Total Artificial Disc Replacement for the Spine

Policy Number: 2023T0437JJ
Effective Date: October 1, 2023

Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

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.

Cervical artificial 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, in a Skeletally Mature individual with a history of cervical spinal fusion at another level (adjacent or non-adjacent).

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

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical.

Click here to view the InterQual® criteria.

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.

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

For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG.

Click here to view the InterQual® criteria.

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

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	

0098T
22856
22857
22858
22861
22862
22899
	Medical notes documenting the following, when applicable:
	• Diagnosis
	• Specific requested procedure
	• History of the medical condition(s) requiring treatment or surgical intervention, including:
	  ○ Level(s) of motor deficit
	  ○ Level(s) of sensory deficit
	  ○ Extremity weakness, numbness, pain, or loss of dexterity including unilateral or bilateral
	  ○ Gait disturbance, including investigation for other etiologies
	  ○ Bowel or bladder dysfunction, including investigation for other etiologies
	• History or signs of infection, malignancy, facet arthritis or spine instability at the level of disc replacement request
	• Documentation of signs and symptoms; including onset, duration, and frequency
	• Physical exam; include spasticity, including investigation for other etiologies
	• Relevant medical history, including:
	  ○ Osteoporosis or osteopenia
	  ○ Spondylosis, including severity and level

CPT Codes*	Required Clinical Information
Total Artificial Disc Replacement for the Spine	
	○ Ankylosing spondylitis ○ Rheumatoid arthritis ○ Ossification of the posterior longitudinal ligament • 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; faxes will not be accepted • Treatments tried, failed, or contraindicated; include the dates, duration of treatment, and reason for discontinuation • Current medications used to treat condition, including start date • Reports of all recent imaging studies and applicable diagnostics, including: ○ Results of imaging including number of pathology level(s) ○ Physician treatment plan • For lumbar surgery, in addition to the above, provide medical notes documenting the following, when 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, refer to the Applicable Codes section.

Definitions

Degenerative Disc Disease (DDD): Degeneration of the disc confirmed by radiographic studies accompanied by a patient history and exam consistent with discogenic back pain.

Grade 1 Spondylolisthesis: Superior vertebral body has slipped forward by 25% of the vertebral diameter relative to the inferior vertebral body at a vertebral junctional level.

Modic Changes: Peridiscal bone signal changes note on MRI in the vertebra superior and inferior to 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
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)

CPT Code	Description
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
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)
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (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
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 (Hayes, 2021).

Clinical Evidence

Hybrid Surgery for Cervical Spine

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.

An ECRI 2021 report focused on Simplify's safety and effectiveness for treating cervical DDD and how they compare with those of other artificial cervical discs and ACDF. One prospective, historical control trial (n = 267) of patients with cervical DDD reported on pain, neurological status, functional status, reintervention rates, and AEs at 2-year follow-up after treatment with Simplify (n = 150) compared with outcomes of a historical control (n = 117) treated with ACDF. The study also reported on quality of life at 2-year follow-up compared with baseline. Both treatments improved NDI and VAS scores from baseline. The 12-Item Short Form Survey quality of life scores improved 19.6 points (physical component) and 9.8 points (mental component) in patients treated with Simplify. The study reported 88% of patients treated with Simplify were "very satisfied" compared with 70% of those treated with ACDF. The study reported no statistical differences in AEs. The report concluded that Simplify appears to be safe and more effective than ACDF for reducing pain and improving functional status in patients with cervical DDD at 24-month follow-up. Evidence is based on one historical control study at high risk of bias due to lack of randomization, blinding, and parallel control groups. There were no studies that compared Simplify with other cervical disc arthroplasty devices. Additional randomized controlled trials are needed to validate Simplify's safety and effectiveness.

A 2021 Hayes comparative effectiveness review of multilevel artificial disc replacement for cervical degenerative disc included two additional studies addressing hybrid surgery. There was a lack of evidence for hybrid surgery treatment of cervical DDD in adult patients (Hayes, 2021).

