ARTIFICIAL TOTAL DISC REPLACEMENT FOR THE SPINE

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COVERAGE RATIONALE

Cervical artificial total disc replacement is proven for the treatment of single level degenerative disc disease in skeletally mature patients when used according to U.S. Food and Drug Administration (FDA) labeled indications.

Cervical artificial total disc replacement is unproven for the treatment of multiple level degenerative disc disease in skeletally mature patients. Cervical artificial discs have only been FDA approved for those who have single level cervical disc disease. There is insufficient clinical evidence evaluating the safety and efficacy of multiple level disc replacement. The true
rate of complications associated with multiple level disc replacement has not been reported. Well designed studies are needed to establish long-term safety.

**Lumbar artificial total disc replacement is unproven for the treatment of single or multiple level degenerative disc disease in skeletally mature patients.** The long-term clinical outcome of lumbar disc replacement is 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.

**Information Pertaining to Medical Necessity Review (When Applicable)**

Cervical artificial total disc replacement via an open anterior approach with an FDA approved implant (including the Pro-Disc C, Prestige® Cervical Disc and Bryan® Cervical Disc) is medically necessary for the treatment of degenerative disc disease at a single level between C3-C7 in skeletally mature patients for:

- Intractable symptomatic radiculopathy AND/OR
- Intractable symptomatic myelopathy

with at least one of the following conditions producing symptomatic nerve root and/or spinal cord compression:

- Herniated disc AND/OR
- Osteophyte formation

AND all of the following:

- Documented patient history of neck and/or arm pain and/or a functional/neurological deficit associated with the cervical level to be treated
- Failed at least six weeks of non-operative treatment prior to implantation (only applicable for elective surgery; emergent surgery does not require non-operative treatment)

**BACKGROUND**

Artificial total disc replacement refers to the replacement of a degenerating intervertebral disc with an artificial disc in adults with degenerative disc disease (DDD) in either the lumbar or cervical region of the spine. An artificial disc is intended to preserve range of motion (ROM) and reduce pain (ECRI, 2009) and was developed to simulate the motion of the natural spine and prevent adjacent disc degeneration.

Artificial discs may consist of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disk that is inserted between the metal endplates, may be metal on metal, metal on plastic, ceramic on ceramic or titanium on polyurethane. Discs are implanted through an anterior approach and are attached to vertebrae with screws, teeth, ridges, or pins.

**CLINICAL EVIDENCE**

**Cervical Artificial Disc**

Jawahar et al. (2010) compared the incidence of adjacent segment disease in 93 patients who were randomized to receive artificial disc (n=59) or anterior cervical discectomy and fusion (n=34). The study was part of 3 different United States Food and Drug Administration (FDA) prospective randomized controlled Investigational Device Exemption (IDE) trials involving 3 different artificial discs (Kineflex-C, Mobi-C and AdventCervical) at their institution. Visual analog pain score (VAS), Neck Disability Index (NDI), and cervical spine radiographs were collected at 6 weeks and at 3 and 6 months, and then annually up to 4 years after their surgery. At median follow-up of 36.4 months (range, 24-49 months), 65 patients were free from symptoms. In the
remaining 28 patients, surgery was not successful. The success rates for artificial disc (71%) were not statistically different from those of fusion (73.5%). The actuarial median symptom-free survival period was not significantly different. The final scores for VAS and NDI were similar for both groups. Eighteen percent of artificial disc patients and 15% fusion patients developed adjacent segment degeneration. Concurrent lumbar DDD significantly increased the risk of adjacent segment degeneration. The authors only reported positive outcomes and did not report the incidence or rate of revision or account for those patients in whom surgery was not successful. Although artificial disc affords a significantly quicker symptomatic relief, the longer-term outcomes do not prove results superior to those with fusion. The authors concluded that artificial disc is equivalent to fusion for providing relief from symptoms in the treatment of one- and two-level DDD of cervical spine. Additionally, the risk of developing adjacent segment degeneration is equivalent after both procedures but is significantly higher in patients with concurrent DDD in lumbar spine. The authors only reported positive outcomes and did not report the incidence or rate of revision. Artificial disc appears to be equivalent to anterior cervical discectomy and fusion.

Huppert et al. (2011) conducted a prospective multicenter study to compare the clinical and radiological outcomes of cervical disc replacement between single- (n=175) and multilevel (n=56) patients receiving the Mobi-C® device. Follow-up (FU) evaluation was performed at 1, 3, 6, 12, and 24 months after surgery. Comparison between both groups was based on Neck Disability Index (NDI), Visual Analog Scale (VAS), and Range of Motion. At 24 months, mean NDI and VAS scores for neck and arm pain were improved in both groups similarly. Improvement in range of motion was also similar with the single level group having an increase of 2.8 degrees compared to 2.2 degrees in the multilevel group. Post operative analgesic use was higher in the multilevel group at 53% compared to 32% for the single level group. Complications occurred in 19 of the 175 (10.9%) single level patients compared to 11 in the 56 (19.6%) multilevel patients. The rate of dysphagia/dysphonia was significantly higher in the multi-level group (9/56 or 16%) versus (6/175 or 3.4%) in the single-level group. Four patients in the single level group underwent a secondary surgery (2 fusions; 2 disc replacement) versus 2 patients in the multilevel group that had a third device implanted. There were no significant differences between the groups however additional studies are needed to evaluate the impact on safety and efficacy for multilevel disc replacement.

