BlueCross BlueShield of Louisiana

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Artificial Intervertebral Disc: Lumbar Spine

Policy # 00145
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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 persistent and disabling nonradicular low back pain.

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, 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 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).

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
While artificial intervertebral discs in the lumbar spine have been used internationally for more than 10 years, only 2 devices (Charité®‡ and ProDisc®‡-L) have received approval from FDA. Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of postmarketing studies. The Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level; Charité is approved for use in levels L4-S1, and the ProDisc-L is approved for use in levels L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The INMOTION®‡ lumbar artificial disc (DePuy Spine) is a modification of the Charité device with a change in name under the same premarket approval. Production under the name Charité was stopped in 2010. 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. Other devices are currently under investigation in the United States as part of the FDA process of approval, including the FlexiCore®‡ (Stryker Spine), and Activ-L™‡ (Aesculap) devices. 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.

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 Charite 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, 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 [national coverage determination] 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 review of this policy was performed through October 14, 2013. Following is a summary of key literature to date.

In February 2005, Technology Evaluation Center (TEC) completed an assessment of artificial disc replacement, focusing on the Charité lumbar disc device. Only 1 completed randomized controlled trial (RCT) had evaluated the Charité artificial disc compared with the BAK fusion cage for the treatment of single-level DDD. The ProDisc, FlexiCore, and Maverick devices were also undergoing investigation in similarly designed randomized trials. The 2005 TEC Assessment concluded that, compared with fusion or other treatments, evidence supporting the effectiveness of artificial vertebral discs in terms of pain relief and restoration of function among patients with chronic discogenic low back pain was insufficient. In August 2006 the ProDisc-L was approved by the U.S. FDA. An updated TEC Assessment in February 2007 reviewed the evidence on artificial lumbar disc replacement devices. The Assessment concluded that given what is known about fusion as a comparator treatment, neither of the noninferiority trials provided convincing evidence of efficacy. TEC concluded that the evidence supporting the effectiveness of the ProDisc-L and Charité artificial disc was limited and that there was no immediately discernible advantage to use of the artificial disc. In 2010, 2 systematic reviews concluded that high-quality RCTs with a relevant control group and long-term follow-up are needed to evaluate the effectiveness and safety of artificial lumbar disc replacement.

In 2012, a systematic review by Wang et al evaluated the risk of adjacent segment disease (ASD) with disc replacement versus fusion. Analysis of data from 2 randomized trials found a pooled risk of ASD treated surgically to be 1.2% following lumbar disc replacement and 7.0% following fusion. The number needed to harm was calculated to be 17. In one of the studies included in this systematic review, ASD was marginally reported, and the number of any reoperations did not differ between disc replacement and fusion. Limitations of the second trial are described next. A 2012 Cochrane review of 7 studies concluded that while differences between disc replacement and fusion were statistically significant, they did not achieve clinically important differences for short-term pain relief, disability, or quality of life. Concerns included the highly selected population, the lack of proper assessment of the primary goal of prevention of adjacent-level disease and facet joint degeneration, and the potential for harm in the long term.

An updated TEC Assessment in 2013 evaluated the 5-year follow-up from the pivotal trial of the ProDisc. 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 and thereby reduces the risk of adjacent-level segment degeneration better than fusion—remains subject to debate.

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Charité (INMOTION)
The Charité device is no longer marketed under that name. The INMOTION artificial disc is a renamed and slightly modified version of the Charité. It is not currently marketed in the United States.

Controlled Trials
The pivotal study for the Charité device consisted of a RCT comparing the artificial intervertebral disc to spinal fusion using a threaded fusion cage with autologous bone graft. Patients were randomly assigned in a 2:1 fashion, with 205 receiving the artificial disc and 99 undergoing fusion. In this trial's analysis of 267 patients followed up for up to 24 months, the Charité artificial disc had a success rate of 63% compared to a success rate of 53% for BAK [Bagby and Kuslich] fusion, using a composite measure of outcomes that incorporated improvement of symptoms and absence of complications. The analysis showed noninferiority compared to BAK fusion using the composite measure of success but did not show statistically significant superiority in most outcome measures. The point estimate of 63% success did not show the artificial disc to be a highly successful treatment. In addition, the long-term effectiveness and health outcomes for artificial vertebral discs were uncertain.

