Total Artificial Disc Replacement for the Spine

Policy Number: 2020T0437Y
Effective Date: November 1, 2020

Instructions for Use

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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 when the following criteria are met:

- Documented individual history of neck and/or upper extremity pain and/or a functional/neurological deficit associated with the cervical level to be treated
- Imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) confirming herniated nucleus pulposus or osteophyte formation
- Failed at least six weeks of non-operative treatment prior to implantation

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.

Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when there are no contraindications and all of the following criteria are met:

- Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 confirmed by complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) that indicate either moderate to severe Degenerative Disease or Modic Changes
- 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 six months
- Failed at least 6 months of conservative treatment immediately 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 psychosocial-behavioral evaluation to be conducted by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome

Contraindications to lumbar artificial total disc replacement include but are 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
- Isolated radicular compression syndromes, especially due to disc herniation
- Spinal stenosis or radiculopathy
- Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain
- 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 is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy:

- More than one spinal level
- Prior history of lumbar fusion or when combined with a lumbar fusion at any level
- Treating any other indications not listed above

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Total Artificial Disc Replacement for the Spine	

0095T
0098T
0164T
22856
22857
22858
22861
22862
22864
22865
22899
	Cervical and Lumbar Surgery
	Medical notes documenting the following, as applicable:
	• Condition requiring procedure
	• History and co-morbid medical condition(s)
	• Documentation of member's symptoms, pain, location, and severity including functional impairment that is interfering with activities of daily living (eating or preparing meals, walking, getting dressed, driving)
	• Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images
	  ○ Note: When requested, diagnostic image(s) must be labeled with:
	  ▪ The date taken
	  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s)
	  ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan or via email at CCR@uhc.com; faxes will not be accepted
	• Diagnostic image (s) report(s)
	• Physical exam, including neurologic exam
	• History and duration of previous therapy, when applicable, including:
	  ○ Physical therapy
	  ○ Medications/injections
	  ○ Previous spinal surgery
	  ○ Other attempted treatments

CPT Codes*	Required Clinical Information
Total Artificial Disc Replacement for the Spine	
	○ Specify the brand-named tools to be used **Lumbar Surgery** For lumbar surgery, in addition to the above, provide medical notes documenting the following, as applicable: • Provide psychological face to face evaluation • Documentation of instability (listhesis-, spondylolisthesis and grade) • Provide the surgical technique to be used and the number of levels involved and their location

**For code descriptions, see the Applicable Codes section.*

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.

Modic Changes: Peridiscal bone signal above and below the disc space in question.

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 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 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)
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)
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
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar

CPT Code	Description
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
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
22899	Unlisted procedure, spine

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. 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 3505 patients (CDA/ACDF: 1913/1592) 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 5 artificial cervical discs. Sixty-five studies (n= 5785) 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 5 devices (P < 0.001) with ProDisc-C (ES, 38%; 95% confidence interval [CI], 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 2-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 cervical disc arthroplasty (CDA) to those of the gold standard, anterior cervical discectomy and fusion (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 anterior cervical discectomy and fusion (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 3160 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 Neck Disability Index (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 randomized controlled trials (RCTs) was conducted by Gutman et al. (2018) to determine whether anterior cervical discectomy and fusion (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, range of motion (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.

Zeng et al. (2018) performed a retrospective study to assess the long-term clinical and radiographic outcomes of cervical disc arthroplasty (CDA) with Prestige-LP Disc at a minimum of 6-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, Neck Disability Index (NDI), and Japanese Orthopedic Association (JOA) score. Radiological evaluations included range of motion (ROM) of the index and adjacent levels, segmental angle, cervical sagittal alignment, heterotopic ossification (HO) and adjacent segment degeneration (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 2-and 4-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 6-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 anterior cervical discectomy and fusion (ACDF) in patients with symptomatic degenerative disc disease. Four randomized controlled trials (RCTs) assessing the effect of Mobi-C versus ACDF on the treatment of symptomatic degenerative disc disease were included. The primary outcomes were neck disability index (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 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 ananterior 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 In an updated 2019 review, nine abstracts were retrieved, including 5 long-term follow-up reports of randomized controlled trials, 3 meta-analyses, and 1 cost-effectiveness analysis. The evidence remains unchanged for the use of single-level total disc replacement (TDR) for treatment of cervical degenerative disc disease (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 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.