Wang et al. (2021) performed a retrospective study to compare the clinical and radiologic outcomes of 3-level hybrid surgery (HS) (cervical disc replacement performed before cervical disc fusion) and 3-level ACDF. The study included 101 patients: 64 patients in the HS group and 37 patients in the ACDF group. The VAS neck scores decreased to 2.58 ±0.66 in the HS group and 2.38 ±0.49 in the ACDF group by the final follow-up. VAS arm scores were 2.19 ±0.79 and 2.38 ±0.49 in the HS and ACDF groups, respectively. The JOA recovery rate was 79.78% in the HS group and 77.40% in the ACDF group. Mean Neck Disability Index scores were 6.77 ±1.42 in the HS group and 6.65±1.40 in the ACDF group. The hybrid surgery group had slightly higher physical and mental 36-Item Short Form Survey scores than the fusion group at 1-year follow-up (physical component summary: 49.34 vs. 46.70; mental component summary: 45.67 vs. 43.95). Both the HS and the ACDF group had decreased ROM compared with the preoperative level (HS: 48.39 vs. 31.26; ACDF: 41.43 vs. 21.27). More ROM was maintained in the HS group than the ACDF group compared with baseline (64.60% vs. 51.34%). Cervical lordosis was decreased with time in both groups. The authors concluded that the safety and effectiveness of HS has been proved in double-level cervical spondylosis but the clinical characteristics in 3-level surgery remain unclear. Study limitations include the retrospective analysis, small study sample and short follow-up time.

Using extracted medical file data consisting of 195 patients with 2 or 3 consecutive levels of mCDD who were treated using HC, a retrospective study was completed by Yilmaz et al. (2021). The aim of the study was to assess the mid-long-term follow-up results, radiographic parameters, clinical outcomes, and complications of hybrid construction (HC). The mean clinical and radiological follow-up timeframe was 45.2 months (range 24 to 102). Primary clinical problems in all patients included radiculopathy and/or myelopathy which was unresponsive to conservative treatment (during at least 6 weeks). The VAS scores of hybrid construction (HC) for arm pain were 7.4 ±0.8 preoperatively; 2.8 ±0.6, 1 month after surgery; 2.3 ±0.6, 6 months after surgery; 1.8 ±0.6, 12 months after surgery; and 1.6 ±0.6, 24 months after surgery. The NDI scores of HC were on admission, 57.2 ±5.5%; 1 month after surgery, 27.35 ±5.3%; 6 months after surgery, 21.43 ±2.8%; 12 months after surgery, 21.9 ±2.3%; 24 months after surgery, 20.6±2.6%. Hoarseness and dysphagia were noted as common complications. Osteophyte formation was frequently noted as a radiographic change. The authors concluded that management of mCDD and spondylotic spinal stenosis using anterior cervical HC is an appropriate treatment option. The study is limited by its retrospective observations and nonrandomized design.

Hollyer et al. (2020) performed a systematic review and meta-analysis comparing outcomes of hybrid surgery (HS) versus anterior cervical discectomy and fusion (ACDF) or cervical disc arthroplasty (CDA) alone for the treatment of multilevel cervical degenerative disc disease (CDDD). Eight research studies were identified for review with a total of 424 patients. Results indicate no significant difference in functional and pain scores (NDI, VAS). Post-operative C2-C7 range of motion (ROM) was greater after HS than ACDF. ROM of the superior adjacent segment was lower after HS than ACDF as well as ROM of the inferior adjacent segment. Patients who had HS returned to work 32 days sooner than ACDF patients and 33 days sooner than the CDA group. The authors concluded that HS may be associated with greater post-operative C2-C7 ROM, reduced ROM in the adjacent segments, and a quicker return to work than ACDF. This was a non-randomized study design without a control group. In addition, there is a lack of high-quality evidence demonstrating a beneficial impact of HS on health outcomes in patients with multilevel CDDD. (This study is included in the 2021 Hayes report).