In 2009, Guyer and colleagues reported 5-year follow-up of a subset of the patient cohort that had participated in the investigational device exemption (IDE) trial of the Charité artificial disc (described above). Of the initial 14 sites, 6 declined participation in the 5-year continuation study, and an additional 8 patients were excluded from analysis, leaving 233 patients from the original randomized study. There were 133 cases included in the 5-year assessment (57% from the 8 sites). Based on a denominator of 375 patients originally enrolled in the IDE trial, this report represents 30% of the study population. Given the limitations of the original RCT and the 50% to 70% loss to follow-up, results from the 5-year follow-up cannot be interpreted.

Observational Studies
Mean 17.3 year (range, 14.5-19.2 years) follow-up was reported for Charité types I – III intervertebral discs from the Charité hospital. For the 53 of 71 patients (75%) who were available for clinical and radiologic examination, there were 16 type I discs (1984-1985), 25 type II discs (1985-1987), and 22 type III discs (1987-1989). The type III prosthesis is the model that is currently available. Clinical evaluation at follow-up showed no significant difference between the 3 types of discs for the Oswestry disability index (ODI), visual analog scale (VAS) for pain, or overall outcome score. Out of the 53 patients, 12 (23%) had a segmental fusion during follow-up due to implant failure or pain. Seven of the 12 (58%) were due to implant fractures, and 5 underwent secondary operative instrumented spondylodesis. Out of the remaining 41 patients, 9 (17% of 53) showed no signs of heterotopic ossification or ankylosis at follow-up while ankylosis was observed in 32 patients (60%) after 17 years. No signs of adjacent segment degeneration were found in the 9 cases (17%) without signs of ankylosis, spondylodesis, or implant failure. Although no adjacent segment degeneration was observed in the small percentage of implants that remained functional (17%), these patients were significantly less satisfied than those with spontaneous ankylosis based on the ODI (52 vs. 38) and VAS (6.1 vs. 4.5). The authors, who had designed the prosthesis, concluded that this study demonstrated dissatisfying results after artificial disc replacement in the majority of the evaluated cases regarding clinical, as well as radiologic outcomes.

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Scott-Young et al. reported average 45-month follow-up (range 2 to 10 years) from a consecutive series of 122 patients who received a single-level Charité disc. VAS back scores decreased from 78.2 preoperatively to 21.9 at final follow-up. ODI scores decreased from 51.1 to 16.2, and Roland-Morris Questionnaire scores decreased from 16.7 to 4.2. Short Form-36 (SF-36) physical component scores increased from 25.7 to 46.4, and SF-36 mental component scores increased from 35.5 to 51.6. In this prospective study, 91% of patients rated their satisfaction with the surgery as "excellent" or "good" at 2 years. There were 4 (3.3%) complications that required revision with fusion. Heterotopic bone formation was reported in 6 cases (4.9%). This series is limited by loss to follow-up, with outcomes reported from 70 patients (57%) at 2 years, 18 patients (15%) at 5 years, and 3 patients (2%) at 7 years.

Long-term follow-up in a larger number of patients is needed to answer questions regarding the potential for device failure, decay, wear, and facet degeneration.

