for services performed on or after August 14, 2007, CMS found that LADR is 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 NCD was revised in 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 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.
Regulatory Status

While artificial intervertebral discs in the lumbar spine have been used internationally for more than 10 years, only 3 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) 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 radiographic studies.

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) IDE trial as part of the FDA process of approval and is currently being used under continued access. (Artificial intervertebral discs for treating the cervical spine are considered in a separate policy, see Related Policies.)

- Kineflex-L™ (Spinal Motion) is a 3-piece modular metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L was scheduled for July 2013, but was cancelled without explanation.

FDA product code: MJO

References


**History**

<table>
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<th>Comments</th>
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<td>08/12/03</td>
<td>Add to Surgery Section - New policy. Hold for notification, effective date December 15, 2003.</td>
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<td>Replace policy - Policy updated with February 2005 TEC Assessment; references added; policy statement unchanged.</td>
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<td>04/21/06</td>
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<td>07/11/06</td>
<td>Replace policy - Policy updated with Medicare noncoverage decision; policy statement unchanged; reference added.</td>
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<td>09/12/06</td>
<td>Replace policy - Updated Description and Benefit Application sections to include information on FDA approval of ProDisk L. No other changes.</td>
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<td>01/26/07</td>
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<td>02/12/08</td>
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<td>12/14/10</td>
<td>Replace policy - Policy updated with literature search through August 2010. References have been added and reordered; the policy statement remains unchanged.</td>
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<td>12/16/11</td>
<td>Replace policy – Policy updated with literature search through August 2011; Rationale section revised; references 11 and 14 added and references reordered; policy statement unchanged.</td>
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<td>11/27/12</td>
<td>Replace policy - Rationale section revised based on literature review through June 2012. References 12, 14,19,20,23,29 added; others renumbered. Policy statement unchanged.</td>
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<td>Coding update. CPT code 22586, effective 1/1/13, added to policy.</td>
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<td>Update Related Policies – Add 7.01.542.</td>
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<td>10/28/16</td>
<td>Coding update. Removed ICD-10 codes from coding section.</td>
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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037338 (07-2016)
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