A prospective study by Phillips et al. (2009) evaluated outcomes of cervical disc replacement performed in patients with and without previous anterior cervical decompression and fusion (ACDF) receiving the porous coated motion (PCM) artificial cervical disc in a United States Federal Drug Administration Investigational Device Exemption trial. One hundred fifty two patients were enrolled in the study; 126 patients without previous ACDF and 26 patients with a previous "adjacent level" fusion surgery. Postoperative follow-up occurred at 6-weeks, 3-month, 6-month, 1-year, and 2-years. At 1 year, 93 of the 126 patients with no prior surgery and 21 of 26 prior surgery patients completed follow-up. Outcomes were measured using the Neck Disability Index and Visual Analog Scores which showed improvement after surgery and were similar between groups at all time points. Revision surgery occurred in 2 of 126 primary patients, and in 2 of 26 patients in the adjacent-to-fusion group. The authors found that while both groups had similar outcomes, additional long-term studies are needed to evaluate complication rates as well as whether outcomes are maintained over time.

**Pro-Disc C**

Nabhan et al. (2007) conducted a prospective, randomized controlled study of 25 patients to analyze and compare segmental motion in patients receiving Pro-Disc C or standard cervical disc fusion. Patients were randomized into the 2 groups. Radiostereometric analysis was used to quantify intervertebral motion. Results were judged using visual analogue scale and neuro-examination. Cervical spine segmental motion decreased over time in both groups; however, the loss of segmental motion was significantly higher in the cervical disc fusion group. Neck and shoulder pain decreased in both groups however the difference was insignificant. Follow-up at 6 months showed that cervical spine motion was present in both study groups, but less motion was
detected in patients who underwent a cervical discectomy with fusion and instrumentation.

In a prospective, randomized, controlled trial by Murrey et al. (2009), 209 patients (106 cervical disc fusion; 103 ProDisc-C) were randomized and treated to compare the safety and efficacy of cervical disc replacement with ProDisc-C to anterior cervical discectomy and fusion (ACDF) surgery. Patients were enrolled and treated in accordance with the US Food and Drug Administration (FDA)-approved protocol. Patients were assessed pre- and postoperatively at six weeks, 3, 6, 12, 18, and 24 months. Outcomes were measured utilizing visual analog scale (VAS) pain and intensity (neck and arm), VAS satisfaction, neck disability index (NDI), neurological exam, device success, adverse event occurrence, and short form-36 (SF-36) standardized questionnaires. Both groups showed equal results post-operatively in clinical outcomes. Therefore, the authors concluded that ProDisc-C implantation was either equivalent or superior to the clinical outcomes seen after fusion.

Delamarter et al. (2010) presented the preliminary 4 year follow-up results of the Murrey IDE study. The follow-up rates at 48 months for ProDisc-C TDR and ACDF were 63.0% and 46.2%, respectively, at the time of publication. After closure of randomized enrollment an additional group of 136 continued access (CA) patients had ProDisc-C TDR surgery. At 24 months, there was no significant difference in neurologic improvement among the 3 groups. At 48 months, the overall neurologic improvement trended toward significance for ProDisc-C TDR patients compared with ACDF patients. VAS scores decreased at 24 months in all 3 groups. At 48 months the ACDF group showed only a 38.7 mm reduction in mean VAS score from preoperative levels compared with 49.3 mm in the ProDisc-C TDR group, although this difference was not statistically significant. On radiographic exam at 24 months, flexion-extension range of motion (ROM) at the index level was similar between the Pro-Disc-C TDR and the CA group (9.38° and 9.50°). ROM was <2° in 91.2% of the ACDF patients at 24 months. At 48 months, flexion-extension ROM was maintained in Pro-Disc-C TDR group (9.12°), and 95.5% of the ACDF group had <2°ROM. Of the original study participants, (103 Pro-Disc and 106 ACDF), 11 patients (2 Pro-Disc C and 9 ACDF) required secondary surgical procedures by 24 months. The 3 Pro-Disc patients converted to fusion. In the ACDF group, 6 underwent additional fusion at both the index and adjacent levels, 1 had a revision due to dysphagia associated with plate liftoff, and 1 had posterior decompression with supplemental fixation. By 48 months, 3 of Pro-Disc-C TDR patients and 12 of ACDF patients had required a secondary surgical procedure. The authors conclude that preliminary data at 4 years shows that both total disc replacement and ACDF are viable surgical options for patients with symptomatic cervical disk disease.

In a prospective study by Mehren et al. (2006), 54 patients who received 77 ProDisc-C prostheses were evaluated to determine the rate of heterotrophic ossification formation and the preservation of segmental motion 1 year following surgery. Radiographic comparisons of flexion, extension, lateral, and anteroposterior views showed: no ossification in 26 segments; grade I ossification in 6 segments; grade II ossification was found in 30 segments; heterotrophic ossification that led to restricted motion was found in 8 segments; and spontaneous fusion in 7 segments. The rate of ossification was found to be statistically significant in patients receiving implants at multiple levels of the cervical spine. Patients reported decreased pain and clinical disability ratings were also improved at this time. Due to 49.4% of the patients developing grade 2-3 ossification, it is unclear what rates of spontaneous fusion may occur after long-term follow-up. Motion preservation after total cervical disc replacement is only guaranteed if spontaneous fusion can be prevented. Thus, since mobility of the implanted segments is the main advantage of artificial disc implantation over fusion, this important issue must be further studied. In addition, this study is limited by small sample size and lack of a comparison group.

