

Total Artificial Disc Replacement for the Spine (for Ohio Only)

Policy Number: CS1210H.Q – P
Effective Date: February 1, 2023

[➔ Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Definitions	2
Applicable Codes	2
Description of Services	3
Clinical Evidence	3
U.S. Food and Drug Administration	11
References	11
Policy History/Revision Information	13
Instructions for Use	13

Related Policies
<ul style="list-style-type: none"> • Spinal Fusion Enhancement Products (for Ohio Only) • Surgical Treatment of Spine Pain (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio.

Coverage Rationale

Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy. 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 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.

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

Contraindications to lumbar artificial total disc replacement include but are not limited to the following:

- Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph
- Lumbosacral spinal fracture
- Scoliosis of the lumbosacral spine
- Active systemic infection or infection localized to the site of implantation

- Tumor in the peritoneum, retroperitoneum or site of implantation
- Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan
- Isolated radicular compression syndromes, especially due to disc herniation
- Spinal stenosis or radiculopathy
- Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain
- Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery

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

Click [here](#) to view the InterQual® criteria.

Lumbar artificial total disc replacement is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy:

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

Definitions

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

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

Modic Changes: Peridiscal bone signal changes note on MRI in the vertebra superior and inferior to the disc space in question.

Skeletally Mature: The apparent stage of development the bones of a growing child or adolescent. It is determined with radiological studies. The determination is used to analyze normal and disordered growth in children.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by 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
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

CPT Code	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy 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 osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22899	Unlisted procedure, spine

CPT® is a registered trademark of the American Medical Association

Description of Services

Artificial total disc replacement refers to the replacement of a degenerating intervertebral disc with an artificial disc in adults with degenerative disc disease (DDD) in either the lumbar or cervical region of the spine. An artificial disc is intended to preserve range of motion (ROM) and reduce pain. These prostheses replace the degenerated disc and have been proposed as a means of improving flexibility, maintaining spinal curvature and providing an equalized weight-bearing surface, while reducing or possibly eliminating pain (Hayes, 2021).

Clinical Evidence

Hybrid Surgery for Cervical Spine

Artificial disc replacement at one level combined with spinal fusion surgery at another level (adjacent or non-adjacent) is referred to as hybrid surgery. There are few clinical trials to support improved health outcomes and patient selection criteria has not been firmly established.

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

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

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

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

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

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

Brotzki et al. (2020) performed an observational analysis based on 88 patients treated for multilevel cervical degenerative disc disease with ACDF only (56 patients), DCI hybrid (17 patients), and TDR hybrid (15 patients) with a mean follow-up of 19.5

months. The self-reported measures used were the Spine-Tango, the PLC questionnaire (Profile of the Life Quality of Chronically Ill), the Neck Disability Index (NDI), and visual analog scale (VAS) scores for neck and arm pain. All patients were asked to complete questionnaires before surgery and at each follow-up examination. The VAS scores decreased significantly in all 3 groups ($P < 0.001$), but the TDR group showed the greatest reduction in VAS score compared with ACDF and DCI (both $P < 0.05$). The overall range of motion (ROM) and the segmental ROM at the treated levels showed significant decreases in all 3 groups. Although the study failed to show difference in the overall ROM at final follow-up among the operatively treated groups, the ROM of the treated segment was lowest in the ACDF group ($P = 0.002$). The authors concluded that the results indicate that both TDR hybrid and DCI hybrid are effective and safe procedures for the treatment of multilevel degenerative disc disease. There is no definitive evidence that DCI or TDR arthroplasty 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 cervical multilevel degenerative disc disease. Additionally, lack of randomization could have resulted in biases in the findings.

Through a systematic review of both published and ongoing studies on single- and multilevel cervical disc arthroplasty (CDA) and hybrid surgeries, Laratta et al. (2018) aimed to provide evidence for their safety and efficacy in the treatment of various cervical pathologies. Among the relevant studies reviewed, 3 were randomized controlled trials, 2 systematic reviews, as well as multiple prospective case series, biomechanical studies, and meta-analyses. The authors concluded that multiple studies show that single-level CDA can offer equivalent clinical outcomes with a reduction in secondary procedures and total cost when compared to ACDF. The authors also observed that recently there has been an increasing prevalence of 2-level CDA and hybrid surgery (HS) and the data regarding these multilevel procedures is less robust. More high quality evidence with large patient populations is necessary to accurately and critically assess the utility of multilevel CDA and HS.

