Medical Policy

Title: Artificial Intervertebral Disc: Lumbar Spine

See also: Artificial Intervertebral Disc: Cervical Spine

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

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, 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 nonoperative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients for whom fusion is indicated. Patients who require procedures in addition to fusion (eg, laminectomy, 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. 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, pseudotumor formation).

Regulatory Status
While a number of artificial intervertebral discs in the lumbar spine have been used internationally, only 3 devices (activL®, Charité®, ProDisc®-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of postmarketing studies. The activL (Aesculap Implant Systems), Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level; activL and Charité are 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 radiographs. 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. 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 was scheduled for July 2013, but was cancelled without explanation. FDA product code: MJ0.

POLICY
Artificial intervertebral discs of the lumbar spine are considered experimental / investigational.

RATIONALE
This evidence review was updated using the MEDLINE database. The most recent literature search of this review was performed through February 9, 2016. Following is a summary of key literature to date.

When this evidence review was created, the only literature was several case series describing the international experience with the SB Charité device. A February 2005 TEC Assessment evaluated artificial disc replacement, focusing on the Charité lumbar disc device.¹ Only 1 randomized controlled trial (RCT) had evaluated the Charité artificial disc compared to the BAK (Bagby and Kuslich) 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 U.S. Food and Drug Administration (FDA).³,⁴ A 2007 updated TEC Assessment reviewed the evidence on artificial lumbar disc replacement devices.⁵ It concluded that given what was 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 insufficient 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 were 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 (Berg et al, Geyer et al) found a pooled risk of ASD treated surgically to be 1.2% after lumbar disc replacement and 7.0% after fusion.⁹,¹⁰ The number needed to harm was calculated to be 17. In Berg et al,⁹ ASD was marginally reported, and the number of any reoperations did not differ between disc replacement and fusion. Geyer et al is discussed in the next section.¹⁰ 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, lack of proper assessment of the primary goal of prevention of adjacent-level disease and facet joint degeneration, and potential for harm in the long term.

A 2013 updated TEC Assessment evaluated the 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 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 United States.

**Controlled Trials**

The pivotal study for the Charité device consisted of an 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 for up to 24 months, the Charité artificial disc had a success rate of 63% compared with a success rate of 53% for BAK fusion, using a composite measure of outcomes that incorporated reduction of symptoms and absence of complications. The analysis showed noninferiority compared with 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 participated in the IDE trial of the Charité artificial disc (previously described). 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 trial. One hundred thirty-three cases were 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 represented 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 (75%) of 71 patients 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 Oswestry Disability Index (ODI) score, visual analog scale (VAS) score 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 (58%) of the 12 were due to implant fractures and 5 underwent secondary operative instrumented fusion. Of the remaining 41 patients, 9 (17%) of 53 showed no signs of heterotopic ossification or ankylosis at follow-up, while 32 (60%) patients had ankylosis after 17 years. No signs of ASD were found in the 9 (17%) cases without signs of ankylosis, fusion, or implant failure. Although no ASD 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 ODI scores (52 vs 38) and VAS scores (6.1 vs 4.5). The authors, who had designed the prosthesis, concluded that this study demonstrated dissatisfying results after artificial disc replacement in most of the evaluated cases based on clinical and radiologic outcomes.

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 an RCT that compared the Kineflex-L to an artificial disc (Charité) already approved for sale. There were 261 patients (204 randomized and 57 training cases) in the Kineflex group and 196 patients (190 randomized and 6 training cases) in the Charité group. The primary outcome measure 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 primarily to lymphocytic reaction (n=2), device migration (n=2), and supplemental fixation implantations (n=5). In 2011, the authors of this study 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.

Five-year follow-up was available for 66.0% of patients randomized to Kineflex-L and 70.9% of patients randomized to the Charité artificial disc. Overall success rates were similar to those reported at 2 years. The percentage of patients undergoing subsequent surgery at the index level was 11.8% for the Kineflex-L group (including 2 device removed due to lymphocytic reaction) and 11.6% for the Charité group. Interpretation of the 5-year results is difficult due to high loss to follow-up.

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 an unblinded RCT that originally followed 242 patients for 24 months. Patients were randomized in a 2:1 ratio to ProDisc-L artificial disc replacement (n=161) or circumferential fusion (n=75). Using an FDA-requested composite outcome measure 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 was statistically significant for a 1-sided statistical test of superiority (p=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 24-month report lacked detail on the number of patients lost to follow-up. The report also used alternative definitions of overall success, which resulted in a greater difference in rates of success between groups (experimental group, 63.5%; control group, 45.1%; p=0.005). 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 year (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. Post hoc analysis of radiographs found fewer patients with adjacent level degeneration in the ProDisc-L group (9.2%) than in the control group (28.6%). Adjacent level reoperations did not differ significantly between groups (1.9% ProDisc-L vs 4% controls). There were 6 (3.7%) ProDisc-L device failures.

