07.01.03 Artificial Intervertebral Disc

Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

Original Effective Date: February 2005

Review Date: June 2025

Revised: June 2024

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Summary

Description

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.

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

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, 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, quality of life, and treatment-related morbidity. Food and Drug Administration approval of Simplify Cervical Disc and Prestige LP for implantation at 2 levels was based on superiority to 2-level anterior cervical discectomy and fusion in overall success at 2 years. For Prestige LP, the increase in overall success rates at 2 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 2 levels (Mobi-C) was found to be superior to anterior cervical discectomy and fusion for Neck Disability Index scores, Neck Disability Index success rates, reoperation rates, and the overall success composite outcome. At 5 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 anterior cervical discectomy and fusion 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.

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. However, even though there is a paucity of peer-reviewed scientific evidence showing consistent evidence regarding the effectiveness of a single-level lumbar artificial disc for individuals who

have degenerative disc disease, for certain carefully-selected individuals the use of a single-level lumber artificial disc will be considered medically necessary when the criteria below are met, see Policy.

Cervical or Lumbar Artificial Intervertebral Disc: Hybrid Surgery for Multi-Level Cervical or Lumbar Degenerative Disc Disease

For individuals who have degenerative disc disease who receive a hybrid surgery of the cervical or lumbar spine, the evidence includes a systematic review of a single, small, nonrandomized study that compared hybrid surgery with cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF), respectively. No studies were identified in individuals receiving hybrid surgery of the lumbar spine. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The single study found no significant between-group differences across the majority of pain and quality-of-life outcomes and the quality of the evidence was rated as low. Hayes Inc. concluded there was "insufficient evidence". The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether:

1. cervical disc arthroplasty improves the net health outcome compared with anterior cervical discectomy and fusion in individuals who have degenerative disc disease.
2. implantation of a lumbar artificial intervertebral disc improves the net health outcome in patients with degenerative disc disease.

PRIOR APPROVAL

Not applicable.

POLICY

Cervical Artificial Disc: Initial

The use of an artificial intervertebral cervical disc prosthesis may be considered **medically necessary** when the individual has met **all of the following** criteria:

- Is skeletally mature
- Has intractable cervical radicular pain *or* myelopathy
- Has failed at least 6 weeks of conservative nonoperative treatment, that includes 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;
  Note: The following circumstances would be considered an exception to completing the above conservative therapy requirements;
  - *If the individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment; or*
  - *Documentation of physical therapy which is contraindicated as explained by the physical therapist's or physician's clinical.*
- Degeneration documented from C3 through C7 by x-ray, magnetic resonance imaging (MRI), computed tomography (CT), or myelography
- Has nerve root and/or cord compression due to herniated disc and/or spondylosis

- The implant is approved by the U.S. Food and Drug Administration (FDA)
- Will be utilized at the number of levels based on the FDA approval for that device *(see Policy Guidelines)*
- The individual is free from contraindications for an artificial intervertebral cervical disc prothesis as identified on the device FDA label. (*Each device may have its own contraindications. See the Cervical Artificial Disc: Investigational, list below for some identified contraindications*)

Two-Level Cervical Artificial Disc (Simultaneous or Subsequent to One Previously Performed)

A two-level cervical disc arthroplasty is considered **medically necessary** when **all of** the following criteria are met:

- The initial criteria above are met, for each disc level;
- The implant is FDA-approved for two levels. (See Policy Guidelines);
- Performed at two (2) contiguous levels simultaneously or at a second contiguous level to a previously performed arthroplasty and the initial cervical artificial intervertebral disc implantation is fully healed.

Cervical Artificial Disc: Revision

Revision of an artificial intervertebral cervical disc prosthesis may be considered **medically necessary** when imaging confirms failure of the implanted device (e.g., loosening, dislodgement, fracture, discitis infection).

