Total Artificial Disc Replacement for the Spine

Policy Number: CS121.Y
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➲ Instructions for Use

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Idaho	Total Artificial Disc Replacement for the Spine (for Idaho Only)
Indiana	None
Kansas	Total Artificial Disc Replacement for the Spine (for Kansas Only)
Kentucky	Total Artificial Disc Replacement for the Spine (for Kentucky Only)
Nebraska	Total Artificial Disc Replacement for the Spine (for Nebraska Only)
New Jersey	Total Artificial Disc Replacement for the Spine (for New Jersey Only)
New Mexico	Total Artificial Disc Replacement for the Spine (for New Mexico Only)
North Carolina	Total Artificial Disc Replacement for the Cervical Spine (for North Carolina Only)
Ohio	Total Artificial Disc Replacement for the Spine (for Ohio Only)
Pennsylvania	Total Artificial Disc Replacement for the Spine (for Pennsylvania Only)
Tennessee	Total Artificial Disc Replacement for the Spine (for Tennessee Only)

Coverage Rationale

Cervical

Cervical total artificial disc replacement (TADR) is proven and medically necessary when all of the following are present and InterQual® criteria are met:

- An FDA-approved prosthetic intervertebral disc is utilized
- Individual diagnosed with only one or two Contiguous Levels of cervical degenerative disc disease (C3-C7)
- Skeletally Mature individual with radiculopathy and/or myelopathy
- The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7)

Note: For two-level contiguous cervical total artificial disc replacement, the device being utilized must be FDA-approved for two levels. When a cervical total artificial disc replacement was previously performed, the second Contiguous Level artificial disc must be FDA approved for two levels.

Cervical total artificial disc replacement in an individual with a history of prior cervical spinal fusion is proven and medically necessary when all of the following are present and InterQual® criteria are met:

- An FDA-approved prosthetic intervertebral disc is utilized
- Treating individuals with only one level or two Contiguous Levels of cervical degenerative disc disease (C3-C7)
- Skeletally Mature individual with radiculopathy and/or myelopathy
- The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7)
- Radiographically Confirmed Complete Arthrodesis of a previous cervical spinal fusion at another level (adjacent or non-adjacent)

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

Click here to view the InterQual® criteria.

Cervical artificial disc removal or replacement with an FDA-approved (one or two-level) prosthetic intervertebral disc is proven and medically necessary in individuals with implant failure after prior disc replacement.

Cervical total artificial disc replacement is unproven and not medically necessary when performed at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan (Hybrid Cervical Surgery).

Lumbar

Lumbar total artificial disc replacement is proven and medically necessary when all of the following are present and InterQual® criteria are met:

- An FDA-approved prosthetic intervertebral disc is utilized
- Treating individuals with only single level of lumbar degenerative disc disease
- Skeletally Mature individual
- Symptomatic intractable discogenic low back pain attributable to that level

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 total artificial disc replacement is unproven and not medically necessary due to insufficient evidence of efficacy when:

- Performed at one level combined with an existing lumbar spinal fusion surgery at another level (adjacent or non-adjacent); or
- Performed with lumbar spinal fusion surgery as part of the same surgical plan (Hybrid Lumbar Surgery); or
- Performed at more than one spinal level

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Contiguous Levels: Vertebral segments adjacent to each other (Tanasansomboon, 2023).

Hybrid Cervical Surgery: The combination of an anterior cervical discectomy and fusion (ACDF) and cervical disc arthroplasty (CDA) (Tanasansomboon, 2023).

Hybrid Lumbar Surgery: The combination of a total disc arthroplasty (TDA) and anterior lumbar interbody fusion (ALIF) (Scott-Young, 2018).

Radiographically Confirmed Complete Arthrodesis: Radiographical evidence of the presence of trabecular bone across the intervertebral space, absence of lucency between the graft and endplate, absence of hardware loosening and < 1 mm of motion between spinous processes on flexion-extension radiographs (Oshina, 2018).

Skeletally Mature: The classification of bone when endochondral ossification ceases and the physis "closes" by becoming totally ossified (Reith, 2018).

Applicable Codes

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

Clinical Evidence

Hybrid Surgery (HS) 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 HS. There are few clinical trials to support improved health outcomes and individual selection criteria has not been firmly established due to factors including heterogeneous study designs, variable implant profiles used, incomplete long-term data and differences in outcome measures.

Yang et al.(2025) conducted a systematic review and meta-analysis to compare patients with two-level cervical degenerative disc disease (DDD) who underwent either HS or two-level anterior cervical discectomy and fusion (ACDF). A

total of 626 individuals from 11 studies were analyzed. HS resulted in less intraoperative blood loss than ACDF when blood loss reached 90 mL or more. However, analysis of functional scores, operative time and complication rates did not show a significant difference between HS and ACDF. The authors concluded HS achieved superior radiographic outcomes compared to two-level ACDF and comparable clinical outcomes. However, further high-quality randomized controlled trials are needed.

