

Subject: Artificial Intervertebral Disc Replacement (ADR) Surgery (Lumbar and Cervical)		Original Effective Date: 6/14/06
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Medical Coverage Guidance Approval Date: 4/2/14		

PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

The FDA classifies artificial discs as Class III devices that are subject to the most stringent regulations enforced by the FDA under Product Code MJO.³⁸

The FDA has approved the following artificial lumbar disc systems for use in the United States: Charité® Artificial Disc (DePuy Spine Inc.) and the ProDisc-L® Total Disc Replacement (Synthes Spine Inc.). Both artificial discs are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD). Patients must also have failed at least 6 months of conservative treatment prior to implantation. The Charité is approved for 1 level between L4-S1, with no more than 3 mm of spondylolisthesis at the involved level. The ProDisc-L is indicated for 1 level between L3-S1, with no more than grade 1 spondylolisthesis at the index level.^{2 38}

The FDA has approved the following five artificial cervical disc systems for single-level treatment: Prestige Cervical Disc System; ProDisc-C Cervical Disc Total Cervical Disc Replacement (Synthes Spine Inc.); Bryan Cervical Disc System (Medtronic Inc.); Secure-C Artificial Cervical Disc (Globus Inc.); and the PCM (porous coated motion) Cervical Disc System (Nuvasive Inc.). All of these devices are indicated for use in skeletally mature patients for reconstruction of the disc from C3 to C7 following single-level discectomy for intractable radiculopathy and/or myelopathy.^{37 38}

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all

Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

There is a NCD for lumbar artificial disc replacement (LADR), #150.10 that has been in effect since 2007. This NCD indicates that it is not reasonable or necessary to provide Medicare coverage for lumbar artificial disc replacement (LADR) for patients > 60 years of age. Patients who are ≤ 60 years of age do not fall under the National Coverage Determination (NCD) and coverage will be determined by local contractors. ¹

CMS does not have a NCD for cervical artificial disc replacement and coverage will be determined by local contractors. ¹

INITIAL COVERAGE CRITERIA

1. Cervical intervertebral disc replacement may be considered medically necessary and authorized in skeletally mature individuals when all of the following criteria is met: ^{37 46 47 48 53} [ALL]
 - Age 18-60 years old
 - Device is FDA approved for cervical disc replacement
 - Diagnosis of single level degenerative cervical disc disease with intractable radiculopathy and/or myelopathy confirmed with imaging studies
 - Symptoms of unremitting neck and arm pain, resulting in disability and/or neurological deficit that is refractory to all of the following:
 - Six weeks or more of standard medical management unless contraindicated: [ALL]
 - ◇ activity restrictions and/or;
 - ◇ exercise; and
 - ◇ analgesics; and
 - ◇ physical therapy
 - The planned implant will be used in the reconstruction of a cervical disc in only one vertebral level between C3-C7, following single-level discectomy
 - Candidate for single-level anterior cervical decompression and interbody fusion
2. Lumbar intervertebral disc replacement is considered investigational and unproven and may **NOT** be authorized. ^{2 43}

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

1. Lumbar intervertebral disc replacement is considered investigational and unproven and may **NOT** be authorized. ^{2 43}
2. The following are contraindications to cervical intervertebral disc replacement according to the FDA and may not be authorized: ^{37 38}
 - Active systemic infection or infection at the operating site

- Allergy to implant materials (cobalt, chromium, molybdenum, titanium, or polyethylene)
 - Osteopenia or osteoporosis
 - Significant cervical anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, previous surgery, or trauma.
 - Significant kyphotic deformity or significant reversal of lordosis or significant spondylolisthesis
 - Symptoms necessitating surgical treatment at more than one cervical level
 - Moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of > 50% of its normal height.
 - Marked cervical instability on radiographs (e.g., radiographic signs of subluxation > 3.5 mm or angulation of the disc space > 11° greater than adjacent segments)
 - Severe facet joint arthropathy
 - Congenital stenosis
3. Presence of any of the following conditions is considered investigational because they have not been proven for cervical intervertebral disc replacement:³⁷
- Combined use of a prosthesis and spinal fusion is planned
 - Simultaneous multilevel implantation is planned
 - Prior fusion at an adjacent cervical level
 - Prior surgery at the treated level
 - Pregnancy
 - Rheumatoid arthritis or other autoimmune disease.
 - Systemic disease, including AIDS, HIV, or hepatitis
 - Paget's disease, osteomalacia, or any other metabolic bone disease
 - Severe diabetes mellitus requiring daily insulin management
 - Active malignancy: A patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless treated with curative intent and there have been no clinical signs or symptoms of the malignancy for > 5 years.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Lumbar Artificial Disc