Zhang et al. (2020) performed a meta-analysis study to compare outcomes and reliability of hybrid surgery (HS) versus anterior cervical discectomy and fusion (ACDF) for the treatment of multilevel cervical spondylosis and disc diseases. The meta-analysis included two prospective and five retrospective clinical controlled trials. One hundred and nine individuals who had HS and 127 individuals who underwent ACDF for multilevel cervical disc disease were followed for 2 years. The results indicated improved recovery of NDI score ($p = 0.038$) and similar recovery of VAS score ($p = 0.058$) after HS when compared with ACDF. Total cervical ROM (C2–C7) after HS was preserved more than the cervical ROM after ACDF. The compensatory increase of the ROM of superior and inferior adjacent segments was significant in ACDF groups at 2-year follow-up ($p < 0.01$), compared with HS. The 2-year follow-up was not enough time to observe the long-term recovery and complications. The authors concluded that this meta-analysis indicates that HS, combining CDA and fusion, provides equivalent outcomes and functional recovery for cervical disc diseases, even better recovery of NDI and preservation of cervical ROM, reducing the risk of adjacent disc degeneration. There were several limitations of this study. There was no RCT comparing the outcomes between HS and ACDF and the studies included were of lower quality evidence than RCTs. The authors stated that more well-designed studies with

large groups of patients and long-term follow-up are required to provide further evidence for the benefit and reliability of HS in the treatment of multilevel cervical disc diseases.

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. The authors also observed that recently there has been an increasing prevalence of 2-level CDA and hybrid surgery (HS)and 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. They also concluded that there is a lack of robust clinical evidence in the literature and that further research with randomized controlled trials is needed to validate these findings.

Chen et al. (2016) retrospectively analyzed data from 108 patients with three-level cervical myelopathy who underwent hybrid surgery in a case series. Implantation of Bryan® artificial discs into two contiguous segments and cage fusion of adjacent segments was performed for all patients. Based on the 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. The study is limited by lack of comparison group.

Shi and colleagues (2015) performed a retrospective case series of 36 patients with adjacent three-level cervical spondylosis who were treated with 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. They also observed that some authors have investigated this method of treatment but the evidence in the published peer-reviewed literature is limited by lack of controls, small sample size and short-term outcomes and that additional research is needed to clearly establish a role for hybrid technologies. This study is limited by lack of comparison group.

CADR With History of Previous Cervical Spinal Fusion Surgery

Lee et al. (2017) conducted a retrospective study (n = 41) to compare the efficacy and safety of anterior cervical discectomy and fusion (ACDF) and cervical total disc replacement (CTDR) as revision surgeries for symptomatic adjacent segment degeneration (ASD) in cases with previous ACDF. Clinical outcomes were obtained before surgery and at 1, 6, 12, and 24 months postoperatively. In the ACDF group, the mean VAS scores for arm pain decreased from 6.6±1.0 preoperatively to 1.8 ±0.5 at 24 months postoperatively. In the CTDR group, the VAS scores decreased from 6.7 ±0.9 before surgery to 1.6 ±0.5 at 24 months after surgery. The mean NDI score in the ACDF group improved from 57.0 ±8.2% before surgery to 24.8 ±1.9% at 24 months after surgery. In the CTDR group, the mean NDI score improved from 55.6 ±10.2% to 22.3 ±2.9%, respectively. The CTDR group demonstrated better NDI improvement than did the ACDF group 12 and 24 months after surgery. According to the Odom criteria, clinical outcomes were excellent in the ACDF group in 6 patients, good in 14, fair in 2, and poor in none. The Odom criteria for the CTDR group were excellent in 6, good in 12, fair in1 and poor in none. The authors concluded that the CTDR group showed better NDI improvement, faster C2-7 ROM recovery, less of an increase in ROM in the inferior adjacent segment, and a lower incidence of adjacent segment degeneration than did the ACDF group.