**Prestige**

Early results from a prospective, randomized controlled trial of 55 patients comparing the efficacy and safety of treatment with the Prestige II artificial disc with anterior cervical fusion were reported by Porchet (2004). Outcomes at 1 year for 37 patients and at 2 years for 9 patients

suggest that artificial cervical disc replacement with the Prestige II is comparable to or better than fusion in relieving pain and other cervical degenerative disc disease symptoms while preserving motion at the treated disc level. In those patients receiving fusion, 19 adverse events were reported, and in those patients receiving artificial disc replacement, 17 adverse events were reported. Adverse events associated with the Prestige II disc included residual neck and shoulder pain, transient recurrent palsy, and temporary dysphagia. This study is limited by small sample size and lack of long term outcomes.

In March 2007, Mummaneni et al. published the results of the pivotal FDA Investigational Device Exemption (IDE) trial that led to approval of the device in July 2007. In this manufacturer-sponsored, prospective randomized multicenter study, 541 patients with single-level intractable cervical DDD were randomized into 2 treatment groups: 276 patients who received the Prestige ST cervical Disc System and 265 patients underwent decompressive anterior cervical disc fusion with allograft and plate fixation. 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. Comparison between the groups showed the Prestige ST group had greater relief of neck pain, returned to work sooner, and had a less adjacent-segment re-operation than the cervical disc fusion group. There were no revision surgeries in the Prestige group, but the control group had 5 revision surgeries. Implant removal was necessary in both treatment groups (1.8% for the Prestige group vs. with 3.4% for the control group). Re-operations were required for adjacent-segment disease in both treatment groups (3 in the Prestige group vs. 11 in the control group). The cervical disc implant group maintained an average of 7 degrees in segmental sagittal angular motion. The study is limited by manufacturer sponsorship and short term follow-up. Additional studies are needed to establish long-term efficacy and impact of implant on adjacent discs.

Burkus et al. (2010) presented 5 year follow-up results of the 2007 Mummaneni manufacturer-sponsored study. Of the 541 patients in the study, 271 (144 investigational and 127 control patients) completed 5 years of follow-up. Mean preoperative Neck Disability Index (NDI) scores for the investigational group were 55.7 and 56.4 for the control group. NDI scores at both 36 and 60 months improved an average of 36.3 and 38.4 points in the investigational group and 31.3 and 34.1 points for the control group. Neck pain and arm pain scores had similar improvements at both 36 and 60 months. Maintenance or improvement of neurological status was seen in both groups, at both 36 and 60 months with greater improvement seen in the investigational group (92.8% and 95%) compared to the control group (83.2% and 88.9%). Angular motion of the Prestige disc averaged more than 7.3° at 36 months and 6.5° at 60 months. At 24 months, there were no revision surgeries in the investigational group compared to 5 revision procedures in the control group. The investigational group had a lower incidence of supplemental fixation than the control group (0.0% vs. 3.4%). Surgery for adjacent level disease trended lower in the investigational group (11 surgeries in 8 patients) compared to the control group (16 surgeries in 13 patients). The authors concluded that cervical disc arthroplasty has the potential to preserve neck motion while providing stability and mobility as demonstrated by these 5 year outcomes.

A prospective pilot study of 15 patients implanted with the Prestige I artificial disc reported improvements in pain scores, physical functioning, and quality of life in all 14 patients at 2 years follow-up. Radiographic evaluation at 2 years indicated that all artificial discs were stable in the intervertebral space, and in all cases, flexion, extension, and translational motion were preserved (Wigfield, 2002). Four-year follow-up of the 14 patients in the study showed that improvements in pain scores, physical functioning and quality of life were maintained. There was no evidence of adjacent segment cervical degenerative disc disease upon radiographic evaluation (Robertson, 2004). Complications and postprocedural adverse events associated with the Prestige I disc included pain on neck extension, transient hoarseness, progressive myelopathy, and recurrent brachialgia. This study is limited by small sample size.
A prospective, randomized, multicenter study by Heller et al. (2009) was conducted on 463 patients to compare the BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion. Patients were divided into 2 groups: 242 received the investigational device (Bryan Cervical Disc), and 221 patients underwent a single-level anterior cervical discectomy and decompression and fusion as a control group. Patients completed clinical and radiographic follow-up examinations at regular intervals for 2 years after surgery. Analysis of 12- and 24-month postoperative data showed improvement in all clinical outcome measures for both groups; however, 24 months after surgery, the investigational group patients treated with the artificial disc had a statistically greater improvement in the primary outcome variables: Neck disability index score and overall success. With regard to implant- or implant/surgical-procedure-associated serious adverse events, the investigational group had a rate of 1.7% and the control group, 3.2%. Patients who received the artificial cervical disc returned to work nearly 2 weeks earlier than the fusion patients. The authors concluded that cervical disc arthroplasty is a viable alternative to anterior cervical discectomy and fusion in patients with persistently symptomatic, single-level cervical disc disease. However, failure rate and conversion to fusion were not reported.