Cervical Artificial Disc: Investigational

An artificial intervertebral cervical disc prosthesis is considered **investigational** when the criteria above has not been met and for all other indications, including but not limited to the following because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes

- Active infection
- Allergy or sensitivity to implant materials
- Any FDA off label utilization
- Anatomic deformity (e.g., ankylosing spondylitis)
- Chronic non-specific neck or arm pain of an unknown etiology
- Combined use of a prosthesis and spinal fusion or other stabilizing procedure (hybrid construct)
- Facet arthritis
- Malignancy
- Non-FDA–approved cervical disc prosthesis
- Osteopenia or osteoporosis (T-score <1.0)
- Planned procedure will lead to disc implantation at more than 2 levels
- Prior fusion at another cervical level or target level
- Prior spine surgery of any form at target level
- History of rheumatoid arthritis, ankylosing spondylitis or other auto-immune disease
- Translational instability

Lumbar Artificial Disc: Initial

The use of an artificial intervertebral lumbar disc prosthesis may be considered **medically necessary** when the individual has met **all of the following criteria:**

- Age between 18 and 60;
- Has chronic, unremitting, severe axial low back pain determined to be discogenic origin;
- Has moderate to severe single level, degenerative disc disease (DDD) confirmed by x-rays magnetic resonance imaging (MRI), computed tomography (CT);

- Has clinically significant functional impairment affecting activities of daily living;
- Has failed at least six months of consistent nonoperative treatment, including an active pain management program or protocol, under the direction of a physician, with pharmacotherapy AND formal physical therapy;
- Absence of untreated, significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, opioid and alcohol use disorders);
- The device is approved by the U.S. Food and Drug Administration (FDA);
- The specified implant will be inserted at **one level** at the FDA approved spinal level specific to the implant to be used (see Policy Guidelines);
- The individual is free from contraindications for an artificial intervertebral lumbar disc prothesis as identified on the device FDA label. *(Each device may have its own contraindications. See the Lumbar Artificial Disc: Investigational, list below for some identified contraindications)*

Lumbar Artificial Disc: Revision

Revision of a lumbar intervertebral disc prosthesis may be considered **medically necessary** when imaging confirms failure of the implanted device (e.g., loosening, dislodgement, fracture, discitis infection).

Lumbar Artificial Disc: Investigational

An artificial intervertebral lumbar disc prosthesis is considered **investigational** when the criteria above has not been met and for all other indications, including but not limited to the following because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes:

- Active infection
- Allergy or sensitivity to implant materials
- Any FDA off label utilization
- Clinically compromised vertebral bodies at the affected level due to current or past trauma
- Combined use of a prosthesis and spinal fusion or other stabilizing procedure (hybrid construct) (see Policy Guidelines)
- Evidence of any of the following on imaging:
    - Degenerative or lytic spondylolisthesis > 3 mm
    - Infection
    - Lumbar nerve root compression and/or moderate or greater lateral recess or neuroforaminal recess
    - Lumbar scoliosis >11 degrees in sagittal plane
    - Malignancy
    - Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative x-ray or magnetic resonance imaging (MRI) scan, computed tomography (CT) scan
    - Moderate or greater boney lumbar spinal stenosis
    - Multilevel degenerative disc disease (2 or more levels)
    - Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
    - Spinal fracture
- History of rheumatoid arthritis, ankylosing spondylitis or other auto-immune disease
- Implantation at more than one lumbar level
- Isolated radicular compression syndromes related to lumbar disc herniation or boney stenosis
- Osteopenia or osteoporosis (T-score <1.0)
- Prior fusion at another lumbar level or target level
- Prior spine surgery of any form at target level

POLICY GUIDELINES

Required Documentation

- Clinical notes that document the requesting surgeon personally evaluated the individual before submitting a request for surgery (except in cases of malignancy, trauma, infection, or rapidly progressive neurologic symptoms)
- Detailed documentation of extent and response to non-operative conservative therapy, if applicable, including outcomes of any procedural interventions, medications used and physical therapy/physiatrist notes
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months. Imaging must be performed and read by an independent radiologist.

Tobacco Use

- Evidence shows that tobacco use is considered a risk factor for poor healing. Tobacco use (e.g., cigarettes, cigars, pipes, vaping, or smokeless tobacco in the form of chew or snuff) within the previous four weeks is a contraindication for the procedure. If the patient utilizes tobacco, tobacco cessation should be encouraged.