Lumbar total disc replacement (LTDR) involves replacement of a degenerating lumbar (L3-S1) intervertebral disc with an artificial, or prosthetic, disc. The artificial disc is designed to maintain the physiological range of motion and stability of the natural spine and restore disc height and vertebral alignment, and, as a result, relieve pain and prevent adjacent disc degeneration.⁵ Implantation of the artificial lumbar disc is performed under general anesthesia using the retroperitoneal or transperitoneal approach. During the surgery, the neurosurgeon may require assistance of a vascular or general surgeon in order to reduce complications that may occur during exposure and instrumentation due to the presence of vital anatomical structures such as the aorta, iliac vessels, sympathetic plexus, and intraperitoneal structures such as the bowel and ureters. An anterior retroperitoneal approach is used to expose the affected disc. The patient is placed in a supine position, and a complete discectomy is performed, including the removal of the posterior lateral recesses of the disc. The bony end plates are prepared by removing the cartilaginous end plates and any osteophytes, although the surrounding spinal

ligaments are saved to maintain the stability of the implant. A trial disc and fluoroscopy may be used to determine the midline of the vertebral body for proper placement of the disc. The trial disc is subsequently removed, and the artificial disc is inserted and secured.²

Cervical Artificial Disc

Cervical artificial disc replacement has been developed as a clinical alternative to anterior cervical discectomy and fusion. The artificial disc is intended to relieve pain, restore disc height, maintain motion of the natural spine, and prevent degeneration of adjacent discs. Cervical Artificial disc implantation is typically performed by an orthopedic surgeon on an inpatient basis. The surgical procedure to implant the Prestige ST artificial disc takes 90 minutes to 2 hours to perform, and involves a cervical discectomy using a standard anterior approach. The patient is placed in a supine position and a complete discectomy is performed, including removal of the posterior lateral recesses of the disc. The bony end plates are prepared by removing the cartilaginous end plates and any osteophytes. A trial disc and fluoroscopy may be used to determine the midline of the vertebral body for proper placement of the disc. The trial disc is then removed and the artificial disc inserted and secured. Hospital stay ranges from 1 to 2 days, after which the patient can resume normal activities with minimal or no restrictions. Following artificial cervical disc replacement, use of a cervical collar is not necessary.³⁷

GENERAL INFORMATION

Summary of Medical Evidence

Cervical:

A prospective randomized multicenter study was conducted by Murrey et al (2009) comparing cervical disc arthroplasty with anterior cervical discectomy and fusion (ACDF) in patients treated for symptomatic single-level cervical degenerative disc disease (DDD). Five hundred forty-one patients with single-level cervical DDD and radiculopathy were enrolled at 32 sites and randomly assigned to one of two treatment groups: 276 patients in the investigational group underwent anterior cervical discectomy and decompression and arthroplasty with the PRESTIGE ST Cervical Disc System (Medtronic Sofamor Danek); 265 patients in the control group underwent decompressive ACDF. Eighty percent of the arthroplasty-treated patients (223 of 276) and 75% of the control patients (198 of 265) completed clinical and radiographic follow-up examinations at routine intervals for 2 years after surgery. A two-point greater improvement in the neck disability index score in the investigational group than the control group following 12 and 24 month analysis of data. A statistically significant higher rate of neurological success ($p = 0.005$) as well as a lower rate of secondary revision surgeries ($p = 0.0277$) and supplemental fixation ($p = 0.0031$) was documented in the investigational group. The mean improvement in neck pain and in the 36-Item Short Form Health Survey Physical Component Summary scores was greater in the investigational group at 12 and 24 months. The patients in the investigational group returned to work 16 days sooner than those in the control group, and the rate of adjacent-segment reoperation was significantly lower in the investigational group as well ($p = 0.0492$, log-rank test). The cervical disc implant maintained segmental sagittal angular motion averaging more than 7° . There were no cases of implant failure or migration in the investigational group. Short term results were positive however, a high percent of patients were eliminated from the study with the following explanation “all currently available patients” were included. A potential for bias due to high percentage of loss to follow-up may be a concern with these results.²⁷

Yu et al (2011) performed a systematic review and meta-analysis to evaluate whether there is a beneficial clinical effect of total disk replacement compared with anterior cervical discectomy and fusion for the treatment of single-level symptomatic cervical disk disease. Eight randomized controlled trials were identified; six of the 8 reported 24-month follow-up results. At 24 months, total disk replacement was demonstrated to be more beneficial for patients compared with anterior cervical discectomy and fusion for the following outcomes: overall success rate (odds ratio [OR], 1.79; 95% confidence interval [CI], 1.37-2.33; $P < .0001$), overall reoperation rate (OR, .36; CI, .21-.61; $P = 0$), reoperation rate for revision (OR, .12; CI, .02 to .64; $P = .01$), and visual analog scale neck pain scores (standard mean differences [SMD], -.48; CI, -.91 to -.05; $P = .03$). Other outcomes, including Neck Disability Index scores (SMD, -.02; CI, -.44 to .27; $P = .67$) and visual analog scale arm pain scores (SMD, -.21; CI, -.63 to .22; $P = .34$), demonstrated no differences between the 2 groups. For patients with single-level symptomatic cervical disk disease, total disk replacement was found to be more effective than anterior cervical discectomy and fusion in the 2 outcomes of overall success rate and overall reoperation rate at 24 months. Long-term results also showed total disk replacement trended to be more effective than anterior cervical discectomy and fusion in some aspects.⁴⁵

