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.

Related Policies
- Artificial Intervertebral Disc: Cervical Spine

Policy
Based on the lack of long term efficacy and safety in comparison to standard spinal fusion techniques, artificial intervertebral discs of the lumbar spine are considered investigational.

Policy Guidelines
There are CPT category I codes specific to total disc arthroplasty when performed at a single lumbar spine interspace.

- **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 one interspace is involved, the following CPT category III 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)

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Rationale

### Background

When conservative treatment of degenerative disc disease (DDD) fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, 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 nonoperative 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 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 the U.S. Food and Drug Administration (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 degenerative disc disease (DDD) at one 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 U.S. The Maverick™ artificial disc (Medtronic) is not marketed in the U.S. due to patent infringement litigation. Other devices are currently under investigation in the U.S. as part of the U.S. Food and Drug Administration process of approval, including the FlexiCore® (Stryker Spine), and Activ-L™ (Aesculap) devices. (Artificial intervertebral discs for treating the cervical spine are considered separately in Blue Shield of California Medical Policy: Artificial Intervertebral Disc: Cervical Spine.

Literature Review

In February 2005, TEC completed an assessment of artificial disc replacement, focusing on the Charité lumbar disc device.(1) Only 1 completed randomized controlled trial (RCT) had evaluated the Charité artificial disc compared to the BAK fusion cage for the treatment of single-level degenerative disc disease (DDD).(2) 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 FDA.(3,4) An updated TEC Assessment in February 2007 reviewed the evidence on artificial lumbar disc replacement devices.(5) 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.(6,7)

In 2012, a systematic review by Wang et al evaluated the risk of adjacent segment disease (ASD) with disc replacement versus fusion.(8) Analysis of data from 2 randomized trials(9,10) 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(9) 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(10) are described below. 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.(11) 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. (12) 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.

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 U.S.

Controlled Trials. The pivotal study for the Charité device consisted of an RCT comparing the artificial intervertebral disc with spinal fusion using a threaded fusion cage with autologous bone graft. (2) 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 with a success rate of 53% for BAK (Bagby and Kuslich [BAK]) 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 et al reported 5-year follow-up of a subset of the patient cohort that had participated in the IDE trial of the Charité artificial disc (described above). (10) 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) follow-up was reported for Charité types I-III intervertebral discs from the Charité hospital. (13) 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). 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. 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. 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.

Scott-Young et al reported average 45-month follow-up (range, 2-10 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 Disability Questionnaire scores decreased from 16.7 to 4.2. Short Form-36 (SF-36) Physical Component Summary scores increased from 25.7 to 46.4, and SF-36 Mental Component Summary 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.

**ProDisc-L**

**Controlled Trials.** The pivotal study for the ProDisc-L was an unblinded RCT 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 prespecified criteria for a noninferiority margin of 10% and just achieved statistical significance for a 1-sided statistical test of superiority with a p of 0.044. The calculations were based on between 88% and 91% of randomized patients—how or which patients were censored was not described. Two-year 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 and 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 and 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 96.3% of ProDisc-L patients and 97.3% of fusion patients. Analysis of VAS scores 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% in ProDisc-L patients and from 76% to 42.5% in fusion patients.

The ProDisc-L for 2-level lumbar degenerative disease was reported in 2011 from a multicenter randomized FDA-regulated noninferiority trial.(18) 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 noninferiority 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 Summary 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° 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.(19)

Observational Studies: One 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.(20) Additional publications report on the implantation of artificial discs at 2 levels in the lumbar spine.(21)
**Maverick**

The Maverick disc is not marketed in the U.S.

In 2011, Gornet et al reported 24-month results from an FDA-regulated multicenter IDE randomized nonblinded trial of the metal-on-metal Maverick artificial disc.(22) 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 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 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, 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., pseudo-tumor formation) with metal-on-metal hip implants (see Blue Shield of California Medical Policy: Hip Resurfacing).

**FlexiCore**

Preliminary results on the FlexiCore metal-on-metal intervertebral disc were presented in 2008 from 2 of the sites involved in the investigational device trial.(23) 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 vs 179 mL, respectively), reduced operating time (82 vs 179 min, respectively), and reduced length of hospital stay (2 vs 3 days, respectively). ODI and VAS pain scores were not significantly different between the groups. At 24 months, the ODI 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 2-year follow-up of an RCT of 1- and 2-level total disc replacement.(9) Five-year follow-up of patients in this study was reported in 2013. (24) 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 on arrival at the hospital for surgery. No patient left the study when informed of the randomization. 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 and 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 (EQ-5D) and the 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. (25)

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. (26) The study is a single-blinded, randomized noninferiority trial comparing Activ-L with a control artificial lumbar disc (Charité or ProDisc-L) for single-level DDD 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 posttreatment.

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. (27) 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. (28) 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%). (29) Another report describes late complications in 75 patients who had received an earlier generation SB Charité prosthesis. (30) 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, 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, and 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.

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 U.S. The 5-year results of the ProDisc-L RCT provide evidence for the noninferiority 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.

Thus, 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 noninferior to fusion, the potential benefits of artificial lumbar disc that would make noninferiority sufficient to demonstrate clinical benefit have not been established. Therefore, artificial intervertebral discs for the lumbar spine are considered investigational.

Practice Guidelines and Position Statements

In 2009, the American Pain Society’s (APS) practice guidelines provided a recommendation of “insufficient evidence” to adequately evaluate long-term benefits and harms of vertebral disc replacement. The guideline was 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 similar outcomes compared 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 (beyond 2 years) benefits and harms following artificial disc replacement were limited.
Guidance in 2004 from the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) concluded that evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine appeared adequate to support the use of this procedure with audit and review; however, there was little evidence on outcomes beyond 2 to 3 years. In 2009, NICE updated the guidance on this procedure with studies reporting 13-year follow-up but with the majority of evidence from studies with shorter durations of follow-up. NICE concluded that evidence appeared 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, including information about patient selection and the need for further surgery.

Medicare National Coverage

Effective for services performed from May 16 through August 13, 2007, the Centers for Medicare and Medicaid Services (CMS) found that lumbar artificial disc replacement (LADR) with the Charité lumbar artificial disc is 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.

Effective for services performed on or after August 14, 2007, CMS found that LADR is 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 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. 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.”

References


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
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**HCPCS**

None

**ICD-9 Procedure**

- 84.65  Insertion of total spinal disc prosthesis, lumbosacral
- 84.68  Revision or replacement of artificial spinal disc prosthesis, lumbosacral

**ICD-10 Procedure**

For dates of service on or after 10/01/2015

- 0SR20JZ  Replacement of Lumbar Vertebral Disc with Synthetic Substitute, Open Approach
- 0SR40JZ  Replacement of Lumbosacral Disc with Synthetic Substitute, Open Approach

**ICD-9 Diagnosis**

All Diagnoses

**ICD-10 Diagnosis**

For dates of service on or after 10/01/2015

All Diagnoses

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### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>3/5/2012</td>
<td>New policy</td>
<td>Medical Policy Committee</td>
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<tr>
<td>4/12/2012</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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<td>5/8/2012</td>
<td>Administrative Update</td>
<td>Administrative Review</td>
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<td>5/18/2012</td>
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<td>2/22/2013</td>
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<td>12/15/2014</td>
<td>Policy title change from Spinal Fusion</td>
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<tr>
<td></td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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</tbody>
</table>
Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.