Total Artificial Disc Replacement for the Cervical Spine (for North Carolina Only)

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Instructions for Use

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Related Policies

- Bone or Soft Tissue Healing and Fusion Enhancement Products
- Surgical Treatment for Spine Pain

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Artificial Disc Replacement, Cervical.

Click here to view the InterQual® criteria.

Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) is unproven and not medically necessary due to insufficient evidence of efficacy.

Definitions

Skeletally Mature: The apparent stage of development the bones of a growing child or adolescent. It is determined with radiological studies. The determination is used to analyze normal and disordered growth in children.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may

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require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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)
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22899	Unlisted procedure, spine

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Description of Services

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). These prostheses replace the degenerated disc and have been proposed as a means of improving flexibility, maintaining spinal curvature and providing an equalized weight-bearing surface, while reducing or possibly eliminating pain.

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 (Single Level)

A systematic review and meta-analysis were performed by Wang et al. (2020) to evaluate the long-term safety and efficiency of cervical disc arthroplasty (CDA) and anterior cervical discectomy (ACDF) for cervical disc disease. A total of 11 randomized controlled trials with 3,505 patients (CDA/ACDF: 1,913/1,592) were included in this meta-analysis. Compared with ACDF, CDA achieved higher overall success (2.10, 95% CI [1.70, 2.59]), neck disability index (NDI) success (1.73, 95% CI [1.37, 2.18]), neurological success (1.65, 95% CI [1.24, 2.20]), patients' satisfaction (2.14, 95% CI [1.50, 3.05]), and patients' recommendation rates (3.23, 95% CI [1.79, 5.80]). Functional outcome measures such as visual analog score neck pain (−5.50, 95% CI [−8.49, −2.52]) and arm pain (−3.78, 95% CI [−7.04, −0.53]), the Short Form-36 physical component score (SF-36 PCS) (1.93, 95% CI [0.53, 3.32]), and the Short Form-36 mental component score (SF-36 MCS) (2.62, 95% CI [0.95, 4.29]), revealed superiority in the CDA group. CDA also achieved a lower rate of symptomatic ASD (0.46, 95% CI [0.34, 0.63]). The authors concluded that compared to ACDF, CDA had a higher long-term clinical success rate and better functional outcome measurements and resulted in less symptomatic ASD and fewer secondary surgeries (Author Radcliff (2017) which was previously cited in this policy is included in this meta-analysis).

A systematic review and meta-analysis were performed by Wahood et al. (2020) to examine the long-term outcomes of five artificial cervical discs. Sixty-five studies (n= 5,785) were included in the analysis; 20 randomized clinical trials, 24 prospective clinical studies, and 21 retrospective observational studies. Comparison of the incidence of grade III/IV heterotopic ossification showed a significant variability between the five devices ($P < 0.001$) with ProDisc-C (ES, 38%; 95% confidence interval [CI],

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24%–54%) having the highest incidence rate. Overall rate of adjacent segment disease was 14% (95% CI, 7%–23%) with significant associated heterogeneity (P < 0.001). Patients who underwent CDR with Bryan devices reported the largest change in NDI scores (n ¼ 1501; WA delta NDI, 34.0 out of 100; SD, 5.8) and the largest change in VAS neck pain scores (n ¼ 1511; WA delta VAS, 51.4 out of 100; SD, 7.2). The two-year reoperation risk overall incidence rate was 2% (95% CI, 1%e3%), with nonsignificant variability between devices (P < 0.63). The authors concluded that the results of this meta-analysis indicated that surgical and clinical outcomes may differ among different CDR devices. Future multicenter efforts are needed to validate associations found in this study. These findings are limited by the observational design of some of the included studies (Authors Chang (2017), Gao (2019) and Huppert (2011) which were previously cited in this policy are included in this meta-analysis).

Latka et al. (2019) performed a meta-analysis to compare the safety and efficacy of CDA to those of the gold standard, ACDF. Both surgical and clinical parameters were employed to verify the hypothesis that CDA can reduce the risk of adjacent segment degeneration (ASD). Twenty randomized controlled trials studies with 3,656 patients (2,140 with CDA and 1,516 with ACDF) met the inclusion criteria. CDA surgery, with mean duration longer than that of ACDF, was associated with higher blood loss. Visual analog scale neck pain score was significantly smaller for CDA. The frequency of dysphagia/dysphonia as well as the long-term ASD rate for CDA was significantly smaller. The authors concluded that a significantly lower probability of ASD reoperations in the CDA cohort after a 60-month or longer follow-up was the most important finding of this study. Despite the moderate quality of this evidence, the pooled data corroborated for the very first time that CDA was efficacious in preventing ASD.

Findlay et al. (2018) conducted a systematic review and meta-analysis to determine how the short- and medium- to long-term outcome measures after total disc replacement (TDR) compare with those of ACDF. Inclusion criteria involved prospective randomized control trials (RCTs) reporting the surgical treatment of patients with symptomatic degenerative cervical disc disease. A total of 14 RCTs were included, representing 3,160 patients with follow-up of up to ten years. Meta-analysis indicated that TDR is superior to ACDF at two years and between four and seven years. In the short-term, patients who underwent TDR had better patient-reported outcomes than those who underwent ACDF. Results between four and seven years showed significant differences in NDI, 36-Item Short-Form Health Survey (SF-36) physical component scores, dysphagia, and satisfaction, all favoring TDR. Most trials found significantly less adjacent segment disease after TDR at both two years (short-term) and between four and seven years (medium- to long-term). The authors concluded that TDR is as effective as ACDF and superior for some outcomes. Disc replacement reduces the risk of adjacent segment disease.

