Artificial Intervertebral Disc: Lumbar Spine

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 of 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 goal 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>
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</table>

Coding

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<td>CPT</td>
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<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>
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<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>
</tr>
<tr>
<td>22865</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar</td>
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</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

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 that leads to disabling symptoms.

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, outcomes with spinal fusion have been controversial, 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. 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 motion at the operative level once the damaged disc has been removed as well as 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 have none of the contraindications for the procedure. These 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 (e.g., laminectomy, decompression) in addition to fusion 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, such as 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

For individuals with 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. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and if long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes which 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>Ongoing</td>
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<td></td>
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<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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</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 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.

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 randomized controlled trial (described above), 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 remain about potential long-term complications with these implants.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (2014) issued coverage recommendations for lumbar artificial disc replacement. 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 multi-level 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 long-term benefits and harms of intervertebral 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 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. 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 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.”
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 (NCD), leaving such determinations to be made by the local contractors.”

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. 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

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 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 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, scheduled for July 2013, was cancelled without explanation.

FDA product code: MJO

References


<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<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>01/01/04</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.</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>02/26/07</td>
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<td>Replace policy - Title expanded for clarification with the addition of “Lumbar Spine”; cross reference added.</td>
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<td>Cross Reference Update - No other changes.</td>
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<td>02/12/08</td>
<td>Replace policy - Policy updated with literature review; no change in policy statement. References added.</td>
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<td>01/13/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Rationale section extensively revised references and codes added.</td>
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<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>
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Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building

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