

TOTAL ARTIFICIAL DISC REPLACEMENT FOR THE SPINE

Policy Number: DME 021.28 T2

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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](#)

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes
Precertification with Medical Director Review Required	Yes ²
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All ¹
Special Considerations	¹ Precertification is encouraged (but not required) for out-of-network services covered under the general benefits package when provided in a physician's office. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered. ² Precertification with review by a Medical Director review or their designee is required.

COVERAGE RATIONALE

Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc for Degenerative cervical Disc Disease with symptomatic intractable radiculopathy and/or myelopathy is proven and medically necessary in a skeletally mature individual when at least one of the following criteria is met:

- Herniated disc
- Osteophyte formation

AND both of the following:

- Documented individual history of neck and/or upper extremity 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 prior non-operative treatment)

Cervical artificial disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating symptoms of Degenerative Disc Disease at one level even if they have radiological evidence of Degenerative Disc Disease at multiple levels.

Radiologic evidence of Degenerative Disc Disease is common in individuals who are middle aged and older and does not necessarily correlate with clinical symptoms.

Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating symptomatic contiguous two-level Degenerative Disc Disease in skeletally mature individuals when used according to U.S. Food and Drug Administration (FDA) labeled indications.

Note: Not all cervical artificial discs have FDA labeling for contiguous two-level Degenerative Disc Disease. Only cervical artificial discs FDA labeled for contiguous two-level disease are proven and medically necessary for this indication. Refer to the [FDA](#) Section below.

Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) performed at the same surgical setting is unproven and not medically necessary. This is commonly referred to as a hybrid surgery. There is insufficient published clinical evidence in peer-reviewed medical literature demonstrating the safety and efficacy of combination cervical spine surgery at multiple adjacent or non-adjacent levels.

Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a skeletally mature individual when ALL of the following criteria are met:

- Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 characterized by moderate to severe Degenerative Disease with Modic changes (defined as peridiscal bone signal above and below the disc space in question) confirmed on current complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI])
- Symptoms correlate with imaging findings
- No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments
- Presence of symptoms for at least one year
- Failed at least 6 months of conservative treatment just prior to implantation of artificial disc. Conservative treatment shall include all of the following, unless contraindicated: physical therapy, anti-inflammatory medications, analgesics, muscle relaxants, and epidural steroid injections
- Age 18 to 60 years
- Favorable face to face psychological evaluation confirming candidacy for surgery
- There are no contraindications to lumbar artificial total disc replacement, including, but not limited to the following:
 - Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph
 - Lumbosacral spinal fracture
 - Scoliosis of the lumbosacral spine
 - Active systemic infection or infection localized to the site of implantation
 - Tumor in the peritoneum, retroperitoneum or site of implantation
 - Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan
 - Previous lumbar spine surgery, spinal stenosis or radicular compression syndromes or radiculopathy, especially due to disc herniation
 - Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery

Lumbar artificial total disc replacement at more than one spinal level is unproven and not medically necessary.

There is insufficient published clinical evidence demonstrating the safety and efficacy of lumbar artificial total disc replacement at multiple adjacent or non-adjacent levels. Further research from larger, well-designed studies is needed to evaluate the safety and long-term effectiveness.

Lumbar artificial total disc replacement is unproven and not medically necessary with a history of prior lumbar fusion or when combined with a lumbar fusion at any level.

There is insufficient published clinical evidence to conclude that lumbar artificial total disc replacement is safe and effective when combined with a lumbar fusion.

Lumbar artificial total disc replacement is unproven and not medically necessary for treating ANY other indication.

DEFINITIONS

Degenerative Disc Disease (DDD): Discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

Grade 1 Spondylolisthesis: 25% of vertebral body has slipped forward.

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 the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies 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)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy 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
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar

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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, and 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)

Cervical intervertebral disc prostheses that have been approved by the FDA for surgical implantation within the spine, for single-level cervical disc replacement include but are not limited to: The Prestige[®] ST Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), the PRODISC-C[®] Total Disc Replacement (Synthes, Inc., New York, NY), the BRYAN[®] Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), SECURE[®]-C Artificial Cervical Disc (Globus Medical Inc., Audubon, PA), and Mobi-C[®] Cervical Disc (LDS Spine USA, Inc. Austin, TX).