A meta-analysis of published RCTs was conducted by Gutman et al. (2018) to determine whether ACDF, cervical disc replacement (CDR), or minimally invasive posterior cervical foraminotomy (MI-PCF) provides the best outcomes for patients with symptomatic single-level, single-side, and cervical radiculopathy. Four RCT reports met the inclusion criteria for this study. Available data from the RCTs analyzed concluded that ACDF, CDR, and MI-PCF result in significant improvements in relevant symptoms, clinical, and functional outcomes in patients with single-level, single side cervical radiculopathy refractory to nonoperative treatment. CDR had the lowest percentage of secondary surgical procedures and MICPF had the lowest percentage of adverse events. The authors concluded that all three techniques are effective in treating cervical radicular symptoms. There is insufficient evidence to show which technique is the most effective and provides the longest-lasting symptom relief.

A prospective study was performed by Pointillart et al. (2018) to assess the clinical and radiological results of Bryan cervical disc replacement at 15-year follow-up. The study included 20 patients who underwent cervical total disc replacement (CTDR), comprising a single-level procedure in 14 patients and two-level procedures in six patients. The mean follow-up period was 15.5 years. Two patients needed re-operation for recurrence of symptoms. According to Odom's criteria, 80.0% (16 of 20 patients) had excellent outcomes, VAS for neck pain was 2.6 (0-10), for shoulder/arm pain it was 1.8 (0-7), and NDI at the final follow up was 14.9. The SF-12 PCS was 46.1, and SF-12 MCS was 51.9. Mobility was maintained in 15 of the 22 (68.2%) operated segments, ROM of prostheses were 9° ± 3.9° (range 4-15°). The prostheses were positioned in kyphosis in 14 of 22 levels (63.6%). There was a positive correlation between the kyphosis of the prosthesis and the occurrence of heterotopic ossification (HO), and their grade. HO had developed at 12 of the 22 levels (54.5%) and upper adjacent segment degeneration in 11 of 18 of patients (64.7%). All these results were not significantly different to outcomes at 8 years follow-up. The authors concluded that in a cohort of 20 patients with 15-year clinical and radiological follow-up, the Bryan CTDR has demonstrated a sustained clinical improvement and implant mobility over time, despite a moderate progression of degenerative processes at the prosthetic and adjacent levels.

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Zeng et al. (2018) performed a retrospective study to assess the long-term clinical and radiographic outcomes of CDA with Prestige-LP Disc at a minimum of six-year follow-up. A total of 61 patients who underwent single- or two-level CDA with Prestige-LP Disc were included. Clinical assessments included visual analogue scale (VAS) for neck and arm pain, NDI, and Japanese Orthopedic Association (JOA) score. Radiological evaluations included ROM of the index and adjacent levels, segmental angle, cervical sagittal alignment, HO, and ASD. Significant and maintained improvement in VAS for neck and arm, NDI and JOA were observed after a mean follow-up of 82.3 months. The preoperative ROM of the index level was 9.7°, which was maintained at two-and four-year follow-up, but was decreased to 8.0° at final follow-up. Mobility was maintained in 80.5% of the implanted prostheses at final follow-up. ROM of the superior and inferior adjacent segments, cervical sagittal alignment and cervical angel were all maintained. The incidence of HO was 42.9% at final follow-up, but it did not influence the clinical outcome. Radiographic ASD were detected in 29.5% of the patients. However, the incidence of symptomatic ASD was only 6.6%. The authors concluded that cervical disc arthroplasty with Prestige-LP Disc demonstrated a maintained and satisfactory clinical outcome at a minimal of six-year follow-up, with majority of the prostheses remained mobile. Cervical disc arthroplasty with Prestige-LP Disc can be considered as an effective surgical method in treating CDDD.

Lu and Peng (2017) conducted a systematic review and meta-analysis to compare the efficacy and safety of Mobi-C cervical artificial disc and ACDF in patients with symptomatic degenerative disc disease. Four RCTs assessing the effect of Mobi-C versus ACDF on the treatment of symptomatic degenerative disc disease were included. The primary outcomes were NDI score, patient satisfaction, and subsequent surgical intervention. Meta-analysis was performed using the random-effect model. When compared with ACDF surgery in symptomatic degenerative disc disease, TDR using Mobi-C cervical artificial disc resulted in a significantly improved NDI score, patient satisfaction, and reduced subsequent surgical intervention. There was no significant difference of neurological deterioration, radiographic success, and overall success between TDR using Mobi-C cervical artificial disc versus ACDF surgery. The authors concluded that TDR using Mobi-C cervical artificial disc should be recommended for the treatment of symptomatic degenerative disc disease.

Chen et al. (2017) performed a systematic review and meta-analysis to assess the durability of CDAs in at least two-year follow-up. The classifications and causes of secondary surgical procedures, as well as the structural designs of the devices that might influence the durability were analyzed. The primary outcome was the rate of secondary surgical procedures following CDA or ACDF. Twelve RCTs met the inclusion criteria and included 2,954 patients. Nine of twelve studies compared single-level CDA with ACDF and three studies investigated 2-level CDA. Follow-up ranged from two years to seven years. A total of 103 secondary surgical procedures were performed. The most frequent classification of secondary surgical procedures was reoperation and removal. Adjacent-level diseases were the most common cause of reoperations. The rates of secondary surgical procedures were significantly lower in Mobi-C, Prestige, Prodisc-C, Secure-C group than in ACDF group. The authors concluded that Mobi-C, Secure-C, and Prodisc-C were more durable than ACDF. Precise selection of device size and proper surgical techniques are crucial to enhance the perdurability.