Cervical Disc

Cervical Device Approved Levels

Devices approved to be used at **one level** include but may not limited to: Bryan cervical disc, M6-C cervical disc, MOBI-C®, PCM cervical disc, Prestige, Prestige-LP™, ProDisc-C total disc replacement, SECURE-C artificial cervical disc, Simplify Cervical Artificial Disc

Devices approved to be used at **two contiguous levels** include but may not limited to: MOBI-C®, Prestige-LP™, Simplify® Disc

Cervical Disc Investigational Additional Information

Investigational uses for cervical disc arthroplasty are derived from pivotal trials' eligibility criteria. Notably, individuals with prior surgery at the treated level were generally excluded from pivotal trials of cervical disc prostheses approved for use in the United States.

- (Mummaneni et al, 2007; PMID 17355018)
- (Gornet et al, 2015; PMID 26230424)
- (Murrey et al, 2009; PMID 18774751)
- (Heller et al, 2009; PMID 19112337)
- (Hisey et al, 2015; PMID 25310394)
- (U.S. Food and Drug Administration (FDA), https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002b.pdf) (Vaccaro et al, 2013; PMID 24335629)
- (U.S. Food and Drug Administration (FDA), https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003b.pdf) Phillips et al, 2021; PMID 33096243)
- (U.S. Food and Drug Administration (FDA), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P17003)
- (U.S. Food and Drug Administration (FDA), https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200022S003B.pdf)

- (Coric et al, 2022; PMID 35364570)(U.S. Food and Drug Administration (FDA), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P090029)
- (Davis et al, 2015; PMID 25380538)

Uniquely, a pivotal trial with PCM (porous-coated motion) Cervical Disc® included approximately 12% of individuals with prior adjacent or non-adjacent single-level fusions. (Phillips et al, 2013; PMID 23591659)

Lumbar Device Approved Levels

Devices approved to be used at one level to include but may not limited to: ActivL® Artificial Disc (L4-S1), Charite Artificial Disc (L4-S1), or ProDisc®-L Total Disc Replacement (L3-S1)

Coding

See the Codes table for details.

BACKGROUND

Cervical Degenerative Disc Disease

Cervical degenerative disc disease is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical degenerative disc disease include arm pain, weakness, and paresthesias 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 degenerative disc disease secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical degenerative disc disease. By age 65 years, 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.

Cervical Degenerative Disc Disease Treatment

Anterior cervical discectomy and fusion has historically been considered the definitive surgical treatment for symptomatic degenerative disc disease of the cervical spine. The goals of anterior cervical discectomy and fusion 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 anterior cervical discectomy and fusion patients. Anterior cervical discectomy and fusion 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 anterior cervical discectomy and fusion without an anterior plate. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90% to 100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level degenerative disc disease and the need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for patients with symptomatic cervical degenerative disc disease. 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 degenerative disc disease above or below a fusion site has been the major reason driving device development and use. Disc arthroplasty and anterior cervical discectomy and fusion 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.

Lumbar Degenerative Disc Disease

Degenerative disc disease, the most frequent cause of back pain requiring surgery, is common with age or trauma. Spine imaging, such as magnetic resonance imaging (MRI), computed tomography, 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 degenerative disc disease, 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 degenerative disc disease fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease 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

Several prosthetic devices are currently available for cervical and lumbar disc arthroplasty*. The below lists are not intended to be all-inclusive.*

FDA Approved Cervical Artificial Disc Device(s): *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*

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval 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, computed tomography, 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 5-year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine), was approved by the FDA through the premarket approval 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 the 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 2 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 adverse event 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.

Please note the below tables are not intended to be all inclusive.

Table 1: Cervical Artificial Discs

Implant & Approval Year	Approved Vertebral Level(s)	Description
Bryan® Cervical Disc (2009)	Single level C3-C7	the device is made of 2 titanium-alloy shells encasing a polyurethane nucleus and is indicated in skeletally mature individuals for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT and/or magnetic resonance imaging (MRI). Patients receiving the Bryan® Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation. (P060023)
M6-C Artificial Cervical Disc (2019)	Single level C3-C7	The device is made of an ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates is indicated for disc reconstruction following single-level discectomy in skeletally mature individuals with intractable