A systematic review was performed by Baumann et al. (2024) that included studies that reported any type of clinical outcomes associated with three types of noncontiguous cervical surgeries; anterior cervical discectomy and fusion (ACDF), cervical disc arthroplasty (CDA), and hybrid cervical surgery (HCS). Ten articles were included (nine observational studies and one randomized controlled trial). Individuals (n = 388) had a mean age of 52 ±5.1 years and a mean follow-up time of 33 ±6.0 months. One hundred and nineteen individuals underwent noncontiguous HCS, 65 underwent noncontiguous CDA, and 204 underwent noncontiguous ACDF. Individuals (47%) who underwent noncontiguous HCS had a preoperative Visual Analog Scale (VAS) score of 5.4 points, a postoperative VAS score of 1.6 points, and an improvement in VAS of 3.8 points. Individuals (78%) who underwent non-contiguous CDA had a preoperative VAS score of 5.6 points, a postoperative VAS score of 1.3, and an improvement in VAS of 4.3 points. Individuals who underwent noncontiguous HCS had an improvement in Japanese Orthopedic Association (JOA) score (47%) of 6.5 points. Individuals who underwent noncontiguous CDA had an improvement in JOA score of 6.5 points. Individuals who underwent noncontiguous ACDF had an improvement in JOA score of 5.6 points. Individuals who underwent noncontiguous HCS had an improvement in Neck Disability Index (NDI) score (47%) of 19 points. Individuals who underwent noncontiguous CDA had an improvement in NDI score of 18 points. Individuals who underwent noncontiguous ACDF had an improvement in NDI score (92%) of 17 points. There was a total of 83 complications (21% of cases) with noncontiguous ACDF having a higher absolute rate of dysphagia (20%) as compared to noncontiguous HCS (6.7%) or noncontiguous CDA (6.2%). Noncontiguous ACDF had a higher absolute rate of adjacent segment degeneration anterior cervical discectomy and fusion as a reported complication (6.4%) as compared to noncontiguous HCS (1.7%) and noncontiguous CDA (0.0%). The authors concluded that there may be no clinically meaningful difference in many clinical outcomes for different noncontiguous surgical interventions for noncontiguous (cervical degenerative disc disease). However, complication rates, such as dysphagia and anterior cervical discectomy and fusion, appear higher for noncontiguous ACDF as compared to noncontiguous CDA or HCS. Several study limitations were identified; the lack of high-level evidence and short follow-up time.

A retrospective study was conducted by Zheng et al. (2024). The clinical and radiographic data of individuals with three-segment cervical spondylosis, who underwent CDR, ACDF and HS were analyzed. The VAS, JOA and NDI were used to evaluate clinical efficacy post-surgery. Cervical spine x-rays were conducted to assess range of motion (ROM), cervical lordosis (CL), T1 slope angle (T1S) and relevant outcomes. Ninety-four individuals were included in the study: 26 in the CDR group, 13 in the HS1 group, 31 in the HS2 group, and 24 in the ACDF group. Most individuals in the CDR group were younger. There was no difference in the follow-up duration, blood loss volume or surgery time. Four groups reported improvements in JOA and NDI scores compared to baseline. There was no significant difference in the final JOA, final NDI or recovery rate among the four groups. The final ROM was smaller in the ACDF group than in the other three groups. There was no difference among the four groups in the final unconscious range of motion (UROM), final lumbar range of motion (LROM) or their changes. There was no difference in the final T1S, final sagittal vertical axis (SVA) or their change among the four groups. All groups showed similar changes in CL and T1S-CL. The authors concluded that there was no difference in the clinical outcomes of ACDF, CDR, or hybrid surgery. CDR can better preserve the mobility of the cervical spine. Neither CDR nor hybrid surgery was significantly advantageous over ACDF in restoring the sagittal sequence in individuals with three-level CSM. This was a retrospective study with a small sample of all groups so high-level grade randomized controlled trials or large sample cohort studies are needed.

An ECRI 2021 report focused on Simplify's safety and effectiveness for treating cervical degenerative disc disease (DDD) and how they compare with those of other artificial cervical discs and anterior cervical discectomy and fusion (ACDF). One prospective, historical control trial (n = 267) of participants with cervical DDD reported on pain, neurological status, functional status, reintervention rates, and adverse events (AEs) at two-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 two-year follow-up compared with baseline. Both treatments improved Neck Disability Index (NDI) and Visual Analogue Scale (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 participants treated with Simplify. The study reported 88% of participants 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 participants 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.