Coric et al. (2006) reported on the safety and efficacy of the Bryan cervical artificial disc compared to fusion in 33 patients with single-level DDD based on data obtained at a single investigational site of the FDA IDE trial (Heller et al., 2009). At 24 month follow-up, no device-related complications had occurred and patients with the Bryan disc had clinical outcomes similar to the patients who had undergone spinal fusion.

In a prospective, randomized study by Sasso et al. (2007), 115 patients were enrolled to compare the Bryan artificial disc replacement to anterior cervical fusion. This study is a pooled data set from 3 centers involved in the FDA IDE trial (Heller et al., 2009) evaluating the Bryan artificial cervical disc. There were 56 patients in the Bryan group and 59 patients in the fusion group. Patients were followed for 24 months with 99 patients completing the study. Disability and pain were assessed using the Neck Disability Index (NDI) and the Visual Analog Scale (VAS) of the neck and of the arm pain. Range of motion was determined by independent radiologic assessment of flexion-extension radiographs. At 2 year follow-up, NDI for the Bryan group is 11 and the control group is 20 and the average arm pain VAS for the Bryan group was 14 and control 28. The disc replacement group retained an average of 7.9 degrees of flexion-extension at 24 months. There were 6 additional operations in this series: 4 in the cervical fusion and 2 in the artificial disc group. Based on these results, the authors concluded the Bryan artificial disc replacement compares favorably to anterior cervical discectomy and fusion for the treatment of patients with 1-level cervical disc disease. The study is limited by short-term follow-up and subjective outcomes. Additional studies are needed to establish long-term efficacy.

A prospective randomized controlled trial by Garrido et al. (2010) reported 4 year follow-up results 47 patients from the Sasso (2007) study randomly assigned to undergo cervical arthroplasty with the Bryan disc (n=21) or spinal fusion (n=26). Outcomes were measured by neck disability index (NDI) score, visual analog score (VAS) for both neck and arm pain, short form (SF-36) physical and mental scores. At the 4 year follow-up, NDI scores changed from 50 preoperatively in both groups to 10 in the cervical disc group and 16.7 in the fusion group. Preoperative neck pain scores on a visual analog scale (VAS) were 76.2 in the disc group and 80.6 in the fusion group. After four years, neck VAS scores were 13.6 in the disc group and 28.1 in the fusion group. Arm pain VAS scores were 78.8 in the disc group and 77.1 in the fusion group preoperatively. After four years, arm pain VAS scores were 10.8 in the disc group and 21.7 in the fusion group. Results were similar between the 2 groups for the SF-36 physical scores; however, for the SF-36 mental scores, there was a 24% improvement in the disc group compared with 13% in the fusion group at 4 years. A total of 6 patients in the control group and 1 patient in the disc group (total of 7 procedures) required reoperation from the initial procedures. In the control group this included 3 procedures for adjacent-level degenerative disc disease (DDD) and 1 procedure for remote-
level DDD which were revised to a fusion, and 2 procedures in 1 patient for pseudarthrosis (failed spinal fusion) that required a facet neurotomy and supplemental fixation. There was 1 procedure for adjacent-level DDD in the disc group that was converted to a fusion. These results appear to show a clinical favorable outcome regarding functional outcomes and adjacent segment disease for cervical disc replacement. Longer term, multicenter studies will be required to definitively prove that cervical arthroplasty does statistically correlate with a lower incidence of adjacent level degeneration and overall better outcomes.

Heidecke et al. (2008) conducted a prospective study of 54 consecutive patients with degenerative cervical disease who underwent ventral discectomy and disc replacement with the Bryan cervical disc prosthesis. A total of 59 prosthetic discs were implanted, in 49 patients at a single level and in 5 at two adjacent levels. Neurological status was evaluated pre-operatively and at one and two years thereafter. Plain X-rays, CT, and MRI were used for pre-operative diagnostics. Post-operative follow-up was done by X-rays. Clinical results and functional outcome at 2 years showed that all patients reported excellent or good neurological outcome. Seven patients experienced loss of mobility, mainly due to the development of heterotopic ossification. Further investigations with longer follow-up periods and with a control group (e.g. fusion with intervertebral cage) will be necessary for a definitive assessment of the long-term functionality and benefits of artificial cervical discs.

Goffin et al. (2010) reported on 4- and 6-year follow-up results after cervical disc replacement surgery using the Bryan Cervical Disc Prosthesis. A total of 98 patients (89 with 1-level and 9 with 2-level implantations) participated in the follow-up studies for up to 10 years postoperatively. Outcomes were measured utilizing the 36-Item Short Form Health Survey, Neck Disability Index, numerical ratings of neck and arm pain, neurological outcomes, Odom classification and angular motion findings from lateral flexion-extension radiographs. The mean angular motion results at 4 and 6 years postoperatively for 1-level patients were 7.3 and 7.7°, respectively. Two-level patients had slightly less motion at 4 and 6 years postoperatively with mean caudad values of 5.7 and 6.0°, respectively, and cephalad values of 4.2 and 6.2°, respectively. A total of 65 patients (61 1-level and 4 2-level patients) had at least 1 adverse event recorded however only 6 of these were judged to be related to the device. These events included device migration, device removal, hoarseness and vocal cord paralysis, as well as 3 cases involving pain and neurological symptoms. In addition, 8 patients underwent further neck surgery to treat symptoms. The authors conclude that favorable outcomes persist after 4-6 years of follow-up. The study was manufacturer sponsored and is limited by small sample size and subjective outcomes.