An August 2017 Hayes Medical Technology Comparative Effectiveness Review evaluated eleven (10 fair quality, 1 poor quality) RCTs that examined the effectiveness and safety of single-level artificial cervical TDR compared with ACDF. Severity of neck disability appeared to be similar between treatments, or may even be lower among TDR patients. Arm and neck pain was either less severe with TDR, or similar between treatments. Neurological status outcomes appeared to be firmly similar with either treatment. Health-related quality of life (HRQOL) outcomes also appeared to be similar between the groups, although there is some evidence of better outcomes with TDR. Rates of adverse events appear to be similar between treatments. Rates of adjacent segment disease appear to be either similar, or lower, among TDR patients. The review found that in adult patients with cervical degenerative disc disease, there is generally consistent evidence that single-level TDR is either comparable with or superior to ACDF for both clinical efficacy and safety outcomes. Uncertainty remains related to outcomes beyond seven years following surgery. In an updated 2019 review, nine abstracts were retrieved, including five long-term follow-up reports of randomized controlled trials, three meta-analyses, and one cost-effectiveness analysis. The evidence remains unchanged for the use of single-level TDR for treatment of cervical DDD in adult patients with symptoms that have not responded to conservative therapies and who have no contraindications to surgery (Hayes, 2019).

Hu et al. (2016) conducted a systematic review and meta-analysis to investigate the mid- to long-term outcomes of CDA versus ACDF for the treatment of 1-level or 2-level symptomatic cervical disc disease. Eight prospective RCTs were included with 1,317 and 1,051 patients in CDA and ACDF groups, respectively. Overall success was considered achieved if a patient met all of the following items: NDI success, neurological success, absences of implant/surgery-related serious adverse events and secondary procedure. Pooled analysis showed patients in CDA group achieved significantly higher rates of overall success, NDI success, neurological success and significantly lower rates of implant/surgery-related serious adverse events and secondary procedure

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compared with that in ACDF group. The long-term functional outcomes (NDI, VAS neck and arm pain scores, the Short Form 36 Health Survey physical component score (SF-36 PCS)), patient satisfaction and recommendation, and the incidence of superior adjacent segment degeneration also favored patients in CDA group with statistical difference. Patients in CDA group had a lower rate of inferior adjacent segment degeneration without statistical significance. The authors concluded that this meta-analysis showed that cervical disc arthroplasty was superior over anterior discectomy and fusion for the treatment of symptomatic cervical disc disease.

A meta-analysis was performed by Wu et al. (2016) which included randomized controlled trials that reported a minimum of 4 years of follow-up with regard to the rates of subsequent surgeries after artificial cervical disc replacement (ACDR) compared with ACDF. The overall rate of subsequent surgery at the operated level and adjacent levels was lower in the ACDR group (7.4%) than in the ACDF group (16.8%). For subsequent surgery at the operated level or adjacent level, patients who received ACDR had a lower rate of subsequent surgery than patients who received ACDF. The authors concluded that ACDR had significantly fewer subsequent surgical interventions compared with ACDF, however, a review of the literature showed that there were an insufficient number of studies with respect to subsequent surgery with a minimum of four years of follow-up. Longer-term, multicenter studies are needed for better evaluation of the rate of subsequent surgery after ACDR.

Yao et al. (2016) performed a meta-analysis to compare the efficacy and safety of total disc arthroplasty (TDA) and ACDF. Clinical indices included NDI, Neurological Success (NS), Overall Success (OS), Return-to-Work Status (RWS), Reoperation (RO) and Implant/Surgical Procedure-Related Adverse Events (ISPRAE). A total of nine articles reporting on six trials with 2,121 patients were included, in which 1,082 underwent TDA and 1,039 underwent ACDF. NDI scores were reported in five studies and did not differ significantly between the two groups. Neurological success was documented in five studies and the TDA group had significantly better neurological success compared with the ACDF group. Five studies provided data on overall success. The TDA group had significantly better overall success compared with the ACDF group. Return-to-work status after operation was reported in three studies and there was no significant difference between the two groups. Six trials reported data on secondary surgical procedures. The results showed that TDA is associated with significantly lower incidence of secondary surgical procedures than ACDF. Six trials reported on secondary surgical procedures at the adjacent level. There was no significant difference between the two groups. The authors summarized that based on the current literature review and meta-analysis; the clinical outcomes of TDA are equivalent or superior to ACDF. In addition, more long-term RCTs will be needed to corroborate the current conclusions.

Gornet et al. (2016) conducted a study to assess the safety and efficacy of the Prestige® LP Disc at 84-months follow-up. Prospective data from 280 CDA patients with single-level cervical disc disease with radiculopathy or myelopathy were compared with 265 historical control ACDF patients. Clinical and radiographic follow up was completed pre-operatively, intraoperatively, and at intervals up to 84 months. Statistical improvements in NDI, neck/arm pain, and SF-36 were achieved by 1.5 months in both groups and maintained through 84 months. At 84 months, 86.1% of CDA versus 80.1% of ACDF patients achieved NDI success, (≥15-point improvement over baseline). Mean NDI score improvements exceeded 30 points in both groups. SF-36 PCS/MCS mean improvements were 13.1±11.9/8.2±12.3 points for CDA and 10.7±11.8/8.3±13.6 points for ACDF. Neurological success was 92.8% for CDA and 79.7% for ACDF patients. The rate of Overall Success was 74.9% for CDA and 63.2% for ACDF. At 84 months, 17.5% of CDA and 16.6% of ACDF patients had a possibly implant- or implant-surgical procedure-related adverse event. Eighteen (6.4%) CDA and 29 (10.9%) ACDF patients had a second surgery at the index level. At 84 months, 90.9% of CDA and 85.6% of ACDF patients were satisfied with the results of their treatment. The authors concluded that Prestige LP maintained significantly improved clinical outcomes and segmental motion; statistical superiority of CDA was concluded for overall success. Additional studies are needed to establish long term efficacy.