		degenerative cervical radiculopathy with or without spinal cord compression at one level from C3 – C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (computed tomography, magnetic resonance imaging, x-ray). The device is implanted via an anterior approach. Patients should have failed at least six weeks of conservative treatment or exhibit progressive neurological symptoms, which could lead to permanent impairment. (P170036) On February 25, 2025, Orthofix announced that the M6-C artificial cervical disc will be discontinued.
Mobi-C® (2013)	Single level or two contiguous levels C3-C7	The device is Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert; approved for both 1 and 2-levels placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc that is causing arm pain and/or weakness or numbness. The device is intended for skeletally mature individuals to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc at one or wo adjacent spinal levels. (P110002 or P110009)
PCM Cervical Disc® (2012)	Single level C3-C7	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert and is placed between two adjacent neck bones (vertebrae) to replace a diseased cervical disc causing arm pain and/or weakness or numbness. The device is intended to be used in skeletally mature patients to replace a cervical disc from C3-C7 following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only one level. (P100012).
Prestige® Cervical Disc System (2007)	Single level C3-C7	The device is indicated in skeletally mature individuals for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation. The safety and effectiveness of the device has not been established in patients who have not undergone at least six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care. (P060018)
Prestige LP® Cervical Disc	Single level or two	Titanium-ceramic composite with a metal-on-metal bearing; approved for both 1- and 2-levels and is indicated in skeletally mature individuals for

(2014; 2016 received approval for implantation at two levels)	contiguous levels C3-C7	reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, x-ray): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. (P0900209)
Prestige® ST Cervical Disc System (2007)	Single level C3-C7	The stainless-steel device received FDA premarket application (PMA) approval as a class III device in 2007.
ProDisc-C® Total Disc Replacement (2007)	Single level C3-C7	The 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert is a device that is indicated for skeletally mature individuals for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes) and/or loss of disc height. The device is implanted via an open anterior approach. Individuals should have failed at least six weeks of non-operative treatment prior to implantation. (P070001).
Simplify® Cervical Artificial Disc (2020)	Single level or two contiguous levels C3-C7	The device has PEEK endplates and a mobile ceramic core and is MRI compatible. (P200022)
SECURE®-C Cervical Disc (2012)	Single level C3-C7	The device is semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert which is intended to be used in skeletally mature individuals to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only one level. (P100003)

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

Cervical Disc Prostheses Device(s) Under Investigation in the U.S.

- Freedom® AxioMed FDA IDE trial
- Kineflex C Spinal Motion FDA IDE clinical trial complete

IDE: investigational device exemption

FDA Approved Lumbar Artificial Disc Device(s):

Three artificial lumbar disc devices (activL, Charité, ProDisc-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval 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 postmarketing studies. The activL (Aesculap Implant Systems) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease. Degenerative disc disease 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 ProDiscL was also limited to patients with disease at 1 level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels. FDA product code: MJO.

Table 2: FDA Approved Lumbar Artificial Discs

Implant & Approval Year	Approved Vertebral Level(s)	Description
ActivL® Artificial Disc (2018)	Single level from L4-S1	The device is intended for disc reconstruction between the fourth and fifth lumbar or fifth lumbar and first sacral vertebrae to treat symptomatic degenerative disc disease (DDD). The weight-bearing total disc replacement (TDR) is intended to match the rotational motion of the lumbar disc in response to physiologic motion. (P120024)
Charite Artificial Disc (2004 & Withdrawn 1/5/2012)	Single level from L4-S1	The Charite Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. 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)
ProDisc®-L Total Disc Replacement (2017 (2020 Supplement)	Single level or two contiguous levels from L3-S1	The PRODISC -L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 or 2 contiguous intervertebral level(s) from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. 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 six months of conservative treatment prior to

		implantation of the PRODISC®-L Total Disc Replacement. (P050010) In April 2020, the ProDiscL indication was expanded to include individuals with disease at up to 2 consecutive levels. (/S020)

Table 3: Lumbar devices without current approval in the United States

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

A number of other devices are under study in FDA Investigational Device Exemption (IDE) trials in the United States.

Thoracic Devices:

Devices for thoracic levels have not been approved through the FDA.

RATIONALE

This evidence review was created in February 2005 with searches of the PubMed database. The most recent literature update was performed through May 2025.

Evidence reviews 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, 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 technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies

must represent 1 or more intended clinical use 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. Randomized controlled trials 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 review.

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 or hybrid construct.

Comparators

Comparators of interest include anterior cervical discectomy and fusion. Cervical degenerative disc disease 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 6 weeks, or if symptoms progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical degenerative disc disease and no contraindications for the procedure.