A study by Walraevens et al. (2010) of the same 89 patients in the Goffin study above assessed the intermediate and long-term radiographic characteristics of disk replacement surgery with the Bryan Cervical Disc. There were no cases of anteroposterior migration or subsidence. Mobility at the treated level was preserved in > or = 85% of cases. The authors concluded that the device maintains preoperative motion at the index and adjacent levels, seems to protect against acceleration of adjacent-level degeneration as seen after anterior cervical discectomy and fusion, and remains securely anchored in the adjacent bone mass in the long run.

In a comparative analysis of two independent studies, 158 patients who underwent cage fusion had a higher incidence of adjacent-segment disease and required more treatments for pain than did 74 patients implanted with the Bryan disc (Robertson, 2005).

An analysis of 10 patients who received the Bryan cervical disc suggested that segmental kyphosis and reduced vertebral body height can result from asymmetrical end plate preparation and intraoperative lordotic distraction (Fong, 2006).

Technology Assessments
A 2010 Hayes Medical Technology Directory report concludes that the evidence suggests that total artificial disc replacement (TDR) provides improvement in signs and symptoms of cervical
degenerative disc disease that is similar to that provided by anterior discectomy and fusion (ACDF), for at least 2 years. In addition, TDR may maintain cervical motion at the treated level, although at the present time, there is insufficient evidence to determine whether TDR will prevent or reduce the development of adjacent-segment disease. Long-term efficacy and safety are also unknown, especially those to device-related complications such as device loosening or breaking.

Blue Cross/Blue Shield (BCBS) Technology Assessment: In 2009, BCBS Technology reviewed the Prestige ST and ProDisc-C artificial discs, and concluded that, "the evidence is insufficient to support conclusions concerning the comparative effect of artificial intervertebral disc arthroplasty on health outcomes."

The California Technology Assessment Forum (CTAF): In 2009, the CTAF concluded that given the uncertainty about the long term risks and benefits of cervical disc replacement, it is not known whether or not it improves health outcomes over the long term.

National Institute for Health and Clinical Excellence (NICE): In 2010, NICE issued a guidance statement on the use of prosthetic intervertebral disc replacement in the cervical spine. NICE concluded that the current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. They further state that the evidence raises no particular safety issues that are not already known in relation to fusion procedures.

Washington State Health Care Authority published the HTA Final Report on Artificial Discs Replacement and concluded that artificial disc replacement is efficacious and effective and that there was moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion, and that C-ADR was safer than anterior cervical discectomy and fusion as measured by the risk of device failure or device/surgical procedure related adverse events or complications up to two years following surgery. However, they also concluded that there is insufficient data at this time to determine long term safety of both lumbar and cervical disc replacement (WHTA, 2008).

Lumbar Artificial Disc
Two studies comparing total disc replacement with lumbar fusion concluded that more high quality randomized controlled trials with long-term follow-up are needed to evaluate the effectiveness and safety of lumbar total disc replacement. A meta-analysis by Yajun et al. (2010) of 837 patients from 5 studies found that total disc replacement does not show significant superiority for the treatment of lumbar degenerative disc disease when compared with fusion. A systematic review by van den Eerenbeemt et al. (2010) of 3 randomized controlled trials and 16 prospective studies found no statistically significant differences in mean pain and physical function scores between lumbar fusion and artificial disc replacement with either the Charite orProdisc artificial discs. Therefore, the existing evidence regarding long-term effectiveness and/or safety is considered insufficient to justify the use of total disc replacement for single level degenerative disc.

Berg et al. (2009) conducted a randomized controlled trial (RCT) comparing total disc replacement (TDR) and instrumented lumbar fusion in 152 patients. Patients in the TDR group were randomized to receive the Charite, Prodisc or the Maverick artificial disc. Outcomes were measured utilizing global assessment (GA), visual analog scale (VAS) for back and leg pain, Oswestry Disability Index, SF36 and EQ5D at 1 and 2 years. There were no differences in outcomes between 1 or 2 level surgery, or between different TDR devices, nor the two different fusion techniques (PLF and PLIF). At 1 year post procedure, the TDR group showed greater improvement in all outcome measurements however by 2 years post procedure, the fusion group had results similar to the TDR group. This study showed that TDR had better outcomes initially however by 2 years, TDR and fusion had similar results. The study is limited by short-term follow-up and subjective outcomes. Additional studies are needed to establish long-term efficacy.
A randomized controlled trial by Guyer et al. (2009), studied 133 patients (90 CHARITE; 43 fusion) to compare the safety and effectiveness at the five-year follow-up time point of lumbar total disc replacement using the CHARITE artificial disc with that of anterior lumbar interbody fusion (ALIF) with BAK cages and iliac crest autograft. Outcomes were measured using visual analog scale (VAS); validated Oswestry disability index (ODI version 1.0); Short-Form 36 Questionnaire, patient satisfaction, radiographic range of motion, disc height, segmental translation work status. Mean changes from baseline for ODI, VAS pain scores, and SF-36 questionnaires were similar across groups. Patient satisfaction surveys showed that 78% of CHARITE patients and 72% of fusion patients were satisfied. 65.6% of patients in the CHARITE group and 46.5% patients in the fusion group were employed full-time. Radiographic findings at the five-year follow-up showed the mean range of motion at the index level was 6.0 degrees for CHARITE patients and 1.0 degrees for fusion patients. Changes in disc height were also similar for both CHARITE and fusion patients. The authors concluded that the results of this five-year study were consistent with the two-year reports of non-inferiority of CHARITE artificial disc vs. ALIF with BAK and iliac crest autograft and there were no statistical differences found in clinical outcomes between groups. The study is limited by subjective outcomes.