A systematic review and meta-analysis was conducted by Lu et al. (2017) to compare the outcomes of hybrid surgery (HS) versus anterior cervical discectomy and fusion (ACDF) for the treatment of multi-level cervical disc disease (mCDD). Eight studies were identified, 169 patients undergoing HS were compared with 193 ACDF procedures. HS was associated with greater C2-C7 range of motion (ROM) preservation and less functional impairment after surgery compared to ACDF. There was no significant difference between HS and ACDF with respect to postoperative pain, postoperative complication rates and length of stay. The authors concluded that HS is a novel surgical approach to treat mCDD, associated with a greater operative time, less intraoperative blood loss and comparable if not superior clinical outcomes compared to ACDF. They also concluded that there is a lack of robust clinical evidence in the literature and that further research with randomized controlled trials is needed to validate these findings.

Chen et al. (2016) retrospectively analyzed data from 108 patients with three-level cervical myelopathy who underwent hybrid surgery in a case series. Implantation of Bryan® artificial discs into two contiguous segments and cage fusion of adjacent segments was performed for all patients. Based on the Japanese Orthopedic Association (JOA) score, Neck Disability Index (NDI), and Odom's criteria, the clinical symptoms and neurological function before and after surgery were evaluated. Mean follow-up duration was 36 months. At the final follow-up, the mean JOA scores were higher compared with preoperative values (15.08 ± 1.47 versus 9.18 ± 1.22) and the NDI values were decreased (12.32 ± 1.03 versus 42.68 ± 1.83). The clinical outcomes were rated as excellent (76 patients), good (22 patients), fair (six patients), and poor (four patients) based on Odom's criteria. For patients with predominant nerve root symptoms, radicular pain of the upper limbs showed remission; in those with dominant symptoms of spinal cord compression, both muscle strength and sensation improved. Mean range of motion of segments with replaced artificial discs was not significantly different from the value obtained before surgery; the overall ROM of the cervical vertebrae was similar to the pre-surgery value. The main complications include postoperative infection, prosthesis movement, dysphagia, dysphonia, and heterotopic ossification. The authors concluded that these findings suggested a satisfactory clinical effectiveness for hybrid surgery but additional multicenter, long-term follow-up studies with large populations are needed to validate these findings. The study is limited by lack of comparison group.

Shi and colleagues (2015) performed a retrospective case series of 36 patients with adjacent three-level cervical spondylosis who were treated with anterior cervical discectomy and fusion (ACDF) combined with cervical disc arthroplasty (CDA) (hybrid surgery) between October 2008 and October 2012. Clinical evaluation was based on the Neck Disability Index (NDI), Japanese Orthopaedic Association (JOA) score, and postoperative JOA score improvement rate (IR). Radiographic parameters, angular range of motion (ROM) for C2-C7, and ROM for the superior and inferior adjacent segments were measured before the operation, at 1, 3, 6, and 12 months post operation, and at the final follow-up evaluation. All cases were followed for at least 28

months. There was a significant postoperative improvement in NDI and JOA scores compared to preoperative levels. The JOA score improvement rate was 70.83 % at the final follow-up evaluation. One patient required a second surgery for symptomatic adjacent segment degeneration. The mean C2-C7 ROM, which was $46.39 \pm 2.41^\circ$ before the operation, was recovered after 12 months ($46.03 \pm 4.64^\circ$) and was maintained at the last follow-up evaluation ($47.50 \pm 4.59^\circ$). The ROM of the superior and inferior adjacent segments, which was $14.25 \pm 1.81^\circ$ and $10.89 \pm 1.65^\circ$ before the operation, respectively, was recovered after 6 months ($14.03 \pm 1.46^\circ$ and $10.75 \pm 2.37^\circ$, respectively) and increased at the last follow-up evaluation ($15.00 \pm 1.15^\circ$ and $11.47 \pm 1.84^\circ$, respectively). During the follow-up period, heterotopic ossification occurred in three patients. Adjacent segment degeneration was encountered in two cases, and one of these required a second surgical treatment. The authors concluded that the results indicate that hybrid surgery seems to be a promising, acceptable, and alternative surgical approach for the treatment of multi-level cervical disc disease. They also observed that some authors have investigated this method of treatment but the evidence in the published peer-reviewed literature is limited by lack of controls, small sample size and short term outcomes and that additional research is needed to clearly establish a role for hybrid technologies. This study is limited by lack of comparison group.

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.