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.

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.

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.

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.

- 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 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 2020 Hayes comparative effectiveness review of multilevel artificial disc replacement for cervical degenerative disc disease included 8 studies; 4 randomized controlled trials, 1 prospective nonrandomized trial, 1 prospective comparative cohort study, 1 prospective trial with historical controls and 1 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 1 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 anterior cervical discectomy and fusion (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 2 and 7 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 anterior cervical discectomy and fusion (ACDF) group and 24 patients in the cervical disc arthroplasty (CDA) group were analyzed before surgery and at 1 week and 3, 6, 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 Neck Disability Index, 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. Range of motion (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 6 months and 1 year after surgery and a significant decrease at the last follow-up period. A total of 8 (33.3%) patients in the CDA group had an occurrence of heterotopic ossification. Adjacent-segment degeneration (ASD) was observed in 2 (8.3%) patients who underwent CDA surgery and 8 (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 5 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 adjacent segment disease (ASD) cohorts being treated by either anterior cervical discectomy and fusion (ACDF) or total disc replacement (TDR). Overall, 103 and 258 ASD cases managed by TDR and ACDF, respectively, were reviewed. At minimum 1-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 Japanese Orthopedic Association (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 anterior cervical decompression and fusion (ACDF) in patients with 2 contiguous levels cervical spondylosis. The following outcome measures were extracted: neck disability index (NDI), visual analog scale (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 adjacent segment degeneration (ASD). Nine randomized controlled trials and 2 clinical controlled trial studies containing 2715 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 total disk replacement (TDR) using a cervical disk prosthesis vs anterior cervical discectomy and fusion (ACDF). Ninety-six patients with a diagnosis of degenerative disk disease with radiculopathy or myeloradiculopathy at 2 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 1 week and 3, 6, 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 3 months. The TDR group had statistically greater range of motion at both the superior and the inferior treated levels at 3, 6, 12, 24, and 81 months postoperatively. The ACDF group had statistically greater range of motion at the superior adjacent levels at 6, 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 2 contiguous levels.

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.

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.

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 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 cervical disc arthroplasty (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 few clinical trials to support improved health outcomes and patient selection criteria has 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 Neck Disability Index (NDI), and visual analog scale (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 3 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 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 cervical disc arthroplasty (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, 3 were randomized controlled trials, 2 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. 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 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 ± 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 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

Scott-Young et al. (2020) conducted a prospective case series to assess the patient reported outcome measures (PROMs) and patient satisfaction of multilevel lumbar total disc arthroplasty (TDA) for symptomatic multilevel degenerative disc disease (MLDDD). Data were prospectively collected preoperatively and postoperatively at 3, 6, and 12 months, then yearly. PROMs included patient satisfaction, Visual Analog Score back and leg, Oswestry Disability Index, and Roland-Morris Disability Questionnaire. One hundred twenty-two patients were included. The mean follow-up was 7.8 years. The majority received two-level TDA, except two patients who received three-level TDA. The two- to three-level TDA's were at the levels L3–4, L4–5, and L5-S1, whereas most two levels (n = 110, 90.2%) were at L4–5 and L5-S1; the remainder (n = 10, 8.2%) being at L3–4 and L4–5. Improvement in pain and disability scores were significant ($P < 0.001$), and this improvement was sustained in those patients over the course of their follow-up. Ninety-two percent of patients reported good or excellent satisfaction with treatment at final review. The authors concluded that the study suggested that multilevel TDA for MLDDD is associated with favorable and sustained clinical outcomes for the majority of patients. They also concluded that provided diagnosis, patient selection, surgeon technique, and rehabilitation are adequate, multilevel lumbar TDA is an effective management technique for individuals identified as being affected by more than one degenerative disc. Future studies should compare long-term clinical outcomes of single-level TDA, multilevel TDA, and hybrid construct surgery for the treatment of DDD. The findings are limited by lack of comparison group.