In a multicenter, prospective, randomized study by Geisler et al. (2004), 304 patients with degenerative disc disease were enrolled to compare neurological complications of lumbar artificial disc replacement to lumbar fusion. Patients were randomized into 2 groups: 205 patients underwent treatment with the Charite artificial disc and 99 patients underwent spinal fusion. The two groups had equivalent neurological status postoperatively at 6, 12, and 24 months. The patients who had fusions had a greater incidence of both major and minor complications postoperatively at 0 to 42 days. In the two year follow-up, treatment was classified as a success for more disc replacement patients than fusion patients. The authors conclude that the Charite artificial disc appears safe and effective in treating lumbar degenerative disc disease; however no long term studies on the durability of the Charite artificial disc have been completed.

Blumenthal et al. and McAfee et al. reported new data in 2005 on what appears to be the same group of patients reported on earlier by Geisler et al. In a prospective, multicenter study, 304 patients were randomized 2:1 to treatment with the Charite artificial disc or an instrumented anterior lumbar interbody fusion, with the fusion acting as a control group. Patients were followed for 24 months. Outcomes were measured with the Oswestry Disability Index questionnaire, a Visual Analog Scale, and the SF-36 Health Survey. Both groups improved following surgery, although patients who received the artificial disc recovered more quickly than the control group. Patients in the artificial disc group had lower levels of disability than the control group at every time interval post surgery, had a shorter hospitalization, and had a lower rate of reoperations (5.4% vs. 9.1%) (Blumenthal, 2005). At 24 months post surgery, the artificial disc recipients had a satisfaction rate of 73.7% and an increase in employment of 9.1%. The control group had a satisfaction rate of 53.1% and an increase in employment of 7.2%. Although the satisfaction rate improved, this is a subjective response. Flexion/extension range of motion in the artificial disc group increased by 13.6%, but in the control group decreased by 82.5% at 24 months post surgery as compared to the baseline (McAfee, 2005). The artificial disc group had better restoration of disc height than the control group and there was less subsidence in the artificial disc group than the control group. This study is limited by lack of outcome data beyond 24 months.

In a prospective, randomized, multicenter, FDA-regulated Investigational Device Exemption clinical trial, McAfee et al. (2006), studied 589 patients (71 nonrandomized, 205 randomized and 313 continued access) who underwent total disc replacement with the Charite artificial disc. The study also had a control group of 99 randomized patients who received anterior lumbar interbody fusion (ALIF) with threaded fusion cages and autograft. Patients requiring reoperation included 52 from the Charite group and 10 from the control group as well as an additional 2 patients requiring
surgery for adjacent level disease. There were 24 TDR patients who underwent a repeated anterior retroperitoneal approach, with 22 (91.7%) having a successful removal of the prosthesis. Seven of the 24 TDR prostheses requiring removal were revised to another Charite Artificial Disc. A total of 29 patients (4.9%) in the TDR group required posterior instrumentation and fusion as did 10 (10.1%) in the control group. At 2 years or more of follow-up, 93.9% (553/589) of patients receiving TDR with the Charite Artificial Disc had a successfully functioning prosthesis with a mean of over 7 degrees of flexion-extension mobility. The authors concluded that lumbar total disc replacement did not preclude additional surgery at the primary site with replacements being revisable to a new motion preserving prosthesis, ALIF and/or posterior instrumentation.

Katsimihas et al. (2010) prospectively followed 64 patients implanted with the Charite disc. Patients were followed for an average of 55 months (range 24 – 84 months). Outcomes were measured by the Oswestry Disability Index (ODI), visual analog scale (VAS), Short Form-36 (SF-36) health survey and pre and postoperative x-ray studies. Of the 64 patients followed, 57 completed follow-up. All outcome measures showed postoperative improvement at 3 months which persisted throughout the follow-up period. Complications were seen in 3 patients.

Radiographic measurement showed that motion was maintained with a mean sagittal rotation during flexion and extension of 6.5° (range 0.5° to 22.4°). The authors conclude that long-term preservation and maintenance of motion is maintained with the Charite artificial disc. Study is limited by lack of a control group, small sample size and no standardized method for radiographic follow-up.

Putzier et al. (2006) reported on 53 patients implanted with the Charite disc at 1 or 2 levels with an average follow-up of 17 years. Segmental fusion or instrumented spondylodesis was required in 23% as a result of pain, implant failure or fracture, or implant subsidence or dislocation. The artificial disc factured in 13% of the patients. Spontaneous ankylosis occurred in 60% of the patients. The authors concluded that the available long-term results of TDR implantation for the treatment of DDD have not proven this procedure to be as good as or better than fusion.

As a condition of FDA approval, the manufacturer of the Charite artificial disc must conduct a post-approval study of a maximum of 366 subjects (201 randomized investigational subjects, 67 training investigational subjects, and 98 control subjects) to be evaluated for a total of 5 years post-implantation (FDA).

