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Artificial Intervertebral Disc

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Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Cervical Artificial Intervertebral Disc
Single Level
Insertion of a single level cervical artificial intervertebral disc, using a disc approved by the U.S. Food and Drug Administration (FDA)*, **may be considered medically necessary** when **ALL** of the following criteria are met:

1. The individual is skeletally mature; AND
2. The disc will be used for single-level reconstruction following cervical discectomy within the C3-C7 region; AND
3. The individual has intractable cervical radiculopathy and/or myelopathy due to herniated disc or osteophyte formation; AND
   a) The individual has failed at least six weeks of conservative nonoperative treatment, including an active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources and physical therapy; **or**
   b) The individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment; AND

4. Symptomatic nerve root and/or spinal cord compression are documented by **ALL** the following:
   a) Neck and/or arm pain; AND
   b) Functional and/or neurological deficit; AND
   c) Radiographic imaging (e.g., Computed Tomography [CT], Magnetic Resonance Imaging [MRI], x-rays, etc.); AND
5. The individual is free from contraindications to cervical disc arthroplasty.

Two Level

Simultaneous cervical disc arthroplasty at a second contiguous level **may be considered medically necessary** if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (e.g., Mobi-C®, Prestige LP™).

Subsequent cervical artificial intervertebral disc arthroplasty at an adjacent level using a disc specifically approved for two levels by the U.S. FDA*, **may be considered medically necessary** for the treatment of symptomatic degenerative disc disease when **ALL** of the following criteria are met:

1. The individual is skeletally mature; AND
2. The disc will be used for single-level reconstruction following cervical discectomy within the C3-C7 region; AND
3. The individual has intractable cervical radiculopathy and/or myelopathy due to herniated disc or osteophyte formation:
   a) Which has failed at least six weeks of conservative nonoperative treatment, including an active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources and physical therapy; OR
   b) The individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment; AND
4. Symptomatic nerve root and/or spinal cord compression are documented by **ALL** the following:
   a) Neck and/or arm pain; and
   b) Functional and/or neurological deficit; and
   c) Radiographic imaging (e.g., CT, MRI, x-rays, etc.); AND
5. The individual is free from contraindications to cervical disc arthroplasty; AND
6. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; AND
7. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

***NOTE:** Please refer to the Regulatory Status section for specific product information.

Artificial intervertebral cervical disc implantation **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to:

- More than two level use whether done simultaneously or at different times;

- Combined use of an artificial cervical disc and fusion;
- Prior surgery at the treated level;
- Previous fusion at another cervical level;
- Translational instability;
- Anatomic deformity (e.g., ankylosing spondylitis);
- Rheumatoid arthritis or other autoimmune disease;
- Presence of facet arthritis;
- Active infection;
- Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia); or
- Malignancy.

Lumbar Artificial Intervertebral Disc
Lumbar artificial intervertebral disc, using a disc that is U.S. FDA cleared and used in accordance with the FDA label, **may be considered medically necessary** for individuals who meet **ALL** of the following criteria:

1) Skeletally mature; AND
2) Degenerative disc disease in the lumbar spine, from L3-S1, confirmed by radiographic studies (CT, MRI, x-rays, etc.); AND
3) Disc will be used for single-level reconstruction following lumbar discectomy within the L3-S1 region; AND
4) Have no more than Grade 1 (0-25%) spondylolisthesis at the involved level; AND
5) Minimum Oswestry Disability Index (ODI) score equal to or greater than 40; AND
6) Radicular back/leg pain that has failed a minimum of 6 months of conservative treatment.

Artificial intervertebral lumbar disc **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to, use at more than two levels whether done simultaneously or at different times.

Policy Guidelines

None.

Description

Cervical Artificial Intervertebral Disc
Several prosthetic devices are currently available for cervical disc arthroplasty. Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for individuals with symptomatic cervical degenerative disc disease (DDD).

Cervical Degenerative Disc Disease
Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesia associated with cervical radiculopathy. Disc herniation,

osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and in severe cases, leads to weakness in the arms or legs, and numbness of the arms or hands. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, 95% of men and 70% of women have at least 1 degenerative change evident at the radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Treatment

Anterior cervical discectomy and fusion (ACDF) has historically been considered the definitive surgical treatment for symptomatic DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurologic symptoms may be expected in 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate. Although there may be slight differences between autograft and allograft sources in the post-operative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%-100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level DDD and the need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In cervical disc arthroplasty, an artificial disc device is secured in the prepared intervertebral space rather than an interbody cage and/or bone. An anterior plate is not used to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. The cervical disc arthroplasty was designed to maintain anatomic disc space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level DDD above or below a fusion site has been the major reason driving device development and use. Disc arthroplasty and ACDF have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in cervical disc arthroplasty candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis or spondylolisthesis.

Regulatory Status

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy.

The device is implanted using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least 1 of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (e.g., magnetic resonance imaging [MRI], computed tomography [CT], x-rays): herniated disc and/or osteophyte formation. The FDA required Medtronic (the Prestige disc manufacturer) to conduct a 7-year post-approval clinical study of the safety and function of the device and a five-year enhanced surveillance study of the disc to more fully characterize adverse events (AEs) in a broader patient population.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine), was approved by the FDA through the PMA process in 2007. As with the Prestige® ST Cervical Disc, the FDA approval of ProDisc-C® was made conditional on the 7-year follow-up of the 209 subjects included in the non-inferiority trial (discussed in Rationale section), 7-year follow-up of 99 continued-access subjects, and a 5-year enhanced surveillance study to characterize more fully adverse events when the device is used under general conditions of use. The ProDisc-C Vivo is currently marketed by Centinel Spine.

More recently, continued FDA approval requires the completion of two post-approval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10-year enhanced surveillance of AE data. Continued approval is contingent on the submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, other serious device-related complications, and analysis of all explanted discs.

Devices with FDA approval for use in the United States are described in Table 1. These devices are for 1 site or 2 contiguous sites; there are no devices approved for non-contiguous sites. FDA Product Code: MJO

Table 1. Cervical Disc Prostheses Approved For Use in the United States

Prosthesis	Manufacturer	Characteristics	FDA Approval	Year
Prestige® ST	Medtronic	Stainless steel	P060018	2007
ProDisc-C®	Centinel Spine	2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P070001	2007
Bryan® Cervical Disc	Medtronic Sofamor Danek	2 titanium-alloy shells encasing a polyurethane nucleus	P060023	2009
PCM Cervical Disc®	NuVasive	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P100012	2012

SECURE®-C	Globus Medical	Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert	P100003	2012
Mobi-C®	Zimmer Biomet (previously LDR Spine)	Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert; approved for both 1 and 2-levels	P110002/P110009	2013
Prestige LP	Medtronic Sofamor Danek	Titanium-ceramic composite with a metal-on-metal bearing; approved for both 1- and 2-levels	P090029	2014/2016
M6®-C	Orthofix (previously Spinal Kinetics)	Ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates	P170036	2019
Simplify® Cervical Artificial Disc	NuVasive (previously Simplify Medical)	PEEK endplates and a mobile ceramic core; MRI compatible	P200022/S003	2020/2021

FDA: U.S. Food and Drug Administration; MRI: magnetic resonance imaging; PCM: porous-coated motion; PEEK: polyetheretherketone.

Lumbar Artificial Intervertebral Disc

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to spinal fusion in patients with DDD leading to disabling symptoms.

Background

DDD, the most frequent cause of back pain requiring surgery, is common with age or trauma. Spine imaging, such as MRI, CT, or plain radiography, shows that lumbar disc degeneration is widespread, but for most people it does not cause symptoms. Potential candidates for artificial disc replacement have chronic low back pain attributed to DDD, lack of improvement with nonoperative treatment, and no contraindications for the procedure, which include multilevel disease, spinal stenosis, spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. Patients who require procedures in addition to fusion (e.g., laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment of DDD fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, the outcomes with spinal

fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. Also, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain normal biomechanics of the adjacent vertebrae and motion at the operative level once the damaged disc has been removed.

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They include device failure (e.g., device fracture, dislocation, or wear), bone-implant interface failure (e.g., subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (e.g., osteolysis, heterotopic ossification, pseudotumor formation).

Regulatory Status

Three artificial lumbar disc devices (activL, Charité, ProDisc-L) have been approved by the FDA through the PMA process (Table 2). Production under the name Charité was stopped in 2010 and the device was withdrawn in 2012.

Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of post-marketing studies. The activL (Aesculap Implant Systems) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. The activL device is approved for use at 1 level. Initial approval for ProDisc-L was also limited to patients with disease at 1 level. In April 2020, the ProDisc-L indication was expanded to include patients with disease at up to 2 consecutive levels. (52)

Table 2. U.S. Food and Drug Administration-Approved Lumbar Artificial Disc Devices

Device	Manufacturer	Indication	PMA Number	Approval Date
activL	Aesculap Implant Systems, LLC	The activL Artificial Disc (activL) is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic DDD with no more than Grade I spondylolisthesis at the involved level. The activL Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL Artificial Disc should have failed at least 6 months	P120024	06/11/2015

		of nonoperative treatment prior to implantation of the device.		
ProDisc-L	Synthes Spine	The ProDisc-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 or 2 contiguous intervertebral level(s) from L3-S1. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients receiving the ProDisc®-L Total Disc Replacement should have failed at least 6 months of conservative treatment prior to implantation of the ProDisc®-L Total Disc Replacement.	P050010/ S020	08/25/2006; 4/10/2020 (supplement)
Charite	DePuy Spine, Inc	The Charite Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level from L4-SI. These DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. Patients receiving the Charite Artificial Disc should have failed at least 6 months of conservative treatment prior to implantation of the Charite Artificial Disc.	P040006	10/26/2004 Withdrawn 1/5/2012

PMA: premarket approval; DDD: degenerative disc disease.