A retrospective study (n = 32) was performed by Bin et al. (2017) to evaluate the outcome of artificial cervical disk replacement (ACDR) for the treatment of adjacent segment disease (ASD) after anterior cervical decompression and fusion (ACDF). In twenty-two patients, ASD occurred above the fusion site, and in 10 it occurred below the site. After ACDR, the patients were followed up for 30-62 months. Before ACDR, neck VAS, upper-limb VAS, JOA score, and NDI were 7.2 ±1.8, 6.9 ±1.1, 9.8 ±2.5, and 40.5 ±4.8, respectively. At the last follow-up, they were 1.2 ±0.3, 0.9 ±0.3, 14.5 ±1.1, and 9.0 ±2.5, respectively.. Preoperatively, the ROMs of the replaced and adjacent segments were 8.7 ±2.6 and 7.6 ±3.0, respectively. At the last follow-up, they were 8.5 ±2.2 and 7.2 ±2.6, respectively. At the last follow-up, 2 patients had grade II heterotopic ossification; 3 patients had aggravated degeneration (vs. preoperative status) of the adjacent unfused segment. The reduction in Goffin grade was not statistically significant. The authors concluded that ACDR is an effective treatment for post-ACDF ASD. It can maintain the ROMs of the replaced segment as well as the adjacent unfused segment.

Rajakumar et al. (2017) conducted a retrospective review analyzing clinical and radiological results in patients who were treated with arthroplasty for new or persistent arm and/or neck symptoms related to neural compression due to adjacent-segment disease after anterior cervical discectomy and fusion (ACDF). The study included 11 patients. Clinical evaluation was performed both before and after surgery, using a visual analog scale (VAS) for pain and the Neck Disability Index (NDI). Radiological outcomes were analyzed using pre- and postoperative flexion/extension lateral radiographs measuring Cobb angle, functional spinal unit (FSU) angle, and range of motion (ROM). The mean VAS score improved from 6.18 preoperatively to 2.18 in the immediate postoperative period and further reduction to 0.87 at 1 year's follow-up. The mean NDI score improved from 58.7 to 22.6 in the immediate postoperative period and to 14.25 at 1 year after surgery. The mean cervical ROM improved after surgery (mean 5.14° vs 7.56° for preoperative and immediate postoperative ROM, respectively). There was no statistically significant

improvement in the mean FSU angle. The authors concluded that ACDR in patients who had previously undergone cervical fusion surgery appeared to be safe, with encouraging early clinical results.

Lumbar Artificial Disc

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

A 2020 Hayes, updated 2022 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. The 2022 annual review found ten abstracts, including 1 randomized controlled trial, 1 prospective cohort study, 2 pretest/posttest studies, 3 case series, 1 systematic review with meta-analysis, and 2 meta-analyses. Evaluation of the literature did not change the previous conclusions.

A prospective cohort study was conducted by Scott-Young et al. (2022) to compare the mid- to long-term patient-reported outcome measures (PROMs) between single-level total disc arthroplasty (TDA), multi-level TDA, and hybrid constructs (combination of TDA and anterior lumbar interbody fusion [ALIF] across multiple levels) for symptomatic degenerative disc disease (DDD). A total of 950 patients underwent surgery for single-level or multi-level DDD with single-level TDA (n = 211), multi-level TDA (n = 122), or hybrid construct (n = 617). Visual Analog Score for the back (VAS-B) and leg (VAS-L) were recorded, along with the Oswestry Disability Index (ODI) and Roland Morris Disability Questionnaire (RMDQ). All PROMs in all groups showed improvements in pain and function. There were no statistically significant differences in the change scores between the surgery groups for VAS back and leg pain, and RMDQ up to 8 years' follow-up. Adjusted analyses showed the ODI improvement score for the single group was 2.2 points better than in the hybrid group. The RMDQ change score was better in the hybrid group than in the multi-level group by 1.1 points at 6 months and a further 0.4 point at 2 years. The authors concluded that the results of this cohort study demonstrated that single-level TDA, multi-level TDA, and hybrid constructs are all effective in treating symptomatic DDD, with no clinical difference in PROMs between the groups up to 8 years follow-up. A limitation of this study was that all cases were performed by a single surgeon at a single institution, which affects the generalizability of the results. Another limitation was the lack of a control group. (This study is included in the Hayes, 2022 review).