In the first long-term follow-up study by Lemaire et al. (2005), the results of clinical and radiological outcomes of the Charite artificial disc were reported. Of the initial 107 patients receiving the Charte artificial disc, 100 were followed for a minimum of 10 years. The prosthesis implanted included 54 one-level, 45 two-level, and 1 three-level procedures were performed for a total of 147 prosthetic implants. Of the 95 patients eligible to return to work, 88 (91.5%) returned to work including 12 patients who worked in heavy labor. Mean flexion/extension motion was 10.3 degrees for all levels. Mean lateral motion was 5.4 degrees. Two patients experienced slight subsidence, although they did not require further surgery. No subluxation of the prostheses and no cases of spontaneous arthrodesis were identified. It appears that clinical outcomes and return to work rates compare to those of fusion for treatment of lumbar degenerative disc disease. This study is limited by small sample size and lack of a comparison group.

David (2007) conducted a retrospective chart and radiographic review of 106 patients who received an arthroplasty with the ChariteSB III prosthesis from 1989-1995. A modified Stauffer-Coventry scale was used to determine clinical outcomes. This classification system is no longer used, as it has been replaced by the Oswestry Disability Index, Visual Analog Scales and the SF-36 questionnaires; therefore, there was no baseline data for the author to compare outcomes. Mean follow-up time was 13.2 years. Mean ROM in flexion-extension was 10.1 degrees, lateral bending was 4.4 degrees, and 90.6% of implanted prostheses were still mobile. Of the 106 patients, 11 experienced postoperative facet arthrosis, subsidence, adjacent-level disease, and
core subluxation. Of the 96 patients working prior to surgery, 86 returned to work. David concluded that clinical outcomes and the rate of return to work was excellent overall. The rate of adjacent-level disease requiring surgical intervention was considerably lower than lumbar fusion therefore demonstrating long-term safety and efficacy of the Charite artificial disc. The study is limited by retrospective study design. Additional studies, preferably long-term randomized controlled trials, are needed to further validate these results.

Kurtz et al. (2007) completed a study of 21 Charite implants from 18 patients undergoing total disc replacement surgery to evaluate the rate of polyethylene wear and surface damage to the implanted discs. The components had been implanted between 1.8 and 16.0 years. These implants were being removed due to pain caused from subsidence, device migration, core dislocation, and osteolysis. The devices showed evidence of adhesive/abrasive wear at both the dome and rim. Additional rim damage included cracking, fracture, and plastic deformation. Radiographic wire marker fracture was observed in 9 of the 21 implants and was always associated with deformation, cracking or fracture of the polyethylene rim. The authors concluded that additional research is warranted to understand the role of polyethylene wear and patients undergoing total disc replacement as they will require regular long-term follow-up.

**Pro-Disc**

In a prospective, randomized, multicenter, Food and Drug Administration-regulated Investigational Device Exemption clinical trial by Zigler et al. (2007), 286 patients were enrolled to study the ProDisc-L total disc replacement system versus circumferential fusion for the treatment of 1-level degenerative disc disease. Patients were evaluated before and after surgery, at 6 weeks, 3, 6, 12, 18, and 24 months. There were no complications reported for the ProDisc-L. Follow-up at 6 weeks and 3 months showed the ProDisc-L patients recorded SF-36 Health Survey scores significantly higher than the control group (P = 0.018, P = 0.0036, respectively). Comparison of the 2 groups using the Oswestry Low Back Pain Disability Questionnaire (Oswestry Disability Index [ODI]) showed improvement in 91.8% of the investigational and 84.5% of the control patients at 24 months. Review of radiographic range of motion showed maintenance within normal functional range to be 93.7% in the investigational patients and averaged 7.7 degrees. It was concluded that in properly chosen patients, ProDisc-L appears to be superior to circumferential fusion by multiple clinical criteria. The study is limited by short-term follow-up and subjective outcomes. Additional studies are needed to establish long-term efficacy.

Zigler (2004) reported on results of the ProDisc artificial disc with at least six months follow-up. 55 patients were randomized to receive the ProDisc II implant and 23 patients were randomized for a lumbar spinal fusion. The ProDisc II patients had shorter hospital stays, tended to have higher satisfaction rates, experienced more improvement in flexion and lateral bend range of motion, and faster improvement in ambulation and recreational activity than the fusion patients. Both groups had reduced scores in the Oswestry Low Back Pain Disability Questionnaire and the visual analog scale as compared to preoperative values. Zigler concludes that the ProDisc appears to have good outcomes; however, long term studies are needed to assess the durability of the device.

Kim et al. (2007) completed a prospective controlled study of 32 patients who underwent lumbar total disc replacement using the ProDisc II prosthesis. Patients were monitored for 24 months. Nineteen patients had single level total disc replacements (TDR), while 11 patients had TDR at two levels. Radiographic documentation of each patient's range of motion (ROM) was obtained prior to and every 6 months following TDR. Differences between these measures were compared and the outcomes were reported using degrees as a control measure. Visual analog and disability indexes improved significantly during the follow up period. ROM improved within the first 6 months at levels L3-4 and L4-5 (mean=4.78° being noted. ROM decreased following TDR at the L5-S1 level, with no significant improvement noted at anytime. The level of the TDR was found to be a potential negative factor in the minimal gains that were achieved in ROM. Long-term patient follow-up is needed to determine the clinical outcomes of using this prosthesis in the lumbar
Delamarter et al. (2003) reported on 53 patients with at least six months followup. In this sample, 35 patients received the ProDisc II implant and 18 patients had lumbar spinal fusion. Disc replacement patients reported less pain and disability than fusion patients in the early period following surgery, however there was no difference after 6 months. These findings are encouraging; however, additional studies are needed to assess the impact on adjacent vertebra.