A number of other artificial lumbar discs are in development or available only outside the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité device with a change in name under the same premarket approval. Production under the name Charité was stopped in 2010. The INMOTION® is not currently marketed in the United States.
- The Maverick artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L was scheduled in 2013 but was cancelled without explanation.

FDA product code: MJO.

This may not be an “all inclusive” list of artificial disc devices and is subject to change. Refer to the FDA web site at <https://www.accessdata.fda.gov> for additional information on devices.

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical uses of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Cervical Artificial Intervertebral Disc

Clinical Context and Therapy Purpose

The purpose of artificial intervertebral disc arthroplasty of the cervical spine in individuals who have cervical radicular pain or myelopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with symptomatic cervical degenerative disc disease (DDD).

Interventions

The therapy being considered is artificial intervertebral disc arthroplasty of the cervical spine.

Comparators

Comparators of interest include anterior cervical discectomy and fusion. Cervical DDD is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve within six weeks, or if symptoms progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical DDD and no contraindications for the procedure.

Outcomes

The general outcomes of interest are symptoms, morbid events, functional outcomes, QOL, and treatment-related morbidity.

The Neck Disability Index (NDI) is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life. (1) It is a modification of the Oswestry Disability Index, based on responses to ten questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Response options to each question range from one to five, with a lower numeric score representing a better pain and disability status for that variable. A total NDI score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, NDI scores range from 0% to 100%, with a lower percentage indicating less pain and disability. Neurologic status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge whether patients are within normative parameters for those categories based on physiologic measurement. The anterior functional spinal unit height is a radiographic measure of interdiscal space. Comparison of the immediate postoperative functional spinal unit height with the six-week postoperative value shows whether the disc space has decreased, which indicates that graft or device subsidence has occurred. Other outcome measures may include the 36-Item Short-Form Health Survey Mental and Physical Component Summary scores, neck and arm pain status, patient satisfaction, patient global perceived effect, gait assessment, foraminal compression test, adjacent-level stability and measurements, return to work, and physician's perception.

<u>Systematic Reviews</u>

Hu et al. (2016) published a systematic review and meta-analysis of 8 RCTs (N=2368) reporting mid-term outcomes (at least 48 months) comparing artificial intervertebral disc arthroplasty (AIDA) with anterior cervical discectomy and fusion (ACDF). (2) This meta-analysis had the highest AMSTAR rating out of 14 meta-analyses published between 2011 and 2017. (3) All eight trials included in Hu et al. were rated as low-risk of bias, despite lack of blinding. Only two trials reported on overall success, (4, 5) and three reported on NDI success. (4-6) Six trials reported neurologic success data; pooled data favored the cervical disc arthroplasty group to a small degree (relative risk [RR], 1.04; 95% confidence interval [CI], 1.01 to 1.08; p=0.01). Pooled data also showed a significant benefit of cervical disc arthroplasty for secondary procedures at the index level (6 studies) (4, 5, 7-10); (RR, 0.40; 95% CI, 0.28 to 0.58; p<0.001) and at the adjacent level (5 studies) (4, 7, 9-11); (RR, 0.42; 95% CI, 0.26 to 0.70; p<0.002). These trials and outcome measures are detailed below.

Latka et al. (2019) conducted a meta-analysis of RCTs on cervical disc arthroplasty to evaluate the safety and long-term efficacy for reducing adjacent segment degeneration. (12) The authors included 20 publications from 13 RCTs (N=3,656) that reported 24- to 60-month results of 1- or 2-level cervical disc arthroplasty versus anterior cervical discectomy and fusion. Visual analog scale (VAS) for neck pain was lower in patients who had cervical disc arthroplasty (mean difference [MD], -2.30; 95% CI, -3.72 to -0.87; p=0.002) along with the frequency of dysphagia/ dysphonia (odds ratio [OR], 0.69; 95% CI, 0.49 to 0.98; p=0.04). Adjacent segment degeneration was lower with cervical disc arthroplasty compared to anterior cervical discectomy and fusion (OR, 0.33; 95% CI, 0.21 to 0.50; p=0.0001). Another meta-analysis by Toci et al. (2022) that included 19 RCTs (N=4655) likewise found a lower risk of adjacent segment degeneration with cervical disc arthroplasty compared to anterior cervical discectomy with fusion (14.4% vs. 19.7%; p<.001), as well as adjacent segment disease (3.8% vs. 6.1%; p<.001) and reoperation rates (3.1% vs. 6.1%; p<.001). (13)

Similar findings were reported by Deng et al. (2020) in a meta-analysis of 9 studies with 48 to 120 months of follow-up. (14) Symptomatic adjacent-level disease requiring surgery was significantly lower following cervical disc arthroplasty compared to anterior cervical discectomy and fusion. Likewise, a meta-analysis by Peng et al. that included 30 RCTs (N range, 79 to 545) and compared cervical disc arthroplasty to anterior cervical discectomy with fusion in patients with cervical degenerative disc disease with either or myelopathy found improved overall success, neurological success, and Neck Disability Index success with cervical disc arthroplasty. (15) Follow-up ranged from 1 to 10 years and most studies included single-level cervical disc arthroplasty.

Single-Level Cervical Disc Arthroplasty

The pivotal trials of 9 artificial cervical discs are described in Table 3 (Kineflex is no longer marketed). All of the trials utilized a non-inferiority design that compared cervical disc arthroplasty to the standard of ACDF with a FDA-mandated composite clinical outcome. The studied populations included patients with cervical radiculopathy or myelopathy, and the composite outcome included improvements in disability and neurologic symptoms with an absence of serious adverse events or secondary surgery at the index level. At the 24-month follow-up, all of the trials met non-inferiority and 4 of the 8 trials achieved superiority compared to ACDF (Table 4). Five of the trials (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM) have reported follow-up at 3 to 10 years. At 3 to 7 years, trial results are consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and/or lower cumulative reoperation rates. The pivotal study of the Bryan cervical disc has the longest follow-up at 10 years, with 100 patients per group planned for the post-approval study. Overall success was 81.3% for cervical disc arthroplasty compared to 66.3% for ACDF (p=.005). There was a statistically significant difference in the improvement of the Neck Disability Index between the groups (cervical disc arthroplasty: -38.3; ACDF: -31.1; p=.01), but there was no significant difference in arm pain or neurologic success between the cervical disc arthroplasty and ACDF groups. There was not a statistical difference in secondary surgeries, with 9.7% of

cervical disc arthroplasty patients and 15.8% of ACDF patients requiring secondary surgery at either the index or adjacent level (p=.146).

Table 3a. Summary of Pivotal Study Characteristics of Cervical Artificial Intervertebral Discs

Study	Device	Design	Primary Outcome Measure
Mummaneni et al. (2007) (16)	Prestige ST	Multicenter non-inferiority RCT	3 primary outcome variables were used in the Prestige pivotal trial: a 15-point improvement in NDI score, neurologic status, and functional spinal unit height.
Gornet et al. (2015) (17)	Prestige LP	Multicenter non-inferiority RCT	Primary outcomes were neurologic success, individual success, and overall success.
Murray et al. (2009) (18)	ProDisc-C	Multicenter non-inferiority RCT	Improvement in VAS pain and intensity (neck and arm), VAS satisfaction, NDI score, neurological exam, device success, adverse event occurrence, and SF-36 questionnaire.
Heller et al. (2009) (19)	Bryan Cervical Disc	Multicenter non-inferiority RCT	Success on all of the following: ≥15-point improvement in NDI score, neurologic improvement, no serious adverse events related to the implant or subsequent surgical procedure, and no subsequent surgery or intervention.
Hisey et al. (2014) (20) FDA SSED (21)	Mobi-C Single level	Multicenter non-inferiority RCT	Composite overall success score (not defined by authors).
Phillips et al. (2013) (22)	Porous Coated Motion (PCM)	Multicenter non-inferiority RCT	Composite measure of overall success measured at 24-weeks post-operatively, defined as at least 20% improvement in NDI; absence of reoperation, revision, or removal; maintenance or improvement in neurological status; and absence of major complications during follow-up period.
Vacarro et al. (2013) (23) FDA SSED (24)	Secure C	Multicenter non-inferiority RCT	Composite measure of overall success measured at 24 months post-operatively, defined as improvement of at least 25% in NDI; no device failure requiring revision, removal or reoperation; and absence of major complications.

Phillips et al. (2021) (26); FDA SSED: M6-C (25)	M6-C	Multicenter non-randomized pragmatic trial	Improvement of NDI ≥ 15 pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures.
FDA SSED: Simplify Cervical Disk (27)	Simplify Cervical Disc	Multicenter non-inferiority RCT	Improvement of NDI ≥ 15 pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures.

FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; NDI: neck disability index; RCT: randomized controlled trial; SF-36: short form-36; VAS: visual analog scale.

Table 3b. Summary of Pivotal Study Characteristics of Cervical Artificial Intervertebral Discs

Study	**Participants**	**Interventions**	
		CDA	*ACDF*
Mummaneni et al. (2007) (16)	Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy	Prestige ST (n=276)	n=265
Gornet et al. (2015) (17)	Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy	Prestige LP (n=280)	n=265 historical controls from the Prestige ST trial
Murray et al. (2009) (18)	Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy unresponsive to nonoperative treatment for at least 6 weeks	ProDisc-C (n=103)	n=106
Heller et al. (2009) (19)	Patients with radiculopathy or myelopathy from single-level cervical disc disease secondary to disc herniation that had not responded to at least 6 weeks of nonoperative management	Bryan disc (n=242)	n=223
Hisey et al. (2014) (20); FDA SSED (21)	Patients with discogenic neck and/or arm pain with degeneration of the disc with radiculopathy or myeloradiculopathy from C3 to C7 at 1 level without prior cervical fusion	Mobi-C (n=169)	n=87
Phillips et al. (2013) (22)	Patients with single-level symptomatic cervical	PCM (n=224)	n=192

	spondylosis with radiculopathy and/or myelopathy unresponsive to nonoperative treatment		
Vacarro et al. (2013) (23); FDA SSED (24)	Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7	Secure C (n=151)	n=140
Phillips et al. (2021); FDA SSED: M6-C (25, 26)	Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7	M6-C (n=160)	n=189 propensity-matched controls selected from concurrent ACDF patients and a previous IDE study
FDA SSED: Simplify Cervical Disk (27)	Patients with intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain or myelopathy at 1 level from C3 to C7	Simplify (n=150)	n=133 historical controls from a previous IDE study from 2005-2007

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; IDE: investigational device exemption.

Table 4a. Summary of Pivotal RCT Results

Outcomes	**24 Months**			**36 to 48 Months**		
	CDA	*ACDF*	*p*	*CDA*	*ACDF*	*p*
Prestige ST	**Mummaneni et al. (2007) (16)**					
n	223	198				
Overall Success	79.30%	67.80%	.004 for superiority			
NDI	mean improvement 36 points	mean improvement 33.6 points	Met non-inferiority			
Neurologic Success	92.80%	84.30%	0.005			
Secondary Surgeries	1.10%	3.40%	0.0492			
Prestige LP	**Gornet et al. (2015) (17)**					
n	272	223				

Overall Success	mean difference, -0.111 (95% CrI, -0.196 to -0.026)		Superiority			
NDI						
Neurologic Success	93.50%	83.50%	Superiority			
Secondary Surgeries	28.60%	34%				
ProDisc C	**Murray et al. (2009) (18)**			**Delamarter et al. (2010) (29)**		
n	101	101		75	67	
Overall Success	72.3%	68.3%	Met non-inferiority			
NDI	21.4±20.2 points	20.5±18.4 points	1.0	20.3±18.6	21.2±14.9	
Neurologic Success	90.9%	88%	0.638	88.9%	74.4%	0.0665
Secondary Surgeries	1.8%	8.5%	0.003	2.9%	11.3%	0.0292
Bryan Cervical Disc	**Heller et al. (2009) (19)**			**Sasso et al. (2011) (5)**		
n	230 (95%)	194 (87%)		181 (75%)	138 (62%)	
Overall Success	82.6%	72.7%	.010 for superiority	85.1%	72.5%	0.004
NDI Success	86%	78.9%	.035 for superiority			
Arm Pain Score	19.1	21.5	0.194	16.6	22.4	0.028
Neurologic Success	93.9%	90.2%	Met non-inferiority			NS
Secondary Surgeries				7.8%	8.6%	NS
Mobi-C (1 level)	**Hisey et al. (2014) (20) FDA SSED (21)**			**Hisey et al. (2015) (9)**		
n	164	81				
Overall Success	73.7%	65.3%	Met non-inferiority	69.5%	58.7%	Met non-inferiority

NDI			Met non-inferiority			
Secondary Surgeries	1.2%	6.2%		3%	9.9%	<.05
PCM	**Phillips et al. (2013) (22)**					
n	189	151	Per protocol			
Overall Success	75.1%	64.9%	Superiority			
NDI Success	83.4%	81.5%	0.667			
Neurologic Success	94.7%	89.5%	0.100			
Secondary Surgeries	5.2%	5.4%				
Secure C	**Vacarro et al. (2013) (23) FDA SSED (24)**					
n	87%					
Overall Success	83.8%	73.2%	Met non-inferiority			
NDI Success	89.2%	84.5%	Met non-inferiority			
Neurologic Success	96.0%	94.9%	Met non-inferiority			
Secondary Surgeries	2.5%	9.7%				
M6-C	**Phillips et al. (2021) (26) FDA SSED: M6-C (25)**					
n	160	189				
Overall Success	86.8%	79.3%	Met non-inferiority			
NDI Success	90.5%	85.1%				
Neurologic Success	93.3%	87.2%				
Secondary Surgeries	1.9%	4.8%				
Pain Medication	14%	38.2%	<.001			
Simplify Cervical Disc	**FDA SSED: Simplify Cervical Disc (2020) (27)**					

n	150	133				
Overall Success	93%	73.6%	<.001			
NDI Success	97.9%	88%	0.009			
Neurologic Success	99.3%	94.7%				
Secondary Surgeries	2.9%	2.9%	0.979			
Pain Medication	10.8%	36.8%				

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; NDI; neck disability index; NS: not significant; RCT: randomized controlled trial.

Table 4b. Summary of Pivotal RCT Results

Outcomes	**60 Months**			**84 Months**		
	CDA	*ACDF*	*p*	*CDA*	*ACDF*	*p*
Prestige ST				**Burkus et al. (2014) (28)**		
n				212	183	
Overall Success				72.6%	60.0%	0.008
NDI				-37.5	-31.9	
Neurologic Success				88.2%	79.7%	0.011
Secondary Surgeries				4.8%	13.7%	
ProDisc C	**Zigler et al. (2013) (30) Delamarter et al. (2013) (31)**			**Janssen et al. (2015) (10)**		
n	72	61		152/209 (72.7%)		
Overall Success						
NDI	50% to 60%		NS			
Neurologic Success	90.3%	91.7%	NS	88%	89%	NS
Secondary Surgeries	2.9%	14.5%	0.0079	7%	18%	0.009
Mobi-C (1 level)	**Hisey et al. (2016) (33)**			**Radcliff et al. (2017) (34)**		
n	85.5%	78.9%				

Overall Success	61.9%	52.2%	Met non-inferiority	55.2%	50.0%	Met non-inferiority
NDI						Met non-inferiority
Secondary Surgeries	4.9%	17.3%	<.01	3%	12.3%	<.05
PCM	**Phillips et al. (2015) (6)**					
n	163 (74.8%)	130 (70.3%)				
Overall Success						
NDI Success	85%	74.2%	0.026			
Neurologic Success	92.4%	87.5%	0.229			
Secondary Surgeries	8.1%	12.0%	NS			

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; NS: not significant; NDI: neck disability index; RCT: randomized controlled trial.

Table 4c. Summary of Pivotal RCT Results

Outcomes	**120 Months**		
	CDA	*ACDF*	*p*
Bryan Cervical Disc	**Lavelle et al. (2018) (32)**		
n	128	104	
Overall Success	81.3%	66.3%	0.005
NDI Success	-38.3	-31.1	0.01
Arm Pain Score	-58.9	-51.6	0.6
Neurologic Success	92.1%	95.1%	0.82
Secondary Surgeries	9.7%	15.8%	0.146

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; NDI: neck disability index; RCT: randomized controlled trial.

Most available products have efficacy and safety results published up to 10 years post-operative. The group originally studying the Bryan Cervical Disc recently published 20-year follow-up data. (35, 36) Forty-seven patients with single-level cervical radiculopathy were randomized to either Bryan cervical disc or anterior cervical discectomy and fusion for an FDA Investigational Device Exemption trial. At 20-years follow-up, both groups showed significantly better Neck Disability Index scores and Visual Analog Scale arm and neck pain scores compared

to preoperative scores. There was no significant difference between cervical disc arthroplasty and discectomy and fusion groups in Neck Disability Index scores or Visual Analog Scale pain scores. Reoperations since the first procedure were reported in 41.7% of patients who initially underwent discectomy and fusion and 10% of cervical disc arthroplasty patients (p=.039). These data continue to demonstrate the long-term benefits with cervical disc arthroplasty.

Subsection Summary: Single-Level Cervical Disc Arthroplasty

At 2-year follow-up, the pivotal trials of 9 artificial cervical discs met non-inferiority criteria, with 5 achieving statistical superiority compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on five devices. At 3 to 7 years, the trial results have been consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and/or lower cumulative reoperation rates. Twenty-year follow-up for the Bryan Cervical Disc continues to support the safety and efficacy of cervical disc arthroplasty. Longer-term results for other discs are expected, given the FDA requirement for 7-year post-approval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to characterize more fully adverse events in a broader patient population. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs but does not appear to lead to a decline in clinical outcomes.

Two-Level Cervical Disc Arthroplasty

Table 5 summarizes key characteristics of RCTs that evaluated cervical disc arthroplasty at 2 continuous levels.