Several individual components of the primary outcome measure were also statistically better in the ProDisc-L group compared to the fusion group at 2 years, but not at 5 years. For example, at 5-year ODI scores improved by 15% or more in 78.6% of ProDisc-L patients compared with 76.5% of controls. A similar percentage of patients maintained or improved 36-Item Short-Form Health Survey (SF-36) Physical Component Summary scores compared with baseline (81.3% ProDisc-L vs 74.0% fusion), and overall neurologic success was achieved 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 not reported). Device success, defined as absence of any reoperation 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. There was no significant difference in VAS scores between groups. For the ProDisc-L group, mean VAS scores improved from 75.9 at baseline to 37.1 at 5 years while for the same interval the fusion group they improved from 74.9 to 40.0. Analysis of VAS pain scores excluded patients who had secondary surgical interventions (11 ProDisc-L, 5 fusion). Narcotic use decreased in both groups, from a baseline of 84% to 44.6% in ProDisc-L patients and from a baseline of 76% to 42.5% in fusion patients.

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).
Postoperative evaluations were performed at 6 weeks and at 3, 6, 12, 18, and 24 months postoperatively. The total disc replacement group had faster surgeries (160.2 min vs 272.8 min), less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital lengths of stay (3.8 days 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 trial criteria for success, demonstrating noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in percentage improvement in ODI scores (52.4% vs 40.9%), a greater percentage of patients who achieved at least a 15-point improvement in the ODI (73.2% vs 59.7%), greater improvement in the SF-36 Physical Component Summary scores (43.9 vs 39.2), and 6-month neurologic success (87.3% vs 71.6%), all 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, there are a number of limitations to this study. 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.\(^{21}\)

**activL Versus 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.\(^{22}\) In this patient-blinded noninferiority trial, patients with DDD at L4-L5 or L5-S1 were randomized to treatment with activL (n=218) or an FDA-approved disc (n=106; ProDisc-L or Charité). Based on the primary composite end point (a ≥15 point improvement on ODI score, maintenance or improvement in neurologic status, maintenance or improvement in range of motion at the index level, freedom from additional surgery at the index level, 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 in back pain (74% vs 68%), ODI scores (75.2% vs 66.0%), device success (84.4% vs 84.9%), surgical reintervention (2.3% vs 1.9%), and patient satisfaction scores for the 2 groups (94.1% vs 93.1%), all respectively. Radiographic success, defined as maintenance or improvement in range of motion at the index level as measured by an independent core radiographic laboratory, was higher in the activL group than in the ProDisc-L and Charité controls (59% vs 43%, p<0.01).

**Maverick**

Although the metal-on-metal Maverick disc is not marketed in the United States, 24-month results from an FDA-regulated multicenter IDE trial have been reported.\(^{23}\) In this randomized nonblinded trial, 577 patients were allocated in a 2:1 ratio to the Maverick disc (n=405) or to anterior interbody fusion (control group) 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 hours vs 1.4 hours) and greater blood loss (240.7 mL vs 95.2 mL). Hospitalization stays were similar for both groups (2.2 days vs 2.3 days). 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 ODI scores, 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 to fusion for overall success (73.5% vs 55.3%) and in the component scores, all of which showed improvement (ODI scores, 82.2% vs 74.6%; back pain,
53.4 points vs 49 points; SF-36 Physical Component Summary scores, 17.0 vs 14.3). Although leg pain scores did not differ between groups, global perceived effect (“completely recovered” or “much improved”) was higher in the Maverick group (78.1% vs 67.4%). The Maverick group also had fewer implant or surgical procedure-related adverse events (1% vs 7%), though 2 implants in the Maverick group were removed, one considered related to an allergic reaction. While return-to-work intervals were shorter, favoring the Maverick group (median, 75 days vs 96 days), the percentage of patients in both groups working at 24 months was similar (74.1% vs 73.4%). Follow-up beyond 24 months with this 2-piece, metal-on-metal implant is needed, particularly in light of emerging complications (eg, pseudotumor formation) with other metal-on-metal implants (see evidence review 7.01.80).

**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. Results were reported for 76 patients enrolled at the 2 sites (of the entire study cohort of 401 patients) who had been randomly assigned with a ratio of 2:1 to 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 better initial outcomes: less blood loss (97 mL vs 179 mL), reduced operating time (82 min vs 179 min), and reduced hospital lengths of stay (2 days vs 3 days). ODI and VAS pain scores did not differ significantly between groups. At 24 months, the ODI scores had improved, decreasing from 62 to 6 in the FlexiCore group and from 58 to 12 in the fusion group. Likewise, VAS scores had improved, decreasing from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group required interventional surgery.