Formica et al. (2020) conducted a retrospective case series of 32 patients who underwent TDR for low back pain from degenerative disc disease (DDD) resistant to conservative treatment. Demographic features, surgical data, clinical and radiographic outcomes, complications and spinopelvic parameters were evaluated. The mean follow-up was 164 ± 36.5 months. The clinical outcomes measured by visual analogue scale and Oswestry Disability Index showed a significant improvement between preoperative and 1-year follow-up ($p < 0.01$). No significant temporal variance had been identified between 1-year and long-term follow-up ($p > 0.05$). The surgical revision rate was 10%. The overall rate of complications was 20%. At final follow-up, the mobility of the prosthesis was preserved in 68.75% of the cases, and 73.3% of the patients were globally well aligned. The authors concluded that the long-term results confirmed the existing evidence about efficacy and safety of TDR as a reliable option, in optimal surgery indication, to treat DDD.

Li et al. (2020) conducted an updated systematic review and meta-analysis to compare the efficacy and safety of total disc replacement (TDR) versus lumbar fusion. A total of 7 randomized controlled trials (RCTs) (1706 patients) were included. Patients in TDR group had significant improvements in ODI, VAS scores, complication rates and had a greater percentage of being satisfied with the surgery. In addition, the clinical success in the TDR group was higher than the fusion group. TDR treated patients had shorter operating time and shorter duration of hospital stay. There was no clinical significance difference between the two groups in blood loss, work status and reoperation rate. The authors concluded that the meta-analysis showed that TDR proved superiorities in improved clinical success, reduced pain, patients' satisfaction, shortened hospital stay and operating time and lessened complication rate. But there were no benefits in blood loss (Authors Delamarter (2011) and Zigler (2012) which were previously cited in this policy are included in this meta-analysis).

A 2020 Hayes comparative effectiveness review of lumbar total disc replacement for degenerative disc disease included 10 RCTs, 1 prospective nonrandomized comparative cohort study, 3 prospective observational studies, and 7 retrospective observational studies. Study population included adults who required lumbar spinal fusion for symptomatic lumbar DDD, either single or multilevel, and were candidates for LTDR; RCTs (50-577); uncontrolled studies (35-201).The review found that the available RCTs "provided moderate-quality evidence that 1-level LTDR is comparable with fusion for the treatment of symptomatic DDD in properly selected patients who have failed conservative treatment. Longer-term follow-up studies have mixed findings regarding durability of treatment effect, but additional safety risks compared with fusion have not emerged. There is insufficient evidence comparing LTDR with continued treatment with more conservative nonsurgical treatment approaches, versus PTDS, between LTDR devices, and for patients with multilevel DDD." There is little evidence on the purported benefit of LTDR to reduce ALD; therefore, no definitive conclusions can be drawn for this outcome. This report also concluded that there was insufficient evidence for two-level lumbar total disc replacement.

A systematic review and meta-analysis was conducted by Bai et al. (2019) to evaluate whether total disc replacement exhibited better outcomes and safety than fusion for lumbar degenerative disease. Fourteen RCTs were included with a total of 1890 participants with lumbar degenerative diseases. The control group included anterior fusion, posterior fusion and circumferential fusion. The intervention period was between 6 months to 5 years. Results from the pooled analysis indicated that there was improving VAS in favor of the total disc replacement (SMD = -0.206; 95% CI: -0.326 to -0.085; P = .001). The total disc replacement group had a decrease in operation time (SMD= 0.294; 95% CI: -0.416 to -0.173; Z = 4.75; P < .00001). There was no difference between the 2 methods of operation for bleeding volume (SMD = -0.077; 95% CI: -0.041 to 0.194; P = .2). The meta-analysis from the 5 independent trials revealed total disc replacement can reduce hospital stay (SMD = -0.447; 95% CI: -0.565 to -0.33; P < .00001). The authors conclude that disc replacement is superior to lumbar fusion in many respects, including ODI, VAS, SF-36, patient satisfaction, overall success, reoperation rate, ODI successful. In addition, postoperative complications of disc replacement surgery are also less than lumbar fusion.

Mu et al. (2018) conducted a systematic review and meta-analysis to compare the efficacy and safety of lumbar total disc replacement (TDR) with the efficacy and safety of anterior lumbar interbody fusion (ALIF) for the treatment of lumbar degenerative disc disease (LDDD). Six studies (5 randomized controlled trials (RCT) and 1 observational study) involving 1093 patients were included. Operative time, intraoperative blood loss, hospital stay, complications and re-operation rate were without significant clinical difference between groups. Patients in the TDR group had higher postoperative satisfaction and, better improvements in ODI, VAS and postoperative lumbar mobility than did patients in the ALIF group. The authors concluded that TDR had significant reduction in clinical symptoms, improved physical function and preserved range of motion for the treatment of LDDD compared to ALIF. TDR may be an ideal alternative for the selected patients with LDDD in the short-term. More studies that are well-designed, that are of high-quality and that have larger samples are needed to further evaluate the efficacy and safety of TDR at the long-term follow-up.