McAfee et al (2012) conducted a meta-analysis of 4 prospective randomized controlled Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical trials by analyzing the combined outcomes of cervical arthroplasty versus fusion at 24-month follow-up. Four cervical arthroplasty randomized clinical trials with comparable enrollment criteria and outcome measures were conducted independently by 3 separate sponsors to study the following devices: Bryan, Prestige, ProDisc-C, and PCM cervical disc replacements. A total of 1608 patients were treated across 98 investigative sites. Data were available for 1352 treated patients, of which 1226 were evaluable at 24 months. Assessments included clinical success definitions based on neck disability index, maintenance or improvement of neurological status, subsequent surgery or intervention at the index level (survivorship), and a composite score comprising these as well as serious device-related adverse events. Trial endpoint comparisons were made at 24 months postoperatively. For each endpoint, a random-effects meta-analysis was performed to compare the success rates of cervical arthroplasty with anterior cervical discectomy and fusion (ACDF). Also, supportive frequentist and bayesian analyses were performed. The pooled primary overall success results indicated a statistically significant treatment effect favoring arthroplasty compared with ACDF. Overall success was achieved by 77.6% of the arthroplasty patients and by 70.8% of the ACDF patients (pooled odds ratio [OR]: 0.699, 95% confidence interval [CI]: 0.539-0.908, $P = 0.007$). The results of the individual subcomponent meta-analyses, all of which favored arthroplasty, were neck disability index success (OR: 0.786, 95% CI: 0.589-1.050, $P = 0.103$), neurological status (OR: 0.552, 95% CI: 0.364-0.835, $P = 0.005$), and survivorship (OR: 0.510, 95% CI: 0.275-0.946, $P = 0.033$). Only the survivorship endpoint suggested low heterogeneity. The authors concluded that these findings suggest that cervical arthroplasty is superior to ACDF in overall success, neurological success, and survivorship outcomes at 24 months postoperatively.⁵³

Mummaneni et al (2012) conducted a systematic review comparing long-term follow-up results from two FDA trials of cervical artificial disc replacement versus fusion in the cervical spine. Two FDA trials reporting outcomes following C-ADR (Bryan disc, Prestige disc) versus ACDF at follow-up periods of 48 months and 60 months were found (follow-up rates are 68.7% [318/463] and 50.1% [271/541], respectively). Patients in the C-ADR group showed a higher rate of overall success, greater improvements in Neck Disability Index, neck and arm pain scores, and SF-36 Physical Component Scores at long-term follow-up compared with those in the ACDF group. The rate of adjacent segment disease was less in the C-ADR group versus the ACDF group at 60 months (2.9% vs 4.9%). Normal segmental motion was maintained in the C-ADR group. Furthermore, rates of revision and supplemental fixation surgical procedures were lower in the arthroplasty group. The authors concluded that C-ADR is a viable treatment option for cervical herniated disc/spondylosis with radiculopathy resulting in improved clinical outcomes, maintenance of normal segmental motion, and low rates of subsequent surgical procedures at 4 to 5 years follow-up.⁴⁹