A meta-analysis of RCTs was performed by Xie et al. (2016) to evaluate the efficacy and safety in CDA and ACDF for treating cervical degenerative disc diseases (CDDDs). Twenty RCTs with a total 4,004 patients (2,212 in the CDA and 1,792 in the ACDF) met inclusion criteria. Fifteen of the included studies were multi-center trials; five were single-center trials. Eight types of disc prostheses were used and patients were followed up for at least two years. The outcome measurements included NDI, neurological success, ROM, VAS, adverse events, ASD, and reoperation. The NDI score, VAS of neck, and VAS of arm of the CDA group was significantly lower than that of the ACDF group. The rate of neurological success and ROM were significantly higher than that of the ACDF group. The authors concluded that the results of this meta-analysis indicated that CDA was superior to ACDF regarding fewer severe advents, fewer ASDs, fewer reoperations, better neurological success, greater ROM, lower NDI scores and greater neck and arm pain functional recovery. They recommended additional large, definitive RCTs.

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Dejaegher et al. (2016) presented the 10-year follow-up results after implantation of the Bryan® Cervical Disc Prosthesis in a single center. Eighty-nine patients underwent implantation of a single-level Bryan® Cervical Disc Prosthesis to treat radiculopathy and/or myelopathy. Clinical outcomes measured include Neurological Success, NDI, Neck- and Arm-Pain, and Short Form-36 (SF-36). Adverse events and second surgeries were recorded and evaluated. Maintenance or improvement of the neurological state was seen in 89% of patients after 10-year follow-up. SF-36 Physical Component Summary (PCS) scores improved significantly at all follow-up points. Significant improvement for NDI, and Neck- and Arm-Pain scores was found. Mean angular motion of the prosthesis at 10-year follow-up was 8.6°. Mobility of the device, defined as >2° of angular motion, was reached in 81% of patients. During the study period, 21 patients (24%) developed new or recurrent radiculopathy or myelopathy, the majority of these being treated conservatively. Seven patients (8%) required eight additional spine surgeries to treat persistent or recurrent symptoms. In this study, favorable long-term clinical outcome after implantation of the Bryan® Cervical Disc Prosthesis was seen, with the majority of prostheses remaining mobile after 10-year follow-up. However, still 6% of patients required adjacent level surgery.

In 2010, the National Institute for Health and Care Excellence (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.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

Although it is not an official position statement, in 2010 the AAOS published a technology overview of cervical disc arthroplasty. The committee addressed four key questions regarding the technology, comparing the outcomes of patients treated with cervical intervertebral disc (IVD) replacement to patients treated with ACDF. The key questions addressed what patient characteristics predicted successful outcomes in patients who underwent cervical IVD replacement compared to ACDF; do patients with herniated disc and arm pain, with or without neck pain, have equal or better outcomes when compared to ACDF, are the revision rates and/or complication rates equal or better in those who receive disc replacement compared to ACDF, and for patients which is more economical, according to hospital length of stay and return to work. Regarding patient characteristics, the data was inconclusive, most studies did not report a statistical analysis, and only one level II study reported no statistically significant difference. For clinical outcomes, five level II studies were included. There was a trend for better NDI scores and NDI success rate at early follow-up, data for long term follow-up was inconclusive. While one study reported arthroplasty had significantly higher neurologic success rates, two level II studies reported no statistically significant differences. A majority of the studies reported no statistically significant difference in either neck or arm pain scores at short term follow-up (six months to 24 months), long term data was inconclusive. The result reported by three level II studies was inconclusive regarding SF-36 scores and there were no differences in the number of patients who returned to work at 24 months. The results of four level II studies were included, three did not report secondary surgery results similarly, and therefore the results could not be compared. The results for adverse events were also inconclusive in these same studies. Patients who underwent arthroplasty returned to work in significantly fewer days although the length of hospital stay did not vary between groups.

International Society for the Advancement of Spine Surgery (ISASS)

The ISASS published a policy statement (ISASS, 2014) supporting the safety and efficacy of cervical disc arthroplasty as an alternative to anterior cervical discectomy and fusion for individuals with one- or two-level cervical radiculopathy or myelopathy.

A 2019 Position Statement states that the ISASS strongly supports cervical total disc replacements as safe and effective treatment alternatives to fusion in appropriately-selected patients. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use, as supported by a strong published database (Schroeder (2019).

North American Spine Society (NASS)

The 2015 Cervical Artificial Disc Replacement (CADR) Coverage Policy Recommendation states that CADR may be indicated for the following diagnoses with qualifying criteria, when appropriate.

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- Radiculopathy related to nerve root compression from one or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
- Myelopathy or myeloradiculopathy related to central spinal stenosis from one or two level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain.

There is not significant evidence to support its use for three or more levels or in the case of adjacent segment disease following an index fusion.