Blumenthal et al. (2022) performed a retrospective record review combined with a mailing to collect data to investigate the outcome of lumbar TDR used to treat adjacent segment degeneration after prior lumbar fusion. The study was based on 30 consecutive patients, who underwent lumbar TDR at one or more levels adjacent to a prior fusion to treat symptomatic disc degeneration unresponsive to nonoperative care. The outcome measures included visual analog scales (VAS) assessing back and leg pain, the Oswestry Disability index (ODI), and the occurrence of re-operations. The mean follow-up duration after TDR was 76.6 months. A total of 40 TDRs were implanted in the 30 patients. The most frequently operated level was L4-5 above a prior L5-S1 fusion. The authors reported that the VAS back pain and ODI scores improved from pre-TDR to final follow-up (VAS back pain from 7.3 to 4.6, and ODI scores 48.9 to 32.4). VAS leg pain scores improved, but not significantly (4.4 to 3.6). Three patients (10.0%) underwent additional lumbar spinal surgery after the TDR procedure. The authors concluded that the current study found that TDR can be used effectively for treating adjacent segment degeneration providing the patient is an appropriate candidate for this procedure. In evaluating these patients, particular attention must be paid to the condition of the facet joints to ensure TDR is not contra-indicated. The study is limited by its retrospective observations and small sample size.

A systematic review and meta-analyses were conducted by Lang et al. (2021) to find the most appropriate surgical technique treating lumbar degenerative disc disease (DDD). The surgical techniques TDR, anterior lumbar interbody fusion (ALIF) and circumferential fusion (CFF) were compared. Primary outcomes were pain measured by the Visual Analogue Scale (VAS) and function measured by the Oswestry Disability Index (ODI). Secondary outcomes were the mean number of complications per

case (MNOC) at surgery and follow-up and the overall MNOC. The review included six prospective studies with the minimum follow-up of two years: four randomized controlled trials and two cohort studies. For VAS and ODI, TDR was shown to be superior to ALIF and CCF ($p < 0.05$), and ALIF was more effective than CFF without statistical significance. CFF presented the best result in complications with the lowest overall MNOC (0.1), followed by TDR (1.2) and ALIF (1.5). The authors concluded that TDR was found to be the most appropriate surgical technique for treating DDD, followed by ALIF. Further studies with a longer follow-up are needed using the same methodical approach to strengthen the VAS and ODI results.

Radcliff et al. (2021) conducted a prospective, multicenter, randomized, controlled investigational device exemption (IDE) study to compare 7-year safety and efficacy outcomes of activL and ProDisc-L lumbar total disc replacements in patients with symptomatic, single-level lumbar degenerative disc disease (DDD) who had failed ≥ 6 months of nonsurgical management. Two hundred and eighty-three individuals were randomized to receive activL (n = 218) or ProDisc-L (n = 65). Approximately 73% (206/283) of patients returned for the 7-year follow-up visit. At seven years, the Oswestry Disability Index (ODI) scores in activL patients decreased from 57 at baseline to 16 and from 59 to 22 in ProDisc-L patients. For the activL patients, mean visual analog scale (VAS) back and leg pain scores decreased from 79 mm to 17 mm and from 43 mm to 13 mm, respectively. In the ProDisc-L patients the VAS back score decreased from 78 mm to 17 mm and with a VAS leg score decrease from 41 mm to 16 mm. The mean physical component summary improved by 13.1 points and 11.4 points, for the activL and ProDisc-L patient, respectively. The mean mental component summary improved in the activL, 17.2 points and in ProDisc-L, 18.3 points. Reoperation rates for both activL and ProDisc-L patients were low and there was no observed increase in SAEs between years 5 and 7. The study found that opioid use was reduced to 0% after 7 years from a preoperative rate of 65%. The authors concluded that the benefits of activL and ProDisc-L are maintained after 7 years, with improvements from baseline observed in pain, function, and opioid use. (This study is included in the 2022 Hayes review).