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

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

Formica et al. (2020) conducted a retrospective case series of 32 patients who underwent TDR for low back pain from degenerative disc disease (DDD) resistant to conservative treatment. Demographic features, surgical data, clinical and radiographic outcomes, complications and spinopelvic parameters were evaluated. The mean follow-up was 164 ± 36.5 months. The clinical outcomes measured by visual analogue scale and Oswestry Disability Index showed a significant improvement between preoperative and 1-year follow-up (p < 0.01). No significant temporal variance had been identified

between 1-year and long-term follow-up ($p > 0.05$). The surgical revision rate was 10%. The overall rate of complications was 20%. At final follow-up, the mobility of the prosthesis was preserved in 68.75% of the cases, and 73.3% of the patients were globally well aligned. The authors concluded that the long-term results confirmed the existing evidence about efficacy and safety of TDR as a reliable option, in optimal surgery indication, to treat DDD. The study is however limited by lack of comparison group.

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

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

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

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

Zigler et al. (2018b) conducted a meta-analysis to evaluate the long-term efficacy and safety of total disc replacement (TDR) compared with fusion in patients with functionally disabling chronic low back pain due to single-level lumbar degenerative disc disease (DDD) at 5 years. PubMed and Cochrane Central Register of Controlled Trials databases were searched for randomized controlled trials reporting outcomes at 5 years for TDR compared with fusion in patients with single-level lumbar

DDD. Outcomes included Oswestry Disability Index (ODI) success, back pain scores, reoperations, and patient satisfaction. The meta-analysis included 4 studies. TDR patients had a significantly greater likelihood of ODI success and patient satisfaction and a significantly lower risk of reoperation than fusion patients. Long-term improvement in back pain scores were similar between TDR and fusion. Results for ODI success and patient satisfaction were sensitive to different outcome definitions but remained in favor of TDR. The authors concluded that TDR is an effective alternative to fusion for lumbar DDD.

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

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

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

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

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

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

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

A prospective case series was conducted by Laugesen et al. (2017) to determine the long-term clinical results and prosthesis survival in patients treated with lumbar total disc replacement (TDR). Fifty-seven consecutive patients treated with TDR from 2003 to 2008 were invited to follow-up at a mean 10.6 years post-operatively and complete a Visual Analog Scale (VAS) for back and leg pain, the Dallas Pain Questionnaire (DPQ), and the Short Form-36. These surveys were also administered to the subjects before their index TDRs. Data on reoperation were collected from the patients' medical records. The authors report that there was a significant improvement in VAS and DPQ in the entire cohort. Nineteen patients (33%) had a revision fusion surgery after their index TDR. Patients who had revision surgery had statistically significant worse outcome scores at last follow-up than patients who had no revision. Thirty patients (52.6%) would choose the same treatment again if they were faced with the same problem. The authors concluded that this study demonstrated significant improvement in long-term clinical outcomes

and two-thirds of the disc prostheses were still functioning at follow-up. They also acknowledge that there is still a lack of well-designed long-term studies, thus requiring further investigation.

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

Garcia et al. (2015) conducted a prospective, multicenter, randomized, controlled, investigational device exemption (IDE) trial to evaluate the comparative safety and effectiveness of lumbar total disc replacement (TDR) in the treatment of patients with symptomatic degenerative disc disease (DDD) who are unresponsive to nonsurgical therapy. The study consisted of patients presenting with symptomatic single-level lumbar DDD who failed at least 6 months of nonsurgical management. They were randomly assigned to treatment with an investigational TDR device (activL[®], n = 218) or FDA-approved control TDR devices (ProDisc-L[®] or Charité[®], n = 106). Patient satisfaction with treatment was over 90% in both groups at 2 years. Back pain severity improved 74% with activL[®] and 68% with controls. Oswestry Disability Index (ODI) improved 67% with activL[®] and 61% with controls and Physical Component Summary score (88%vs. 81%) favored the activL[®] group. The percentage of patients working full-time with no restrictions increased from 33% at pretreatment to 57% at 2 years with activL[®] and from 33% to 49% with control. Return to work was approximately 1 month shorter with activL[®] versus controls. The percentage of patients with disc height increase >3mm was 94% with activL[®] and 87% with controls. Change in range of motion in lateral flexion– extension radiographs was statistically greater with activL[®] compared with controls in segmental rotation and translation but not in lateral rotation on side-bending radiographs. The rate of device-related serious adverse events was lower in patients treated with activL[®] versus controls (12% vs. 19%). Surgical reintervention rates were comparable (activL 2.3%, control 1.9%). The authors concluded that the single-level activL[®] TDR is safe and effective for the treatment of symptomatic lumbar DDD through 2 years and that the long-term durability of the activL[®] TDR is unknown and requires further investigation.