Cervical Artificial Disc (Two Level)

A 2020 Hayes comparative effectiveness review of multilevel artificial disc replacement for cervical degenerative disc disease included eight studies; four randomized controlled trials, one prospective nonrandomized trial, one prospective comparative cohort study, one prospective trial with historical controls and one retrospective comparative cohort study. Studies were selected for inclusion if they met the following criteria: patients with cervical DDD, comparative evaluation of multilevel TDR with ACDF control group, at least one year of follow-up, and evaluated pain, disability, HRQOL, and/or safety outcomes. The report found that based on the evidence reviewed, patients with cervical DDD who undergo cervical total disc replacement may achieve higher rates of overall success compared with patients who undergo ACDF. Improvements in the severity of neck disability appear to be similar between treatments or may even be greater among TDR patients. Arm and neck pain are either less severe with TDR, or similar between treatments, as are neurological status outcomes. The evidence regarding health-related quality of life (HRQOL) outcomes shows better outcomes are more likely with TDR. Rates of adverse events appear to be similar between treatments. The evidence suggests that TDR generally results in lower rates of reoperation. The authors concluded that there is a need for additional, well-designed and executed RCTs to further evaluate the long-term safety and effectiveness of 2-level and multilevel cervical TDR and to further refine patient selection criteria (Authors Lanman (2017) and Radcliff (2016) which were previously cited in this policy are included in this report).

As part of a cohort study with adjustment using propensity scores, Gornet et al. (2019) compared outcomes of 1-level CDA to 2-level CDA and of 1-level ACDF to 2-level ACDF at two and seven years in patients enrolled in Food and Drug Administration (FDA)-approved clinical trials involving the same devices and the same efficacy and safety measures for both. In total, 545 and 397 patients with degenerative disc disease were studied in 1-level and 2-level: CDA (n = 280 and 209), ACDF (n = 265 and 188). At 7 years, the CDA groups had the following score improvements compared to baseline for 1 and 2 levels, respectively: NDI (38.2 vs 39.0, P = 0.768), neck pain (11.7 vs 12.3, P = 0.374), arm pain (11.3 vs 11.0, P = 0.736), SF-36 PCS (12.6 vs 14.5, P = 0.220), and MCS (8.5 vs 9.3, P = 0.605). At 7 years, the ACDF groups had the following score improvements for 1-level and 2-levels, respectively: NDI (31.1 vs 31.6, P = 0.859), neck pain (9.7 vs 9.9, P = 0.796), arm pain (9.9 vs 10.1, P = 0.848), SF-36 PCS (10.8 vs 12.1, P = 0.424), and MCS (7.9 vs 7.6, P = 0.828). The 7-year rate of implant-related AEs was higher for 2-level than 1-level ACDF (27.7% vs 18.9%, P ≤ .036). Secondary surgery rates were not statistically different between 1-level and 2-level procedures (CDA or ACDF) at the index or adjacent levels. The authors concluded that 1 and 2-level CDA appear equally safe and effective in the treatment of cervical degenerative disc disease. Two-level ACDF appears to be as effective as 1-level ACDF but with a higher rate of some AEs at long-term follow-up.

A 2019 Ontario health technology assessment (Pron et al., 2019) examined the effectiveness, safety, durability, and cost-effectiveness of cervical artificial disc replacement (C-ADR) versus fusion for treating cervical degenerative disc disease. A systematic literature search of the clinical evidence comparing C-ADR with fusion was performed. Eight studies of C-ADR for one-level cervical degenerative disc disease and two studies of C-ADR for two-level disease were included. In two studies of C-ADR for two-level disease, C-ADR was statistically superior to fusion surgery for the same primary outcome. C-ADR was also noninferior to fusion for perioperative outcomes (e.g., operative time, blood loss), patient satisfaction, and health-related quality of life. C-ADR was superior to fusion for recovery and return to work, had higher technical success, and had lower rates of re-operation at the index site. C-ADR also maintained motion at the index-treated cervical level, but evidence was insufficient to determine if adjacent-level surgery rates differed between C-ADR and fusion. The authors concluded that current evidence was insufficient to determine the long-term durability of C-ADR, and that for carefully selected patients with cervical degenerative disc disease, C-ADR provides patient-important and statistically significant reductions in pain and disability. Unlike fusion, C-ADR allows people to maintain relatively normal cervical spine motion.

A cohort study was performed by Gao et al. (2019) to present a long-term clinical and radiographic comparison between the Prestige LP cervical disc replacement and the Zero-P spacer cervical disc fusion in the treatment of patients with symptomatic 2-level cervical degenerative disease. In total, 36 patients in the ACDF group and 24 patients in the CDA group were analyzed

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before surgery and at one week and three, six, 12, 24, and 60 months after surgery. Mean follow-up period was 65.6 months. Both the ACDF and CDA groups showed significant clinical improvements in terms of Japanese Orthopaedic Association score, visual analog scale, and NDI, but there was no significant difference between groups at the last follow-up period. A significant increase of cervical lordosis was observed in the CDA group after surgery whereas a significant difference was not observed between groups. ROM of the total cervical spine and functional spinal unit (FSU) were maintained during the follow-up, and a significant decrease was observed in the ACDF group after surgery. The ROM of the superior adjacent segment did not show any difference whereas the ROM of the inferior adjacent segment in the ACDF group presented a significant increase at six months and one year after surgery and a significant decrease at the last follow-up period. A total of eight (33.3%) patients in the CDA group had an occurrence of heterotopic ossification. ASD was observed in two (8.3%) patients who underwent CDA surgery and eight (22.2%) patients who underwent ACDF surgery. The authors concluded that the use of the Prestige-LP and ZERO-P Spacer implantations is safe and effective. At five years after surgery, CDA with Prestige-LP is superior in terms of ROM of the total cervical spine, FSU, and inferior adjacent segment. It also has a relatively low occurrence rate of ASD.

A systematic review and meta-analysis were conducted by Lu et al. (2019) to compare clinical outcomes of all available ASD cohorts being treated by either ACDF or TDR. Overall, 103 and 258 ASD cases managed by TDR and ACDF, respectively, were reviewed. At minimum one-year follow-up, follow-up ROM of C2-C7 was higher for TDR group compared to ACDF (40.2 vs 35.1, $P < .001$). There were no significant differences noted between TDR and ACDF groups in terms of VAS neck, VAS upper limb, NDI, or JOA scores. The authors concluded that TDR confers similar surgical and postoperative outcomes to the treatment of ASD as ACDF. Both procedures lead to improvement in all performance outcomes. Study limitations such as limited follow-up, small cohort size, retrospective nature, and lack of randomization weaken the findings of this meta-analysis.

