Artificial Intervertebral Disc: Lumbar Spine

Policy Number: 7.01.87  Last Review: 6/2017
Origination: 12/2005  Next Review: 12/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for artificial intervertebral discs of the lumbar spine. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Artificial intervertebral discs of the lumbar spine are considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>With lumbar degenerative disc disease</td>
<td>▪ Lumber artificial intervertebral disc</td>
<td>▪ Conservative therapy</td>
<td>▪ Symptoms</td>
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<td></td>
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<td>▪ Lumbar spinal fusion</td>
<td>▪ Functional outcomes</td>
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</table>

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling degenerative disc disease.

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 longer term case series. 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. Superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. At this time, 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 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.

**Background**

When conservative treatment of degenerative disc disease 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, in part due to the difficulty in determining if a patient's back pain is 
related to degenerative disc disease (DDD) and in part due to the success of the 
procedure itself. In addition, spinal fusion alters the biomechanics of the back, 
potentially leading to premature disc degeneration at adjacent levels, 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 non-operative treatment, and none of 
the contraindications for the procedure, which include multilevel disease, spinal 
stenosis, or 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).

**Regulatory Status**

While a number of artificial intervertebral discs in the lumbar spine have been 
used internationally, 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), 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.

**Rationale**

This evidence review was originally created in April 2003 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through February 23, 2017. This review was informed by TEC Assessments in 2005, 2007, and 2013.(1-3) Following is a summary of key literature to date for artificial discs currently available in the United States.

**ARTIFICIAL INTERVERTEBRAL DISCS**

**Systematic Reviews**

The 2013 updated TEC Assessment evaluated 5-year follow-up from the ProDisc pivotal trial.(3) The Assessment concluded that:

- Additional study of ProDisc in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption (IDE) trial in patients with single-level chronic symptomatic degenerative disc disease (DDD) unresponsive to conservative management.
- Questions remain about the durability of the disc, in particular the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue.
- The main claim of the artificial disc—that it maintains range of motion (ROM) and thereby reduces the risk of adjacent-level segment degeneration better than fusion—remains subject to debate.

In 2017, Ding et al reported on a systematic review of 5 overlapping meta-analyses that compared total disc replacement (TDR) to fusion for DDD.(4) The primary studies for the meta-analyses were published between 2005 and 2011. The 5 meta-analyses arrived at different conclusions, but the highest quality review was determined to be a 2012 Cochrane review with an AMSTAR rating of 9.(5) Cochrane reviewers concluded that, although there were statistically
significant improvements in clinical outcomes of disability, pain relief, and quality of life with TDR for DDD in the short term, the differences were not clinically significant. In addition, prevention of adjacent segment and facet joint degeneration had not been adequately evaluated. Given the uncertainty of risks and benefits in the long-term, caution was advised. A limitation of the 2012 Cochrane review is that many of the selected studies used a Charité disc, which is no longer marketed in the United States.

Randomized Controlled Trials

**ProDisc-L**
The pivotal study for the ProDisc-L was an unblinded noninferiority trial that originally followed 242 patients for 24 months.(6,7) Patients were randomized in a 2:1 ratio to ProDisc-L artificial disc replacement (n=161) or circumferential fusion (n=75). Using a composite outcome measure, requested by the Food and Drug Administration (FDA), which incorporated symptom improvement and absence of complications, the ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%. This met prespecified criteria for a noninferiority margin of 10% and was statistically significant for a 1-sided statistical test of superiority (p=0.044).

Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012.(8-10) Of the 236 patients randomized, 186 (79%; 134 ProDisc-L, 52 controls) were included in the 5-year follow-up of clinical outcomes and 166 (70%; 123 ProDisc-L, 43 controls) were included for radiographic outcomes. Results showed noninferiority but not superiority of artificial disc replacement, with 53.7% of ProDisc-L patients and 50.0% of fusion patients achieving overall success at 5 years. This change in overall success in ProDisc-L patients between 2 years (63.5%) and 5 years (53.7%) indicates a possible decrement in response over time with the artificial disc. This decline in response rate was not observed in the standard fusion group, and resulted in between-group convergence of the primary outcome measure over time. Several individual components of the primary outcome measure and secondary outcome measures (Oswestry Disability Index [ODI], 36-Item Short-Form Health Survey [SF-36] Physical Component Summary [PCS], neurologic success, device success) were also statistically better in the ProDisc-L group than in the fusion group at 2 years, but not at 5 years. Post hoc analysis of radiographs found fewer patients with adjacent-level degeneration in the ProDisc-L group (9.2%) than in the control group (28.6%), however, adjacent-level reoperations did not differ significantly between groups (1.9% ProDisc-L vs 4% controls).