Coric et al. (2013) performed a prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion to evaluate the long-term results of cervical total disc replacement (TDR) and anterior cervical discectomy and fusion (ACDF) in the treatment of single-level cervical radiculopathy. The results of 2 separate prospective, randomized, US FDA Investigational Device Exemption pivotal trials (Bryan Disc and Kineflex|C) from a single investigational site were combined to evaluate outcomes at long-term follow-up. The primary clinical outcome measures included the Neck Disability Index (NDI), visual analog scale (VAS), and neurological examination. Patients were randomized to receive cervical TDR in 2 separate prospective, randomized studies using the Bryan Disc or Kineflex|C cervical artificial disc compared with ACDF using structural allograft and an anterior plate. Patients were evaluated preoperatively; at 6 weeks; at 3, 6, and 12 months; and then yearly for a minimum of 48 months. Plain radiographs were obtained at each study visit. A total of 74 patients were enrolled and randomly assigned to either the cervical TDR (n = 41) or ACDF (n = 33) group. A total of 63 patients (86%) completed a minimum of 4 years follow-up. Average follow-up was 6 years (72 months) with a range from 48 to 108 months. In both the cervical TDR and ACDF groups, mean NDI scores improved significantly by 6 weeks after surgery and remained significantly improved throughout the minimum 48-month follow-up ($p < 0.001$). Similarly, the median VAS pain scores improved significantly by 6 weeks and remained significantly improved throughout the minimum 48-month follow-up ($p < 0.001$). There were no significant differences between groups in mean NDI or median VAS scores. The range of motion (ROM) in the cervical TDR group remained significantly greater than the preoperative mean, whereas the ROM in the ACDF group was significantly reduced from the preoperative mean. There was significantly greater ROM in the cervical TDR group compared with the ACDF group. There were 3 reoperations (7.3%) at index or adjacent levels in the cervical TDR group; all were cervical lamino-foraminotomies. There were 2 adjacent-level reoperations in the cervical TDR group (4.9%). There was 1 reoperation (3.0%) in the ACDF group at an index or adjacent level (a second ACDF at the adjacent level). There was no statistically significant difference in overall reoperation rate or adjacent-level reoperation rate between groups. The authors concluded that both cervical TDR and ACDF groups showed excellent clinical outcomes that were maintained over long-term follow-up. Both groups showed low index-level and adjacent-level reoperation rates. Both cervical TDR and ACDF appear to be viable options for the treatment of single-level cervical radiculopathy.⁴⁶

Gao et al. (2013) performed a meta-analysis comparing the results of cervical disc arthroplasty with anterior cervical discectomy and fusion (ACDF) for the treatment of symptomatic cervical disc disease. Twenty-seven randomized clinical trials were included; twelve studies were Level I and fifteen were Level II. The results of the meta-analysis indicated longer operative times, more blood loss, lower neck and arm pain scores reported on a visual analog scale, better neurological success, greater motion at the operated level, fewer secondary surgical procedures, and fewer such procedures that involved supplemental fixation or revision in the arthroplasty group compared with the anterior cervical discectomy and fusion group. These differences were significant ($p < 0.05$). The two groups had similar lengths of hospital stay, Neck Disability Index scores, and rates of adverse events, removals, and reoperations ($p > 0.05$). The meta-analysis revealed that anterior cervical discectomy and fusion was associated with shorter operative times and less blood loss compared with arthroplasty. Other outcomes after arthroplasty (length of hospital stay, clinical indices, range of motion at the operated level, adverse events, and secondary surgical procedures) were superior or equivalent to the outcomes after anterior cervical discectomy and fusion.⁴⁷

Blumenthal et al (2013) conducted a post hoc analysis of data collected from multiple prospective, randomized studies to compare the reoperation rates in patients with cervical total disc replacement (TDR) versus patients with anterior cervical fusion (ACF). Data were collected prospectively for patients enrolled in 1 of 6 Food and Drug Administration regulated investigational device exemption trials conducted at a single site. Results are based on 136 patients (84 TDR, 52 ACF) with mean follow-up of 55.1 months (range, 24-98 mo). Data collected included general demographics, operative details, length of follow-up, the occurrence of a reoperation, the reason for the reoperation, length of time between the index study procedure and reoperation. For this study, reoperation was defined as any surgical procedure involving the cervical spine. The reoperation rates as well as the length of time after the index surgery the reoperation occurred were compared for the TDR and ACF groups. The reoperation rate in the TDR group was significantly less than in the ACF group (8.3% vs. 21.2%; $P < 0.05$). There was a trend for the reoperation rate attributed to adjacent segment degeneration to be significantly less in the TDR group than in the ACF group (4.8% vs. 13.5%; $0.05 < P < 0.07$). In the ACF group, 4 patients (7.7%) underwent reoperation for pseudoarthrosis. Reoperations occurred significantly later in the TDR group versus the fusion group when comparing the mean number of months between index and subsequent procedures ($P < 0.01$). Kaplan-Meier survival analysis also found that the TDR group had a significantly longer survival period before undergoing reoperation than ACF ($P < 0.05$). The authors concluded that this study found the reoperation rate was significantly less in the TDR group compared with ACF group and that the survival time to reoperation was greater in the TDR group. Reoperations for adjacent segment changes were less frequent and occurred later in patients who were randomized to TDR compared with ACF.⁴⁸

et al (2013) conducted a prospective, randomized, US FDA investigational device exemption pivotal trial of the Mobi-C cervical artificial disc conducted at 24 centers in the US. The primary clinical outcome was a composite measure of study success at 24 months. The comparative control treatment was ACDF using allograft bone and an anterior plate. A total of 330 patients were enrolled, randomized, and received study surgery. All patients