Outcomes

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

The Neck Disability Index is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life. It is a modification of the Oswestry Disability Index, based on responses to 10 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 1 to 5, with a lower numeric score representing a better pain and disability status for that variable. A total Neck Disability Index score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, Neck Disability Index 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 6-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.

Systematic Reviews

In August of 2017 Hayes completed a Health Technology Assessment which was last reviewed in September 2021 on the use of single-level total disc replacement (TDR) for treatment of cervical degenerative disc disease (DDD) in adult patients with symptoms that have not responded to conservative therapies and who have no contraindications to surgery. Hayes provided a B rating. According to Hayes a B rating indicates, “some proven benefit. The published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.” Hayes further rates the use of single-level TDR for treatment of cervical DDD in adult patients who are not candidates for anterior cervical discectomy and fusion (ACDF) or who have contraindications that would be expected to interfere with successful arthroplasty a D^2 rating was provided which indicates, “insufficient evidence. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.”

Hu et al. (2016) published a systematic review and meta-analysis of 8 RCTs (l nN=2368) reporting mid-term outcomes (at least 48 months) comparing artificial intervertebral disc arthroplasty with anterior cervical discectomy and fusion. This meta-analysis had the highest AMSTAR rating out of 14 meta-analyses published between 2011 and 2017. All 8 trials included in Hu et al were rated as low risk of bias, despite lack of blinding. Only 2 trials reported on overall success, and 3 reported on Neck Disability Index success. 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) (RR, 0.40; 95% CI, 0.28 to 0.58; p<0.001) and at the adjacent level (5 studies) (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. They 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 for neck pain was lower in patients who had cervical disc arthroplasty (mean difference, -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).

Similar findings were reported by Deng et al. (2020) in a meta-analysis of 9 studies with 48 to 120 months of follow-up. 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 radiculopathy or myelopathy found improved overall success, neurological success, and Neck Disability Index success with cervical disc arthroplasty. 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 4 (Kineflex is no longer marketed). All of the trials utilized a non-inferiority design that compared cervical disc arthroplasty to the standard of anterior cervical discectomy and fusion with a Food and Drug Administration (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 anterior cervical discectomy and fusion (Table5). 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 anterior cervical discectomy and fusion (p=.005) There was a statistically significant difference in the improvement of the Neck Disability Index between the groups (cervical disc arthroplasty: -38.3 ; anterior cervical discectomy and fusion: -31.1; p=.01), but there was no significant difference in arm pain or neurologic success between the cervical disc arthroplasty and anterior cervical discectomy and fusion groups. There was not a statistical difference in secondary surgeries, with 9.7% of cervical disc arthroplasty patients and 15.8% of anterior cervical discectomy and fusion patients requiring secondary surgery at either the index or adjacent level (p=.146).

Table 4: Summary of Pivotal Study Characteristics of Cervical Artificial Intervertebral Discs

Study	Device	Design	Primary Outcome Measure	Participants	Interventions	
					CDA	ACDF
Mummaneni et al. (2007)	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.	Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy	Prestige ST (n=137)	n= 265

Gornet et al. (2015)	Prestige LP	Multicenter non-inferiority RCT	Primary outcomes were neurologic success, individual success, and overall success.	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)	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	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)	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.	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) FDA SSED	Mobi-C Single level	Multicenter non-inferiority RCT	Composite overall success score (not defined by authors)	Patients with discogenic neck and/or arm pain with degeneration of the disc with radiculopathy or myeloradiculopathy	Mobi-C (n=169)	n=87

				from C3 to C7 at 1 level without prior cervical fusion		
Phillips et al. (2013)	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	Patients with single-level symptomatic cervical spondylosis with radiculopathy and/or myelopathy unresponsive to nonoperative treatment	PCM (n=224)	n=192
Vacarro et al. (2013) FDA SSED	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.	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	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.	Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7	M6-C (n=160)	189 propensity matched controls selected from concurrent ACDF patients and a previous IDE study
FDA SSED: Simplify Cervical Disk[1]	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.	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: U.S. Food and Drug Administration; IDE: investigational device exemption; NDI: neck disability index; RCT: randomized controlled trial; SF-36: short form-36; VAS: visual analog scale; SSED: summary of safety and effectiveness.