Zigler et al. (2018b) conducted a meta-analysis to evaluate the long-term efficacy and safety of total disc replacement (TDR) compared with fusion in patients with functionally disabling chronic low back pain due to single-level lumbar degenerative disc disease (DDD) at 5 years. PubMed and Cochrane Central Register of Controlled Trials databases were searched for randomized controlled trials reporting outcomes at 5 years for TDR compared with fusion in patients with single-level lumbar DDD. Outcomes included Oswestry Disability Index (ODI) success, back pain scores, reoperations, and patient satisfaction. The meta-analysis included 4 studies. TDR patients had a significantly greater likelihood of ODI success and patient satisfaction and a significantly lower risk of reoperation than fusion patients. Long-term improvement in back pain scores were similar between TDR and fusion. Results for ODI success and patient satisfaction were sensitive to different outcome definitions but remained in favor of TDR. The authors concluded that TDR is an effective alternative to fusion for lumbar DDD.

Zigler et al. (2018a) conducted a network meta-analysis to compare the efficacy and safety of total disc replacement, lumbar fusion, and conservative care in the treatment of single-level lumbar degenerative disc disease (DDD). Outcomes measured at 2 year follow-up included Oswestry Disability Index (ODI) success, back pain score, patient satisfaction, employment status, and reoperation. Randomized controlled trials that included patients with discogenic low back pain due to single-level lumbar DDD, who were unresponsive to conservative therapy, were considered if they compared a TDR device (Charite, ProDisc-L, Maverick, Kineflex-L, Flexicore, activL) with other total disc replacement devices, fusion (anterior, posterior, or circumferential) or conservative care (rehabilitation, exercise). Six studies were included (1417 participants). Evidence from several studies shows that arthroplasty is superior to fusion and conservative care. The authors concluded that overall, the activL total disc

replacement device had the most favorable results for ODI success, back pain, and patient satisfaction. Results for employment status and reoperation were similar across therapies.

A systematic review was conducted by Cui et al. (2018) to evaluate the mid- to long-term clinical outcomes of artificial total disc replacement (TDR) for lumbar degenerative disc diseases. Thirteen studies, including eight prospective studies and five retrospective studies, were included. A total of 946 patients were identified who reported at least 3 years of follow-up results. A total of 1048 prostheses were implanted, single-segment TDRs were performed on 872 patients, and multi-segment TDRs were performed on 88 patients. A total of 369 prostheses were implanted into level L4/L5, 543 prostheses were implanted into level L5/S1, and 51 were implanted into other segments. Patients with lumbar TDR demonstrated significant improvements in VAS scores of 51.1 to 70.5% and of - 15.6 to - 44.4 for Oswestry disability index (ODI) scores at the last follow-up. Patient satisfaction rates were reported in eight studies and ranged from 75.5 to 93.3%. Complication rates were reported in 11 studies, ranging from 0 to 34.4%. The overall reoperation rate was 12.1% (119/986), ranging from 0 to 39.3%, with eight of the 13 studies reporting a reoperation rate of less than 10%. The authors concluded that the study shows that lumbar TDR effectively resulted in pain relief and an improvement in quality of life at mid- to long-term follow-up. Complication and reoperation rates were acceptable. This study did not provide sufficient evidence to show that lumbar TDR is superior to fusion surgery. A greater number of high-quality randomized controlled trials (RCTs) are needed.

A prospective case series was performed by Scott-Young et al. (2018) to evaluate clinical and patient outcomes post combined total disc arthroplasty (TDA) and anterior lumbar interbody fusion (ALIF), known as hybrid surgery for the treatment of multilevel symptomatic degenerative disc disease (DDD). A total of 617 patients underwent hybrid surgery for chronic back pain between July 1998 and February 2012. Visual Analog Pain Scale for the back and leg were recorded along with the Oswestry Disability Index and Roland Morris Disability Questionnaire. The authors report both statistically and clinically significant reductions were seen in back and leg pain, which were sustained for at least 8 years post surgery. Significant improvements were also seen in self-rated physical disability and function, also maintained for at least 8 years. Patient satisfaction was rated as good or excellent in >90% of cases. They concluded that the results of this study suggest TDA with ALIF is a suitable option for patients suffering chronic back and leg pain secondary to multilevel DDD when conservative management fails. A limitation to the present study is that not all patients experienced leg pain preoperatively and, therefore, their baseline score would be zero. The findings of this study need to be validated by well-designed studies. The study is limited by lack of comparison group.