Chen et al. (2017) performed a systematic review and meta-analysis to assess the durability of cervical disc arthroplasties (CDAs) in at least 2-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 anterior cervical decompression and fusion (ACDF). Twelve randomized control trials (RCTs) met the inclusion criteria and included 2954 patients. Nine of twelve studies compared single-level CDA with ACDF and 3 studies investigated 2-level CDA. Follow-up ranged from 2 years to 7 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) randomized controlled trials (RCTs) that examined the effectiveness and safety of single-level artificial cervical total disc replacement (TDR) compared with an anterior cervical discectomy and fusion (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 7 years following surgery.

Hu et al. (2016) conducted a systematic review and meta-analysis to investigate the mid- to long-term outcomes of cervical disc arthroplasty (CDA) versus anterior cervical discectomy and fusion (ACDF) for the treatment of 1-level or 2-level symptomatic cervical disc disease. Eight prospective randomized controlled trials (RCTs) were included with 1317 and 1051 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, Neck Disability Index (NDI) success, neurological success, and significantly lower rates of implant/surgery-related serious adverse events and secondary procedure compared with that in ACDF group. The long-term functional outcomes (NDI, Visual Analog Scale (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 anterior cervical discectomy and fusion (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 4 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 anterior cervical discectomy and fusion (ACDF). Clinical indices included Neck Disability Index (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 2121 patients were included, in which 1082 underwent TDA and 1039 underwent ACDF. NDI scores were reported in five studies and did not differ significantly between the two groups. Neurological success was documented in 5 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 3 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.

Bakar et al (2014) concluded that "Given the long-term outcomes that have been studied for anterior cervical discectomy and fusion, it is difficult to assess the future potential of anterior cervical disc arthroplasty as an alternative to anterior cervical discectomy and fusion. It is important to note that current studies with follow-up to 4 years have shown promising outcomes. The ability of anterior cervical disc arthroplasty to decrease the potential for common and well-known late complications of anterior cervical discectomy and fusion (such as adjacent segment disease) is an important and interesting possibility. Future long-term randomized controlled trials and cost effectiveness studies are needed to properly assess the continued use of artificial cervical disc arthroplasty and to determine the relative cost effectiveness compared with anterior cervical discectomy and fusion."

In September 2012 ECRI Institute published an evidence based report evaluating cervical disc replacement that included evidence published until April 2012. Eleven publications met the inclusion criteria, six were randomized controlled trials and five consisted of case series. The evidence reviewed by ECRI did not permit conclusions regarding rate of occurrence of adverse events.

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.

Pro-Disc C®

The ProDisc-C® Total Disc Replacement is composed of three components: a cobalt chromium molybdenum alloy plate that is anchored into the inferior vertebral body, an ultra-high molecular weight polyethylene insert that is attached to the alloy plate providing an inferior convex bearing surface, and a second cobalt chromium molybdenum alloy plate that anchors to the superior vertebral body and has a concave bearing surface.

Kelly et al. (2011) compared adjacent segment motion following disc arthroplasty using the ProDisc-C® device versus anterior cervical discectomy and fusion (ACDF) in 209 patients in a prospective randomized controlled trial at 13 sites. The authors reported no significant difference in adjacent segment range of motion (ROM) was observed between ACDF and TDA. Only time was a significant predictor of postoperative ROM at both the cranial and caudal adjacent segments. The ROM decreased over time with fusion whereas disc replacement results in immediate motion sustained throughout the follow-up period.

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.

Prestige[®]

Evidence in the peer-reviewed published scientific literature evaluating early models of the PRESTIGE[®] cervical disc included case series with few randomized trials.

The PRESTIGE[®] ST Cervical Disc consists of a two-piece articulating metal-on-metal device that is inserted into the intervertebral disc space at a single cervical level using an anterior approach. As part of approval, the FDA is requiring a seven-year post-approval study to evaluate long-term safety and effectiveness of the Prestige[®] ST Cervical Disc. 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 cervical disc arthroplasty (CDA) patients with single-level cervical disc disease with radiculopathy or myelopathy were compared with 265 historical control anterior cervical discectomy and fusion (ACDF) patients. Clinical and radiographic follow up was completed pre-operatively, intraoperatively, and at intervals up to 84 months. Statistical improvements in Neck Disability Index (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.