Cuellar et al. (2021) conducted a prospective cohort study to present the radiographic and clinical outcomes of a group of patients undergoing a ''hybrid'' procedure involving one, two, or three simultaneous lumbar artificial disc replacements above an arthrodesis at the L5-S1 level. Forty-six patients underwent simultaneous lumbar total disc replacement (TDR) at one to three levels and anterior lumbar interbody fusion (ALIF) at L5-S1. Patients were evaluated preoperatively and at 6 weeks, 3 months, 6 months, and annually for 24 to 72 months postoperatively. At 2-6 years post operation, all patients had reductions in ODI and VAS scores. At the nonsurgical level adjacent to the TDR + ALIF constructs, the mean preoperative ROM was 9.40 ±1.80° compared with 10.50 ±2.25° postoperatively. The mean preoperative ROM at levels undergoing TDR was 10.4 ±2.71° versus 12.6 ±2.25° postoperatively. The mean preoperative ROM at the L5-S1 segment to undergo fusion was 2.4 ±2.44°, with all patients having a postoperative ROM of 0.00°. No patients required reoperation. The authors concluded that lumbar artificial disc replacement can successfully be performed at multiple levels with an ALIF during the same procedure. Limitations of this study included lack of control group and small sample size.

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. (This study is included in the 2022 Hayes report).

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. The study is however limited by lack of comparison group.

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 (Author Zigler (2012) which was previously cited in this policy is included in this meta-analysis). (This study is included in the 2022 Hayes review).

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. (This study is included in the 2022 Hayes report).

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.

Clinical Practice Guidelines

American Pain Society

A multidisciplinary panel was convened by the American Pain Society to develop evidence-based recommendations on use of interventional diagnostic tests and therapies, surgeries, and interdisciplinary rehabilitation for low back pain of any duration, with or without leg pain. Their recommendation was as follows:

- In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, there is insufficient evidence to adequately evaluate long-term benefits and harms of vertebral disc replacement. Data on long-term (beyond 2 years) benefits and harms following artificial disc replacement are limited (Chou, 2009).

International Society for the Advancement of Spine Surgery (ISASS)

A 2021 ISASS Policy Statement concludes that both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, are safe and effective treatment alternatives to fusion for patients meeting well established selection criteria. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use (Schroeder et al., 2021).

National Institute for Health and Care Excellence (NICE)

In a 2020 NICE guideline on low back pain and sciatica assessment and management they recommend that physicians do not offer disc replacement in people with low back pain (NICE, 2020).

In a 2009 Interventional Procedures Guidance, NICE concluded that the current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure. 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 (NICE, 2009).

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

Lumbar disc arthroplasty is not indicated in the following scenarios:

- Any case that does not fulfill all of the above criteria
- Presence of symptomatic degenerative disk disease at more than one level
- Age greater than 60 years or less than 18 years

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.

Artificial discs are regulated by the FDA, but products are too numerous to list. Refer to the following website for more information (use product code MJO). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm (Accessed August22, 2022)

References

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.

Bin S, Xiangwang H, Sheng X, et al. Artificial cervical disk replacement for the treatment of adjacent segment disease after anterior cervical decompression and fusion. Clin Spine Surg. 2017 Jun;30(5):E587-E591.

Blumenthal Scott, Guyer Richard, Shellock Jessica, et al. Lumbar total disc replacement for the treatment of adjacent segment degeneration after lumbar fusion. The Spine Journal 22 (2022) S43–ion.

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.

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.

Chou R, Loeser JD, Owens DK, et al. American Pain Society Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). 2009 May 1;34(10):1066-77.