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 compared 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 case series 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 discus 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. The authors concluded that 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.

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 and that the long-term durability of the activL® TDR is unknown and requires further investigation.

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 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 2007) 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. The authors suggest that vertebral fusion be performed for patients who undergo surgical intervention for chronic low back pain.

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

A 2019 Position Statement states that the ISASS strongly supports lumbar 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)

A 2019 NASS Coverage Policy Recommendation states that lumbar artificial disc replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria:

- Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
- Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
- Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

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.

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 July 1, 2020)
- 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. Removed from the market in 2012.
- The ProDisc L® Total Disc Replacement received FDA Premarket Approval on August 14, 2006 for use in patients who have single-level degenerative disc disease of the lumbar spine (L3-S1) and who have had no relief from low-back pain after at least 6 months of nonsurgical treatment. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010A.pdf. (Accessed July 1, 2020)

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 6 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 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 2 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)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for cervical artificial total disc replacement for the spine. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; see the LCDs/LCAs for Cervical Disc Replacement.

Medicare does not cover lumbar artificial disc replacement (LADR) for Medicare population over 60 years of age. For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to continue to be made by the local contractors. Refer to the NCD for Lumbar Artificial Disc Replacement (LADR) (150.10). Also see the LCDs/LCAs for Lumbar Artificial Disc Replacement.
(Accessed October 19, 2020)

References

American Academy of Orthopaedic Surgeons. Technology Overview. Cervical Disc Arthroplasty. March 2010.

Bai DY, Liang L, Zhang BB, et al. Total disc replacement versus fusion for lumbar degenerative diseases - a meta-analysis of randomized controlled trials. Medicine (Baltimore). 2019;98(29):e16460.

Brotzki C, Petridis AK, Steiger HJ, et al. Comparison of different hybrid techniques for the treatment of multilevel cervical degenerative disc disease-analysis of prospectively collected clinical, radiologic, and psychological parameters. World Neurosurg. 2020 Aug;140:e112-e120.

Chang KE, Pham MH, Hsieh PC. Adjacent segment disease requiring reoperation in cervical total disc arthroplasty: a literature review and update. J Clin Neurosci. 2017 Mar;37:20-24.

Chen C, Zhang X, Ma X. Durability of cervical disc arthroplasties and its influence factors. a systematic review and a network meta-analysis. Medicine (Baltimore). 2017 Feb;96(6):e5947.

Chen J, Lin X, Jia Y, et al. Cervical anterior hybrid technique with bi-level Bryan® artificial disc replacement and adjacent segment fusion for cervical myelopathy over three consecutive segments. Journal of Clinical Neuroscience 2016. May;27:59-62.

Cui XD, Li HT, Zhang W, et al. Mid- to long-term results of total disc replacement for lumbar degenerative disc disease: a systematic review. J Orthop Surg Res. 2018 Dec 26;13(1):326.

Delamarter R, Zigler JE, Balderston RA, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L® total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. J Bone Joint Surg Am. 2011 Apr 20;93(8):705-15.

Dejaegher J, Walraevens J, van Loon J, et al. 10-year follow-up after implantation of the Bryan® cervical disc prosthesis. Eur Spine J. 2016 Nov 30.

Ding F, Jia Z, Zhao Z, et al. Total disc replacement versus fusion for lumbar degenerative disc disease: a systematic review of overlapping meta-analyses. Eur Spine J. 2017 Mar;26(3):806-815.

ECRI Institute. M6-C Artificial Cervical Disc (Spinal Kinetics LLC) for Treating Degenerative Disc Disease. Plymouth Meeting (PA): ECRI Institute; 2020 March 15. (Custom Product Brief).

ECRI Institute. Mobi-C Artificial Cervical Disc (Zimmer Biomet) for Treating Degenerative Cervical Disc Disease. Plymouth Meeting (PA): ECRI; 2020 Apr 10. (Custom Product Brief).