Bryan[®]

The BRYAN[®] cervical disc is composed of a plastic (polyurethane) center with titanium endplates. It is designed as a one-piece device that allows unconstrained motion. According to the manufacturer, the BRYAN[®] cervical disc is indicated for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3–C7. The BRYAN[®] cervical artificial disc has a flexible membrane that surrounds the nucleus (the inner portion of the disc) that is filled with a lubricant. This membrane is designed for two purposes: to contain any wear debris that forms and to prevent any soft tissue in-growth. The articulating surfaces of this device are polyurethane on titanium. It has beaded porous coated endplates intended for biological fixation instead of fixation using screws into the vertebrae or fixation by use of stabilizing keels.

A meta-analysis of randomized controlled trials (RCTs) was performed by Xie et al. (2016) to evaluate the efficacy and safety in cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF) for treating cervical degenerative disc diseases (CDDDs). Twenty RCTs with a total 4004 patients (2212 in the CDA and 1792 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 2 years. The outcome measurements included neck disability index (NDI), neurological success, range of motion (ROM), Visual Analogue Score (VAS), adverse events, adjacent segment disease (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.

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, Neck Disability Index (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 8 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.

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.

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, Odum 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 caudal 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 ≥ 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 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.

Professional Societies

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 anterior cervical disc fusion (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.

The 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.

1. 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.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2 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 3 or more levels or in the case of adjacent segment disease following an index fusion.

Cervical Artificial Disc (Two Level)

A systematic review was performed (Chang et al. 2017) to evaluate the difference in rate of reoperation for adjacent segment disease (ASD) between anterior cervical decompression and fusion (ACDF) and total disc replacement (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 cervical disc arthroplasty (CDA) (2 or more levels). Fourteen studies met inclusion criteria and included: 1) studies comparing multilevel CDA versus anterior cervical discectomy and fusion (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.

Zou et al. (2016) conducted a meta-analysis of randomized controlled trials to evaluate the clinical effects requiring surgical intervention between anterior cervical discectomy and fusion (ACDF) and cervical disc arthroplasty (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 significant superiorities 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 CDA group of sagittal range of motion (ROM) of the operated and adjacent levels, functional segment units (FSU) and C2-7 is superior to ACDF group by radiographic data of preoperation, postoperation and follow-up. The authors concluded that the cervical disc arthroplasty (CDA) group is equivalent and in some aspects has more significant clinical outcomes than the ACDF group at two contiguous levels cervical disc degeneration.

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 anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative disc disease (DDD) at 2 adjacent levels. Individuals were randomized to 1 of 2 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 4 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 2 contiguous levels and is an alternative treatment for intractable radiculopathy or myelopathy at 2 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 2 adjacent levels compared with anterior cervical discectomy and fusion (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 2 adjacent levels, maintains improved clinical outcomes and segmental motion and is a safe and effective alternative to fusion.

A 2017 Hayes Medical Technology Comparative Effectiveness Review included eight studies that examined the effectiveness and safety of 2-level artificial cervical total disc replacement (TDR) compared with anterior cervical discectomy and fusion (ACDF). The overall quality of the evidence was rated as low. The review found that two-level TDR is at least as effective as ACDF and sometimes more effective for improving symptoms of patients with cervical degenerative disc disease (DDD), with clinically meaningful effects lasting as long as 7 years. TDR poses no obvious safety concerns compared with ACDF. It concluded that there is a need for additional, well-designed RCTs to further evaluate the long-term safety and effectiveness of 2-level and multilevel cervical TDR.

The purpose of a study by Radcliff et al. (2016) was to report the outcome of a study of 2-level cervical total disc replacement (Mobi-C[®]) versus anterior cervical discectomy and fusion (ACDF). This study reports the 5-year results of a prospective, randomized US FDA investigational device exemption (IDE) study conducted at 24 centers in patients with 2-level, contiguous, cervical spondylosis. Clinical outcomes at up to 60 months were evaluated, including validated outcome measures, incidence of reoperation, and adverse events. A total of 225 patients received the Mobi-C[®] cervical total disc replacement device and 105 patients received ACDF. The Mobi-C[®] and ACDF follow-up rates were 90.7% and 86.7%, respectively, at 60 months. There was significant improvement in all outcome scores relative to baseline at all time points. The Mobi-C[®] patients had significantly more improvement than ACDF patients in terms of Neck Disability Index score, SF-12 Physical Component Summary, and overall satisfaction with treatment at 60 months. The reoperation rate was significantly lower with Mobi-C[®] (4%) versus ACDF (16%). There were no significant differences in the adverse event rate between groups. The authors concluded that there was significantly greater improvement in general in disease-specific outcome measures and a lower rate of reoperation in the 2-level disc replacement patients versus ACDF control patients.