In 2021, the Simplify Cervical Disc received FDA approval for implantation at 2 levels (previously approved for implantation at only 1 level). Overall success was achieved in 86.7% of Simplify Cervical Disc patients and 77.1% of anterior cervical discectomy and fusion controls at 24 months follow-up (Table 6). (37)

In 2016, the Prestige LP received the FDA approval for implantation at 2 levels. (38) Overall success was achieved in 81.4% of Prestige LP patients and 69.4% of ACDF controls, meeting both non-inferiority and superiority margin, with a posterior probability of near 100% and 99.3%, respectively (Table 6). Table 6 provides data on patients who reached follow-ups at intervals up to 120 months. The difference in success rates between the Prestige LP and ACDF patients achieved at 24 months was maintained through 10 years.

Two and 4-year results from the 2-level Mobi-C investigational device exemption trial were reported by Davis et al. (2013, 2015) with 5- and 7-year results published by Radcliff et al. (2016, 2017). (8, 34, 39, 40). Clinically relevant heterotopic ossification (grade III or IV) was observed in 29.7% of the Mobi-C patients at 5 years, but the Mobi-C patients had significantly less adjacent-segment degeneration (50.7%) than ACDF patients (90.5%; p<0.001).

Table 5a. Summary of Pivotal RCT Characteristics of Cervical Disc Arthroplasty at 2 Continuous Levels

Study	Device	Design	Blinding
Coric et al. (2022) (37)	Simplify Cervical Disc	Multicenter non-randomized	None
FDA SSED (2016) (41)	Prestige LP	Multicenter non-inferiority Trial	Unknown
Davis et al. (2013) (39)	Mobi-C	Multicenter RCT	Patient and independent review blinding; radiologist not able to be blinded

FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; RCT: randomized controlled trial.

Table 5b. Summary of Pivotal RCT Characteristics of Cervical Disc Arthroplasty at 2 Continuous Levels

Study	Primary Outcome Measure	Participants	Interventions	
			CDA	ACDF
Coric et al. (2022) (37)	Improvement of NDI ≥15 pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures	Patients with 2-level, symptomatic cervical disc disease with medically refractory radiculopathy and/or myelopathy	Simplify Cervical Disc (n=182)	n=170 historical controls from a previous IDE study from the mid-2000s
FDA SSED (2016) (41)	Overall Success[a]	Patients with 2-level, symptomatic cervical disc disease with medically refractory radiculopathy and/or myelopathy	Prestige LP at 2 contiguous levels (n=209)	n=188
Davis et al. (2013) (39)	Overall Success[a]	Patients with 2-level, symptomatic cervical disc disease with medically	Mobi-C at 2 contiguous levels (n=225)	n=105

		refractory radiculopathy and/or myelopathy		

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; IDE: investigational device exemption; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; NDI: neck disability index; RCT: randomized controlled trial.

[a] Overall success was achieved if the postoperative score improvement in the NDI was ≥ 15 points, neurological status did not worsen, and no serious implant/surgical procedure–associated adverse event, or second surgery, which was deemed "failure," occurred.

Table 6a. Follow-Up and Success Rates for 2-Level Cervical Discs Compared With 2-Level Anterior Cervical Discectomy and Fusion

Outcomes	**24 Months**			**48 Months**		
	CDA	**ACDF**	**p**	**CDA**	**ACDF**	**p**
Simplify Cervical Disc	**Coric et al. (2022) (37)**					
n (%)	182 (100%)	170 (100%)				
Overall success %	86.7%	77.1%	<.05			
NDI Success n/N (%)	156/168 (92.3%)	106/127 (85.5%)	<.10			
Neurologic Success	168/168 (100%)	125/128 (97.7%)	NA			
No additional surgery	177/181 (97.8%)	152/166 (91.6%)	<.10			
No SAEs due to implant or procedure	176/182 (96.3%)	158/170 (94.7%)	>.50			
Prestige LP	**FDA SSED (41)**					
n (%)	199 (95)	160 (86)		185 (89)	149 (80)	
Overall Success n/N (%)	162/199 (81.4%)	111/160 (69.4%)	Superiority	151/185 (81.6%)	105/149 (70.5%)	
NDI Success	87.9%	79.2%	Superiority	89.7%	82.3%	Superiority
Neurologic Success	91.5%	86.2%	NS	90.3%	83.8%	Superiority

Secondary Surgeries	2.4%	3.2%				
Mobi-C	**Davis et al. (2013) (39)**			**Davis et al. (2015) (8)**		
n	225	105		89.0%	81.2%	
Overall Success	69.7%	37.4%	<.0001	66.0%	36.0%	
NDI Success	78.2%	61.8%	<.05	79.3%	53.4%	<0.001
Secondary Surgeries	3.1%	11.4%		4.0%	15.2%	

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA: SSED: US Food and Drug Administration Summary of Safety and Effectiveness; NA: not applicable; NDI: neck disability index; NS: not significantly different; SAEs: serious adverse event.

Table 6b. Follow-Up and Success Rates for 2-Level Cervical Discs Compared With 2-Level Anterior Cervical Discectomy and Fusion

Outcomes	**60 Months**			**84 Months**		
	CDA	**ACDF**	**p**	**CDA**	**ACDF**	**p**
Prestige LP						
n (%)	166 (80)	138 (74)		126 (67)	99 (58)	
Overall Success n/N (%)	132/166 (79.6%)	91/138 (65.5%)		99/126 (78.6%)	62/99 (62.6%)	
NDI Success	89.2%	77.8%	Superiority	87.0%	75.6%	Superiority
Neurologic Success	90.4%	87.5%	NS	91.6%	82.1%	Superiority
Secondary Surgeries						
Mobi-C	**Radcliff et al. (2016) (40)**			**Radcliff et al. (2017) (34)**		
n	90.7%	86.7%		84.4%	75%	
Overall Success	61%	31%	<0.001	60.8%	34.6%	Superiority
NDI Success			Significant	79.0%	58.9%	<0.05
Secondary Surgeries	7.1%	21.0%	<0.001	4.4%	16.2%	<0.05

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; NDI: neck disability index; NS: not significantly different.

Table 6c. Follow-Up and Success Rates for 2-Level Cervical Discs Compared With 2-Level Anterior Cervical Discectomy and Fusion

Outcomes	**120 Months**

	CDA	ACDF	P
Prestige LP	**Gornet et al. (2019)[a] (42)**		
n (%)	148 (86%[a])	118 (85%)	
Overall Success n/N (%)	80.4%	62.2%	Superiority
NDI Success	88.4%	76.5%	Superiority
Neurologic Success	92.6%	86.1%	Superiority
Secondary Surgeries	13.7%	35.5%	Significant

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; NDI: neck disability index.
[a] Not all sites were involved in the 10 yr follow-up. Patients who died (n=5) or had withdrawn from the study (n=25) were also excluded from the analysis.

Post hoc analysis of data from the pivotal 1- and 2-level Mobi-C trials was reported by Bae et al. (2015). (43) The comparison showed no significant differences between 1- and 2-level cervical disc arthroplasty on clinical outcomes (NDI, VAS, and 12-Item Short-Form Health Survey scores), major complication rates (4.3% for 1-level cervical disc arthroplasty vs. 4.0% for 2-level cervical disc arthroplasty), or subsequent surgery rates (3.0% of 1-level vs. 4.0% of 2-level). Clinically relevant heterotopic ossification was observed in 23.8% of 1-level patients and 25.7% of 2-level patients. Huppert et al. (2011) compared outcomes between single-level (n=175) and multilevel (2-4 levels, n=56) cervical disc arthroplasty with the Mobi-C device in a prospective multicenter study from Europe. (44) At two years, there were no significant differences between groups for overall success, radicular and cervical VAS scores, NDI scores, and range of motion. There was a trend for more patients in the single-level group than in the 2-level group to return to work (70% vs 46%) and for the return to work to occur sooner (4.8 months vs 7.5 months), respectively.

Subsection Summary: Two-Level Cervical Disc Arthroplasty

The FDA approval of Simplify Cervical Disc for implantation at 2 levels (previously approved for implantation at only 1 level) was based on superiority to 2-level anterior cervical discectomy and fusion in overall success at 2-year follow-up.

The FDA approval for the Prestige LP disc at 2 levels was based on superiority to 2-level ACDF at 2-year follow-up. At present, over 80% of patients have reached 3-year follow-up, and 85% of expected patients have reached 10-year follow-up. The difference in overall success rates at 2 years has been maintained at 10 years. Secondary outcome measures showed the superiority of cervical disc arthroplasty over ACDF.

The first artificial cervical disc approved for 2 levels (Mobi-C) was found to be noninferior to ACDF in the investigational device exemption trial. Superiority to ACDF was achieved for NDI scores, NDI success rates, and the overall success composite outcome. Reoperation rates were

significantly lower in the Mobi-C group. At 5 and 7 years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Although a third of patients who received the Mobi-C had clinically significant heterotopic ossification, adjacent-segment degeneration with Mobi-C was found in a lower percentage of patients than in ACDF patients.