The ProDisc-L for 2-level lumbar DDD was reported in 2011 from a multicenter, randomized, FDA-regulated noninferiority trial.(11) All patients had DDD at 2 contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of 6 months of conservative therapy, and a minimum ODI score of 40. A total of 237 patients were treated in a 2:1 ratio with total disc arthroplasty or open circumferential arthrodesis (performed using both anterior and posterior open incisions). The TDR group had faster surgeries (160.2 minutes vs 272.8 minutes),
less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital lengths of stay (3.8 days vs 5.0 days) than the arthrodesis group. At 24 months, 58.8% patients in the ProDisc-L group and 47.8% patients in the arthrodesis group achieved the trial criteria for success, demonstrating noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in the percentage of patients who achieved at least a 15-point improvement in ODI scores (73.2% vs 59.7%) and greater improvement in the SF-36 PCS scores (43.9 vs 39.2), both respectively. A greater percentage of patients in the arthrodesis group required secondary surgical procedures (8.3% vs 2.4%). As noted in an accompanying commentary, the study had a number of limitations. Comparison with a procedure (open 360° fusion) that is not the criterion standard precludes decisions on the comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of patients and providers.(12)

**activL vs ProDisc-L or Charité**

Two-year outcomes from the multicenter IDE trial of the activL artificial intervertebral disc were reported by Garcia et al in 2015.(13) In this patient-blinded noninferiority trial, patients with DDD at L4-L5 or L5-S1 were randomized to treatment with activL (n=218) or to an FDA-approved disc (n=106; ProDisc-L or Charité). Based on the primary composite end point (15-point improvement in ODI scores, neurologic status, ROM, freedom from additional surgery, and freedom from serious device-related adverse events), activL was both noninferior (p<0.001) and superior (p=0.02) to the control group. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls. ROM at the index level, measured by an independent core radiographic laboratory, was higher in the activL group (59%) than in the ProDisc-L and Charité controls (43%; p<0.01).

**Observational Studies**

Five-year results of lumbar disc arthroplasty from the SWISSspine Registry were published in 2014.(14) Five devices were used during the period of study (ActivL, Charité, Dynardi, Maverick, ProDisc-L). Of 248 patients eligible for the 5-year study, follow-up was obtained from 77% at 1 year, 44% at 2 years, and 51.2% at 5 years. In the 127 patients followed through 5 years, there was a significant reduction of visual analog scale (VAS) scores for back pain (73 to 29) and leg pain (55 to 22). The presence of radiculopathy did not appear to have been an exclusion for disc arthroplasty at these institutions. The overall complication rate at 5 years was 23.4%, which included a new radiculopathy in 10.5% of patients; the rate of adjacent-segment degeneration was 10.7%, and 43.9% of patients had osteophytes that might have affected ROM. The cumulative probability of device survivorship at 5 years was 90.4%.

Siepe et al (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution.(15) This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review. Disc replacement was performed to treat predominantly axial low back pain (≥80%). Radiculopathy was a contraindication, and all patients underwent
fluoroscopically guided infiltrations of the facet and sacroiliac joints to rule out non-discogenic pain sources. Baseline ODI and VAS pain scores, assessed by investigators not involved in pre- or postoperative decision making, were 42 and 7, respectively. After a mean of 7.4 years (range, 5.0-10.8 years), VAS pain scores remained significantly improved over baseline (mean, 3.3; p<0.000). ODI scores remained stable throughout follow-up, with a final score of 22 (p<0.001). The complication rate for single-level disc replacement was 11.9% compared with 27.6% for bisegmental disc replacement (p=0.031). Overall satisfaction rates were 89.1% for single-level and 69.0% for 2-level disc replacement.

Another case series (2005) identified followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.(16) Additional studies (2007) have reported on the implantation of artificial discs at 2 levels in the lumbar spine.(17)

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 longer-term case series. 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. 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 (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 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

CLINICAL INPUT 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 considering the clinical input in 2008, it was concluded that, due to limitations of the available randomized controlled trials (described herein), combined with the marginal benefit compared with fusion, evidence was insufficient to determine whether artificial lumbar discs are beneficial in the short term. In addition, serious questions remained about potential long-term complications with these implants.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**North American Spine Society**
In 2014, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement.(18) 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 multilevel 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 published a policy statement on the lumbar artificial disc.(19) 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.

**American Pain Society**
In 2009, the American Pain Society’s (APS) practice guidelines concluded there was “insufficient evidence” to adequately evaluate the long-term benefits and harms of vertebral disc replacement. The guidelines were based on a systematic review commissioned by APS 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. In addition, 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, U.K.’s National Institute for Health and Care Excellence (NICE) 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.” NICE concluded that evidence was “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, which should include information about patient selection and the need for further surgery.”

**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 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.(24) CMS provided this explanation,

“The original NCD for LADR 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 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 manufacture’s implant.”(25)

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

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<th>NCT No.</th>
<th>Trial Name</th>
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<tr>
<td>NCT02381574</td>
<td>French Lumbar Total Disk Replacement Observational Study (FLTDR Observational Study)</td>
<td>600</td>
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<td><strong>Unpublished</strong></td>
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<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>
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</table>

NCT: national clinical trial.

References:
8. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc


Bill Coding/Physician Documentation Information

22857  Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar

22862  Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

22865  Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

0163T  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)

0164T  Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

0165T  Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

ICD-10 Codes

M51.05-M51.9  Thoracolumbar, and lumbosacral intervertebral disc disorders code range (except codes that end in “4” which are thoracic)

Effective January 1, 2007, CPT category I codes became available that are specific to total disc arthroplasty when performed at a single lumbar spine interspace. The language of the codes was revised for 2009, and the codes now appear as below:

22857  Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar

22862  Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

22865  Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

When more than 1 interspace is involved, the following CPT category III add-on codes would be used:

0163T  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)

0164T  Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T Revision including replacement of total disc arthroplasty, anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.