In September 2016 ECRI Institute published a Health Technology Assessment Information Service Product Brief evaluating Mobi-C[®] Artificial Cervical Disc (Zimmer Biomet) for Treating Two-level Degenerative Cervical Disc Disease. They searched and selected web-based resources for documents relevant to the topic and published between January 1, 2011, and August 11, 2016. The report concluded that evidence from the review suggests that, compared with results of patients undergoing ACDF, patients with symptomatic cervical disc disease who underwent two-level Mobi-C[®] TDR had greater improvement in general and disease-specific outcomes, a lower reoperation rate, and less radiographic adjacent segment pathology. Results would need confirmation in another RCT to provide more definitive conclusions. It further states that evidence from the review suggests that two-level Mobi-C[®] was as safe and effective as one-level Mobi-C[®] TDR at two- to four-year follow-up. No differences between groups were found in clinical outcomes, overall complication rates, and subsequent surgery rates. Post-hoc analyses have certain limitations, however, so these findings would need to be confirmed in another prospective comparative study for definitive conclusions.

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 few clinical trials to support improved health outcomes and patient selection criteria has not been firmly established.

A systematic review and meta-analysis was conducted by Lu et al. (2017) to compare the outcomes of hybrid surgery (HS) versus anterior cervical discectomy and fusion (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 range of motion (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. There is a lack of robust clinical evidence in the literature. 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. Implantation of Bryan® artificial discs into two contiguous segments and cage fusion of adjacent segments was performed for all patients. Based on the Japanese Orthopedic Association (JOA) score, Neck Disability Index (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.

Shi and colleagues (2015) performed a retrospective review of 36 patients with adjacent three-level cervical spondylosis who were treated with anterior cervical discectomy and fusion (ACDF) combined with cervical disc arthroplasty (CDA) (hybrid surgery) between October 2008 and October 2012. Clinical evaluation was based on the Neck Disability Index (NDI), Japanese Orthopaedic Association (JOA) score, and postoperative JOA score improvement rate (IR). Radiographic parameters, angular range of motion (ROM) for C2-C7, and ROM for the superior and inferior adjacent segments were measured before the operation, at 1, 3, 6, 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 $46.39 \pm 2.41^\circ$ before the operation, was recovered after 12 months ($46.03 \pm 4.64^\circ$) and was maintained at the last follow-up evaluation ($47.50 \pm 4.59^\circ$). The ROM of the superior and inferior adjacent segments, which was $14.25 \pm 1.81^\circ$ and $10.89 \pm 1.65^\circ$ before the operation, respectively, was recovered after 6 months ($14.03 \pm 1.46^\circ$ and $10.75 \pm 2.37^\circ$, respectively) and increased at the last follow-up evaluation ($15.00 \pm 1.15^\circ$ and $11.47 \pm 1.84^\circ$, 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 indicate that hybrid surgery seems to be a promising, acceptable, and alternative surgical approach for the treatment of multi-level cervical disc disease. 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. Additional research is needed to clearly establish a role for hybrid technologies.

Lumbar Artificial Disc

ProDisc®-L: The second IVD device that has been proposed for use in the lumbar spine for the treatment of DDD is the ProDisc®-L. The ProDisc®-L Total Disc Replacement (Synthes Spine, Inc., West Chester, PA) is a weight-bearing modular implant consisting of two endplates and one polyethylene inlay. The endplates (i.e., one inferior and one superior) are manufactured from cobalt-chromium alloy, with the superior endplate available in two sizes (i.e., medium and large) and two lordotic angles (i.e., 6 and 11 degrees). The polyethylene inlays snap-locks into the inferior endplate of the inferior convex-bearing surface that articulates with the concave-bearing surface of the superior endplate. According to the manufacturer, the ProDisc®-L (previously known as the ProDisc® II) allows a range of 13 degrees of flexion and 7 degrees of extension, with lateral bending of ± 10 and axial rotation of ± 3 .

activL® Artificial Disc is an implant that replaces the function of a damaged or diseased spinal disc. The activL® consists of two metal (cobalt-chromium with a titanium coating) endplates surrounding a plastic (polyethylene) insert. The endplates attach to the patient's vertebrae, and the plastic insert fits between them. The insert is designed to move during daily activities. The device replaces a disc in the lumbar spine and is intended to relieve pain and allow forward and backward motion at the spinal level. Additional information is available at: <http://www.spine-health.com/treatment/artificial-disc-replacement>.