**Other Artificial Intervertebral Discs**

In 2009, Berg et al published 2-year follow-up of 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). Randomization was stratified for number of levels, with 56% of total disc replacement patients having 1-level surgery compared with 46% of fusion patients. Only patients without a preference for type of treatment were enrolled in the trial; they were informed about randomized allocation on arrival at the hospital for surgery. No patient left the study when informed of assignment. There was 100% follow-up at the 1- and 2-year assessments and 99.3% at the 5-year assessment. The primary outcome, which does not appear to be a validated measure, was a global assessment of back pain (“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-ups, and 38% at 5-year follow-up. The fusion group reported poorer outcomes: 10% reported being pain-free at 1 year and 15% reported being pain-free at 2 and 5 years. The total disc replacement group had lower mean VAS scores for pain at 1 and 2 years (25.4 vs 29.2, respectively) and better outcome scores on a quality-of-life scale 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 VAS back pain (23 vs 31) and ODI (17 vs 23) scores. The most common reason for additional surgeries in the disc replacement group was fusion of the index level believed to cause persistent or recurrent pain (5%). The most
common reason in the fusion group was surgery 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, maintenance of mobility with disc replacement) and clinical outcomes at 2 years.26

**Hybrid Procedures**

In 2015, Hoff et al published an RCT with 62 patients that compared a hybrid procedure (anterior lumbar interbody fusion at 1 level and a Maverick disc at another level) to 2-level circumferential fusion.27 VAS score for pain was significantly lower by about 1 point on a 10-cm scale in the hybrid group compared to the 2-level fusion group both postoperatively and at 3-year follow-up. There was no significant difference between groups in ODI scores. ASD did not differ significantly between groups.

**Longer Term Follow-Up**

Siepe et al (2014) reported minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution.28 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), although a slight increase (more pain) in score (0.66 on a 10-point scale) was observed between 48 and 120 months (p<0.05). 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.

Five-year results of lumbar disc arthroplasty from the Swiss Spine Registry were published in 2014.29 Five devices were used during the period of study (ActivL, Charité, Dynardi, Maverick, ProDisc-L). Of 248 patients eligible for the 5-year study, follow-up was obtained from 77% at 1 year, 44% at 2 years, and 51.2% at 5 years. In the 127 patients followed through 5 years, there was a significant reduction of 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 potentially affect range of motion. The cumulative probability of device survivorship at 5 years was calculated to be 90.4%. Another case series identified followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.30 Additional studies have reported on the implantation of artificial discs at 2 levels in the lumbar spine.31

In 2015, Lu at al reported minimum 11-year follow-up on 32 of 35 patients implanted with the Charité III.32 Of the 3 patients not included in this prospective study, 1 chose not to participate, 1 was lost to follow-up, and 1 died of unrelated causes. Prior to surgery, VAS score for back pain was 8.5 and ODI score was 41.4; the mean duration of symptoms was 5.4 years. At an average of 11.8 years after device implantation (range, 11.3-13.8 years), VAS score improved to 1.5.
(p=0.0015), ODI score improved to 13.2 (p=0.0047), and 87.5% had a successful outcome based on FDA criteria. There were no device failures or major complications (1 patient developed severe leg pain associated with adjacent segment degeneration and had spinal decompression). Heterotopic ossification was observed in 71.4% of segments, but was associated with a decrease in range of motion in only 25.7% of segments. The authors proposed several reasons for the high success rate in this group, including strict selection criteria and the lighter body weight of most Chinese compared to Western patients (eg, less load on the prosthesis).

**Adverse Events**

Complications with artificial lumbar discs are emerging with longer term follow-up. One study from Asia reported that clinical outcomes with 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 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 sex, malposition of the prosthesis on the frontal plane, and 2-level total disc replacement. Analysis of postoperative pain patterns in 58 (33%) patients of 175 implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%). Another report described late complications in 75 patients who had received an earlier generation SB Charité prosthesis. Because all patients had been originally treated by other surgeons, the percentage of implant failure cannot be determined from this report. Nonetheless, the mean interval between insertion and retrieval of the prosthesis 9 years (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 patients, adjacent-disc degeneration was seen in many patients, and polyethylene wear with inflammatory fibrous tissue containing wear debris was observed. The report suggested that wear mechanisms of artificial discs may be similar to artificial hips and knees and that, due to nearby vasculature and scar tissue from the original surgery, disc retrieval could be difficult and dangerous. These durability issues suggest that long-term health outcomes after 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 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.
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<td></td>
<td>Ongoing</td>
<td></td>
<td></td>
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<tr>
<td>NCT02381574</td>
<td>French Lumbar Total Disk Replacement Observational Study (FLTDR Observational Study)</td>
<td>600</td>
<td>Dec 2020</td>
</tr>
<tr>
<td></td>
<td>Unpublished</td>
<td></td>
<td></td>
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<tr>
<td>NCT01704677</td>
<td>Lumbar Disc Prosthesis Versus Multidisciplinary Rehabilitation in Chronic Back Pain and Localized Degenerative Disc. Long Term Follow-up of a Randomized Multicentre Trial</td>
<td>151</td>
<td>Nov 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Summary of Evidence
The evidence for the lumbar artificial intervertebral disc in individuals who have lumbar degenerative disc disease includes randomized controlled trials (RCTs) with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The Charité disc has been withdrawn from the U.S. market, and its successor, the INMOTION, is not marketed in the United States. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. Superiority of ProDisc-L with circumferential fusion was achieved at 2 but not 5 years in this unblinded trial. At this time, the potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. In addition, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Some randomized trials have concluded that this technology is noninferior to fusion, but 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 From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. The 4 reviewers disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational. After considering the clinical input in 2008, it was concluded that, due to limitations of the only 2 available RCTs (described herein), combined with the marginal benefit compared with fusion, evidence was insufficient to determine whether artificial lumbar discs are beneficial in the short term. In addition, serious questions remained about potential long-term complications with these implants.
Practice Guidelines and Position Statements