Wang et al. (2021) performed a retrospective study to compare the clinical and radiologic outcomes of three-level HS (cervical disc replacement performed before cervical disc fusion) and three-level ACDF. The study included 101 individuals: 64 individuals in the HS group and 37 individuals 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 Japanese Orthopedic Association (JOA) recovery rate was 79.78% in the HS group and 77.40% in the ACDF group. Mean NDI scores were 6.77 ±1.42 in the HS group and 6.65 ±1.40 in the ACDF group. The HS group had slightly higher physical and mental 36-Item Short Form Survey scores than the fusion group at one 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 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 three-level surgery remain unclear. Study limitations include retrospective analysis, small study sample and short follow-up time.

Using extracted medical file data consisting of 195 individuals with two or three consecutive levels of mCDD who were treated using hybrid construction (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 HC. The mean clinical and radiological follow-up timeframe was 45.2 months (range 24 to 102). Primary clinical problems in all individuals included radiculopathy and/or myelopathy which was unresponsive to conservative treatment (during at least six weeks). The VAS scores of HC for arm pain were 7.4 ±0.8 preoperatively; 2.8 ±0.6, one month after surgery; 2.3 ±0.6, six 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%; one month after surgery, 27.35 ±5.3%; six 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 HS versus ACDF or cervical disc arthroplasty (CDA) alone for the treatment of multilevel cervical DDD. Eight research studies were identified for review with a total of 424 individuals. Results indicate no significant difference in functional and pain scores (NDI, VAS). Post-operative C2-C7 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. Individuals who had HS returned to work 32 days sooner than ACDF individuals 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 individuals with multilevel CDDD.

Zhang et al. (2020) performed a meta-analysis study to compare outcomes and reliability of HS versus 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 mCDD were followed for two 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 two-year follow-up ($p < 0.01$), compared with HS. The two-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 individuals and long-term follow-up are required to provide further evidence for the benefit and reliability of HS in the treatment of mCDD.

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

decreases in all three 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 led 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 CDDD. Additionally, lack of randomization could have resulted in biases in the findings.

Cervical Artificial Disc Replacement (CADR) With History of Previous Cervical Spinal Fusion Surgery

Lu et al. (2019) conducted a systematic review and meta-analysis to compare clinical outcomes of adjacent segment disease (ASD) cohorts being treated by either total disc replacement (TDR) or anterior cervical discectomy and fusion (ACDF). The primary indication for the surgical treatment of ASD is symptomatic relief, with the most common being neck pain (97%), followed by cervical radiculopathy (71%) and sensory deficits in the cervical distribution (57%). One double-armed study and eight single-armed studies were identified from which data of five TDR and five ACDF cohorts treating ASD were extracted. Compared with ACDF, TDR demonstrated superior range of motion of C2-C7 (p = .011), at the final follow-up one year post surgery. Other performance parameters including complications, Neck Disability Index, Japanese Orthopedic Association score, Visual Analog Scale neck and Visual Scale upper extremity measures were comparable between cohorts. The authors conclude similar surgical and post-operative outcomes when comparing TDR and ACDF for the treatment of ASD. The study findings require further investigation as only two TDR and one ACDF cohorts were able to be pooled. ASD secondary to previous ACDF typically presents with neck pai and disability which are effectively treated by both TDR and ACDF procedures. TDR appears to be statistically noninferior to ACDF with respect to performance outcomes. Longer term studies are required to evaluate the recurrence of ASD following either procedure and in order to further validate the clinical utility of TDR compared to ACDF for the treatment of ASD.

Lee et al. (2017) conducted a retrospective study (n = 41) to compare the efficacy and safety of 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 six individuals, good in 14, fair in two, and poor in none. The Odom criteria for the CTDR group were excellent in six, good in 12, fair in one 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. Study limitations include a small number of individuals and relatively short-term follow-up.

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 ASD after ACDF. In twenty-two individuals, ASD occurred above the fusion site, and in ten it occurred below the site. After ACDR, the individuals 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, two individuals had grade II heterotopic ossification; three individuals had aggravated degeneration (vs. preoperative status) of the adjacent unfused segment. 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 individuals who were treated with arthroplasty for new or persistent arm and/or neck symptoms related to neural compression due to adjacent-segment disease after ACDF. The study included 11 individuals. Clinical evaluation was performed both before and after surgery, using VAS for pain and the NDI. Radiological outcomes were analyzed using pre- and post-operative flexion/extension lateral radiographs measuring Cobb angle, functional spinal unit (FSU) angle, and 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 one-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 one 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 individuals who had previously undergone cervical fusion surgery appeared to be safe, with encouraging early clinical results.