Park et al. (2015) conducted a retrospective analysis to evaluate successful outcomes following lumbar total disc replacement (TDR) using ProDisc[®] II on 54 patients (81 segments) between March 2002 and February 2007. Data was reviewed at 1, 2, 5 and 7 year follow-up. Clinical outcomes were evaluated using Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and subjective satisfaction (4-point scale). Radiographic results included segmental range of motion (ROM). Total VAS scores decreased significantly at postoperative 1 year and 2 year, compared with preoperative VAS score. Although total VAS scores increased until the last follow-up, they remained significantly lower than the preoperative value. All postoperative ODI scores at any follow-up time were significantly lower than the baseline value. There was significant increase in ODI scores between 2-year and last follow-up. The final range of motion (ROM) was shown to be lower than the preoperative ROM and lumbar lordosis was increased and well-maintained during all postoperative follow-up times. Five patients (9.3%) required revision fusion surgeries.

Clinical Practice Guidelines

American Pain Society

Guidelines from the American Pain Society (Chou 2007) found insufficient evidence regarding long-term benefits and harms of disc replacement to support recommendations. Vertebral fusion is the most common surgery for chronic, nonspecific low back pain. Surgical instrumentation (use of pedicle screws or other hardware) increases fusion rates, but it is not known if instrumentation improves clinical outcomes. More research with longer follow-up is needed to determine the appropriate role of artificial disc replacement versus fusion. The authors suggest that vertebral fusion be performed for patients who undergo surgical intervention for chronic low back pain.

International Society for the Advancement of Spine Surgery (ISASS)

A 2021 ISASS Policy Statement concludes that both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, are safe and effective treatment alternatives to fusion for patients meeting well established selection

criteria. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use (Schroeder et al., 2021).

National Institute for Health and Care Excellence (NICE)

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

In a 2009 Interventional Procedures Guidance, NICE concluded that the current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure. They recommend specialist with expertise in the treatment of degenerative spine disease should be involved in patient selection and the procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated (NICE, 2009).

North American Spine Society (NASS)

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

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

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 August 18, 2021)

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.
- Brotzki C, Petridis AK, Steiger HJ, et al. Comparison of different hybrid techniques for the treatment of multilevel cervical degenerative disc disease-analysis of prospectively collected clinical, radiologic, and psychological parameters. *World Neurosurg*. 2020 Aug;140:e112-e120.
- Chen J, Lin X, Jia Y, et al. Cervical anterior hybrid technique with bi-level Bryan® artificial disc replacement and adjacent segment fusion for cervical myelopathy over three consecutive segments. *Journal of Clinical Neuroscience* 2016. May;27:59-62.
- Cui XD, Li HT, Zhang W, et al. Mid- to long-term results of total disc replacement for lumbar degenerative disc disease: a systematic review. *J Orthop Surg Res*. 2018 Dec 26;13(1):326.
- Delamarter R, Zigler JE, Balderston RA, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L® total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. *J Bone Joint Surg Am*. 2011 Apr 20;93(8):705-15.
- Ding F, Jia Z, Zhao Z, et al. Total disc replacement versus fusion for lumbar degenerative disc disease: a systematic review of overlapping meta-analyses. *Eur Spine J*. 2017 Mar;26(3):806-815.
- ECRI. Simplify Cervical Artificial Disc (Simplify Medical, Inc.) for treating cervical degenerative disc disease. Plymouth Meeting (PA): ECRI; 2021 Mar 30. (Clinical Evidence Assessment).

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

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

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

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

Hayes, Inc. Hayes Medical Technology Directory Report. Comparative Effectiveness Review of multilevel artificial disc replacement for cervical degenerative disc disease. Lansdale, PA: Hayes, Inc.; October 3, 2017. Updated. February 12, 2021

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

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.

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.

Li Y, Sun P, Chen D, et al. Artificial total disc replacement versus fusion for lumbar degenerative disc disease: an update systematic review and meta-analysis. *Turk Neurosurg*. 2020;30(1):1-10.

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

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

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

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

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

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

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

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

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

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

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

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

Yue J and Garcia R. Five-year results of a randomized controlled trial for lumbar artificial discs in single-level degenerative disc disease. *Spine Journal*, 2017-10-01, Volume 17, Issue 10, Pages S70-S70.

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

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

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

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

Policy History/Revision Information

Date	Summary of Changes
02/01/2023	<ul style="list-style-type: none"> Created state-specific policy version
12/01/2021	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to clarify cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), <i>as part of the same surgical plan</i>, is unproven and not medically necessary due to insufficient evidence of efficacy <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information Archived previous policy version CS121.P

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.