Formica et al. (2017) performed a systematic review to summarize the available evidence about total lumbar disc replacement (TDR), focusing on clinical and functional outcomes, comparison with fusion surgery results, rate of complications and influence on sagittal balance. Fifty-nine studies were included. Clinical and functional scores showed statistically significant improvements to baseline. There was no significant difference between TDR groups and fusion groups. There were similar rates of complications between the two surgical procedures. TDR showed significant safety and efficacy, comparable to lumbar fusion. The authors summarized that the major advantages of a lumbar TDR over fusion included maintenance of segmental motion and the restoration of the disc height, allowing patients to find their own spinal balance. The authors concluded that disc arthroplasty could be a reliable option in the treatment of degenerative disc disease. They recommended further studies with larger groups of patients and a longer follow-up period to better evaluate the outcomes and safety of lumbar TDR.

A systematic review of overlapping meta-analyses comparing total disc replacement (TDR) with fusion for treating lumbar degenerative disc disease (LDDD) was conducted by Ding et al. (2017). Five meta-analyses only comprising randomized controlled trials (RCTs) were included. This systematic review showed that there are conflicting results among these overlapping meta-analyses. Based on this systematic review, the best available evidence indicated that TDR compared with fusion for LDDD had statistically, but not clinically, significant superiority regarding disability, pain relief, and quality of life in a selected group of patients in the short term. The prevention of adjacent segment and facet joint degeneration, as the primary reason for adopting TDR noted by the manufactures, was not appropriately evaluated. This study could not assess the long-term results, because almost all of the primary studies only have data for 2 years. The authors concluded the current best available evidence suggests that TDR may be an effective technique for the treatment of selected patients with LDDD, and is at least equal to lumbar fusion in the short term. However, considering that disadvantages may appear after years, spine surgeons should be cautious about performing TDR on a large scale.

A multicenter randomized controlled trial was conducted by Furunes et al. (2017) to assess the long-term relative efficacy of lumbar total disc replacement (TDR) compared with multidisciplinary rehabilitation (MDR). One hundred seventy-three patients with chronic low back pain (LBP) and localized degenerative changes in the lumbar intervertebral discs were randomly assigned treatment. The primary outcome was self-reported physical function (Oswestry Disability Index [ODI]) at 8-year follow-up in the intention-to-treat population. Secondary outcomes included self-reported LBP (visual analogue scale [VAS]), quality of life (EuroQol [EQ-5D]), emotional distress (Hopkins Symptom Checklist [HSCL-25]), occupational status, patient satisfaction, drug use, complications, and additional back surgery. Seventy-seven patients (90%) who were randomized to surgery and 74 patients (85%) randomized to rehabilitation responded at 8-year follow-up. Mean improvement in the ODI was 20.0 points in the surgery group and 14.4 points in the rehabilitation group. Mean difference in favor of surgery on secondary outcomes were 9.9 points on VAS and 0.16 points on HSCL-25. There were 18 patients (24%) in the surgery group and 4 patients (6%) in the rehabilitation group who reported full recovery. There were no significant differences between the groups in EQ-5D, occupational status, satisfaction with care, or drug use. Forty-three of 61 patients (70%) in the surgery group and 26 of 52 patients (50%) in the rehabilitation group had a clinically important improvement (15 ODI points or more) from baseline. Twenty-one patients (24%) randomized to rehabilitation had crossed over and had undergone back surgery and 12 patients (14%) randomized to surgery had undergone additional back surgery. One serious adverse event after disc replacement was reported. The authors concluded that long-term improvement can be expected after both disc replacement and MDR. The difference between groups is statistically significant in favor of surgery, but smaller than the prespecified clinically important difference of 10 ODI points that the study was designed to detect. Future research should aim to improve selection criteria for disc replacement and MDR.

A prospective, multicenter, randomized, controlled, investigational device exemption study with 5-year follow-up was conducted by Yue and Garcia (2017) to compare the safety and effectiveness of lumbar total disc replacement with activL (Test group) or ProDisc-L or Charité (Control group) in the treatment of patients with symptomatic, single-level degenerative disc disease. Patients who failed at least 6 months of nonsurgical management were randomly allocated to treatment with the Test device (n=218) or Control devices (n=106). At 5-year follow-up, 185 Test patients and 90 Control patients provided 5-year follow-up data. Device effectiveness outcomes were comparable between Test and Control devices. Reductions in back pain severity were reported in 88% of Test patients and 90% of Control patients. Oswestry Disability Index (ODI) improvement was reported in 83% and 86% of patients, respectively. Patient satisfaction was very high in both groups (96% vs 94%). No significant differences were observed between groups in radiographic outcomes, including disc height, disc angle, flexion-extension ROM, translation ROM, and lateral rotation. Lack of a serious adverse event through 5 years was 58% in Test patients and 40% in Control patients. The authors concluded that total disc replacement is safe and effective for the treatment of symptomatic lumbar degenerative disc disease and is maintained through 5 years.