Revision or Replacement of a Cervical Artificial Intervertebral Disc

Lee et al. (2022) conducted a retrospective study examining the associated indications, procedures and postoperative outcomes after revision Anterior Cervical Disc Arthroplasty (ACDA) in adults (age ≥ 18). A multicentered national-level database was utilized to identify individuals who underwent either a primary anterior cervical disc arthroplasty (ACDA) or removal of ACDA from 2008-2017. Both Current Procedural Terminology (CPT) and International Statistical Classification of Diseases (ICD-9,10) coding was utilized to identify the reasons for revisional surgery and the subsequent procedures performed after the removal of ACDA. From 2008 to 2017, a total of 3,350 elective, primary ACDA surgeries were performed. A total of 69 individuals required revision surgery for the removal of the ACDA. The most common reasons for revision surgery included cervical spondylosis (59.4%, n = 41) and mechanical complications (27.5%, n = 19). After removal of ACDA, common procedures performed included anterior cervical fusion with or without decompression (69.6%), combined anterior/posterior fusion/decompression (11.6%), and replacement of ACDA (7.2%). The authors conclude that over a 10-year period, the rate of revision surgery for ACDA was low (2.1%). Limitations of the study include a need for additional high-quality studies, and a lack of comparative analysis involving different number of levels operated. Additionally, the author's reported 2.1% is likely lower than the true prevalence as primary cases performed in 2017 may have eventually required revisional surgery beyond the study's time-frame. The authors concluded it remains unclear how surgeons treat individuals when ACDA fails.

Kim et al. (2021) conducted a retrospective study of individuals who underwent revisional surgery due to the failure of cervical total disc replacement (C-TDR) and outcomes between May 2005 to March 2019. The study size consisted of 13 individuals (eight males and five females). The main complaints of the individuals were posterior neck pain (77%), radiculopathy (62%), and/or myelopathy (62%). The outcome measures of functional impairment and pre- and post-operative neck and arm pain were accessed using a visual analogue scale (VAS), a modified Japanese Orthopedic Association (JOA) scale and the Neck Disability Index (NDI). After revision surgery, the neck and arm pain VAS (preoperative vs. postoperative: 5.46 vs. 1.31; 4.86 vs. 1.08), a modified JOA scale (14.46 vs. 16.69), and the NDI (29.77 vs. 9.31) scores were much improved. The authors conclude the results of reoperations were good regardless of the approach, therefore reoperation options could be a consideration in individuals with failed C-TDR. A limitation of the study was the small number of reoperation cases. The authors state this number may not be enough to establish the cause of all complications and their required operative revisions. According to the authors, this study consisted of mainly individuals in which the affected artificial disc requiring replacement was accompanied by osteolysis or infection and therefore, fusion was chosen rather than an alternative artificial disc. Additional well-designed, high-quality studies including larger samples sizes are needed to further establish the diagnostic accuracy for failure of C-TDR and a more summarized algorithm for reoperation strategy.

A systematic literature review was performed by Joaquim et al. (2020) according to the PRISMA guidelines to elucidate the incidence, etiology, consequence and subsequent treatment of osteolysis after a cervical disc arthroplasty (CDA). Nine studies were included. The authors divided the studies into two groups: (1) large case series which included radiological evaluation for osteolysis (six studies), (2) case report studies which discussed symptomatic cases of osteolysis (three studies). The authors concluded that although osteolysis after CDA is common, the majority of cases are mild or asymptomatic presentations and do not require revision surgery. Symptomatic individuals with osteolysis frequently required revision surgery which involved removal of the implant and conversion to a fusion in most cases.

A systematic review was performed by Oshina et al. (2018) following PRISMA guidelines to evaluate the evidence for confirming fusion after anterior cervical fusion surgery (ACDF). Fusion rates and assessment methods at one and two years were evaluated to identify reliable radiographical criteria. A final total of 59 articles were included in this review. The authors identified ten types of fusion criteria and organized them as four major and six minor groups. All but two articles reported 1- or 2-year fusion rates using the bridging trabecular bone criterion between the endplates as the definition of fusion. Evaluation of plain radiographs and CT images may be needed for this assessment, and even the evaluation of CT can be subjective. The relative motion of spinous processes allows for objective evaluation, is easy to use, and is clear to every evaluator. The authors note the fluctuation of fusion rates and fusion levels as study limitations and conclude the published evidence supports a cutoff value of < 1 mm of movement between the spinous processes on lateral flexion-extension radiographs is recommended when confirming fusion.

Park et al. (2016) conducted a case series to determine causes and results of revision surgeries after cervical spine artificial disc replacement (C-ADR). Twenty-one individuals (mean age: 52.8) who underwent revision surgery after C-ADR and who had a minimum two-year of follow-up were included in the study. The mean time between the primary and revision surgeries was 21 months. 14 individuals underwent single level C-ADR, 2 two-level C-ADR, and 5 two-level