Registry Data

Staub et al. (2016) evaluated the clinical effectiveness of cervical disc arthroplasty for 987 patients in the Spine Tango registry. (45) The primary outcome measures were the neck and arm pain relief and the Core Outcome Measures Index (COMI). One analysis evaluated outcomes from a matched pair of patients (190 pairs) who met the selection criteria of published RCTs. With an average follow-up of 17 months, there were small but statistically significant differences in outcomes between cervical disc arthroplasty and ACDF. The mean group differences on a 10-point scale for both pain measures were 0.6 points in postoperative neck pain (p=0.04) and 0.7 points in arm pain (p=0.02); mean COMI score difference was 0.8 points (p=0.01). Change scores did not differ significantly. The probability of being a responder (2-point change) was significantly better in the cervical disc arthroplasty group than in the ACDF group for arm pain relief (78.4% vs 67.4%; p=0.02) and COMI score (81.6% vs 67.9%; p<0.01) but not neck pain relief (62.1% vs 57.9%; p-value not significant), respectively.

For patients who would have been excluded from the RCTs, most commonly due to an age greater than 60 years or spondylosis, there were no significant differences in clinical outcomes between cervical disc arthroplasty and ACDF. A third analysis compared outcomes of cervical disc arthroplasty with ACDF in patients who had a follow-up of more than 2 years (mean, 55.0 months; range, 27.0-76.5 months). After controlling for patient age, patients treated with cervical disc arthroplasty had significantly higher responder rates for arm pain relief (80.0%) compared with patients treated with ACDF (64.9%; p=0.05), with no significant difference in responder rates between groups for neck pain relief or COMI. Rates of adjacent-level degeneration and secondary surgeries were not assessed.

MacDowall et al. compared 5-year outcomes of cervical disc arthroplasty and ACDF from the Swedish Spine Registry. (46) Using propensity matching, the investigators identified 185 patients in each group who had cervical DDD and radiculopathy. The primary outcome was the NDI, with a minimum clinically important difference of >15%. Scores on the NDI were halved in both groups, but there was no significant difference (3.0%; 95% CI, -8.4 to 2.4; p=0.28) between the groups. There were also no differences between the groups in EuroQol-5 Dimensions or in pain scores for the neck and arm.

Limitations of registry studies include the possibility of selection bias, which can be reduced by propensity matching.

Adverse Events

Heterotopic ossification appears to be common with cervical disc arthroplasty, but there is no evidence of a large impact on clinical outcomes. A meta-analysis by Chen et al. (2012)

evaluating rates of heterotopic ossification (McAfee grade 3-4) after cervical disc arthroplasty included 8 studies (N=617 patients). (47) The pooled prevalence of any heterotopic ossification was 58.2% at 24 months after cervical disc arthroplasty and the pooled prevalence of advanced heterotopic ossification was 16.7% after 24 months.

Nunley et al. (2018) evaluated the effect of heterotopic ossification on clinical outcomes. (48) Heterotopic ossification was radiographically graded for 164 1-level and 225 2-level cervical disc arthroplasty patients from the Mobi-C pivotal trials and correlated with clinical outcomes. At 7 years, clinically relevant (grade 3 or 4) heterotopic ossification that affects range of motion was present in 28.7% of 1-level patients and 37.4% of 2-level patients. Patients were divided into non-clinically relevant heterotopic ossification and clinically relevant (motion restricting) heterotopic ossification. Arm pain and 12-Item Short Form Health Survey scores were not significantly different between the groups. There was an interaction between heterotopic ossification and time for the NDI ($p=0.04$), with a statistically significant difference between groups of 4.0 beginning at 48 months. There was also a statistical interaction between heterotopic ossification and VAS neck pain, with a difference of 5 to 8 mm out of 100. The clinical significance of these differences is uncertain.

Summary of Evidence - Cervical Artificial Intervertebral Disc

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life (QOL), and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met non-inferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [Porous Coated Motion]). At 4 to 5 years, the trial results have been consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige, ProDisc-C, and Mobi-C pivotal trials continue to show lower secondary surgery rates, although this is not a consistent finding in other reports. Twenty-year follow-up for the Bryan Cervical Disc continues to support the safety and efficacy of cervical disc arthroplasty. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of anterior cervical discectomy and fusion. There have been no safety signals with discs approved by the U.S. Food and Drug Administration (FDA) for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs and a non-randomized trial. Relevant outcomes are symptoms, morbid events, functional outcomes, QOL, and treatment-related morbidity. FDA approval of Simplify Cervical Disc and Prestige LP for implantation at 2 levels was based on superiority to 2-level ACDF in overall success at two years. For Prestige LP, the increase in overall success rates at two years has been

maintained for those patients who have reached the 10-year follow-up. At 2- and 4-year follow-ups, the first artificial cervical disc approved for two levels (Mobi-C) was found to be superior to ACDF for NDI scores, NDI success rates, reoperation rates, and overall success composite outcome. At five years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared with 2-level ACDF patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty with any of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements - Cervical Disc Arthroplasty

International Society for the Advancement of Spine Surgery

In 2021, the International Society for the Advancement of Spine Surgery issued a position statement on cervical and lumbar disc replacement. (49) Based on a review of the available evidence-based scientific literature, the Society "strongly supports both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, as safe and effective treatment alternatives to fusion in appropriately selected patients. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use."

North American Spine Society

In 2024, the North American Spine Society guidelines were updated and indicated that (50): “Cervical artificial disc replacement (also known as cervical total disc replacement or cervical total disc arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Radiculopathy related to nerve root compression from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3 to C7 in the following scenarios:
   a. Persistent symptoms despite at least 6 weeks of nonoperative management.
   b. Progressive or functionally limiting weakness correlating with the compressed nerve root.
   c. Inability to perform normal work duties or necessary activities of daily living because of severity of symptoms, despite nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-C7.
3. Use can be considered for radiculopathy or myeloradiculopathy due to multilevel degenerative disease (either herniated disc or spondylotic osteophyte) as part of a hybrid construct, i.e., in concert with an anterior cervical discectomy and fusion (ACDF) for cervical levels that do not satisfy the stringent criteria for TDA. There remain strict indications as to whether an arthroplasty is indicated at a given level... Indication for ACDF is addressed in a separate coverage recommendation.

There is not significant evidence at this time to support its use for 3 or more levels, nor is there evidence for its use for isolated axial neck pain. Neck pain, in addition to radiculopathy/

myeloradiculopathy, is not an exclusionary criterion. There is early evidence for use in treatment of adjacent segment disease following an index fusion."

National Institute for Health and Care Excellence (NICE)
In 2010, the NICE issued guidance on the artificial cervical disc, concluding that (51):
"Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures….

This procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly.

NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include long-term data on preservation of mobility, occurrence of adjacent segment disease, and avoidance of revision surgery."

Ongoing and Unpublished Clinical Trials - Cervical Disc Arthroplasty
Some currently ongoing and unpublished trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT05691231[a]	Long-Term Assessment of the Safety and Performance of the NuVasive Simplify Disc at Two Levels	158	May 2029
NCT05740176[a]	A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing the Safety and Effectiveness of the Synergy Disc to Anterior Cervical Discectomy and Fusion in Patients With Two-Level Symptomatic Cervical Degenerative Disc Disease (DDD)	200	Dec 2026
NCT05489822[a]	Sponsor-initiated, Prospective, Single-center, Non-interventional Clinical Observational Study to Evaluate the VERTICALE® Cervical System in Spine Surgery According to Its Intended Use.	20	Apr 2026
NCT04520776[a]	A Multicenter, Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of the BAGUERA®C Cervical Disc Prosthesis to the Mobi-C® Cervical Disc for the Treatment of Patients With	284	Feb 2026

	Symptomatic Cervical Disc Disease at a Single Level		
NCT04564885[a]	A Multicenter, Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of the BAGUERA®C Cervical Disc Prosthesis to the Mobi-C® Cervical Disc for the Treatment of Patients With Symptomatic Cervical Disc Disease at Two Contiguous Levels	300	Apr 2030
NCT03367052	Clinical and Radiological Outcomes of a 7-year Follow-up, Multi-center, Prospective, Randomized, Controlled Trial: Two-level Cervical ProDisc-C Vivo Versus Hybrid Construct.	542	Dec 2025
NCT04469231[a]	A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing The Safety And Effectiveness Of The Synergy Disc To Anterior Cervical Discectomy And Fusion In Patients With One-Level Symptomatic Cervical Degenerative Disc Disease (DDD)	175	Jan 2026
NCT03123549[a]	Clinical Study Protocol for the Investigation Of The Two Level Simplify® Cervical Artificial Disc	182	Mar 2022
NCT02667067[a]	Clinical Study Protocol for the Investigation Of The Simplify® Cervical Artificial Disc	150	Jul 2021

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Lumbar Artificial Intervertebral Disc

This review focuses only on artificial discs currently available in the United States.

Clinical Context and Therapy Purpose

The purpose of the lumbar artificial intervertebral disc in individuals with degenerative disc disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with lumbar degenerative disc disease.

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs.

Intervention
The therapy being considered is implantation of a lumbar artificial intervertebral disc.

Two artificial intervertebral discs are currently marketed in the U.S.: ProDisc-L and activL.

Comparators
The following therapies are currently being used to make decisions about lumbar artificial intervertebral disc.

Relevant comparators are conservative therapy and lumbar spinal fusion.