A prospective observational cohort study was conducted by Laugesen et al. (2017) to determine the long-term clinical results and prosthesis survival in patients treated with lumbar total disc replacement (TDR). Fifty-seven consecutive patients treated with TDR from 2003 to 2008 were invited to follow-up at a mean 10.6 years post-operatively and

complete a Visual Analog Scale (VAS) for back and leg pain, the Dallas Pain Questionnaire (DPQ), and the Short Form-36. These surveys were also administered to the subjects before their index TDRs. Data on reoperation were collected from the patients' medical records. The authors report that there was a significant improvement in VAS and DPQ in the entire cohort. Nineteen patients (33%) had a revision fusion surgery after their index TDR. Patients who had revision surgery had statistically significant worse outcome scores at last follow-up than patients who had no revision. Thirty patients (52.6%) would choose the same treatment again if they were faced with the same problem. The authors concluded that this study demonstrated significant improvement in long-term clinical outcomes and two-thirds of the disc prostheses were still functioning at follow-up. They also acknowledge that there is still a lack of well-designed long-term studies, thus requiring further investigation.

A systematic review and meta-analysis was performed by Lackey et al. (2016) to assess the effect of hybrid constructs which involve a total disc arthroplasty (TDA) with stand-alone anterior lumbar interbody fusion (ALIF) versus non-hybrid constructs including posterior transpedicular fixation or multi-level stand-alone ALIF as a surgical intervention for degenerative disc disease (DDD) in the lumbar spine. Primary outcomes analyzed included the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) for back pain. Three studies met inclusion criteria. When comparing hybrid constructs to multi-level TDA or lumbar fusion (LF) improvements in back pain were found with a VAS back pain score reduction of 1.38 postoperatively and a VAS back pain score reduction of 0.99 points at 2-years follow-up. Current results slightly favor clinically significant improved VAS back pain score outcomes postoperatively and at 2-years follow-up for hybrid constructs in multi-level lumbar DDD of the spine when compared with non-hybrid multi-level LF or TDA. The authors stated that it cannot be concluded that a hybrid construct is superior to multi-level LF or TDA based on this meta-analysis and recommend further prospective studies to delineate best practice in the management of degenerative disc disease of the lumbar spine.

Pimenta et al. (2016) conducted a prospective nonrandomized single-center study to analyze results of XL-TDR for the treatment of symptomatic degenerative disc disease. Sixty cases were enrolled. Eleven of 60 patients (18%) had not completed at least a 5-year follow-up (FUP), and 49 were enrolled in the analysis. The mean FUP was 93 months. End points included visual analog scale (VAS) and Oswestry Disability Index (ODI) questionnaires, radiographic outcomes (radiographs and CT) such as heterotopic ossification (HO) and maintenance of disc motion, complications, reoperation, and heterotopic ossification grades. All but 3 patients stood up/walked at the same day. Five levels (10%; 5/53) required fusion. Two cases (4%; 2/49) evolved with adjacent level disease that required surgery. One case required sacroiliac fusion. One partial disc migration was identified. Flexion extension films from 38 levels were available at least at a 5-year FUP. HO grade 0 = 13%; grade I = 18%; grade II = 32%; grade III = 16%; grade IV = 21% (8 cases). Most heterotopic ossification cases (85%) occurred in the lateral aspect of the disc space. Patient-reported outcomes showed significant improvement maintained up to a minimum of 5 years. VAS back pain: preoperative 8.5, postoperative early 2.5, and last FUP 3.0. ODI: preoperative 54%, postoperative early 31%, and last FUP 21%. The authors concluded that the data show satisfactory sustained pain relief and improved physical function for the patients and lumbar artificial disc replacement done by the lateral approach seems to be a feasible effective treatment for mild degenerative disc disease. Further research with larger randomized controlled trials is needed to validate these findings.