hybrid surgery as the primary surgery. Sixteen for radiculopathy, three for myelopathy, and two for adjacent segment diseases. The causes for revision surgeries were at least one of the followings: seventeen poor individual selections, seven insufficient decompressions, seven malpositions, six subsidences, three osteolysis, and one postoperative infection. 16 individuals underwent anterior removal of C-ADR, one-level discectomy and fusion (n = 11), two-level discectomy (n = 3) or one-level corpectomy (n = 2) and fusion. Three individuals of keel type C-ADR with heterotopic ossification underwent posterior laminoforaminotomy and fusion. Two individuals underwent combined procedures due to severe subsidence and osteolysis or infection. The two-year follow-up demonstrated improved (all, $p < 0.05$); neck (7.3 vs. 1.6) and arm (7.0 vs. 1.3) visual analog scales and Neck Disability Index score (46.7 vs. 16.32). Solid fusion was achieved in 91% and 86% of the individuals were satisfied. Transient dysphagia in six individuals was the only complication. The authors reported revision surgeries provided successful outcomes in failed C-ADR without major complications. A limitation of the study includes small sample size. More studies that are well-designed, are of high-quality and have larger samples are needed to further evaluate the efficacy and safety of revision surgeries after artificial disc replacement of cervical spine (C-ADR).

Lumbar Artificial Disc

There is insufficient published clinical evidence demonstrating the safety and efficacy of lumbar total artificial disc replacement at multiple adjacent or non-adjacent levels with or without lumbar spinal fusion surgery. Further research from larger, well-designed studies is needed to evaluate the safety and long-term effectiveness.

A 2025 ECRI Evidence Analysis reviewed five full text studies and one study abstract which included a total of 894 individuals with a diagnosis of degenerative disc disease (DDD) who received little benefit from ≥ six months of conservative management receiving the ProDisc-L Lumbar Total Disc Replacement System versus other artificial disc implants or fusion procedures. The ProDisc-L Lumbar Total Disc Replacement System is intended to replace one or two adjacent spinal discs in individuals with DDD. The Analysis documented evidence from one randomized controlled trial (RCT) and two nonrandomized comparative studies suggesting similar improvements for individuals with lumbar DDD in functional status and quality of life (QOL) with fusion and ProDisc-L. Limitations include a high risk of bias due to the lack of masking and reporting of long-term outcomes due to a high number of individuals who were lost to follow-up. Additionally, the non-randomized studies and case series lacked masking and were of retrospective design with small sample sizes. Larger multicenter RCTs that compare the ProDisc-L with other DDD treatments which include individual-oriented long-term follow-up are needed to verify the clinical utility of the ProDisc-L over other surgical procedures for the treatment of one or two adjacent spinal discs affected by DDD (ECRI, 2025).

A 2024 Hayes Evolving Evidence Review titled Hybrid Lumbar Disc Arthroplasty with Fusion for Treatment of Multilevel Degenerative Disc Disease, updated in 2025, evaluated clinical studies and systematic reviews. The review continues to suggest minimal support for the use of hybrid lumbar total disc replacement with fusion to treat multilevel DDD. No significant statistical difference was seen in disability score or complication rate between the hybrid and nonhybrid surgery groups at any follow-up point. No new position statements were identified and guidance appears to confer no/unclear support for the use of lumbar hybrid disc arthroplasty with fusion as surgical treatment of multilevel DDD (Hayes, 2024a).

A 2024 Hayes Evidence Analysis Research Brief titled Two-Level Lumbar Disc Replacement for Degenerative Disc Disease reviewed published peer-reviewed literature to evaluate the evidence related to two-level lumbar total disc replacement (LTDR) for DDD. Seven abstracts evaluating two-level LTDR for DDD, including 2 randomized controlled trials (RCTs), 2 comparative studies, and 3 single-arm studies were identified. No systematic reviews with or without meta-analyses were identified. Additionally, no position statements or guidelines were identified suggesting no/unclear support for the use of two-level LTDR in individuals with DDD. The report is based on a review of study abstracts only and is not intended to evaluate the safety or efficacy of the health technology (Hayes, 2024b).

A 2024 Hayes Evolving Evidence Review titled, Two-Level Lumbar Total Disk Replacement for Two-Level Degenerative Disk Disease reviewed full-text systematic reviews and clinical studies which suggested minimal support for utilization of two-level lumbar total disc replacement (LTDR) for the treatment of two-level lumbar degenerative disc disease (DDD). The review noted two-level LTDR appears to provide similar disability improvement and pain relief when compared with two-level fusion (1-study) and hybrid surgery (three studies). No studies were identified that compared two-level LTDR with other two-level surgical fusion approaches besides anterior (e.g., posterior, transforaminal, oblique, lateral, and minimally invasive). Review of position statements and guidelines confer no/unclear support for two-level LTDR for the treatment of two-level lumbar DDD. Additionally, very limited data exists for LTDR in lumbar spine levels above L4 as well as individuals who are obese or had prior lumbar spine surgery (Hayes, 2024c).