were diagnosed with intractable symptomatic cervical DDD at 2 contiguous levels of the cervical spine between C-3 and C-7. Patients were randomized in a 2:1 ratio (TDR patients to ACDF patients). A total of 225 patients received the Mobi-C TDR device and 105 patients received ACDF. At 24 months only 3.0% of patients were lost to follow-up. On average, patients in both groups showed significant improvements in Neck Disability Index (NDI) score, visual analog scale (VAS) neck pain score, and VAS arm pain score from preoperative baseline to each time point. However, the TDR patients experienced significantly greater improvement than ACDF patients in NDI score at all-time points and significantly greater improvement in VAS neck pain score at 6 weeks, and at 3, 6, and 12 months postoperatively. On average, patients in the TDR group also maintained preoperative segmental range of motion at both treated segments immediately postoperatively and throughout the study period of 24 months. The reoperation rate was significantly higher in the ACDF group at 11.4% compared with 3.1% for the TDR group. Furthermore, at 24 months TDR demonstrated statistical superiority over ACDF based on overall study success rates. The authors concluded that the results of this study represent the first available Level I clinical evidence in support of cervical arthroplasty at 2 contiguous levels of the cervical spine using the Mobi-C cervical artificial disc. These results continue to support the use of cervical arthroplasty, but specifically demonstrate the advantages of 2-level arthroplasty over 2-level ACDF.⁵⁴

Lumbar:

Kovacs et al. (2006) performed a systematic review regarding the efficacy and safety of intervertebral disc prosthesis (CHARITE and ProDisc in the lumbar spine). They evaluated all controlled studies and found four articles for the CHARITE III model, all based upon the same study- a multi-center randomized, controlled clinical trial sponsored by the FDA. The evidence was rated as low methodological quality. The study results reviewed for ProDisc II were considered inconsistent. The evidence conclusion was documented from this review as “not sufficient to recommend the use of CHARITE III or Pro-Disc II for the treatment of lumbar discal pain in routine clinical practice. More high quality controlled clinical trials with sufficiently large study populations are necessary.”²²

Blumenthal et al. (2006) evaluated data from continued trials from the original FDA trial report (304 patients randomized (unclear allocation concealment, unblinded, controlled trial with 24 month follow-up).³⁴ Data was collected from 14 centers in The United States. The published results indicated “the groups did not differ for operative time or blood loss. Patients in the Charite group had a shorter hospital stay than patients in the fusion group (mean, 3.7 versus 4.2 days; $p=0.004$. Patients in the Charite group had greater improvement in ODI and VAS scores than patients in the fusion group at all end-points with the exception of 24 months where there was no statistical significance. Clinical success was 64% in the Charite group and 56% in the fusion group, supporting the hypothesis that Charite was at least as good as fusion. Range of motion increased by 13.6% in the Charite group at 24 months and decreased by 82.5% in the fusion group. Sixty four percent of patients in the disc replacement group required narcotics at 24 months versus 80 percent in the fusion group. Seventeen percent of the patients had suboptimal placement of the artificial disc determined by radiology examination. Patients in the Charite group also had better restoration and maintenance of disc height ($p<0.05$)”.²⁰

A retrospective clinical-radiological study was performed by Putzier et al (2006) to evaluate long-term outcomes following artificial disc replacement. Long-term results after implantation of a modular type artificial disc prosthesis in patients with degenerative disc disease (DDD) was evaluated. Seventy-one patients with moderate to severe DDD were treated with 84 Charité TDRs types I-III. Fifty-three patients (63 TDRs) were available for long-term follow-up of 17 years. Implantation of Charité TDR implantation resulted in a 60% rate of spontaneous ankylosis after 17 years. No significant difference between the three types of prostheses was found. Reoperation was necessary in 11% of patients. Although no adjacent segment degeneration was observed in the functional implants (17%), these patients were significantly less satisfied than those with spontaneous ankylosis. The authors indicate that “proof that long-term results of TDR implantation in DDD are at least as good as fusion results is still missing.”³⁵

Kurtz et al. (2007) conducted the first international multicenter study on Charite implants after 1.8 to 16.0 years. From 21 patients that underwent revision total disc replacement surgery and conversion to fusion. In all cases the implants were removed as a result of pain associated with one of the following: migration, core dislocation, endplate loosening, subsidence, lateral subluxation, osteolysis, and wear with fracture. The authors indicated “The dominant wear mechanism was adhesive/abrasive wear at both the dome and rim. Endplate penetration (dome wear) ranged from 0.1 to 0.9 mm (average: 0.3 mm), and was correlated with implantation time (Spearman’s rho = 0.48, p = 0.03). There was also evidence of macroscopic rim damage, including radial and transverse cracking, fracture, plastic deformation, and third body damage. Endplate penetration measured at the rims ranged from 0.02 to 0.8 mm (average: 0.3 mm). Cracks in the core were oriented transversely in 11/21 implants (52%), and radially around the rim in 11/21 implants (52%). Radiographic wire marker fracture, observed in 9/21 implants (43%), was always associated with deformation, cracking, and/or fracture of the PE rim. In two cases, a fractured wire marker became lodged in the articulating surface between the PE and the metallic endplate. Conclusions: This is the first study to quantitatively analyze the long-term PE damage mechanisms in contemporary TDRs. The TDRs displayed surface damage observed previously in both hip and knee replacements. Due to the evidence of increasing wear with implantation time, along with the demonstrated potential for osteolysis in the spine, regular long-term follow-up for patients undergoing TDRs is warranted.”²¹