An August 2015 Hayes Medical Technology assessment evaluated 7 randomized controlled trials (RCTs), 1 nonrandomized trial, and 6 uncontrolled studies with long-term (7 to 17 years) results published between 2002 through July 2015. A total of 2882 patients who underwent one or two level disc replacement treatment were included. The findings suggest that 1-level lumbar disc replacement (LDR) is comparable in efficacy and safety to fusion for the treatment of symptomatic degenerative disc disease in selected patients who have failed conservative treatment. Questions remain regarding the long-term safety of lumbar disc replacement and there is insufficient evidence comparing LDR with continued treatment with more conservative nonsurgical treatment options.

A July 2017 updated cumulative literature search retrieved eight abstracts, including 2 prospective randomized trials (RCTs); 1 follow-up to a multicenter randomized controlled trial; 1 prospective nonrandomized single-center study; 1 comparison study; 1 prospective observational cohort study; 1 systematic review and meta-analysis; and 1 systematic review. The available RCTs provided moderate-quality evidence that 1-level lumbar total disc replacement (LTDR) is comparable to fusion for the treatment of symptomatic degenerative disc disease (DDD) in highly selected patients who have failed conservative treatment. They found insufficient evidence to determine whether motion preservation with LTDR will prevent symptomatic adjacent segment DDD. There was insufficient evidence investigating LTDR for the treatment of 2-level DDD. The report concluded that further longer-term follow-up studies are required to determine whether LTDR poses any additional risk compared with fusion beyond 5 years.

A Cochrane review (Jacobs, et al., 2012) was conducted to determine how total disc replacement compared with other treatments for chronic low back pain. The review included seven randomized trials involving 1474 subjects in total, and involved the use of four discs: Charite[®], Maverick[®], Prodisc-L[®], and Flexicore[®]. Six of the trials compared disc replacement to lumbar fusion and one compared disc replacement to nonsurgical treatment consisting of a rehabilitation protocol with cognitive treatment and physical therapy. Follow-up was 24 months in all studies with the

exception of one which was five years. The subjects who had disc replacement surgery had slightly better back pain and function outcome scores compared to those who had fusion surgery; the differences did not appear clinically significant. The studies did not demonstrate any other benefit and did not provide any information regarding long-term risks. As a result, the review concluded the spine surgery community should be cautious with regards to adopting the technology on a large scale; long-term outcomes are lacking. Pain relief outcomes are short-term and studies evaluating adjacent segment degeneration and facet joint degeneration are lacking.

Pro-Disc®

Park et al. (2015) conducted a retrospective analysis to evaluate successful outcomes following lumbar total disc replacement (TDR) using ProDisc® II on 54 patients (81 segments) between March 2002 and February 2007. Data was reviewed at 1, 2, 5 and 7 year follow-up. Clinical outcomes were evaluated using Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and subjective satisfaction (4-point scale). Radiographic results included segmental range of motion (ROM). Total VAS scores decreased significantly at postoperative 1 year and 2 year, compared with preoperative VAS score. Although total VAS scores increased until the last follow-up, they remained significantly lower than the preoperative value. All postoperative ODI scores at any follow-up time were significantly lower than the baseline value. There was significant increase in ODI scores between 2-year and last follow-up. The final range of motion (ROM) was shown to be lower than the preoperative ROM and lumbar lordosis was increased and well-maintained during all postoperative follow-up times. Five patients (9.3%) required revision fusion surgeries. In 2011 Delamarter et al. published the results of a prospective randomized multicenter FDA IDE trial evaluating the ProDisc-L® compared to circumferential fusion for two-level DDD. Reported outcomes included patient self-assessments, physical, neurological and radiograph assessment pre-operatively and six weeks, three, six, twelve, eighteen and twenty-four months postoperatively. Although ODI scores significantly improved in both groups from preoperative to postoperative, results were significantly better in the total disc group). A significant reduction in narcotic usage was also reported for the disc group. In the authors opinion two-level lumbar disc replacement using the ProDisc-L® device was a viable alternative to lumbar arthrodesis for the treatment of two-level disc disease.

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 being noted. ROM decreased following TDR at the L5-S1 level, with no significant improvement noted at any time. The level of the TDR was found to be a potential negative factor in the minimal gains that were achieved in ROM.