Zhao et al. (2018) conducted a systematic review and meta-analysis to compare the efficacy and safety of anterior cervical artificial disc replacement (ACDR) and ACDF in patients with two contiguous levels cervical spondylosis. The following outcome measures were extracted: NDI, VAS neck, VAS arm, Short Form (SF)-12 mental component summary (MCS), SF-12 physical component summary (PCS), overall clinical success (OCS), patient satisfaction (PS), device-related adverse event (DRAE), subsequent surgical intervention (SSI), neurological deterioration (ND), and ASD. Nine randomized controlled trials and 2 clinical controlled trial studies containing 2,715 patients were included for this meta-analysis. The pooled analysis indicated that the ACDR group is superior to ACDF in NDI, VAS neck, PCS score, OCS, PS, DRAE, ASD, and SSI. There was no significant difference in the ND, VAS arm and in MCS score. The authors concluded that the meta-analysis suggests that for bi-level cervical spondylosis, ACDR appears to provide superior clinical effectiveness and safety effects than ACDF. More well designed studies with large samples are needed to provide further evidence for the effect and reliability of ACDR compared with ACDF in the treatment of cervical spondylosis

Yang et al. (2018) performed a study to evaluate the superiority of TDR using a cervical disk prosthesis versus ACDF. Ninety-six patients with a diagnosis of degenerative disk disease with radiculopathy or myeloradiculopathy at two contiguous levels from C-3 to C-7 were randomly allocated to the TDR group (n=48) or the ACDF group (n=48). Outcome measures were recorded preoperatively and one week and three, six, 12, 24, and 81 months postoperatively. A total of 80 patients completed the follow-up, including 38 in the TDR group and 42 in the ACDF group. Japanese Orthopaedic Association, visual analog scale, and Neck Disability Index scores showed statistically significant improvement from baseline in both groups. The ACDF group had statistically greater visual analog scale scores from 12 months and Neck Disability Index scores from three months. The TDR group had statistically greater range of motion at both the superior and the inferior treated levels at three, six, 12, 24, and 81 months postoperatively. The ACDF group had statistically greater range of motion at the superior adjacent levels at six, 12, 24, and 81 months and at the inferior adjacent levels at 24 and 81 months postoperatively. The occurrence of adjacent-segment degeneration at both the superior and the inferior adjacent levels was greater in the ACDF group than in the TDR group. The authors concluded that total disk replacement was safe and effective and a statistically superior alternative to ACDF for degenerative disk disease at two contiguous levels.

A systematic review was performed (Chang et al. 2017) to evaluate the difference in rate of reoperation for ASD between ACDF and TDR. Nine studies met the inclusion criteria with a length of follow-up between 24 and 80 months. The total number of patients treated with TDR was 1,864 and 1,572 treated with ACDF. The average reoperation rate for ASD was 3.1% for the TDR cohort and 6.0% in the ACDF group. The authors concluded that further studies and follow-up data are needed to determine if cervical TDR preserves adjacent segment motion more efficiently than the natural history of the disease.

A systematic review was conducted by Joaquim et al. (2017) of clinical studies evaluating patients who underwent multilevel CDA (two or more levels). Fourteen studies met inclusion criteria and included: 1) studies comparing multilevel CDA versus

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ACDF; 2) studies comparing single-level CDA versus multilevel CDA; and 3) multilevel CDA after a previous cervical spine surgery. The authors reported that multilevel CDA was at least as safe and effective as ACDF, with preservation of cervical motion when compared with ACDF and with fewer reoperations. Multilevel CDAs are clinically effective as single-level surgeries, with good clinical and radiological outcomes. Some studies reported a higher incidence of heterotopic ossification in multilevel CDA when compared with single-level procedures, but without clinical relevance during the follow-up period. The authors concluded that the current literature supports the use of multilevel CDA, but caution is necessary regarding the more restrictive indications for CDA when compared with ACDF.

Gornet et al. (2017) conducted a prospective, multicenter randomized control trial to compare the efficacy and safety of arthroplasty using the Prestige LP cervical disc with those of ACDF for the treatment of DDD at two adjacent levels. Individuals were randomized to one of two groups: investigational patients (209) underwent arthroplasty using a Prestige LP artificial disc, and control patients (188) underwent ACDF and were followed up to 24 months. Treatment was considered an overall success when all four of the following criteria were met: 1) NDI score improvement of ≥ 15 points over the preoperative score, 2) maintenance or improvement in neurological status compared with preoperatively, 3) no serious AE caused by the implant or by the implant and surgical procedure, and 4) no additional surgery (supplemental fixation, revision, or nonelective implant removal). The overall success rate was 81.4% for the investigational group and 69.4% for the control group. There was no statistical difference between the groups in terms of adverse events (AE) but the ACDF group had a higher rate of Grade 3 or 4 AEs. Heterotopic ossification was identified in 27.8% of the superior levels and 36.4% of the inferior levels of the investigational patients at 24 months. The authors concluded that arthroplasty with the Prestige LP cervical disc is as effective and safe as ACDF for the treatment of cervical DDD at two contiguous levels and is an alternative treatment for intractable radiculopathy or myelopathy at two adjacent levels.