Punt et al (2008) performed a review of complications and reoperations resulting from artificial disc prosthesis have noted late complications following implantation.¹⁸ One study evaluated 75 patients with persistent leg and back pain following implantation of the Chartite disc. Results were reported as diverse with short to mid-term results being fair to good. Long term results are now more available with the incidence of late complications poorly understood. Frequent complications in the group included disc wearing, adjacent disc degeneration, subsidence, facet joint degeneration and migration. Forty-six of the patients required one or more salvage operations. The mean interval between insertion and retrieval of the disc prosthesis was eight years and eleven months. A total of 22 patients had the prosthesis removed and had anterior and posterior fusion performed. Fifteen patients received posterior fusion without disc removal. Seven patients required posterior fusion in a different region. In 30 patients, late complications included subsidence of the prosthesis and 36 patients had signs of adjacent segment degeneration, narrowing of the disc and osteophytes. Eleven patients developed degenerative scoliosis. Six patients experienced posterior migration of the disc prosthesis. Ten patients a breakage of metal wire around the core were discovered. A radiographic analysis of 56 patients noted that posterior impingement was seen in a considerable number of patients with ProDisc-L prosthesis.¹⁹

Yajun et al. (2010) performed a meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease. Five relevant randomized controlled trials involving 837 patients were identified. Patients in TDR group have slightly better functioning and less back or leg pain without clinical significance, and significantly higher satisfaction status in TDR group compared with lumbar fusion group at the 2-year follow-up. But these outcomes are highly influenced by the study with BAK cage interbody fusion, the function/pain and patient satisfaction status are no longer significantly different between two groups after excluding this study. At 5 years, these outcomes are not significantly different between comparing groups. The complication and reoperation rate of two groups are similar both at 2 and at 5 years. In conclusion, TDR does not show significant superiority for the treatment of lumbar DDD compared with fusion. The benefits of motion preservation and the long-term complications are still unable to be concluded. To assess the benefits of motion preservation and the long-term complications more high-quality RCTs with long-term follow-up are needed.⁵¹

Zigler et al. (2012) evaluated the long-term safety and effectiveness of the ProDisc-L total disc replacement (TDR) as part of an FDA-mandated postmarket approval study. This report summarizes the clinical findings after 5 years of follow-up. Two hundred thirty-six patients were treated and followed up for 5 years; 161 TDRs and 75 fusions had been performed in these patients. The primary outcome was a 10-component success end point. Secondary outcome measures included neurological status, secondary surgery, Oswestry Disability Index (ODI), 36-Item Short Form Health Survey (SF-36), visual analog scale (VAS) assessing pain and satisfaction, radiographic data, narcotic use, activity, and recreation status. Patients were monitored through their 5-year postoperative visits under the FDA postmarket surveillance provisions in the original investigational device exemption approval. The overall follow-up rate at 5 years was 81.8%. Study success demonstrated that TDR was noninferior to fusion with a 12.5% margin ($p = 0.0099$). Both TDR and fusion treatment groups maintained significant improvement on the ODI at 5 years compared with baseline ($p < 0.0001$). Secondary surgeries at the index level were performed in 12% of fusion patients and 8% of TDR patients. Radiographically, none of the TDRs developed spontaneous fusion. The segmental range of motion following TDR remained within normal range, although it decreased by approximately 0.5° in years 3 to 5. The VAS pain scores decreased from preoperative values by 48% in both treatment groups at 5 years. Patient satisfaction remained high in both groups (77%), while the percentage of patients indicating that they would have the surgery again was higher in TDR patients (82.5%) than in fusion patients (68.0%). The authors concluded that patients in both groups maintained significant improvement during the 5-year follow-up. The TDR group had significantly better improvement on some scales. Although TDR patients avoid the stiffness of fusion and are more satisfied than fusion patients, both fusion and TDR are reasonable surgical options in this specific patient population.⁵²

Wei et al. (2013) conducted a meta-analysis to compare the efficacy and safety of TDR to that of the fusion for the treatment of lumbar degenerative disc disease (LDDD) Six relevant randomized controlled trials (RCTs) involving 1,603 patients were identified and reported two year follow-up results. Patients in TDR group compared with lumbar fusion group demonstrated significant improvements in ODI, VAS scores and complication rates at the two year follow-up. Meanwhile, except for operating time in anterior group, intra-operative blood loss, operating time in posterior group, and reoperation rate were without clinical significance between the two groups. In addition, the range of motion (ROM) was maintained within normal ranges after