Kineflex-L Versus Charité
The pivotal study for the Kineflex artificial disc was a RCT that compared the Kineflex-L with an artificial disc (Charité) that was already approved for sale. There were 261 patients in the Kineflex group and 196 patients in the Charité group. The primary outcome measure for the published study was a composite success measure at 24 months of at least 15-point improvement in ODI score, no subsequent operative intervention related to the device, and no major adverse events. Twenty-four-month follow-up was obtained in 94.8% of the Kineflex-L group and 91.3% of the Charité group. There were no significant differences between the Kineflex-L and Charité groups for overall success (76.5% vs 74.7%, respectively) or in the individual components of success. Reoperations were performed in 10.3% of the Kineflex-L group and 8.4% of the Charité group. In the Kineflex group, the 11 reoperations were due to lymphocytic reaction (n=2), device migration (n=2), and supplemental fixation implantations (n=5). In 2011, the authors of this study had published a report of early failure of metal-on-metal disc prostheses in 4 patients due to a lymphocytic reaction, similar to that observed in metal-on-metal hip implants.16 An FDA advisory committee meeting on the Kineflex lumbar disc was scheduled for July 2013 but was cancelled without explanation.

ProDisc-L
Controlled Trials
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 just achieved statistical significance for a one-sided statistical test of superiority with a p=0.0438. The calculations were based on between 88% and 91% of randomized patients—how or which patients were censored was not described. Twenty-four month results from this trial were published in 2007, and 5-year follow-up was reported in 2012. The published 24-month report included 236 patients but did not provide information about the number of patients lost to follow-up. The report included alternative definitions of overall success, which resulted in a greater difference between the two groups (experimental group 63.5%, control group 45.1%, p=0.005). Of an original 236 patients randomized, 186 (79%) were included in the 5-year follow-up of clinical outcomes (134 ProDisc-L, 52 controls) and 166 (70%) (123 ProDisc-L and 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 and 5 years (63.5%-53.7%, respectively) indicate a possible decrement in response over time with the artificial disc. This decrement in response rate was not observed in the standard fusion group and resulted in convergence of the primary outcome measures between groups over time. On post hoc analysis of radiographs, adjacent level degeneration was observed in fewer ProDisc-L patients (9.2% vs 28.6%, respectively). Adjacent level reoperations were not significantly different (1.9% ProDisc-L, 4% controls). There were 6 (3.7%) ProDisc-L device failures.

Several of the individual components of the primary outcome measure were also statistically better in the ProDisc-L group at 2 years, but were no longer significantly different at 5 years. For example, at 5 years ODI scores improved by 15% or more in 78.6% of ProDisc-L patients compared to 76.5% of controls. A similar percentage of patients maintained or improved SF-36 physical component scores compared with baseline (81.3% ProDisc-L and 74.0% fusion), and overall neurologic success was obtained in 88.8% of ProDisc-L patients and 89.6% of fusion patients. Secondary surgeries at the index level occurred in 8% of ProDisc-L patients and 12% of fusion patients (p value not reported). Device success, defined as the absence of any reoperation required to modify or remove implants and no need for supplemental fixation, was achieved in 93.3% of ProDisc-L patients and 93.2% of fusion patients. Analysis of VAS for pain excluded patients who had secondary surgical interventions (11 ProDisc-L and 5 fusion). For the ProDisc-L group, VAS improved from a mean of 75.9 at baseline to 37.1 at 5 years. Mean VAS for the fusion group improved from 74.9 at baseline to 40.0 at 5 years. There was no significant difference in VAS between the groups. Narcotic use decreased from a baseline of 84% to 44.6% of ProDisc-L patients and from 76% to 42.5% of fusion patients.