Conservative treatment may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. For example, professional societies recommend that surgery for lumbar spinal stenosis should be considered only after a patient fails to respond to conservative treatment, but there is no consensus about what constitutes an adequate treatment course or duration.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Outcome measures for back surgery are relatively well-established (Table 8). These include back and leg visual analog scores to assess pain and the Oswestry Disability Index to assess functional limitations related to back pain. Broader functional status indices such as the 12-Item Short Form Health Survey or 36-Item Short Form Health Survey, particularly the physical function subscale of 36-Item Short Form Health Survey, are also used.

Table 8. Patient-reported Outcome Measures for Back Pain

Measure	Outcome Evaluated	Description	MDD and MCID
Oswestry Disability Score (ODI)	Functional disability and pain related to back conditions	Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0-100% of maximum score	MDD: 8-10 points MCID varies; often 15 points (30 percentage points)
Visual analog scale for back pain	Degree of back pain	Patients indicate the degree of pain on a 0-100 scale	MDD: 2 points
Visual analog scale for leg pain	Degree of leg pain	Patients indicate the degree of pain on a 0-100 scale	MDD: 5 points

MDD: minimal detectable difference; MCID: minimal clinically important difference.

Both short-term and long-term outcomes are important in evaluating back treatments. Net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, 36-Item Short Form Health Survey (SF-36), or VAS measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures. Lumbar artificial disc devices are theorized to reduce the occurrence of adjacent-level degeneration, which has been observed after fusion more often than occurs naturally in nonfused segments; some RCTs have reported the occurrence of adjacent level degeneration at 5 years.

Patient preferences are important in decision-making about elective back surgery. In particular, to avoid the morbidity and risk of complications of the surgery, some patients may choose to prolong conservative treatments even if it means they have additional pain and functional limitation. Conversely, some patients will accept long-term outcomes of surgery similar to those of conservative therapy to get faster relief of symptoms and improvement in function. Patient preferences have not been compared in a systematic fashion.

Group means are commonly designated as primary outcome measures in spine studies. Variation in the calculation and definition of minimal clinically important difference makes it difficult to compare response rates across studies. Nevertheless, clinical trials should prespecify a minimal clinically important difference for ODI and other measures when used, and report response rates in addition to group means.

The primary outcome in FDA regulated trials was a composite measure of success, which incorporates symptom improvement and absence of complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

Three RCTs have compared the treatment of degenerative disc disease using lumbar fusion with artificial lumbar intervertebral discs currently available in the United States. They include the pivotal trials for the ProDisc-L and activL discs, and a U.S. Food and Drug Administration (FDA) regulated trial of the ProDisc-L for 2-level degenerative disc disease. A fourth trial compared ProDisc-L with multidisciplinary rehabilitation. The composite success endpoint included improvements in Oswestry Disability Index scores (typically 15 points), improvement or maintenance in neurologic status, radiologic measures of range of motion, freedom from additional surgery, and freedom from serious device-related adverse events. Five-year

outcomes have been reported from the pivotal trials for both ProDisc-L and activL. Eight-year data have been reported from a comparison of ProDisc II with multidisciplinary rehabilitation.

A key feature all of these trials is the recruitment of patients specifically with degenerative disease of the intervertebral disc. Degenerative disc disease is partly a diagnosis of exclusion where the degenerated disc is believed to be the pain generator. Radiographic evidence of degenerative disc disease may include a reduction of disc height and Modic changes, a posterior high-intensity zone, or a dark/black nucleus pulposus on T2-weighted images. Patients with common indications for spinal fusion such as scoliosis, spondylolisthesis, instability, or radiculopathy were excluded.

Characteristics of these trials are summarized in Table 9, results in Table 10, and study relevance, design, and conduct limitations are summarized in Tables 11 and 12.

ProDisc-L at a Single Level Compared to Fusion

The pivotal study for the ProDisc-L was an unblinded noninferiority trial that originally followed patients for 24 months. (53, 54) In the per-protocol analysis reported to FDA, ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%, which achieved both non-inferiority and superiority. Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012. (55-57) The definition of success was changed from the analysis requested by FDA and was reported to be higher at 63.5% at 2 years and 53.7% at 5 years. Noninferiority, but not superiority, of artificial disc replacement was achieved at 5 years. This change in overall success in ProDisc-L patients indicates a possible decrement in response over time with the artificial disc. This decline in response rate was not observed in the standard fusion group and resulted in a between-group convergence of the primary outcome measure over time. Several individual components of the primary outcome measure and secondary outcome measures (Oswestry Disability Index, 36-Item Short-Form Health Survey Physical Component Summary, neurologic success, device success) were also statistically better in the ProDisc-L group than in the fusion group at 2 years, but not at 5 years. Post hoc analysis of radiographs found fewer patients with adjacent-level degeneration in the ProDisc-L group than in the control group. However, the adjacent-level reoperations did not differ significantly between groups (1.9% ProDisc-L vs 4% controls).

Additional study of ProDisc in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption trial in patients with single-level chronic symptomatic degenerative disc disease unresponsive to conservative management. Questions remain about the durability of the disc, in particular, the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue. The main claim of the artificial disc-that it maintains range of motion and thereby reduces the risk of adjacent-level segment degeneration better than fusion-remains subject to debate.

ProDisc-L at 2 Levels Compared to Fusion

The ProDisc-L for 2-level lumbar degenerative disc disease was reported in 2011 from a multicenter, randomized, FDA regulated noninferiority trial. (58) All patients had degenerative disc disease at 2 contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of 6 months of conservative therapy, and a minimum Oswestry Disability Index score of 40. The ProDisc-L group had faster surgeries (160.2 minutes vs 272.8 minutes), less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital lengths of stay (3.8 days vs 5.0 days) than the arthrodesis group. The composite measure of success demonstrated noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in the percentages of patients who achieved at least a 15-point improvement in Oswestry Disability Index scores and greater improvements in the SF-36 scores. A greater percentage of patients in the arthrodesis group required secondary surgical procedures. As noted in an accompanying commentary, the study had a number of limitations. (59) Comparison with a procedure (open 360° fusion) that is not the criterion standard precludes decisions on the comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of patients and providers.

ProDisc-L Compared to Conservative Treatment

Hellum et al. (2011) reported an RCT that compared the use of the ProDisc-L with a multidisciplinary rehabilitation program. (60) Patients (N=173) were ages 25 to 55 years, had low back pain for a least a year, received physical therapy or chiropractic treatment for at least 6 months without sufficient effect, had an Oswestry Disability Index score of at least 30, and showed degenerative intervertebral changes that included at least 40% reduction of disc height, Modic changes, a high-intensity zone in the disc, and morphologic changes identified as changes in the signal intensity in the disc of grade 3 or 4. The multidisciplinary rehabilitation included a cognitive approach and supervised physical exercise. The primary outcome was Oswestry Disability Index score, and the trial was powered to detect a 10-point difference in Oswestry Disability Index score. The analysis was intention-to-treat with the last observation carried forward. There were 13 (15%) dropouts in the surgical arm and 21 (24%) in the rehabilitation arm. Also, 5 (6%) patients crossed over from rehabilitation to surgery. Of the 34 patients lost to follow-up, 26 answered a questionnaire between 2.5 and 5 years after treatment. In the intention-to-treat analysis, there was a statistically significant benefit of surgery, but the mean difference did not achieve the 10-point difference in Oswestry Disability Index score considered clinically significant. There were significantly more patients who achieved a 15-point improvement in Oswestry Disability Index score in the ProDisc group, with a number needed to treat of 4.4. The radiographic assessment identified a similar level of adjacent segment degeneration in both groups, but an increase in facet arthropathy in the ProDisc II group. (61)

Eight-year follow-up of this trial was reported by Furunes et al. (2017). (62) In both the intention-to-treat and per-protocol analysis there was a statistically significant benefit of surgery as measured by the mean Oswestry Disability Index, but these differences did not reach the clinically significant threshold of 10 points (see Table 10). More patients in the surgery group (43/61 [70%]) reached a clinically important difference of 15 Oswestry Disability Index points than in the rehabilitation group (26/52 [50%]; p=0.03). Twenty-one (24%) patients

randomized to rehabilitation crossed over to surgery while 12 (14%) patients randomized to surgery had undergone additional back surgery.

activL Artificial Disc
There are no RCTs of activL® compared to fusion or conservative treatment.

Two-year outcomes from the multicenter investigational device exemption trial of the activL artificial intervertebral disc were reported by Garcia et al. (2015). (63) In this patient-blinded noninferiority trial, patients with degenerative disc disease were randomized to treatment with activL or an FDA approved disc (ProDisc-L or Charité). At 2 years, activL was both noninferior and superior to the control group of patients treated with ProDisc-L or Charité. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls. Range of motion at the index level, measured by an independent core radiographic laboratory, was higher in the activL group than in the controls.

Five-year results from this trial were reported in Yue et al. (2019). (64) Of 341 patients enrolled, 261 contributed data at 5 years (76.5%). The primary composite endpoint results were reported graphically only and demonstrated noninferiority at 5 years for activL versus control artificial discs. Sensitivity analyses using various imputation methods for missing data also showed noninferiority of activL, with the exception of the worst-case scenario (missing data counted as failure for activL and success for control). Freedom from serious adverse events through 5 years was 64% with activL and 47% with control artificial discs (p=.0068). Seven-year results for 206 individuals who received activL or ProDisc-L were reported in Radcliff et al. (2021) and showed no increase in serious adverse events between years 5 and 7. (65)

Because this study compared activL to other fusion devices, it provides only indirect evidence of effectiveness compared to fusion or conservative care. The study was not powered to detect differences by different control devices, and the control group included patients who received a device that is no longer available in the United States (Charite). Additional limitations were a high loss to follow-up at 5 and 7 years, unblinded outcome assessment, and no blinding of patients at the 5-year and 7-year assessments.