North American Spine Society
In 2014, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement. The following recommendation was made: “Lumbar artificial disc replacement (LADR) is indicated as an alternative to lumbar fusion for patients with discogenic low back pain who meet all of the following criteria from the Lumbar Fusion Recommendation:

- Advanced single-level disease noted on an MRI [magnetic resonance image] and plain radiographs of the lumbar spine at L4-5 or L5-S1, characterized by moderate to severe degeneration of the disc with Modic changes (defined as a peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)
- Presence of symptoms for at least one year AND that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
- Absence of active significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain
- Age 18 to 60 years old (unique to disc replacement, not fusion)
- Absence of significant facet arthropathy at the operative level (unique to disc replacement, not fusion)”

Contraindications included multi-level degeneration, facet arthropathy, and hybrid procedures (ie, in combination with a spinal fusion or other stabilizing-type procedure).

International Society for the Advancement of Spine Surgery
In 2015, the International Society for the Advancement of Spine Surgery published a policy statement on the lumbar artificial disc. The goal of the policy statement was “to educate patients, physicians, medical providers, reviewers, adjustors, case managers, and all others involved or affected by insurance coverage decisions regarding lumbar disc replacement surgery.” Authors of the statement were selected for their expertise and experience with the artificial lumbar disc and included an investigator from the ProDisc-L IDE trial and another from the ActivL IDE trial. RCT and long-term results favorable to the LADR were discussed.

American Pain Society
In 2009, the American Pain Society’s (APS) practice guidelines concluded there was “insufficient evidence” to adequately evaluate 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 with 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.
National Institute for Health and Clinical Excellence
Guidance in 2004 from the U.K.’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.\(^43\) In 2009, NICE updated the guidance on this procedure with studies reporting 13-year follow-up but with most of the evidence from studies with shorter durations of follow-up.\(^44\) NICE concluded that evidence appeared adequate to support the use of this procedure, provided that normal arrangements were 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 additional surgery.

U.S. Preventive Services Task Force Recommendations
Not applicable.

CODING
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>22857</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar</td>
</tr>
<tr>
<td>22862</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar</td>
</tr>
<tr>
<td>22865</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar</td>
</tr>
<tr>
<td>0163T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
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<tr>
<td>0164T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0165T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)</td>
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</table>

- There are CPT category I codes specific to total disc arthroplasty when performed at a single lumbar spine interspace: 22857, 22862, 22865.
- When more than one interspace is involved, the following CPT category III codes would be used: 0163T, 0164T, 0165T.

DIAGNOSIS
Experimental / investigational for all diagnoses related to this medical policy.
## REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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</table>
| 09-23-2008 | *In Description section:*  
• Updated wording  
*In Policy section:*  
• Removed "Removal or revision of artificial disc(s) is a non-covered service."  
*In Coding section:*  
• Removed CPT codes 0090T, 0092T, 0093T, 0095T, 0096T, 0098T  
• Added Rationale section |
| 02-22-2010 | *In Coding Section:*  
Updated wording for CPT codes: 22857, 22862, 22865, 0163T, 0164T, 0165T  
• Rationale and References updated. |
| 03-10-2011 | *Description section updated*  
• Rationale section updated  
• References updated |
| 03-08-2013 | *Description section updated*  
• Rationale section updated  
• In Coding section:*  
• Coding notations updated.  
• References updated |
| 06-23-2015 | *Description section update*  
• Rationale section updated  
• References updated |
| 08-04-2016 | *Description section update*  
• Rationale section updated  
• In Coding section:*  
• Coding notations updated  
• References updated |

## REFERENCES


