Artificial Intervertebral Disc: Lumbar Spine

Policy # 00145
Original Effective Date: 01/31/2005
Current Effective Date: 05/17/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Artificial Intervertebral Disc: Cervical Spine is addressed in medical policy number 00229.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers artificial intervertebral discs of the lumbar spine to be investigational.*

Background/Overview
Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with degenerative disc disease (DDD) leading to disabling symptoms.

When conservative treatment of 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, 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. In addition, 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 and 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 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).

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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Three artificial lumbar disc devices (activL®, Charité®, ProDisc®-L)† have been approved by the 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 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.

FDA product code: MJO.

Centers for Medicare and Medicaid Services (CMS)
Effective for services performed from May 16 through August 13, 2007, the CMS found that lumbar artificial disc replacement (LADR) with the Charité lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, CMS issued a national non-coverage determination for LADR with the Charité lumbar artificial disc for the Medicare population over 60 years of age.

Effective for services performed on or after August 14, 2007, CMS found that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 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 was revised in 2007 to reflect a change from non-coverage for a specific implant (the Charité), to non-coverage 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 (Charite) 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 manufacture’s implant.”
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Rationale/Source
This policy has been periodically updated using 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. 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. 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 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. 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.

ProDisc-L
Randomized Controlled Trials (RCTs)
The pivotal study for the ProDisc-L was a randomized unblinded clinical trial of 242 patients followed up for 24 months. Patients were originally randomized in a 2:1 ratio to ProDisc-L artificial disc replacement (n=161) or circumferential fusion (n=75). Using an FDA-requested composite measure of outcome that 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 pre-specified 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. 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 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. 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.

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. 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. 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
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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. 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. Additional studies (2007) have reported on the implantation of artificial discs at 2 levels in the lumbar spine.

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>
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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<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>
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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 spinal 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.

Clinical Input Received through 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.

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Policy History

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12/07/2004 Medical Director review
12/21/2004 Medical Policy Committee review
01/31/2005 Managed Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. Format revision. No change to policy statement.
01/01/2007 Medical Director review
01/17/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
02/13/2008 Medical Director review
02/20/2008 Medical Policy Committee approval
02/04/2009 Medical Director review
02/19/2009 Medical Policy Committee approval. No change to coverage.
02/04/2010 Medical Director review
02/17/2010 Medical Policy Committee approval. No change to coverage.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. No change to coverage.

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01/03/2013 Medical Policy Committee review
01/09/2013 Medical Policy Implementation Committee approval. No change to coverage.
01/09/2014 Medical Policy Committee review
01/15/2014 Medical Policy Implementation Committee approval. No change to coverage.
04/02/2015 Medical Policy Committee review
04/20/2015 Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016 Medical Policy Committee review
04/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017 Medical Policy Committee review
05/17/2017 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 05/2018

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
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B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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