Total Artificial Disc Replacement for the Spine

Policy Number: CS121.W
Effective Date: March 1, 2024

➲ Instructions for Use

Table of Contents **Page**

Related Community Plan Policies

- Interspinous Fusion and Decompression Devices
- Spinal Fusion and Bone Healing Enhancement Products
- Spinal Fusion and Decompression

Commercial Policy

- Total Artificial Disc Replacement for the Spine

Application

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

State	Policy/Guideline
Indiana	None
Kentucky	Total Artificial Disc Replacement for the Spine (for Kentucky Only)
Louisiana	Total Artificial Disc Replacement for the Spine (for Louisiana 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 artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary in certain circumstances 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.

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 at more than one spinal level due to insufficient evidence of efficacy.

Definitions

Skeletally Mature: The apparent stage of development of 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 (Venes, 2021).

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 patient selection criteria has not been firmly established.

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 patients with cervical DDD reported on pain, neurological status, functional status, reintervention rates, and adverse events (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 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 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.

Wang et al. (2021) performed a retrospective study to compare the clinical and radiologic outcomes of 3-level 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 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 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 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 patients included radiculopathy and/or myelopathy which was unresponsive to conservative treatment (during at least 6 weeks). The VAS scores of 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 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 patients. 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. 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.

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 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 mCDD.

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

Through a systematic review of both published and ongoing studies on single- and multi-level CDA and hybrid surgeries, Laratta et al. (2018) aimed to provide evidence for their safety and efficacy in the treatment of various cervical pathologies. Among the relevant studies reviewed, three were randomized controlled trials, two systematic reviews, as well as multiple prospective case series, biomechanical studies, and meta-analyses. The authors concluded that multiple studies show that single-level CDA can offer equivalent clinical outcomes with a reduction in secondary procedures and total cost when compared to ACDF. The authors also observed that recently there has been an increasing prevalence of 2-level CDA and 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.

Cervical Artificial Disc Replacement (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 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. Study limitations include a small number of patients 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 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 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 ACDF. The study included 11 patients. Clinical evaluation was performed both before and after surgery, using a 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 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 DDD 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 LTDR. 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 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).

A systematic review and meta-analyses were conducted by Lang et al. (2021) to find the most appropriate surgical technique for 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 patients with symptomatic, single-level lumbar 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 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 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 serious AEs (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 TDR at one to three levels and ALIF at L5-S1. Patients were evaluated preoperatively and at 6 weeks, 3 months, 6 months, and annually for 24 to 72 months post-operatively. 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° post-operatively. The mean pre-operative 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 TDA for symptomatic multilevel degenerative disc disease (MLDDD). Data were prospectively collected pre-operatively and post-operatively at 3, 6, and 12 months, then yearly. PROMs included patient satisfaction, VAS back and leg, ODI, 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 TDAs 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).

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 7 RCTs (1,706 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 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 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 TDR group had a decrease in operation time. There was no difference between the 2 methods of operation for bleeding volume. The meta-analysis from the 5 independent trials revealed TDR can reduce hospital stay. The authors conclude that disc replacement is superior to lumbar fusion in many respects, including ODI, VAS, short form 36 (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 TDR with the efficacy and safety of ALIF for the treatment of LDDD. Six studies (five RCTs) and one observational study) involving 1,093 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 post-operative satisfaction and, better improvements in ODI, VAS and post-operative 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 TDR compared with fusion in patients with functionally disabling chronic low back pain due to single-level lumbar 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 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 TDR, lumbar fusion, and conservative care in the treatment of single-level LDDD. Outcomes measured at 2 year follow-up included ODI success, back pain score, patient satisfaction, employment status, and reoperation. RCTs that included patients 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 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 LDDD. 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 1,048 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 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.

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 TDR with activL (test group) or

ProDisc-L or Charité (control group) in the treatment of patients with symptomatic, single-level DDD. 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. 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 TDR is safe and effective for the treatment of symptomatic LDDD 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 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 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.

A systematic review and meta-analysis was performed by Lackey et al. (2016) to assess the effect of HC which involve 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 post-operatively 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 post-operatively 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 patients with symptomatic 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. ODI improved 67% with activL® and 61% with controls and Physical Component Summary score (88%v s. 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 > 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 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.

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 non-radicular 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).

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 September 1, 2023)

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.

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.

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.

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

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. Archived November 3, 2022.

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.

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.

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

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.

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, 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.

Venes, Donald, editor. Taber's Medical Dictionary. 24th ed. Philadelphia: F.A. Davis Company; 2021.

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
07/01/2024	**Application** ***New Mexico*** • Added language to indicate this policy does not apply to the state of New Mexico; refer to the state-specific policy version

03/01/2024	**Related Policies**
	• Removed reference link to the:
	  ○ Medical Policy titled *Minimally Invasive Spine Surgery Procedures*
	  ○ Medicare Advantage Coverage Summary titled *Spine Procedures*
	Coverage Rationale
	• Replaced language indicating:
	  ○ "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" with "cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary *in certain circumstances* 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"
	  ○ "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*" with "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"
	• Removed list of contraindications to lumbar artificial total disc replacement
	• Removed language indicating lumbar artificial total disc replacement is unproven and not medically necessary due to insufficient evidence of efficacy [when the individual has] prior history of lumbar fusion or when combined with a lumbar fusion at any level
	Definitions
	• Removed definition of:
	  ○ Degenerative Disc Disease (DDD)
	  ○ Grade 1 Spondylolisthesis
	  ○ Modic Changes
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS121.V

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, please 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.