Lanman et al. (2017) reported on the prospective, randomized, controlled, multicenter FDA-approved clinical trial which assessed the long-term clinical safety and effectiveness in patients (n=209) undergoing anterior cervical surgery using the Prestige LP artificial disc replacement (ADR) prosthesis to treat degenerative cervical spine disease at two adjacent levels compared with ACDF (n=188). There was no statistically significant difference in the overall rate of implant-related or implant/surgical procedure-related adverse events. The Prestige LP group had fewer serious (Grade 3 or 4) implant or implant/surgical procedure-related adverse events. Patients in the Prestige LP group also underwent fewer second surgical procedures at the index levels (4.2%) than the fusion group (14.7%). Angular range of motion at superior- and inferior-treated levels was maintained in the Prestige LP ADR group to 84 months. The authors concluded that at 84 months, the Prestige LP ADR demonstrated statistical superiority over fusion for overall success and implanted at two adjacent levels, maintains improved clinical outcomes and segmental motion and is a safe and effective alternative to fusion.

Zou et al. (2016) conducted a meta-analysis of randomized controlled trials to evaluate the clinical effects requiring surgical intervention between ACDF and CDA at two contiguous levels cervical disc degeneration. The overall sample size at baseline was 650 patients (317 in the TDR group and 333 in the ACDF group). The results of the meta-analysis indicated that the CDA patients had better outcomes in mean blood loss, reoperation, adjacent segment degeneration and Neck Disability Index. No significant difference was identified between the two groups regarding mean surgical time, neck and arm pain scores reported on a visual analog scale and rate of postoperative complications. The authors concluded that CDA is superior to ACDF group by radiographic data of preoperation, postoperation and follow-up. The authors also concluded that the CDA group is equivalent and, in some aspects, has better clinical outcomes than the ACDF group at two contiguous levels cervical disc degeneration.

Hybrid Surgery

Artificial disc replacement at one level combined with spinal fusion surgery at another level (adjacent or non-adjacent) is referred to as hybrid surgery. There are only a few low-quality clinical trials to support improved health outcomes and patient selection criteria have not been firmly established.

Brotzki et al. (2020) performed an observational analysis based on 88 patients treated for multilevel cervical degenerative disc disease with ACDF only (56 patients), DCI hybrid (17 patients), and TDR hybrid (15 patients) with a mean follow-up of 19.5 months. The self-reported measures used were the Spine-Tango, the PLC questionnaire (Profile of the Life Quality of Chronically Ill), the NDI, and VAS scores for neck and arm pain. All patients were asked to complete questionnaires before surgery and at each follow-up examination. The VAS scores decreased significantly in all three groups ($P < 0.001$), but the TDR group showed the greatest reduction in VAS score compared with ACDF and DCI (both $P < 0.05$). The overall range of motion ROM and the segmental ROM at the treated levels showed significant decreases in all 3 groups. Although the study failed to

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show difference in the overall ROM at final follow-up among the operatively treated groups, the ROM of the treated segment was lowest in the ACDF group (P= 0.002). The authors concluded that the results indicate that both TDR hybrid and DCI hybrid are effective and safe procedures for the treatment of multilevel degenerative disc disease. There is no definitive evidence that DCI or TDR arthroplasty lead to better intermediate-term results than ACDF over an average observation time of 19.5 months. The authors identified several limitations to this study. First, there is no classification or grading scale for adjacent segment disease; thus, the radiographic reviewing focused only on HO. Second, the mean follow-up period was too short to evaluate the long-term efficacy of DCI arthroplasty and cervical TDR compared with ACDF for the treatment of cervical multilevel degenerative disc disease. Additionally, lack of randomization could have resulted in biases in the findings.

Through a systematic review of both published and ongoing studies on single- and multilevel CDA and hybrid surgeries, Laratta et al. (2018) aimed to provide evidence for their safety and efficacy in the treatment of various cervical pathologies. Among the relevant studies reviewed, three were randomized controlled trials, two systematic reviews, as well as multiple prospective case series, biomechanical studies, and meta-analyses. The authors concluded that multiple studies show that single-level CDA can offer equivalent clinical outcomes with a reduction in secondary procedures and total cost when compared to ACDF. The authors observed that recently there has been an increasing prevalence of 2-level CDA and hybrid surgery (HS). The data regarding these multilevel procedures is less robust. More high quality evidence with large patient populations is necessary to accurately and critically assess the utility of multilevel CDA and HS.

A systematic review and meta-analysis was conducted by Lu et al. (2017) to compare the outcomes of hybrid surgery (HS) versus ACDF for the treatment of multi-level cervical disc disease (mCDD). Eight studies were identified, 169 patients undergoing HS were compared with 193 ACDF procedures. HS was associated with greater C2-C7 ROM preservation and less functional impairment after surgery compared to ACDF. There was no significant difference between HS and ACDF with respect to postoperative pain, postoperative complication rates and length of stay. The authors concluded that HS is a novel surgical approach to treat mCDD, associated with a greater operative time, less intraoperative blood loss and comparable if not superior clinical outcomes compared to ACDF. They also concluded that there is a lack of robust clinical evidence in the literature and that further research with randomized controlled trials is needed to validate these findings.