The ProDisc-L for 2-level lumbar degenerative disease was reported in 2011 from a multicenter randomized FDA-regulated non-inferiority trial. All patients in the study 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 equal to or greater than 40. A total of 237 patients were treated in a 2:1 ratio with total disc arthroplasty or open circumferential arthrodesis (performed through both anterior and posterior open incisions). Postoperative evaluations were performed at 6 weeks and at 3, 6, 12, 18, and 24 months postoperatively. The total disc replacement group had decreased operative times (160.2 vs. 272.8 min), estimated blood loss (398.1 vs. 569.3 mL), and length of hospital stay (3.8 vs. 5.0 days). At 24 months, 58.8% patients in the ProDisc-L group and 47.8% patients in the arthrodesis group achieved the criteria for success, demonstrating non-inferiority but not superiority. The ProDisc-L group showed significant benefit in percentage improvement in the ODI (52.4% vs. 40.9%), a greater percentage of patients who achieved equal to or greater than 15-point improvement in the ODI (73.2% vs. 59.7%), the SF-36 physical component score (43.9 vs. 39.2), and 6-month neurologic success (87.3% vs. 71.6%). A greater percentage of patients in the arthrodesis group required secondary surgical procedures (8.3% vs. 2.4%). As noted in an accompanying commentary, there are a number of limitations to this study. Comparison with a procedure (open 360-degree fusion) that is not the gold 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 both patients and providers.

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Maverick
The Maverick disc is not marketed in the United States.

In 2011, Gornet et al. reported 24-month results from a FDA-regulated multicenter IDE randomized non-blinded trial of the metal-on-metal Maverick artificial disc. A total of 577 patients were randomized in a 2:1 ratio to the Maverick disc (n=405) or to anterior interbody fusion with INFUSE Bone Graft and tapered fusion cages (n=172). All patients underwent a single-level, open anterior surgical procedure between the L4 and S1 level. The Maverick group had longer surgical times (1.8 vs. 1.4 hours) and greater blood loss (240.7 mL vs. 95.2 mL). Hospitalization stays were similar for both groups (2.2 vs. 2.3 days for fusion). At 24 months, radiographic fusion was observed in 100% of the control patients. Heterotopic ossification was observed in 2.6% of patients with the artificial disc.

The FDA-defined measure of overall success was a combination of a successful outcome in ODI, neurologic status, disc height, no additional surgery classified as failure, and no serious device or device/surgical procedure-related adverse events at the 24-month follow-up. Patients who received the Maverick artificial disc had superior outcomes in overall success (73.5% vs. 55.3%) and in the component scores of ODI success (82.2% vs. 74.6% improved), back pain (improvement of 53.4 points vs. 49 points), and SF-36 Physical Component Summary score (17.0 vs. 14.3). Leg pain scores did not differ between the 2 groups. Global perceived effect (“completely recovered” or “much improved”) was higher in the Maverick group (78.1% vs. 67.4%). The Maverick group had fewer implant or surgical procedure-related adverse events (1% vs. 7%), and return-to-work intervals were reduced (median of 75 vs. 96 days). The percentage of patients who were working at 24 months was similar (74.1% vs. 73.4%). There were 2 implant removals in the Maverick group, one was considered to be related to an allergic reaction. Longer follow-up with this 2-piece metal-on-metal implant is needed, particularly in light of emerging complications (e.g., pseudotumor formation) with metal-on-metal hip implants.

FlexiCore
Preliminary results on the FlexiCore metal-on-metal intervertebral disc were presented from 2 of the sites involved in the investigational device trial in 2008. Results were reported for 76 patients enrolled at the 2 sites (out of the entire study cohort of 401 patients) who had been randomly assigned with a ratio of 2:1 to either FlexiCore or fusion control; 9 subjects did not receive the index surgery, 44 patients were treated with the artificial disc, and 23 patients were treated with fusion. Compared with fusion, placement of the artificial disc was associated with less blood loss (97 mL vs. 179 mL, respectively), reduced operating time (82 min vs. 179 min, respectively), and reduced length of hospital stay (2 vs. 3 days, respectively). Oswestry disability index and VAS pain scores were not significantly different between the groups. At 24 months, the Oswestry scores had decreased from 62 to 6 in the Flexicore group and from 58 to 12 in the fusion group. VAS scores decreased from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group had complications requiring interventional surgery.