ECRI Institute. Prestige LP Cervical Disc (Medtronic plc.) for Treating Degenerative Disc Disease. Plymouth Meeting (PA): ECRI; 2020 Apr 8. (Custom Product Brief).

ECRI Institute. ProDisc C Cervical Total Disc Replacement System (Centinel Spine, LLC) for Treating Degenerative Disc Disease. Plymouth Meeting (PA): ECRI Institute; 2020 March 25. (Custom Product Brief).

ECRI Institute. Secure-C Cervical Artificial Disc (Globus Medical, Inc.) for Treating Degenerative Cervical Disc Disease. Plymouth Meeting (PA): ECRI Institute; 2020 March 30. (Custom Product Brief).

Findlay C, Ayis S, Demetriades AK. Total disc replacement versus anterior cervical discectomy and fusion: a systematic review with meta-analysis of data from a total of 3160 patients across 14 randomized controlled trials with both short- and medium- to long-term outcomes. Bone Joint J. 2018 Aug;100-B(8):991-1001.

Formica M, Divano S, Cavagnaro L,et al. Lumbar total disc arthroplasty: outdated surgery or here to stay procedure? A systematic review of current literature. J Orthop Traumatol. 2017 Jul 6.

Formica C, Zanirato A, Divano S, et al. Total disc replacement for lumbar degenerative disc disease: single centre 20 years experience. Eur Spine J. 2020 Jul;29(7):1518-1526.

Furunes H, Storheim K, Brox JI, et al. Total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain and degenerative discs: 8-year follow-up of a randomized controlled multicenter trial. The Spine Journal 17 (2017) 1480–1488.

Gao X, Yang Y, Liu H, et al. A comparison of cervical disc arthroplasty and anterior cervical discectomy and fusion in patients with two-level cervical degenerative disc disease: 5-year follow-up results. World Neurosurg. 2019 Feb;122:e1083-e1089.

Garcia R Jr, Yue JJ, Blumenthal S, et al. Lumbar total disc replacement for discogenic low back pain: Two-year outcomes of the activL® multicenter randomized controlled IDE clinical trial. Spine (Phila Pa 1976). 2015 Dec;40(24):1873-81.

Gornet MF, Burkus JK, Shaffrey ME, et al. Cervical disc arthroplasty with Prestige® LP disc versus anterior cervical discectomy and fusion: Seven-year outcomes. Int J Spine Surg. 2016 Jun 22;10:24.

Gornet MF, Lanman TH, Burkus JK, et al. Cervical disc arthroplasty with the Prestige LP disc versus anterior cervical discectomy and fusion, at 2 levels: Results of a prospective, multicenter randomized controlled clinical trial at 24 months. J Neurosurg Spine. 2017 Jun;26(6):653-667.

Gornet MF, Lanman TH, Burkus JK, et al. One-level versus 2-level treatment with cervical disc arthroplasty or fusion: outcomes up to 7 years. Int J Spine Surg. 2019 Dec 31;13(6):551-560.

Gutman G, Rosenzweig DH, Golan JD. Surgical treatment of cervical radiculopathy: meta-analysis of randomized controlled trials. Spine (Phila Pa 1976). 2018 Mar 15;43(6):E365-E372.

Hayes, Inc. Medical Technology Directory. Comparative Effectiveness Review. Lumbar total disc replacement for degenerative disc disease. Lansdale, PA: Hayes, Inc.; August 25, 2020.

Hayes, Inc. Hayes Medical Technology Directory Report. Comparative Effectiveness Review of multilevel artificial disc replacement for cervical degenerative disc disease. Lansdale, PA: Hayes, Inc.; October 3, 2017. Updated January 9, 2020.

Hayes, Inc. Hayes Medical Technology Directory Report. Comparative Effectiveness Review of single level artificial disc replacement for cervical degenerative disc disease. Lansdale, PA: Hayes, Inc.; August 21, 2017. Updated October 29, 2019.

Hu Y, Lv G, Ren S, Johansen D. Mid- to long-term outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion for treatment of symptomatic cervical disc disease: A systematic review and meta-analysis of eight prospective randomized controlled trials. PLoS One. 2016 Feb 12;11(2):e0149312.

Huppert J, Beaurain J, Steib JP, et al. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. Eur Spine J. 2011 Feb 20.