Table 9a. Summary of Key RCT Characteristics for Lumbar Artificial Discs Available in the United States

Study	Publications	Countries	Sites	Follow-Up
ProDisc-L IDE Study		United States	17	
	Zigler et al. (2007) (55)			2 years
	Zigler et al. (2012) (56)			5 years
	Zigler et al. (2012) (57)			5 years

ProDisc-L IDE Study NCT00295009	Delamarter et al. (2011) (58)	United States	16	2 years
activL IDE Study NCT00589797	Garcia et al. (2015) (63)	United States	17	2 years
	Yue et al. (2019) (64)			5 years
ProDisc II vs Conservative Treatment NCT00394732	Hellum et al. (2011) (60)	Norway	5	2 years
	Hellum et al. (2012) (61)			2 years
	Furunes et al. (2017) (62)			8 years

IDE: Investigational Device Exemption; RCT: randomized controlled trial.

Table 9b. Summary of Key RCT Characteristics for Lumbar Artificial Discs Available in the United States

Study	**Publications**	**Study Design and Participants**	**Interventions Number Analyzed**	
			Active	***Control***
ProDisc-L IDE Study		Noninferiority trial of patients with single-level DDD	ProDisc-L n=161	Circumferential fusion n=75
	Zigler et al. (2007) (55)	2-year results	n=156	n=73
	Zigler et al. (2012) (56)	5-year results	n=137	n=56
	Zigler et al. (2012) (57)	5-year adjacent level degeneration results	n=123	n=43
ProDisc-L IDE Study NCT00295009	Delamarter et al. (2011) (58)	Noninferiority trial of patients with DDD at 2 contiguous levels	ProDisc-L at 2 levels n=158	Circumferential fusion n=79
activL IDE Study NCT00589797	Garcia et al. (2015) (63)	Patient-blinded noninferiority trial of patients with DDD	activL n=218	ProDisc-L or Charité n=106
	Yue et al. (2019) (64)	5-y follow-up (open label)	n=176	n=85

ProDisc II vs Conservative Treatment NCT00394732	Hellum et al. (2011) (60)	Patients with chronic low back pain, ODI score ≥30, and DDD in 1 or 2 levels	ProDisc II n=87	Multidisciplinary rehabilitation n=86
	Hellum et al. (2012) (61)	Adjacent-level degeneration and facet arthropathy results	ProDisc II n=59	Multidisciplinary rehabilitation n=57
	Furunes et al. (2017) (62)	8-year follow-up	ProDisc II n=77	Multidisciplinary rehabilitation n=74

IDE: Investigational Device Exemption; DDD: degenerative disc disease; ODI: Oswestry Disability Index; RCT: randomized controlled trial.

Table 10a. Summary of Key RCT Outcomes for Artificial Intervertebral Discs Available in the United States

Study	Success Rate at 2 Years	Success Rate at 5 Years	ODI Score at 2 years Mean (SD) % change (SD)	ODI Score at 5 years Mean (SD) % change (SD)	VAS Score at 2 years Mean (SD) % change (SD)
Zigler et al. (2007, 2012) (55-57)					
Number analyzed	219	193	220	177	220
ProDisc-L	63.5%	53.7%	34.5 (24.5) - 47.4 (34.7)	34.2 (24.3) - 47.5 (34.7)	36.6 (30.1) - 49.9 (41.9)
Fusion	45.1%	50.0%	39.8 (24.3) - 37.8 (36.0)	34.5 (24.5) - 47.4 (34.7)	43.3 (31.6) - 42.4 (42.9)
p inferiority	<0.01	0.024			
p superiority	0.044	0.7438	0.055	0.455	0.134
Delamarter et al. (2011) (58)					
Number analyzed	203				
ProDisc-L	58.8%	NR	52.4% improvement	NR	-43.3
Fusion	47.8%	NR	40.9% improvement	NR	-36.7
p non-inferiority	0.0008				
p superiority	0.09		0.03		0.118
Garcia et al. (2015) (63); Yue et al. (2019) (64)					

Number analyzed			324	324	
activ-L	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 75.2% Mean improvement: 67%	% with ≥15 point improvement 82.7%	Improvement from baseline 74%
ProDisc-L or Charité	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 66.0%; Mean improvement: 61%	% with ≥15 point improvement 89.6%	Improvement from baseline 68%
p noninferiority	<0.001	NR; activL noninferior to control group			
p superiority	0.02	NR	0.09	0.10	NR
Hellum et al. (2011, 2012) and Furunes (2017) (60-62)					
Number analyzed	173	151 (8 years)		151 (8 years)	
ProDisc II	51 (70%)	19.8 (16.7)	20.0 (16.4 to 23.6)		35.4
Rehab	31 (47%)	26.7 (14.5)	14.4 (10.7 to 18.1)		49.7
p	0.006			0.02	0.009
	NNT 4.4 (95% CI 2.6 to 14.5)	MD=-6.9 (-11.7 to 2.1)		MD=6.1 (1.2 to 11.0)	

MD: mean difference; NNT: number needed to treat; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog score.

Table 10b. Summary of Key RCT Outcomes for Artificial Intervertebral Discs Available in the United States

Study	VAS Score at 5 years % change (SD)	SF-36 at 2 years % change (SD)	SF-36 at 5 years % change (SD)	Adjacent-Level Degeneration at 5 Years	Reoperation at 5 years

Zigler et al. (2007, 2012) (55-57)					
Number analyzed	176	217	177	161	193
ProDisc-L	37.1 (29.3) - 48.7 (44.6)	42.8 (11.1) 39.4 (43.5)	42.0 (11.3) 40.1 (43.9)	9.2% (1.9% required surgery)	6/137 (4.4%)
Fusion	40.0 (32.1) - 47.5 (43.8)	38.8 (11.3) 29.8 (40.9)	40.1 (13.6) 29.9 (43.7)	28.6% (4.0% required surgery)	5/56 (9.0%)
p inferiority					
p superiority	0.567	0.036	0.168	0.004	NR
Delamarter et al. (2011) (58)					
Number analyzed					
ProDisc-L	NR	54.2% (54.6)	NR	NR	NR
Fusion	NR	36.2% (44.9)	NR	NR	NR
p noninferiority					
p superiority		0.014		0.047	
Garcia et al. (2015) (63) Yue et al. (2019) (64)					
Number analyzed					
activ-L	Decrease from baseline (mm) -64	≥15% improvement: 88%	≥15% improvement: 87%	1%	5%
ProDisc-L or Charité	Decrease from baseline (mm) -62	≥15% improvement: 81%	≥15% improvement: 82%	6%	10%
p noninferiority					
p superiority	NR	NR	0.24	0.01	0.07
Hellum et al. (2011, 2012) and Furunes (2017) (60-62)					
Number analyzed	151 (8 years)			8 years	173 (8 years)
ProDisc II		NR	NR	34%	12/86 (14%)
Rehab		NR	NR	4%	21/87 (24%)
p	0.04			<0.001	NR

	MD=9.9 (0.6-19.2)				

MD: mean difference; NR: not reported; RCT: randomized controlled trial; SD: standard deviation; SF-36: 36-Item Short Form Health Surve; VAS: visual analog score.

Study Limitations

Tables 11 and 12 summarize the relevance, design, and conduct limitations of the RCTs of artificial discs available in the U.S. The most serious limitations included a lack of blinding, insufficient follow-up to evaluate potential harms, and comparators that are not relevant to current practice.

Table 11. Study Relevance Limitations for RCTs of Artificial Intervertebral Discs Available in the United States

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
ProDisc-L IDE Study Zigler et al. (2007, 2012)				Outcome changed from protocol	
ProDisc-L 2-level Delamarter et al. (2011)	4. Patients with DDD at 2 levels		2. Comparator not criterion standard		1, 2. Insufficient follow-up to assess benefits and harms
activL IDE study Garcia et al. (2015) Yue et al. (2019)			2. No comparison to fusion or conservative care; control group includes patients who received a device not currently available in the U.S.		2. 5-year follow-up not sufficient to assess potential harms
ProDisc II vs conservative care Hellum et al.	4. 33% of surgery patients underwent 2-level surgery		4. 24% of patients randomized to rehabilitation		

			crossed over to surgery		

DDD: degenerative disk disease; RCT: randomized controlled trial.
The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 12. Study Design and Conduct Limitations for RCTs of Artificial Intervertebral Discs Available in the United States

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
ProDisc-L IDE Study Zigler et al. (2007, 2012)		1, 2. Not blinded		1. High and differential loss to follow-up at 5 years (25% (fusion vs 15% artificial disc)		
ProDisc-L 2-level Delamarter et al. (2011)		1, 2. Not blinded				
activL IDE study Garcia et al. (2015) Yue et al. (2019)		1, 2. Outcome assessment not blinded, patients blinded at 2 years but not 5 years		1. high loss to follow-up at 5 years		
ProDisc-L vs conservative care Hellum et al.				1. high and differential loss to follow-up		

RCT: randomized controlled trial.
The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

While observational studies do not provide evidence of efficacy or comparative efficacy, they may provide information about the durability of any observed improvements and potential impacts of patient selection factors (see Tables 13 and 14).