Table 5: Summary of Pivotal Randomized Controlled Trials (RCT) Results

Outcomes	**24 Months**			**36 to 48 Months**			**60 Months**			**84 Months**			**120 Months**		
	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p
Prestige ST	Mummaneni et al. (2007)									Burkus et al. (2014)					
n	223	198								212	183				
Overall Success	3%	67.8%	.004 for superiority							72.6%	60.0%	.008			

NDI	mean improvement, 36 points	mean improvement, 33.6 points	Met non-Inferiority							-37.5	-31.9					
Neurologic Success	92.8%	84.3%	.005							88.2%	79.7%	.011				
Secondary Surgeries	1.1%	3.4%	.0492							4.8%	13.7%					
Prestige LP	Gornet et al. (2015)															
n	272	223														
Overall Success	mean difference, -0.111 (95% CrI, -0.196 to -0.026)		Superiority													
NDI																
Neurologic Success	93.5%	83.5%	Superiority													
Secondary Surgeries	28.6%	34%														
ProDisc C	Murray et al (2009)			Delamarter et al (2010)			Zigler et al (2013) Delamarter et al (2013)			Janssen et al (2015)						
n	101		101	75	67					152/209 (72.7%)						
Overall Success	72.3%	68.3%	Met non-inferiority				72	61								

NDI	21.4±20.2 points	20.5±18.4 points	1.0	20.3±18.6	21.2±14.9	21.4±20.2 points	50% to 60%		NS						
Neurologic Success	90.9%	88%	.638	88.9%	74.4%	.0665	90.3%	91.7%	NS	88%	89%	NS			
Secondary Surgeries	1.8%	8.5%	.003	2.9%	11.3%	.0292	2.9%	14.5%	.0079	7%	18%	.009			
Bryan Cervical Disc	Heller et al (2009)			Sasso et al (2011)									Lavelle et al (2018)		
n	230 (95%)	194 (87%)		181 (75%)	138 (62%)								128[b]	104	
Overall Success	82.6%	72.7%	.010 for superiority	85.1%	72.5%	.004							81.3%	66.3%	.005
NDI	86%	78.9%	.035 for superiority										-38.3	-31.1	.01
Arm Pain	19.1	21.5	.194	16.6	22.4	.028							-58.9	-51.6	.60
Neurologic Success	93.9%	90.2%	Met noninferiority			NS							92.1%	95.1%	.82
Secondary Surgeries				7.8%	8.6%	NS							9.7%	15.8%	.146

Mobi-C (1 level)	Hisey et al (2014) FDA SSED			Hisey et al (2015)			Hisey et al (2016)			Radcliff et al (2017)					
n	164%		81	9.5%	58.7%	Met non-inferiority	85.5%	78.9%							
Overall Success	73.7%	65.3%	Met non-inferiority	3%	9.9%	<.05	61.9%	52.2%	Met non-inferiority	55.2%	50.0%	Met non-inferiority			
NDI			Met non-inferiority									Met non-inferiority			
Secondary Surgeries	1.2%	6.2%					4.9%	17.3%	<.01	3%	12.3%	<.05			
PCM	Phillips et al (2013)						Phillips et al (2015),								
n	189	151	Per protocol				163 (74.8%)	130 (70.3%)							
Overall Success	75.1%	64.9%	Superiority												
NDI Success	83.4%	81.5%	.667				85%	74.2%	.026						
Neurologic Success	94.7%	89.5%	.100				92.4%	87.5%	.229						
Secondary Surgeries	5.2%	5.4%					8.1%	12.0%	NS						

Secure C	Vacarro et al (2013) FDA SSED															
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) FDA SSED: M6-C															
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 Disk														
n	150	133													
Overall Success	93%	73.6%	<.001												
NDI Success	97.9%	88%	.009												
Neurologic Success	99.3%	94.7%													
Secondary Surgeries	2.9%	2.9%	.979												
Pain Medication	10.8%	36.8%													

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; Crl: credible interval; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; NDI; neck disability index; NS: not significant; PCM: porous coated motion.

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. 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.

Section 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 5 devices. At 3 to 7 years, 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.