International Society for the Advancement of Spine Surgery (ISASS). Policy Statement: Cervical total disc arthroplasty. 2014.

Joaquim AF, Riew KD. Multilevel cervical arthroplasty: current evidence. A systematic review. Neurosurg Focus. 2017 Feb;42(2):E4.

Lackey A, Phan K, Mobbs. A systematic review and meta-analysis of outcomes in hybrid constructs for multilevel lumbar degenerative disc disease. Clin Neurosci. 2016 Jul 27.

Lanman TH, Burkus JK, Dryer RG, et al. Long-term clinical and radiographic outcomes of the Prestige LP artificial cervical disc replacement at 2 levels: results from a prospective randomized controlled clinical trial. J Neurosurg Spine. 2017; 27(1):7-19.

Laratta JL, Shillingford JN, Saifi C, Riew KD. Cervical disc arthroplasty: a comprehensive review of single-level, multilevel, and hybrid procedures. Global Spine J. 2018 Feb;8(1):78-83.

Latka D, Kozlowska K, Miekisiak G, et al. Safety and efficacy of cervical disc arthroplasty in preventing the adjacent segment disease: a meta-analysis of mid- to long-term outcomes in prospective, randomized, controlled multicenter studies. Ther Clin Risk Manag. 2019;15:531–539.

Laugesen LA, Paulsen RT, Carreon L, et al. Patient-reported outcomes and revision rates at a mean follow-up of 10 years after lumbar total disc replacement. Spine (Phila Pa 1976). 2017 Nov 1;42(21):1657-1663.

Li Y, Sun P, Chen D, et al. Artificial total disc replacement versus fusion for lumbar degenerative disc disease: an update systematic review and meta-analysis. Turk Neurosurg. 2020;30(1):1-10.Lu H and Peng L. Efficacy and safety of Mobi-C cervical artificial disc versus anterior discectomy and fusion in patients with symptomatic degenerative disc disease: a meta-analysis. Medicine (Baltimore). 2017 Dec;96(49):e8504.

Lu VM, Mobbs RJ, Phan K. Clinical outcomes of treating cervical adjacent segment disease by anterior cervical discectomy and fusion versus total disc replacement: a systematic review and meta-analysis. Global Spine J. 2019;9(5):559-567.

Lu VM, Zhang L, Scherman DB, et al. Treating multi-level cervical disc disease with hybrid surgery compared to anterior cervical discectomy and fusion: a systematic review and meta-analysis. Eur Spine J. 2017 Feb;26(2):546-557.

Mu X, Wei J, A J, et al. The short-term efficacy and safety of artificial total disc replacement for selected patients with lumbar degenerative disc disease compared with anterior lumbar interbody fusion: a systematic review and meta-analysis. PLoS One. 2018 Dec 28;13(12):e0209660.

National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine. Interventional procedure guidance 341. May 2010.

National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine. Interventional procedure guidance 306. July 2009.

North American Spine Society (NASS). Cervical artificial disc replacement. Coverage Policy Recommendations. November 2015.

North American Spine Society (NASS). Lumbar artificial disc replacement. Coverage Policy Recommendations. February 2019.

Park SJ, Lee CS, Chung SS, et al. Long-term outcomes following lumbar total disc replacement using ProDisc®-II average 10-year follow-up at a single institute. Spine (Phila Pa 1976). 2016 Feb 18.

Pointillart V, Castelain JE, Coudert P, et al. Outcomes of the Bryan cervical disc replacement: fifteen year follow-up. Int Orthop. 2018 Apr;42(4):851-857.

Pron G, Zivaripiran H, Wells D, Walter M. Health Quality Ontario. Cervical artificial disc replacement versus fusion for cervical degenerative disc disease: a health technology assessment. Ont Health Technol Assess Ser. 2019 Feb;19(3):1–223.

Radcliff K, Coric D, Albert T. Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. J Neurosurg Spine. 2016 Aug;25(2):213-24.

Radcliff K, Davis RJ, Hisey MS, et al. Long-term evaluation of cervical disc arthroplasty with the Mobi-C© cervical disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. Int J Spine Surg. 2017 Nov 28;11:31.

Schroeder G, Vaccaro A, Divi S. ISASS Position Statement on Cervical and Lumbar Disc Replacements (2019).