TDR. The results showed the TDR has significant safety and efficacy comparable to lumbar fusion at two year follow-up. Although superiority compared to fusion could not be proved, by comparing clinical symptoms relieved, motion preserved, and the low reoperation rate during long-term follow-up on TDR, TDR was considered safe and effective. Therefore, the authors suggest adopting TDR on a large scale; with failure of TDR, interbody fusion would be performed.⁵⁰

Hayes, Cochrane, UpToDate, etc.

Hayes:

There is a directory report called “Lumbar Total Disc Replacement for Degenerative Disc Disease” that was published in 2013. This report outlines that the available evidence suggests that, compared with spinal fusion, lumbar total disc replacement (LTDR) for degenerative disc disease (DDD) using the ProDisc or Charité may lead to improved outcomes lasting ≥ 5 years after surgery. However, the longer-term clinical outcome of LTDR is still unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed. Long-term follow-up results from randomized controlled studies are available from only 2 randomized trials, and it is, therefore, not known if the benefits of LTDR are maintained. Furthermore, patient selection criteria still need to be refined.²

There is another directory report called “Artificial Disc Replacement for Cervical Degenerative Disc Disease” that was updated in 2013. This report outlines that several moderate-size randomized controlled trials (RCTs) comparing different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF) have been published. Evidence to date demonstrates that total disc replacement (TDR) is at least as effective as ACDF in improving signs and symptoms associated with degenerative disease and improving quality of life (QOL) for up to 2 years. The evidence also shows that total disc replacement (TDR) reduces the need for reoperation and reduces the incidence of dysphagia. Low-quality evidence suggests that TDR reduces the risk of new adjacent segment disease (ASD) but may have higher rates of intraoperative and perioperative complications. Reliable follow-up data for more than 3 years are lacking, which is an especially serious limitation regarding the evidence for the intended advantage of TDR (reduction in long-term ASD). Positive but sparse evidence suggests that bilevel TDR is less safe than single-level TDR, but a few studies with several limitations suggest that it is comparable to bilevel ACDF in safety and efficacy. This report recommends single-level TDR for the treatment of cervical disc disease in patients who are candidates for ACDF and who do not have forms of degenerative disc disease, allergies, comorbidities, or concomitant treatments that are expected to interfere with successful arthroplasty. TDR is not recommended in patients with multilevel cervical disc disease who are candidates for ACDF based on positive but very sparse evidence regarding the efficacy and safety of TDR for the treatment of multilevel disease.³⁷

Cochrane:

A Cochrane review on total disc replacement for chronic discogenic low back pain (2012) was performed to assess the effect of total disc replacement for chronic low back pain due to lumbar degenerative disc disease compared with fusion or other treatment options. 7 randomized controlled trials with a follow-up of 24 months

were included. One study compared disc replacement with rehabilitation and found a significant advantage in favor of surgery, which, however, did not reach the predefined threshold. Six studies compared disc replacement with fusion and found that the mean improvement in visual analogue scale score of back pain was 5.2 mm higher (2 studies; 95% confidence interval 0.2-10.3) with a low quality of evidence. The improvement of Oswestry disability index score at 24 months in the disc replacement group was 4.3 points more than in the fusion group (5 studies; 95% confidence interval 1.85-6.68) with a low quality of evidence. Both upper bounds of the confidence intervals were below the predefined clinically relevant difference. The review indicated that although statistically significant, the differences in clinical improvement were not beyond generally accepted boundaries for clinical relevance. Prevention of adjacent level disease and/or facet joint degeneration was not properly assessed. Therefore, the authors concluded that harm and complications may occur after some years, the spine surgery community should be prudent to adopt this technology on a large scale, despite the fact that total disc replacement seems to be effective in treating low back pain in selected patients, and in the short term is at least equivalent to fusion surgery. Of note, there is risk of bias in the included studies due to sponsoring and absence of any kind of blinding.⁴³

UpToDate:

In a report called “Treatment of Cervical Radiculopathy” the authors indicate that artificial cervical disc replacement surgery or arthroplasty is a developing technique for the treatment of single level cervical radiculopathy that has been used in situations when an anterior cervical discectomy and fusion (ACDF) would otherwise be appropriate. The available evidence suggests that cervical disc replacement is equal to ACDF in terms of clinical outcomes. However, the long-term durability of the devices that have been developed is not known.³⁹