Cervical Artificial Intervertebral Disc: Two-Level Cervical Disc Arthroplasty

In October of 2017 Hayes completed a Health Technology Assessment which was last reviewed November 2021 on multilevel artificial disc replacement for cervical degenerative disc disease. Hayes rated 2-level total disc replacement (TDR) for treatment of cervical degenerative disc disease (DDD) in adult patients with symptoms that have not responded to conservative therapies and who have no contraindications to surgery a C. A C rating according to Hayes indicates, “potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.”

The table below 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.

In 2016, the Prestige LP received FDA approval for implantation at 2 levels. Overall success was achieved in 81.4% of Prestige LP patients and 69.4% of anterior cervical discectomy and fusion controls, meeting both non-inferiority and superiority margin, with a posterior probability of near 100% and 99.3%, respectively. The table below provides data on individuals who reached follow-ups at intervals up to 120 months. The difference in success rates between the Prestige LP and anterior cervical discectomy and fusion 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). 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 anterior cervical discectomy and fusion patients (90.5%; p<.001).

Table 6: Summary of Pivotal Randomized Controlled Trial (RCT) Characteristics of Cervical Disc Arthroplasty at 2 Continuous Levels

Study	Device	Design	Blinding	Primary Outcome Measure	Participants	Interventions

						CDA	ACDF
Coric et al. (2022)	Simplify Cervical Disc	Multicenter non-randomized	None	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	Simplify Cervical Disc (n=182)	n=170 historical controls from a previous IDE study from the mid-2000s
FDA SSED (2016)	Prestige LP	Multicenter non-inferiority trial	Unknown	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)	Mobi-C	Multicenter RCT	Patient and independent review blinding; radiologist not able to be blinded	Overall Success[a]	Patients with 2-level, symptomatic cervical disc disease with medically refractory radiculopathy and/or myelopathy	Mobi-C at 2 contiguous levels (n=225)	n=105

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplastty; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; IDE: investigational device exemption; 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 7: Follow-Up and Success Rates for 2-Level Cervical Discs Compared With 2-Level Anterior Cervical Discectomy and Fusion

Outcomes	24 Months	48 Months	60 Months	84 Months	120 Months

	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p
Simplify Cervical Disc	Coric et al. (2022)														
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 NO	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												Gornet et al (2019)[a]		
n (%)	199 (95)	160 (86)		185 (89)	149 (80)		166 (80)	138 (74)		126 (67)	99 (58)		148 (86%a)	118 (85%)	

Overall success n/N (%)	162/199 (81.4%)	111/160 (69.4%)	Superiority	151/185 (81.6%)	105/149 (70.5%)		132/166 (79.6%)	91/138 (65.5%)		99/126 (78.6%)	62/99 (62.6%)		80.4%	62.2%	Superiority
NDI Success	87.9%	79.2%	Superiority	89.7%	82.3%	Superiority	89.2%	77.8%	Superiority	87.0%	75.6%	Superiority	88.4%	76.5%	Superiority
Neurologic Success	91.5%	86.2%	NS	90.3%	83.8%	Superiority	90.4%	87.5%	NS	91.6%	82.1%	Superiority	92.6%	86.1%	Superiority
Secondary Surgeries	2.4%	3.2%											13.7%	35.5%	Significant
Mobi-C		Davis et al (2013)			Davis et al (2015)			Radcliff et al (2016)			Radcliff et al (2017)				
n	225	105		89.0%	81.2%		90.7%	86.7%		84.4%	75%				
Overall success	69.7%	37.4%	<.0001	66.0%	36.0%		61%	31%	<.001	60.8%	34.6%	Superiority			
NDI Success	78.2%	61.8%	<.05	79.3%	53.4%	<.001			Significant	79.0%	58.9%	<.05			
Secondary Surgeries	3.1%	11.4%		4.0%	15.2%		7.1%	21.0%	<.001	4.4%	16.2%	<.05			

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; NS: not significantly different; SAE: serious adverse event.

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). The comparison showed no significant differences between 1- and 2-level cervical disc arthroplasty on clinical outcomes (Neck Disability Index, Visual Analog Scale 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 to 4 levels, n=56) cervical disc arthroplasty with the Mobi-C device in a prospective multicenter study from Europe. At 2 years, there were no significant differences between groups for overall success, radicular and cervical visual analog scale scores, Neck Disability Index 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.