Scott-Young M, McEntee L, Schram B, et al. Concurrent use of lumbar total disc arthroplasty and anterior lumbar interbody fusion: the lumbar hybrid procedure for the treatment of multilevel symptomatic degenerative disc disease: a prospective study. Spine (Phila Pa 1976). 2018 Jan 15;43(2):E75-E81.

Scott-Young M, McEntee L, Zotti M, et al. Patient-reported outcome measures after multilevel lumbar total disc arthroplasty for the treatment of multilevel degenerative disc disease. Spine (Phila Pa 1976). 2020;45(1):18-25.

Shi Ji-Sheng, Lin Bin, Xue C, et al. Clinical and radiological outcomes following hybrid surgery in the treatment of multi-level cervical spondylosis: over a 2-year follow-up. Journal of Orthopaedic Surgery and Research (2015) 10:185.

The International Society for the Advancement of Spine Surgery. ISASS Policy Statement – Lumbar artificial disc. 2015.

Wahood W, Yolcu YU, Kerezoudis P, et al. Artificial discs in cervical disc replacement: a meta-analysis for comparison of long-term outcomes. World neurosurgery. 2020;134:598-613.e595.

Wang QL, Tu ZM, Hu P, et al. Long-term results comparing cervical disc arthroplasty to anterior cervical discectomy and fusion: a systematic review and meta-analysis of randomized controlled trials. Orthop Surg. 2020;12(1):16-30.

Wu T, Liu H, Wang B, Meng Y. Minimum four-year subsequent surgery rates of cervical disc replacement versus fusion: a meta-analysis of prospective randomized clinical trials. Orthop Traumatol Surg Res. 2016 Nov 24.

Xie L, Liu M, Ding F, et al. Cervical disc arthroplasty (CDA) versus anterior cervical discectomy and fusion (ACDF) in symptomatic cervical degenerative disc diseases (CDDDs): an updated meta‑analysis of prospective randomized controlled trials (RCTs). SpringerPlus (2016) 5:1188.

Yang W, Si M, Hou Y, Nie L. Superiority of 2-level total disk replacement using a cervical disk prosthesis versus anterior cervical diskectomy and fusion. Orthopedics. 2018 Aug 17:1-8.

Yao Q, Liang F, Xia Y, et al. A meta-analysis comparing total disc arthroplasty with anterior cervical discectomy and fusion for the treatment of cervical degenerative diseases. Arch Orthop Trauma Surg (2016) 136:297–304.

Yue J and Garcia R. Five-year results of a randomized controlled trial for lumbar artificial discs in single-level degenerative disc disease. Spine Journal, 2017-10-01, Volume 17, Issue 10, Pages S70-S70.Zeng J, Liu H, Rong X, et al. Clinical and radiographic outcomes of cervical disc arthroplasty with Prestige-LP Disc: a minimum 6-year follow-up study. BMC Musculoskelet Disord. 2018 Aug 7;19(1):285.

Zhao H, Duan LJ, Gao YS, et al. What is the superior surgical strategy for bi-level cervical spondylosis-anterior cervical disc replacement or anterior cervical decompression and fusion?: a meta-analysis from 11 studies. Medicine (Baltimore). 2018 Mar;97(13):e0005.

Zigler J and Garcia R. The International Society for the Advancement of Spine Surgery Policy Statement – Lumbar artificial disc. March 12, 2015.

Zigler J, Ferko N, Cameron C and Patel L. Comparison of therapies in lumbar degenerative disc disease: a network meta-analysis of randomized controlled trials. Journal of Comparative Effectiveness Research. 2018a;7(3):233-246.

Zigler JE, Glenn J, Delamarter RB. Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L® versus circumferential fusion. Neurosurg Spine. 2012 Oct 19.

Zigler J, Gornet MF, Ferko N, et al. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: a meta-analysis of 5-year outcomes from randomized controlled trials. Global Spine J. 2018b Jun;8(4):413-423.

Zou S, Gao J, Xu B, et al. Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials. Eur Spine J. 2016 Jun 17.

Policy History/Revision Information

Date	Summary of Changes
12/09/2020	• Corrected typographical error; added language to clarify lumbar artificial total disc replacement is unproven and not medically *necessary*
11/01/2020	Documentation Requirements • Replaced language indicating “diagnostic image(s) *are* required” with “diagnostic image(s) *may be* required *upon request*” Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2020T0437X

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare 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 reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical 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.