Other
In 2009, Berg et al. published an RCT of 1- and 2- level total disc replacement. Patients (n=152) with symptomatic DDD in 1 or 2 motion segments between L3 and S1, with lower back pain as a predominant symptom, were randomly assigned to 1 of 3 total disc replacement devices available in Sweden (Charité,

Prodisc, or Maverick, n=80) or to instrumented fusion (posterolateral or posterior lumbar interbody fusion, n=72). The randomization was stratified for number of levels, with 56% of total disc replacement patients having 1-level surgery compared to 46% of fusion patients. Only patients who did not have a preference to the type of treatment were enrolled in the trial, and they were informed of the result of randomization upon arrival at the hospital for surgery. No patient left the study when informed of the randomization, and there was 100% follow-up at the 1- and 2-year assessments, and 99.3% follow-up at the 5-year assessment. The primary outcome, which does not appear to be a validated measure, was a global assessment of back pain consisting of "total relief", "much better", "better", "unchanged", or worse. The percentage of patients in the disc replacement group who reported being pain-free was 30% at the 1- and 2-year follow-up, and 38% at 5-year follow-up. In the fusion group, 10% reported being pain-free at 1 year and 15% reported being pain-free at 2 and 5 years. At 5 years, a similar percentage of patients reported being either totally pain free or much better (72.5% for disc replacement, 66.7% for fusion). The total disc replacement group showed lower mean VAS for pain at 1 and 2 years (25.4 vs 29.2, respectively) and had better outcome scores on a quality-of-life scale and ODI at 1 year (19.5 vs 24.9, respectively) but not the 2-year follow-up (20.0 vs 23.0, respectively). At 5 years, the disc replacement group had modestly improved outcome scores for both VAS back pain (23 vs 31) and ODI (17 vs 23). The most common cause of reoperation in the disc replacement group was to fuse the index level that was believed to cause persistent or recurrent pain (5%). The most common cause of reoperation in the fusion group was operation at an adjacent level (7%). Twenty-two disc replacement patients underwent postoperative facet block due to remaining pain. Twenty fusion patients had their instrumentation removed due to persistent or recurrent pain. The investigators found no association between achievement of surgical goals (absence of mobility with fusion and maintenance of mobility with disc replacement) and clinical outcomes at 2 years.

The design of a U.S. multicenter clinical trial to evaluate the safety and effectiveness of the Aesculap Activ-L artificial disc has also been reported. The study is a single-blinded, randomized non-inferiority trial comparing Activ-L with a control artificial lumbar disc (Charité or ProDisc-L) for single-level degenerative disc disease of the lumbar spine. Following surgeon training with an initial 90 patients, it is expected that 324 patients will be randomly assigned in a 2:1 ratio. The patients will be followed for 5 years post-treatment.

Longer Term Follow-Up

Siepe et al in 2014 reported 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 study. Disc replacement was performed for the treatment of predominant (≥80%) axial low back pain. Radiculopathy was a contraindication, and all patients underwent fluoroscopically guided infiltrations of the facet and sacroiliac joints to rule out nondiscogenic pain sources. Baseline ODI and VAS pain scores, assessed by investigators who were not involved in pre- or postoperative decision making, were approximately 42 and 7.1, 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, $p<0.000$), although a slight deterioration (0.66 on a scale of 10) was observed between 48 and 120 months ($p<0.05$). ODI scores remained stable throughout follow-up, with a final score of approximately 22 ($p<0.001$). The complication rate for single-level disc replacement was 11.9% compared with 27.6% for bisegmental disc replacement ($p=0.031$). The overall satisfaction rate was 89.1% for single-level and 69.0% for 2-level disc replacement.