A post hoc analysis was performed on 5-year follow-up data collected prospectively in the multi-center FDA-regulated trial for the activL® artificial disc which included 376 individuals treated for single-level symptomatic disc degeneration (Blumenthal et al., 2023). Clinical outcome measures included the Oswestry Disability Index (ODI), visual analog scales

(VAS) assessing back and leg pain, SF-36, adverse events, and re-operations. Radiographic outcomes included flexion/extension ROM and translation of the operated segment. Participants were divided into two groups: Prior Lumbar Surgery (PLS, n = 92) and No Prior Lumbar Surgery (NPLS, n = 284). ODI, VAS, and SF-36 Physical Component Scale scores improved ($p < 0.05$) from baseline in both groups with improvements maintained through 5-year post-TDR with no significant differences between groups. There were no statistically significant differences in rates of serious device-related events, procedure-related events, or re-operations. While ROM was less prior to TDR surgery in the PLS group, there was no significant difference in ROM at post-operative points. The authors concluded that the study results demonstrated that lumbar TDR could produce good outcomes in individuals with prior surgery, provided that individuals otherwise meet selection criteria for the procedure.

A 2020 Hayes, updated 2022 comparative effectiveness review of lumbar total disc replacement for DDD included ten RCTs, one prospective nonrandomized comparative cohort study, three prospective observational studies, and seven retrospective observational studies. The 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); and 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 participants 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 individuals 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 LTDR. The 2022 annual review found ten abstracts, including one randomized controlled trial, one prospective cohort study, two pretest/post-test studies, three case series, one systematic review with meta-analysis, and two 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 participant-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 DDD. A total of 950 participants 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 eight 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 six 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 eight 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, 2024a, and 2024b reviews.)

A systematic review and meta-analyses were conducted by Lang et al. (2021) to find the most appropriate surgical technique treating lumbar DDD. The surgical techniques TDR, anterior lumbar interbody fusion (ALIF) and circumferential fusion (CFF) were compared. Primary outcomes were pain measured by the VAS and function measured by the 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 participants with symptomatic, single-level lumbar DDD who had failed ≥ six 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 participants returned for the seven-year follow-up visit. At seven years, the ODI scores in activL participants decreased from 57 at baseline to 16 and from 59 to 22 in ProDisc-L participants. For the activL participants, mean 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 participants 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 participant, 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 participants 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 seven years from a preoperative rate of 65%. The authors concluded that the benefits of activL and ProDisc-L are maintained after seven 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 participants undergoing a "hybrid" procedure involving one, two, or three simultaneous lumbar artificial disc replacements above an arthrodesis at the L5-S1 level. Forty-six participants underwent simultaneous lumbar TDR at one to three levels and ALIF at L5-S1. Participants were evaluated preoperatively and at six weeks, three months, six months, and annually for 24 to 72 months postoperatively. At 2-6 years post operation, all participants 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 participants having a postoperative ROM of 0.00°. No participants 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 participant reported outcome measures (PROMs) and participant satisfaction of multilevel lumbar 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 participant satisfaction, VAS back and leg, ODI, and Roland-Morris Disability Questionnaire. One hundred twenty-two participants were included. The mean follow-up was 7.8 years. The majority received two-level TDA, except two participants 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 participants over the course of their follow-up. Ninety-two percent of participants reported good or excellent satisfaction with treatment at the 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 participants. They also concluded that provided diagnosis, participant 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 the lack of a comparison group. (This study is included in the 2022 Hayes report.)

Li et al. (2020) conducted an updated systematic review and meta-analysis to compare the efficacy and safety of TDR versus lumbar fusion. A total of seven RCTs (1,706 individuals) were included. Individuals in the TDR group had significant improvements in ODI, VAS scores, complication rates and had a greater percentage of being satisfied with the surgery. In addition, clinical success in the TDR group was higher than the fusion group. TDR treated individuals 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 superiority in improved clinical success, reduced pain, individuals' 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 were conducted by Bai et al. (2019) to evaluate whether TDR exhibited better outcomes and safety than fusion for lumbar degenerative disease. Fourteen RCTs were included with a total of 1,890 participants with lumbar degenerative diseases. The control group included anterior fusion, posterior fusion, and circumferential fusion. The intervention period was between six months to five 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 TDR group had a decrease in operation time. There was no difference between the two methods of operation for bleeding volume. The meta-analysis from the five independent trials revealed TDR can reduce hospital stay. The authors concluded that disc replacement is superior to lumbar fusion in many respects, including ODI, VAS, SF-36, individual 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 TDR with the efficacy and safety of ALIF for the treatment of LDDD. Six studies (five RCTs and one observational study) involving

1,093 individuals were included. Operative time, intraoperative blood loss, hospital stay, complications and re-operation rate were without significant clinical difference between groups. Individuals in the TDR group had higher postoperative satisfaction and better improvements in ODI, VAS and postoperative lumbar mobility than did individuals 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 individuals 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.