Siepe et al. (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution. (66) This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review. Oswestry Disability Index and visual analog score pain scores were assessed by investigators not involved in pre- or postoperative decision making. At final follow-up, Oswestry Disability Index and visual analog score pain scores were significantly improved over baseline. Overall satisfaction rates were 89.1% for single-level and 69.0% for 2-level disc replacement.

Laugesen et al. (2017) found significant improvements in pain and function with 1- or 2-level ProDisc II implantation at follow-up of 10.6 years, but pain remained moderate, and about one-third of patients required revision to fusion. (67) The authors noted the need for appropriate selection criteria.

Another case series, by Tropiano et al. (2005), followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results. (68)

Table 13. Summary of Prospective Cohort Study Characteristics

Study	Country	Participants, N (% of total treated)	Treatment Delivery	Follow-Up (Range), Years
Siepe et al. (2014) (66)	Germany	181 (90%)	ProDisc-II at 1 or 2 levels	7.4 (5.0-10.8)

Laugesen et al. (2017) (67)	Denmark	57 (84%) with DDD	ProDisc-II at 1 or 2 levels	10.6 (8.1-12.6)

DDD: degenerative disc disease.

Table 14. Summary of Key Cohort Study Results

Study	Siepe et al. (2014) (66)	Laugesen et al. (2017) (67)
Treatment	1 or 2 level ProDisc-II	1 or 2 level ProDisc-II
Functional Status at Baseline	42 (ODI)	63.2 (PDQ)
Score at Follow Up	22	45.6
p	<0.001	<0.001
VAS Score at Baseline	7	6.8
VAS at Follow Up	3.3	3.2
p	<0.001	<0.001
Complication Rate	• 11.9% 1 level • 27.6% 2 levels	33% revised to fusion

ODI: Oswestry Disability Index; PDQ: Dallas Pain Questionnaire; VAS: visual analog scale.

Summary of Evidence - Lumbar Artificial Intervertebral Disc

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) of artificial discs versus fusion with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement compared to spinal fusion. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (e.g., faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. No RCTs compared activL to spinal fusion or conservative care. In general, RCTs were limited by a lack of blinding, insufficient follow-up to evaluate potential harms, and lack of comparison to the criterion standard for treatment of degenerative disc disease. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements - Lumbar Artificial Intervertebral Disc

American Pain Society

In 2009, the American Pain Society's practice guidelines concluded there was "insufficient evidence" to adequately evaluate the long-term benefits and harms of vertebral disc replacement. (69) The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center. (70) The rationale for the recommendation was that, although artificial disc replacement has been associated with

outcomes similar to fusion, the trial results were only applicable to a narrowly defined subset of patients with single-level degenerative disease, and the type of fusion surgery in the trials is no longer widely used due to frequent poor outcomes. Also, all trials had been industry-funded, and data on long-term (>2 years) benefits and harms following artificial disc replacement were limited.

National Institute for Health and Care Excellence

In 2009, the National Institute for Health and Care Excellence updated its guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine with studies reporting 13-year follow-up but with most of the "evidence from studies with shorter durations of follow-up." (71) The Institute concluded that evidence was "adequate to support the use of this procedure."

North American Spine Society

In 2024, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement. (72) The following recommendation was made:

Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria:

1. Pain arising from 1- or 2-level disc disruption involving L3-L4, L4-L5, and/or L5-S1 segments.
2. Presence of symptoms for at least 6 months or greater, that are not responsive to multi-modal nonoperative treatment over that period, which 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.
3. Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention.
4. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain.

Lumbar disc arthroplasty is NOT indicated in ANY of the following scenarios:

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

Medicare National Coverage

Effective for services performed on or after August 14, 2007, Centers for Medicare & Medicaid Services (CMS) found "that lumbar artificial disc replacement is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, lumbar artificial disc replacement is non-covered for Medicare beneficiaries older than 60 years of age." "For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for lumbar artificial disc replacement, leaving such determinations to be made by the local contractors." (73)

The national coverage determination was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charité), to noncoverage for the lumbar artificial disc replacement procedure for the Medicare population older than 60 years of age. CMS provided this explanation:

"The original NCD [national coverage determination] for LADR [lumbar artificial disc replacement] was focused on a specific lumbar artificial disc implant (Charite) because it was the only one with FDA [Food and Drug Administration] approval at that time. In the original decision memorandum for LADR CMS stated that when another lumbar artificial disc received FDA approval [CMS] would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc-L, received FDA approval, which initiated the reconsideration of [the] NCD [national coverage determination] on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of lumbar artificial disc replacement rather than lumbar artificial disc replacement with a specific manufacture's implant." (74)

Ongoing and Unpublished Clinical Trials - Lumbar Artificial Intervertebral Disc

A search of ClinicalTrials.gov in February 2025 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22856, 22857, 22858, 22860, 22861, 22862, 22864, 22865, 0095T, 0098T, 0164T, 0165T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following changes were made to Coverage: 1) Removed "at one level" from lumbar artificial intervertebral disc criteria; and 2) Revised existing lumbar artificial intervertebral disc experimental, investigational and/or unproven statement to include "at more than two levels". Added references 52-55, 58-70, and 73-77; others updated/removed.
02/01/2025	Document updated with literature review. Coverage unchanged. Added references 13, 15, 35-37, 52, and 63-64; others updated.
07/15/2023	Reviewed. No changes
03/15/2023	Document updated with literature review. The following changes were made to Coverage: 1) Modified conditional criteria for both single level and two level cervical disc arthroscopy; and 2) Added multiple examples to cervical disc implantation experimental, investigational, and/or unproven list. References 29 and 44 added; others removed.
09/01/2021	Document updated with literature review. Coverage unchanged. References 3, 12, 13, 30, 31, 32, 36, 37, 38, 42, and 44 added; others removed.
03/01/2020	Document updated with literature review. The following change was made to Coverage: For both single level and two level cervical artificial disc placement, added “the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment” as an alternative to failure of at least six weeks of conservative treatment. Added/updated the following references: 1, 3, 6, 9-11, 15, 17, 24, 25, 29-31, 33, 36, 41-44, 55-57.
11/15/2017	Reviewed. No changes.
04/01/2017	Document updated with literature review. The following phrase: “cleared and used in accordance with the FDA label” was added to the following Lumbar Artificial Intervertebral Disc statement: “Lumbar artificial intervertebral disc, using a disc that is U.S. Food and Drug Administration

	(FDA) cleared and used in accordance with the FDA label, may be considered medically necessary for patients who meet ALL of the following criteria".
04/15/2016	Document updated with literature review. Coverage for Cervical Artificial Intervertebral Disc has been divided into Single Level and Two Level criteria. Insertion of a cervical artificial intervertebral disc at two contiguous levels, using a disc approved by the U.S. Food and Drug Administration (FDA), may be considered medically necessary for the treatment of symptomatic degenerative disc disease when criteria are met. Coverage unchanged for Lumbar Artificial Intervertebral Disc.
10/01/2015	Document updated with literature review. Skeletal maturity was added to the listing of medically necessary criteria for coverage of cervical artificial intervertebral disc.
09/15/2014	Document updated with literature review. Coverage unchanged.
04/15/2013	Document updated with literature review. Title changed from "Vertebral Disc Replacement with Artificial Disc". Lumbar artificial intervertebral disc has changed to the following: Lumbar artificial intervertebral disc, using a disc that has the approval of the U.S. Food and Drug Administration (FDA), may be considered medically necessary for patients who meet ALL of the following criteria: 1) Skeletally mature; AND 2) Degenerative disc disease at only 1 level in the lumbar spine, from L3-S1, confirmed by radiographic studies (CT, MRI, x-rays, etc); AND 3) Have no more than Grade 1 (0-25%) spondylolisthesis at the involved level; AND 4) Minimum Oswestry Disability Index (ODI) score equal to or greater than 40; AND 5) Radicular back/leg pain that has failed a minimum of 6 months of conservative treatment.
02/15/2011	Document updated with literature review. Coverage unchanged.
06/15/2008	Revised/updated entire document. Medical policy title changed. The following has changed: Artificial intervertebral cervical discs may be considered medically necessary when ALL of the following criteria are met: 1) Disc has the approval of the U.S. Food and Drug Administration (FDA); AND 2) Disc will be used for single-level reconstruction (C3-C7) following discectomy; AND 3) Patient has intractable radiculopathy and/or myelopathy due to herniated disc or osteophyte formation; AND 4) Patients has failed at least six weeks of conservative therapy; AND 5) Symptomatic nerve root and/or spinal cord compression documented by ALL the following: a) Neck and/or arm pain; and b) Functional and/or neurological deficit; and c) Radiographic studies (e.g., Computed Tomography (CT), Magnetic Resonance Imaging (MRI), x-rays, etc.).
07/13/2005	New medical document. Artificial intervertebral discs are considered investigational, experimental and/or unproven for replacement of one or more vertebral discs at any level.