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Five-year results of lumbar disc arthroplasty from the Swiss Spine Registry were published in 2014. Five devices were used during the period of study (Activ L, Charité, Dynardi, Maverick, ProDisc-L). Of 248 patients who were eligible for the 5-year study, follow-up was obtained from 77% of patients at 1 year, 44% at 2 years, and 51.2% at 5 years. In the 127 patients with follow-up through 5 years, there was a significant reduction of VAS back pain (73 to 29) and leg pain (55 to 22). Note that the presence of radiculopathy does 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 could potentially affect the range of motion. The cumulative probability of survivorship at 5 years was calculated to be 90.4%. Another case series was identified that followed up 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients report an excellent result. Additional publications report on the implantation of artificial discs at 2 levels in the lumbar spine.

Adverse Events
Complications with artificial lumbar discs are emerging with longer-term follow-up. One study from Asia reported that clinical outcomes of both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients, regardless of the device used. Another study reported that progression of facet degeneration (29% of levels replaced with the ProDisc II) was associated with female gender, malposition of the prosthesis on the frontal plane, and 2-level total disc replacement. Analysis of postoperative pain patterns in 58 patients of 175 (33%) implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%). Another report describes late complications in 75 patients who had received an earlier generation SB Charité prosthesis. As all of the patients had been originally treated by other surgeons, the percentage of implant failure cannot be determined from this report. The mean interval between insertion and retrieval of the prosthesis was 8 years and 11 months (range of 3–16 years). The most frequent complications included subsidence (n=39), disc prosthesis too small (n=24), adjacent disc degeneration (n=36), degenerative scoliosis (n=11), facet joint degeneration (n=25), and metal wire breakage (n=10). The report indicated that good placement and good sizing of the disc prosthesis appeared problematic for many of the patients, adjacent disc degeneration was seen in many patients, and polyethylene wear with inflammatory fibrous tissue containing wear debris was observed. The report concluded that wear mechanisms of artificial discs may be similar to artificial hips and knees and that, due to nearby vascular structures and scar tissue from the original surgery, retrieval of an artificial disc prosthesis can be difficult and dangerous. Therefore, long-term health outcomes following disc implantation in young active patients may become a clinically significant issue.

In 2011, Guyer et al reported 4 cases of a lymphocytic reaction to a metal-on-metal artificial disc (1 Kineflex-C cervical disc, 2 Kineflex-L lumbar discs, 1 Maverick lumbar disc) that required revision. The mode of failure was determined to be compression of neural tissue or other adjacent structures by a soft-tissue mass. Three patients had a good outcome after the explantation and revision surgery; 1 patient continued to have residual symptoms related to the neural compression caused by the mass. Two other cases of a granulomatous mass (pseudotumor) with the metal-on-metal Maverick prosthesis have been reported. One caused iliac vein occlusion and spinal stenosis; the second resulted in spinal compression and paraplegia.

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

Summary
Overall, the available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on the net health outcome. The Charité has been withdrawn from the market and its successor, the INMOTION, is not marketed in the United States.The 5-year results of the ProDisc-L randomized controlled trial provide evidence for the non-inferiority of artificial disc replacement. Superiority of ProDisc-L to 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, as well as the potential for long-term complications with these implants.

Evidence is insufficient to determine whether artificial lumber discs improve outcomes in the short term, and questions remain about potential long-term complications with these implants. While some randomized trials have concluded that this technology is non-inferior to fusion, the potential benefits of artificial lumbar disc that would make non-inferiority sufficient to demonstrate clinical benefit have not been established. Therefore, artificial intervertebral discs for the lumbar spine are considered investigational.

References

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Policy History

Original Effective Date: 01/31/2005
Current Effective Date: 04/20/2016

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

Artificial Intervertebral Disc: Lumbar Spine

Policy # 00145
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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.
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

Next Scheduled Review Date: 04/2017

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2015 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Code Type	Code
CPT	0163T, 0164T, 0165T, 22857, 22862, 22865
HCPCS	No codes
ICD-10 Diagnosis	M46.46 M46.47 M51.06 M51.26 M51.27 M51.34 M51.35 M51.36 M51.37 M51.46 M51.47 M51.86 M51.87 M51.9 M96.1

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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
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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