A prospective study was conducted by Scott-Young et al. (2018) to evaluate participant and clinical outcomes post total disc TDA and ALIF, known as hybrid surgery for the treatment of multilevel symptomatic DDD. A total of 617 participants underwent hybrid surgery for chronic back pain and with or without leg pain between July 1998 and February 2012. All participants suffered from greater than 12 months of chronic low back pain which was unresponsive to nonoperative treatments. All Visual Analog Pain Scale for the back and leg were recorded along with the Oswestry Disability Index and Roland Morris Disability Questionnaire. A statistically significant difference can be seen at all follow-up intervals up to 96 months post-surgery when compared to baseline (from $p < 0.001$ to $p = 0.004$). Results of the research study indicate participants' satisfaction post hybrid surgery was higher than both fusion and TDR alone. The authors conclude that hybrid surgery is a viable alternative to multilevel TDA or fusion stating statistically, participant's pain is sustained for at least eight years. A limitation of the study is the fact not all participants experienced pre-operative leg pain and, therefore, their baseline score would be zero. The analyses considered all individuals as a homogeneous group, this difference at baseline may explain why the improvement in leg pain is generally lower than for back pain. (This study is included in the 2024b Hayes report.)

Zigler et al. (2018b) conducted a meta-analysis to evaluate the long-term efficacy and safety of TDR compared with fusion in individuals with functionally disabling chronic low back pain due to single-level lumbar DDD at five years. PubMed and Cochrane Central Register of Controlled Trials databases were searched for randomized controlled trials reporting outcomes at five years for TDR compared with fusion in individuals with single-level lumbar DDD. Outcomes included ODI success, back pain scores, reoperations, and individual satisfaction. The meta-analysis included four studies. TDR individuals had a significantly greater likelihood of ODI success and individual satisfaction and a significantly lower risk of reoperation than fusion individuals. Long-term improvement in back pain scores was similar between TDR and fusion. Results for ODI success and individual 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 TDR, lumbar fusion, and conservative care in the treatment of single-level LDDD. Outcomes measured at two-year follow-up included ODI success, back pain score, individual satisfaction, employment status, and reoperation. RCTs that included individuals with discogenic low back pain due to single-level LDDD, 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 (1,417 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 individual 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 TDR for LDDD. Thirteen studies, including eight prospective studies and five retrospective studies, were included. A total of 946 individuals were identified who reported at least three years of follow-up results. A total of 1,048 prostheses were implanted, single-segment TDRs were performed on 872 individuals, and multi-segment TDRs were performed on 88 individuals. 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. Individuals with lumbar TDR demonstrated significant improvements in VAS scores of 51.1 to 70.5% and of -15.6 to -44.4 for ODI scores at the last follow-up. Individual 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.

A prospective, multicenter, randomized, controlled, investigational device exemption study with five-year follow-up was conducted by Yue and Garcia (2017) to compare the safety and effectiveness of lumbar TDR with activL (Test group) or ProDisc-L or Charité (Control group) in the treatment of participants with symptomatic, single-level DDD. Participants who failed at least six months of nonsurgical management were randomly allocated to treatment with the Test device (n = 218)

or Control devices (n = 106). At five-year follow-up, 185 Test participants and 90 Control participants provided five-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 participants and 90% of Control participants. ODI improvement was reported in 83% and 86% of participants, respectively. Participant 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 five years was 58% in Test participant and 40% in Control participants. The authors concluded that TDR is safe and effective for the treatment of symptomatic LDDD and is maintained through five years.

A prospective case series was conducted by Laugesen et al. (2017) to determine the long-term clinical results and prosthesis survival in participants treated with lumbar TDR. Fifty-seven consecutive participants treated with TDR from 2003 to 2008 were invited to follow-up at a mean 10.6 years post-operatively and complete a 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 was collected from the participants' medical records. The authors report that there was a significant improvement in VAS and DPQ in the entire cohort. Nineteen participants (33%) had revision fusion surgery after their index TDR. Participants who had revision surgery had statistically significant worse outcome scores at last follow-up than participants who had no revision. Thirty participants (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.

A systematic review and meta-analysis were performed by Lackey et al. (2016) to assess the effect of HC which involves a TDA with stand-alone ALIF versus non-hybrid constructs including posterior transpedicular fixation or multi-level stand-alone ALIF as a surgical intervention for DDD in the lumbar spine. Primary outcomes analyzed included the ODI and the VAS for back pain. Three studies met inclusion criteria. When comparing HC 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 HC 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 HC 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 DDD 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 TDR in the treatment of participants with symptomatic DDD who are unresponsive to nonsurgical therapy. The study consisted of participants presenting with symptomatic single-level lumbar DDD who failed at least six 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). Participant satisfaction with treatment was over 90% in both groups at 2 years. Back pain severity improved 74% with activL® and 68% with controls. ODI improved 67% with activL® and 61% with controls and Physical Component Summary score (88% vs. 81%) favored the activL® group. The percentage of participants 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 one month shorter with activL® versus controls. The percentage of participants with disc height increase > 3 mm was 94% with activL® and 87% with controls. Change in range of motion in lateral flexion-extension radiographs were 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 participants 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 two years.

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 two 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).

