MEDICAL POLICY – 7.01.87
Artificial Intervertebral Disc: Lumbar Spine

BCBSA Ref. Policy: 7.01.87
Effective Date: July 1, 2020
Last Revised: June 4, 2020
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 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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Artificial intervertebral discs – lumbar spine</strong></td>
<td><strong>Artificial intervertebral discs of the lumbar spine are considered investigational.</strong></td>
</tr>
</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<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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<tr>
<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>
</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).
Evidence Review

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.

Background

The most frequent cause of back pain requiring surgery, degenerative disc disease is common with age or trauma. Spine imaging, such as magnetic resonance imaging (MRI), computed tomography, or plain radiography, shows that lumbar disc degeneration is widespread but for most people does not cause symptoms. Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with nonoperative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (eg, laminectomy, decompression) are not candidates for the artificial disc.

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 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.

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They 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

For individuals with 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. 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 which 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.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02381574a</td>
<td>French Lumbar Total Disk Replacement Observational Study (FLTDR Observational Study)</td>
<td>600</td>
<td>Dec 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial; a Denotes industry-sponsored or cosponsored 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

In 2019, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement. 19 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:

- Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
- 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
- Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
- 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:

- Any case that does not fulfill ALL of the above criteria
- Presence of symptomatic degenerative disk disease at more than one level
- Presence of spinal instability with spondylolisthesis greater than Grade I
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)
- Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
- Poorly managed psychiatric disorder
- Significant facet arthropathy at the index level 8. Age greater than 60 years or less than 18 years
- 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 long-term benefits and harms of intervertebral 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 similar 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.”^22 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.”^23 “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.”

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.^24

**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 listed in Table 2. Production under the name Charité® 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), Charité® (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 2. 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 1 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>8/25/2006</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-S. DDD is defined as discogenic back pain with degeneration of the disc.</td>
<td>P040006</td>
<td>10/26/2004</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Indication</td>
<td>PMA Number</td>
<td>Approval Date</td>
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<tr>
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<td>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></td>
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</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 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 in 2013, was cancelled without explanation.

FDA product code: MJO

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/12/08</td>
<td>Replace policy - Policy updated with literature review; no change in policy statement. References added.</td>
</tr>
<tr>
<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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<tr>
<td>12/08/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
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<td>09/14/10</td>
<td>Cross Reference Update - No other changes.</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>01/10/13</td>
<td>Coding update. CPT code 22586, effective 1/1/13, added to policy.</td>
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<tr>
<td>04/17/13</td>
<td>Update Related Policies – Add 7.01.542.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.120.</td>
</tr>
<tr>
<td>12/09/13</td>
<td>Replace policy. Rationale section updated. Added references 8,9,11,12,13,23,31,32. No change to policy statement. CPT codes 63030 and 63035 removed from policy; these do not apply.</td>
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<tr>
<td>03/25/14</td>
<td>Replace policy. Policy updated with literature search through October, 2013. References 12, 16, 17 and 24 added; others renumbered/removed. Policy statement unchanged. ICD-9 diagnosis and ICD-10-CM codes removed from the policy; these are not utilized in adjudication.</td>
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<td>08/12/14</td>
<td>Update Related Policies. Change title to 7.01.542.</td>
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<td>01/08/15</td>
<td>Update Related Policies. Add 7.01.551.</td>
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<tr>
<td>06/09/15</td>
<td>Coding update. ICD-10-PCS codes added to support remediation efforts.</td>
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<td>08/11/15</td>
<td>Annual Review. Policy updated with literature review through November 25, 2014; references 15, 27-28, and 37 added; policy statement unchanged.</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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<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; reference 4 added. Discussion of</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.</td>
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<tr>
<td>06/01/20</td>
<td>Interim Review, approved May 12, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.</td>
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</tbody>
</table>

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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