Tropiano et al. (2005) reported on 64 patients who had single or multiple-level implantation with a ProDisc total lumbar disc replacement. The follow-up period was 7 to 11 years with a mean of 8.7 years. There were significant improvements in back pain, radiculopathy, disability, and modified Stauffer-Coventry scores. Radiographs did not identify loosening, migration, or mechanical failure in any patient. A patient age of less than 45 years and a history of prior lumbar surgery had small but significant negative effects on outcome. Five patients had approach-related complications. The relatively small number of patients and lack of randomization and a control group are weaknesses of this study.

A retrospective study by Yaszay et al. (2008) of 42 patients enrolled in a prospective randomized FDA ProDisc-L trial, were analyzed to determine factors that could influence motion and patient satisfaction following total disc replacement (TDR) at L4/5 or L5/S1. The patients selected received a TDR at L4/5 or L5-S1. Pre- and postoperative disc height and range of motion (ROM) were measured from standing lateral and flexion-extension radiographs. Anterior and posterior disc heights increased; however, the patients' ROM had decreased. Threshold factors (i.e., anterior and posterior disc heights) that were analyzed showed patients with <9 mm of anterior disc height had an increased ROM of 2.2°of disc height had a -2.2 decrease in their ROM. These findings were considered significant. While improvements were noted based on patient reported visual analog scale scores and Oswestry Disability Index measures, no significant difference between the groups could be found that would explain the average decrease in ROM from 7.0° to 5.7°patients following the use of TDR will determine if the ROM gains will be maintained.

In 3 case series (n=22, 25, 104 patients) of ProDisc implants, Bertagnoli reported statistically significant improvements in pain and disability at 2 to 4 year follow-up (Bertagnoli, 2005a; Bertagnoli, 2005b; Bertagnoli, 2006). The relatively small number of patients, lack of control groups and short-term follow-up are weaknesses of these studies.

National Institute for Health and Clinical Excellence (NICE): In 2009 NICE concluded that the current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support its use in the lumbar spine.

Additional Search Terms
disc ablation, disc excision, disc extrusion, disc nucleotomy, disc prolapse, discotomy, discectomy, nucleus pulposus, intervertebral disc herniation, laminotomy, lumbar disc herniation, lumbar disc protrusion, protruded disc, ruptured disc, slipped disc

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
The Charite® intervertebral disc (DePuy Spine, Inc., Raynham, MA) received FDA Premarket Approval on October 26, 2004. It is approved for use in patients who have single-level degenerative disc disease (L4-S1) of the lumbar spine and who have had no relief from low back pain after at least six months of nonsurgical treatment. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040006a.pdf. Accessed June 14, 2011.

The ProDisc - L Total Disc Replacement received FDA Premarket Approval on August 14, 2006 for use in patients who have single-level degenerative disc disease of the lumbar spine (L3-S1)
and who have had no relief from low-back pain after at least 6 months of nonsurgical treatment. Additional information is available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077620.htm. Accessed June 14, 2011.

The following cervical disc replacement products (product code MJO) have received FDA approval:

- ProDisc-C Total Disc Replacement received premarket approval on December 17, 2007 (P070001). The device is indicated for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes) and/or loss of disc height. The ProDisc-C total disc replacement is implanted via an open anterior approach. Patients receiving the ProDisc-C total disc replacement should have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=940. Accessed January 31, 2012.

- Prestige® Cervical Disc System received premarket approval on July 16, 2007 (P060018). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation. The safety and effectiveness of the device has not been established in patients who have not undergone at least six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=10351. Accessed January 31, 2012.

- Bryan® Cervical Disc received premarket approval on May 12, 2009 (P060023). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Bryan device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT and/or magnetic resonance imaging (MRI). Patients receiving the Bryan Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=14205. Accessed January 31, 2012.

**Additional Products**

**Lumbar:** FlexiCore Artificial Disc; The PCM (Porous Coated Motion) device; DASCOR disc nucleus replacement, Freedom Lumbar Disc

**Cervical:** Mobi-C
In Clinical Trials: Kineflex Artificial Disc, MAVERICK™, CerviCore, Discover Artificial Cervical Disc, Advent Cervical Disc

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover lumbar artificial disc replacement (LADR) for Medicare population over 60 years of age. There is no national coverage determination for LADR for Medicare beneficiaries 60 years of age and younger, leaving such determinations to continue to be made by local contractors. See the National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10).

Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the LCD for Artificial Disc.

(Accessed March 18, 2011)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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REFERENCES


Coric D, Finger F, Boltes P. Prospective randomized controlled study of the Bryan Cervical Disc:


**POLICY HISTORY/REVISION INFORMATION**

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| 04/01/2012 | • Revised coverage rationale for cervical total disc replacement for the treatment of single level degenerative disc disease in skeletally mature patients:  
  o Removed language indicating treatment is proven when used with FDA approved implants  
  o Added language to indicate treatment is proven when used according to U.S. Food and Drug Administration (FDA) labeled indications  
  • Added language to support medical necessity review, when applicable  
  • Archived previous policy version 2011T0437J |