Cuellar JM, Rasouli A, Lanman TH, et al. Single and multilevel lumbar total disc replacement adjacent to L5-S1 ALIF (lumbar hybrid): 6 years of follow-up. Int J Spine Surg. 2021 Oct;15(5):971-977.

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.

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. Simplify Cervical Artificial Disc (Simplify Medical, Inc.) for treating cervical degenerative disc disease. Plymouth Meeting (PA): ECRI; 2021 Mar 30. (Clinical Evidence Assessment).

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.

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.

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 November 18, 2021.

Hayes, Inc. Medical Technology Directory. Comparative Effectiveness Review. Lumbar total disc replacement for degenerative disc disease. Lansdale, PA: Hayes, Inc.; March 24, 2022.

Hollyer MA, Gill EC, Ayis S, Demetriades AK. The safety and efficacy of hybrid surgery for multilevel cervical degenerative disc disease versus anterior cervical discectomy and fusion or cervical disc arthroplasty: a systematic review and meta-analysis. Acta Neurochir (Wien). 2020 Feb;162(2):289-303.

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.

Lang SAJ, Bohn T, Barleben L, et al. Advanced meta-analyses comparing the three surgical techniques total disc replacement, anterior stand-alone fusion and circumferential fusion regarding pain, function and complications up to 3 years to treat lumbar degenerative disc disease. Eur Spine J. 2021 Dec;30(12):3688-3701.

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.

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.

Lee SB, Cho KS. Cervical arthroplasty versus anterior cervical fusion for symptomatic adjacent segment disease after anterior cervical fusion surgery: Review of treatment in 41 patients. Clin Neurol Neurosurg. 2017 Nov;162:59-66.

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 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). Low back pain and sciatica in over 16s: assessment and management. NICE guideline [NG59]. Published: 30 November 2016. Last updated: 11 December 2020.

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). 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.

Radcliff K, Zigler J, Braxton E, et al. Final long-term reporting from a randomized controlled IDE trial for lumbar artificial discs in single-level degenerative disc disease: 7-year results. Int J Spine Surg. 2021 Aug;15(4):612-632. Epub 2021 Jul 15.

Rajakumar DV, Hari A, Krishna M, et al. Adjacent-level arthroplasty following cervical fusion. Neurosurg Focus. 2017 Feb;42(2):E5.

Schroeder G, Vaccaro, A, Divi S., et al. 2021 position statement from the International Society for the Advancement of Spine Surgery on cervical and lumbar disc replacement. Int J Spine Surg. 2021;15(1): 37-46.

Scott-Young M, Lee SMS, Nielsen D, et al. Comparison of mid- to long-term follow-up of patient-reported outcomes measures after single-level lumbar total disc arthroplasty, multi-level lumbar total disc arthroplasty, and the lumbar hybrid procedure for the treatment of degenerative disc disease. Spine (Phila Pa 1976). 2022 Mar 1;47(5):377-386.

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.

Wang H, Huang K, Liu H, et al. Is cervical disc replacement valuable in 3-level hybrid surgery compared with 3-level anterior cervical discectomy and fusion? World Neurosurg. 2021 Feb;146:e151-e160.

Yilmaz M, Yucesoy K, Erbayraktar RS, Altinag RS. Anterior hybrid construction of multilevel cervical disc disease and spondylotic spinal stenosis: surgical results and factors affecting adjacent segment problems. J Orthop Surg Res. 2021 May 5;16(1):298.

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.

Zhang J, Meng F, Ding Y, et al. Comprehensive analysis of hybrid surgery and anterior cervical discectomy and fusion in cervical diseases: a meta-analysis. Medicine (Baltimore). 2020 Jan;99(5):e19055.

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.

Policy History/Revision Information

Date	Summary of Changes
10/01/2023	**Application** ***Individual Exchange Plans*** • Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York **Supporting Information** • Archived previous policy version 2023T0437II

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 InterQual® criteria, 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.