Chen et al. (2016) retrospectively analyzed data from 108 patients with three-level cervical myelopathy who underwent hybrid surgery in a case series. Implantation of Bryan® artificial discs into two contiguous segments and cage fusion of adjacent segments was performed for all patients. Based on the JOA score, NDI, and Odom's criteria, the clinical symptoms and neurological function before and after surgery were evaluated. Mean follow-up duration was 36 months. At the final follow-up, the mean JOA scores were higher compared with preoperative values (15.08 ± 1.47 versus 9.18 ± 1.22) and the NDI values were decreased (12.32 ± 1.03 versus 42.68 ± 1.83). The clinical outcomes were rated as excellent (76 patients), good (22 patients), fair (six patients), and poor (four patients) based on Odom's criteria. For patients with predominant nerve root symptoms, radicular pain of the upper limbs showed remission; in those with dominant symptoms of spinal cord compression, both muscle strength and sensation improved. Mean range of motion of segments with replaced artificial discs was not significantly different from the value obtained before surgery; the overall ROM of the cervical vertebrae was similar to the pre-surgery value. The main complications include postoperative infection, prosthesis movement, dysphagia, dysphonia, and heterotopic ossification. The authors concluded that these findings suggested a satisfactory clinical effectiveness for hybrid surgery but additional multicenter, long-term follow-up studies with large populations are needed to validate these findings. The study is limited by lack of comparison group.

Shi and colleagues (2015) performed a retrospective case series of 36 patients with adjacent three-level cervical spondylosis who were treated with ACDF combined with CDA (hybrid surgery) between October 2008 and October 2012. Clinical evaluation was based on the NDI, JOA score, and postoperative JOA score improvement rate (IR). Radiographic parameters, angular ROM for C2-C7, and ROM for the superior and inferior adjacent segments were measured before the operation, at one, three, six, and 12 months post operation, and at the final follow-up evaluation. All cases were followed for at least 28 months. There was a significant postoperative improvement in NDI and JOA scores compared to preoperative levels. The JOA score improvement rate was 70.83 % at the final follow-up evaluation. One patient required a second surgery for symptomatic adjacent segment degeneration. The mean C2-C7 ROM, which was 46.39 ± 2.41° before the operation, was recovered after 12 months (46.03 ± 4.64°) and was maintained at the last follow-up evaluation (47.50 ± 4.59°). The ROM of the superior and inferior adjacent segments, which was 14.25 ± 1.81° and 10.89 ± 1.65° before the operation, respectively, was recovered after 6 months (14.03 ± 1.46° and 10.75 ± 2.37°, respectively) and increased at the last follow-up evaluation (15.00 ± 1.15° and 11.47 ± 1.84°, respectively). During the follow-up period, heterotopic ossification occurred in three patients. Adjacent segment degeneration was encountered in two cases, and one of these required a second surgical treatment. The authors concluded that the results

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indicate that hybrid surgery seems to be a promising, acceptable, and alternative surgical approach for the treatment of multi-level cervical disc disease. They also observed that some authors have investigated this method of treatment but the evidence in the published peer-reviewed literature is limited by lack of controls, small sample size and short term outcomes and that additional research is needed to clearly establish a role for hybrid technologies. This study is limited by lack of comparison group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Cervical

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

- M6-C™ Artificial Cervical Disc Prosthesis received premarket approval on February 6, 2019 (P170036). The M6 has two titanium outer plates with keels for anchoring the disc into the bone of the vertebral body. These outer plates are coated with a titanium plasma spray that promotes bone growth into the metal plates, providing long term fixation and stability of the disc in the bone. The M6-C™ Artificial Cervical Disc is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3–C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (CT, MRI, X-rays). The M6-C™ Artificial Cervical Disc is implanted via an anterior approach. Patients should have failed at least six weeks of conservative treatment or exhibit progressive neurological symptoms which could lead to permanent impairment prior to implantation of the M6-C™ Artificial Cervical Disc. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/p170036a.pdf. (Accessed July 1, 2020)
- Mobi-C® Cervical Disc Prosthesis received premarket approval on August 7, 2013. (P110002). The Mobi-C® Cervical Disc Prosthesis consists of two metal (cobalt-chrome alloy2) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc that is causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc at only one spinal level. The device should help stabilize the operated spinal level. Unlike a fusion procedure7, the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002a.pdf. (Accessed July 1, 2020)
- Mobi-C® Cervical Disc Prosthesis (two-level) received premarket approval of August 23, 2013. (P110009). The Mobi-C® Cervical Disc Prosthesis consists of two metals (cobalt-chrome endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc at two adjacent levels that are causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace two adjacent cervical discs in the neck (from C3-C7) following removal of the discs for conditions that result from diseased or bulging discs at two adjacent spinal levels. The two devices should help stabilize the operated spinal levels. Unlike a fusion procedure the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal levels. The effects of removing the diseased discs should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009a.pdf. (Accessed July 1, 2020)
- 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/cdrh_docs/pdf7/p070001a.pdf. (Accessed July 1, 2020)
- Prestige® LP Cervical Disc received premarket approval on July 24, 2014. Indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy with or

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without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, x-ray): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. In July 2016, the Prestige® LP received FDA approval for implantation at two levels. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029a.pdf. (Accessed July 1, 2020)

- 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=P060018. (Accessed July 1, 2020)
- 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=P060023. (Accessed July 1, 2020)
- SECURE®-C Artificial Cervical Disc received premarket approval on September 28, 2012 (P100003) The SECURE®-C Artificial Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy3 or myelopathy4) at only one level. The device should help stabilize the operated disc in the neck. Unlike a fusion procedure5, the SECURE®-C Artificial Cervical Disc is designed to allow motion at the operated disc. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100003. (Accessed July 1, 2020)
- PCM® Cervical Disc System received premarket approval on October 26, 2012 (P100012). The PCM Cervical Disc consists of two metal (cobalt-chrome alloy) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (vertebrae) to replace a diseased cervical disc2 that is causing arm pain and/or weakness or numbness. The PCM Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc from C3-C7 following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy3 or myelopathy4) at only one level. The device should help stabilize the operated disc in the neck (spinal level). Unlike a fusion procedure5, the PCM Cervical Disc is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100012. (Accessed July 1, 2020)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	• New Medical Policy

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