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.

activL® Artificial Disc

Garcia et al. (2015) conducted a prospective, multicenter, randomized, controlled, investigational device exemption (IDE) trial to evaluate the comparative safety and effectiveness of lumbar total disc replacement (TDR) in the treatment of patients with symptomatic degenerative disc disease (DDD) who are unresponsive to nonsurgical therapy. The study consisted of patients presenting with symptomatic single-level lumbar DDD who failed at least 6 months of nonsurgical management. They were randomly assigned to treatment with an investigational TDR device (activL®, n = 218) or FDA-approved control TDR devices (ProDisc-L® or Charité®, n = 106). Patient satisfaction with treatment was over 90% in both groups at 2 years. Back pain severity improved 74% with activL® and 68% with controls. Oswestry Disability Index (ODI) improved 67% with activL® and 61% with controls and Physical Component Summary score (88% vs. 81%) favored the activL group. The percentage of patients working full-time with no restrictions increased from 33% at pretreatment to 57% at 2 years with activL® and from 33% to 49% with control. Return to work was approximately 1 month shorter with activL® versus controls. The percentage of patients with disc height increase >3mm was 94% with activL® and 87% with controls. Change in range of motion in lateral flexion-extension radiographs was statistically greater with activL® compared with controls in segmental rotation and translation but not in lateral rotation on side-bending radiographs. The rate of device-related serious adverse events was lower in patients treated with activL® versus controls (12% vs. 19%). Surgical reintervention rates were comparable (activL®

2.3%, control 1.9%). The authors concluded that the single-level activL[®] TDR is safe and effective for the treatment of symptomatic lumbar DDD through 2 years. The long-term durability of the activL[®] TDR is unknown and requires further investigation.

In 2009 the National Institute for Health and Care Excellence (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. They recommend specialist with expertise in the treatment of degenerative spine disease should be involved in patient selection and the procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.

Professional Societies

American Pain Society

Guidelines from the American Pain Society (Chou, 2014.) found insufficient evidence regarding long-term benefits and harms of disc replacement to support recommendations. Vertebral fusion is the most common surgery for chronic, nonspecific low back pain. Surgical instrumentation (use of pedicle screws or other hardware) increases fusion rates, but it is not known if instrumentation improves clinical outcomes. More research with longer follow-up is needed to determine the appropriate role of artificial disc replacement versus fusion. We suggest that vertebral fusion be performed for patients who undergo surgical intervention for chronic low back pain.

North American Spine Society (NASS)

A 2014 NASS Coverage Policy Recommendation states that lumbar artificial disc replacement is indicated as an alternative to lumbar fusion for patients with discogenic low back pain who meet ALL of the following criteria:

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

The International Society for the Advancement of Spine Surgery (ISASS)

- A 2015 ISASS Policy Statement states that there is sufficient evidence-based scientific evidence to support the safety and efficacy of single level lumbar total disc replacement for patients meeting well established selection criteria.
- Inclusion criteria include:
 - skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1
 - patients should have no more than Grade 1 spondylolisthesis at the involved level
 - patients failed at least six months of conservative treatment prior to implantation

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Lumbar

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

- The **activL[®] Artificial Disc** (Aesculap Implant Systems, LLC) received FDA Premarket Approval on June 11, 2015. It is indicated for people who have fully formed and fully grown bones (are skeletally mature), have low back pain due to a problem with one lumbar disc (as determined by a doctor), have been diagnosed as having degenerative disc disease (DDD) in only one lumbar disc at either level L4/L5 or L5/S1 (as determined by a doctor), and have gone through at least six months of non-surgical treatment without relief. The device is designed to help stabilize the operated spinal level and allow motion at the level. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120024A.pdf (Accessed February 15, 2018)
- 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. Removed from the market in 2012. (Accessed February 15, 2018)
- 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: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010A.pdf. (Accessed February 15, 2018)

Cervical

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

- **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 device is indicated 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 February 15, 2018)
- **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 February 15, 2018)
- **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 April 24, 2018)
- **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 (arm pain and/or a neurological deficit) with or 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[®] received FDA approval for implantation at 2 levels. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029a.pdf. (Accessed February 15, 2018)
- **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 February 15, 2018)
- **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 February 15, 2018)

- **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 February 15, 2018)
- **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 February 15, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2018	<ul style="list-style-type: none">• Reorganized policy template:<ul style="list-style-type: none">○ Simplified and relocated <i>Instructions for Use</i>○ Removed <i>Benefit Considerations</i> section• Updated coverage rationale; modified language to clarify the listed services are:<ul style="list-style-type: none">○ Proven and medically necessary (as described)○ Unproven and not medically necessary (as described)• Archived previous policy version DME 021.27 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.