North American Spine Society (NASS)

A February 2024 NASS cervical artificial disc replacement Coverage Policy Recommendation stated the following:

- There is increasing evidence that hybrid surgery, combining a TDA with an anterior discectomy/fusion to treat radiculopathy or myeloradiculopathy, is safe and efficacious. The evidence is not as robust as for single-level TDAs, there are prospective trials and systematic reviews that demonstrate similar or improved outcome measures in hybrid surgery and improved range of motion, without any significant difference in adverse events.
- There is not significant evidence at this time to support its use for three or more levels.

A 2024 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:

- Pain arising from 1- or 2-level disc disruption involving L3-4, L4-5, and/or L5-S1 segments.
- Presence of symptoms for at least six months or greater and that are not responsive to multi-modal nonoperative treatment over that period which should include a physical therapy/rehabilitation program, and may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain.

Lumbar disc arthroplasty is not indicated in any of the following scenarios:

- Any case that does not fulfill all of the above criteria
- Presence of symptomatic degenerative disc disease at more than two levels
- Significant facet arthropathy at the index level or signs that the source of pain is primarily facet mediated
- Presence of spinal instability with spondylolisthesis greater than Grade I
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms, extending over a period of at least one year)
- Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
- Poorly managed psychiatric disorder (any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized before surgical intervention)
- Age greater than 60 years or less than 18 years
- Presence of infection or tumor

There is a limited body of literature investigating the use of hybrid lumbar disc replacement constructs.

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 July 21, 2025)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2026	**Template Update** • Removed content/language pertaining to the state of Louisiana
03/01/2026	**Coverage Rationale** • Revised language to indicate: ***Cervical*** ○ Cervical total artificial disc replacement (TADR) is proven and medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Individual diagnosed with only one or two Contiguous Levels of cervical degenerative disc disease (C3-C7) ▪ Skeletally Mature individual with radiculopathy and/or myelopathy ▪ The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) ○ For two-level Contiguous cervical total artificial disc replacement, the device being utilized must be FDA-approved for two levels; when a cervical total artificial disc replacement was previously performed, the second Contiguous Level artificial disc must be FDA approved for two levels ○ Cervical total artificial disc replacement in an individual with a history of prior cervical spinal fusion is proven and medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Treating individuals with only one level or two Contiguous Levels of cervical degenerative disc disease (C3-C7) ▪ Skeletally Mature individual with radiculopathy and/or myelopathy ▪ The arthroplasty will be performed at all symptomatic Contiguous Levels (up to two levels between C3-C7) ▪ Radiographically Confirmed Complete Arthrodesis of a previous cervical spinal fusion at another level (adjacent or non-adjacent) ○ For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical ○ Cervical artificial disc removal or replacement with an FDA-approved (one or two-level) prosthetic intervertebral disc is proven and medically necessary in individuals with implant failure after prior disc replacement ○ Cervical total artificial disc replacement is unproven and not medically necessary when performed at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan (Hybrid Cervical Surgery) ***Lumbar*** ○ Lumbar total artificial disc replacement is proven and medically necessary when all of the following are present and InterQual® criteria are met: ▪ An FDA-approved prosthetic intervertebral disc is utilized ▪ Treating individuals with only single level of lumbar degenerative disc disease ▪ Skeletally Mature individual ▪ Symptomatic intractable discogenic low back pain attributable to that level ○ For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG ○ Lumbar total artificial disc replacement is unproven and not medically necessary due to insufficient evidence of efficacy when: ▪ Performed at one level combined with an existing lumbar spinal fusion surgery at another level (adjacent or non-adjacent) ▪ Performed with lumbar spinal fusion surgery as part of the same surgical plan (Hybrid Lumbar Surgery) ▪ Performed at more than one spinal level **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews: ○ Added:

Date	Summary of Changes
	▪ Relevant imaging and diagnostic testing, including documentation of instability ▪ For total artificial disc removal or replacement, also include: – Details of complication – Surgical plan ○ Replaced: ▪ "Physical exam, including *spasticity, including investigation for other etiologies*" with "physical exam, including *detailed neurological findings*" ▪ "Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ▪ "Physician treatment plan" with "physician treatment plan, *including surgical technique to be used and the number of levels involved and their location*" ▪ "For lumbar surgery, in addition to the [listed documentation requirements], *provide medical notes documenting the following, when applicable: provide* psychosocial-behavioral, *documentation of instability (listhesis-, spondylolisthesis and grade), and provide the surgical technique to be used and the number of levels involved and their location*" with "for lumbar surgery, in addition to the [listed documentation requirements], *also include* psychosocial-behavioral *evaluation*" **Definitions** • Added definition of: ○ Contiguous Levels ○ Hybrid Cervical Surgery ○ Hybrid Lumbar Surgery ○ Radiographically Confirmed Complete Arthrodesis • Updated definition of "Skeletally Mature" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS121.X

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. 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.

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