In a report called “Subacute and chronic low back pain: Surgical treatment” the authors indicate that artificial lumbar disc replacement is a newer alternative to fusion. A theoretic advantage of lumbar disc replacement compared to fusion is that a prosthetic disc could help preserve normal range of motion and spine mechanics. This could reduce the long-term degenerative changes in adjacent vertebral segments that have been observed following spinal fusion. However, the evidence to date suggests that the efficacy of this approach is similar to that of spinal fusion and that a key limitation of existing evidence for the role of lumbar disc replacement is the lack of longer-term follow-up to assess efficacy and failure rates necessitating device removal and potential conversion to a fusion procedure. Regardless of treatment (disc replacement, fusion, or nonsurgical), few patients report complete symptom resolution.¹⁷

Professional Organizations

Blue Cross Blue Shield (BCBS) Technology Evaluation Center (TEC): A TEC Assessment published in 2011 concluded that cervical disc arthroplasty for degenerative disc disease (DDD) does not meet the TEC criteria. The review indicated that the evidence reviewed shows that clinical outcomes are similar at the 2-year outcome point between artificial intervertebral disc arthroplasty (AIDA) and anterior cervical discectomy and fusion (ACDF.) The long-term follow-up studies show continued similarity in clinical outcomes at 4 to 6 years and lower cumulative reoperation rates in AIDA patients. The long-term studies have considerable losses to follow-

up, and thus the outcomes are uncertain. The rationale for a non inferiority endpoint has never been established, as there is no proven offsetting benefit for AIDA. Thus, there remains uncertainty regarding the health benefit of AIDA.⁴⁰

National Institute for Health and Clinical Excellence (NICE):

NICE issued a guidance document on prosthetic intervertebral disc replacement in the cervical spine (2010). The document concludes that: “...prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is at least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.” NICE recommends that the procedure should only be performed in specialist units experienced in surgery of the cervical spine. In addition, NICE states that there is a need for long-term studies on the preservation of mobility, occurrence of adjacent segment disease, and the avoidance of revision surgery.⁴⁴

NICE issued a guidance document on prosthetic intervertebral disc replacement in the lumbar spine (2009). The document indicates that current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.⁴²

North American Spine Society (NASS): The NASS issued evidence-based guidelines on Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders in 2010.⁴¹ The guideline outlines the following conclusions regarding surgical choices and characterizes them as recommendations with “B” strength (fair-quality evidence from randomized controlled trials with some weaknesses or observational studies and consistent findings across studies):

- Anterior cervical discectomy alone produces similar outcomes equivalent to ACDF but addition of an interbody graft for fusion improves sagittal alignment.
- ACDF with and without plating results in similar clinical outcomes, but plating improves sagittal alignment.
- Anterior and posterior surgery produce comparable clinical outcomes (but the working group came to a non-evidence-based conclusion that anterior surgery is preferred in certain situations).
- ACDF and total disc replacement produce similar short-term outcomes for single-level disease.

CODING INFORMATION

CPT	Description
0092T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and

	microdissection), each additional interspace, cervical (List separately in addition to code for primary procedure)
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
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) (NOT COVERED)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure) (NOT COVERED)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure) (NOT COVERED)
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar (NOT COVERED)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar (NOT COVERED)
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar (NOT COVERED)
HCPCS	Description
	N/A
ICD-9	Description Procedure Codes
84.60	Insertion of spinal disc prosthesis, not otherwise specified
84.62	Insertion of total spinal disc prosthesis, cervical
84.65	Insertion of total spinal disc prosthesis, lumbosacral
84.66	Revision or replacement of artificial spinal disc prosthesis, cervical
84.68	Revision or replacement of artificial spinal disc prosthesis, lumbosacral
84.69	Revision or replacement of artificial spinal disc prosthesis, not otherwise specified
ICD-9	Description Diagnosis Codes
722.4	Cervical/cervicothoracic degenerative disc disease
722.52	Lumbar/lumbosacral degenerative disc disease
ICD-10	Description Procedure Codes PCS
84.60	Insertion of spinal disc prosthesis, not otherwise specified

84.62	Insertion of total spinal disc prosthesis, cervical
84.65	Insertion of total spinal disc prosthesis, lumbosacral
84.66	Revision or replacement of artificial spinal disc prosthesis, cervical
84.68	Revision or replacement of artificial spinal disc prosthesis, lumbosacral
84.69	Revision or replacement of artificial spinal disc prosthesis, not otherwise specified
ICD-10	Description Diagnosis Codes CM
M50.31	Other Cerv Disc Degeneration Occipito-Atlanto-Axial RGN
M50.32	Other Cerv Disc Degeneration Mid-Cervical Region
M50.33	Other Cerv Disc Degeneration Cervicothoracic Region
M51.36	Other Intervertebral Disc Degen Lumbar Region
M51.37	Other Intervertebral Disc Degen Lumbosacral Region

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2014 Update

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