Section 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 anterior cervical discectomy and fusion.

The first artificial cervical disc approved for 2 levels (Mobi-C) was found to be noninferior to anterior cervical discectomy and fusion in the investigational device exemption trial. Superiority to anterior cervical discectomy and fusion was achieved for Neck Disability Index scores, Neck Disability Index success rates, and 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 anterior cervical discectomy and fusion patients.

Cervical Artificial Intervertebral Disc: Hybrid Surgery for Multi-Level Cervical Degenerative Disc Disease

In October of 2017 Hayes completed a Health Technology Assessment (HTA) which was last reviewed November 2021 on multilevel artificial disc replacement for cervical degenerative disc disease. This HTA included 1 prospective nonrandomized study that compared hybrid surgery with cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF), respectively. There were no significant between-group differences across the majority of pain and quality-of-life outcomes and the quality of the evidence was rated as low. Hayes rated a multilevel total disc replacement or hybrid surgery for treatment of cervical DDD in adult patients a D^2. According to Hayes a D^2 rating indicates, “Insufficient evidence. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.”

Cervical Artificial Intervertebral Disc: Registry Data

Staub et al. (2016) evaluated the clinical effectiveness of cervical disc arthroplasty for 987 patients in the Spine Tango registry. The primary outcome measures were the neck and arm pain relief and the Core Outcome Measures Index. 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 anterior cervical discectomy and fusion. 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 Core Outcome Measures Index 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 anterior cervical discectomy and fusion group for arm pain relief (78.4% vs 67.4%, p=0.02) and Core Outcome Measures Index 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 individuals 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 anterior cervical discectomy and fusion. A third analysis compared outcomes of cervical disc arthroplasty with anterior cervical discectomy and fusion 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 anterior cervical discectomy and fusion (64.9%; p=0.05), with no significant difference in responder rates between groups for neck pain relief or Core Outcome Measures Index. Rates of adjacent-level degeneration and secondary surgeries were not assessed.

MacDowall et al. compared 5 - year outcomes of cervical disc arthroplasty and anterior cervical discectomy and fusion from the Swedish Spine Registry. Using propensity matching, the investigators identified 185 patients in each group who had cervical degenerative disc disease and radiculopathy. The primary outcome was the Neck Disability Index, with a minimum clinically important difference of > 15%. Scores on the Neck Disability Index 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 (total n=617 patients). 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. 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 Neck Disability Index (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 visual analog scale neck pain, with a difference of 5 to 8 mm out of 100. The clinical significance of these differences is uncertain.

Lumbar Artificial Intervertebral Disc

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 review.

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 or hybrid construct.

Two artificial intervertebral discs are currently marketed in the U.S.: ProdiscL 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. 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 7: 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 Oswestry Disability Index, 36-Item Short Form Health Survey (SF-36), or visual analog scale 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.

Individual 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 Oswestry Disability Index 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.

Review of Evidence

Lumbar Artificial Intervertebral Disc: 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 the tables below.

Lumbar Artificial Intervertebral Disc: 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. 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. 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.

Lumbar Artificial Intervertebral Disc: 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. 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. 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.

Lumbar Artificial Intervertebral Disc: 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. 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.

Eight-year follow-up of this trial was reported by Furunes et al. (2017). 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 the table below). 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.

Lumbar Artificial Intervertebral Disc: 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). 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). 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.

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 8: Summary of Key RCTCharacteristics for Lumbar Artificial Discs Available in the United States

Study	Publications	Countries	Sites	Follow-Up	Study Design and Participants	Interventions Number Analyzed	
						Active	***Control***
ProDisc-L IDE Study		U.S.	17		Noninferiority trial of patients with single-level DDD	ProDisc-L n=161	Circumferential fusion n=75
				2 y	2-year results	n=156	n=73
				5y	5-year results	n=137	n=56
				5 y	5-year adjacent level degeneration results	n=123	n=43
ProDiscL IDE Study NCT00295009	Delamarter et al (2011	U.S.	16	2 y	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)	U.S.	17	2 y	Patient-blinded noninferiority trial of patients with DDD	activL n=218	ProDisc-L or Charité n=106

	Yue et al (2019)			5y	5-y follow-up (open label)	n=176	n=85
ProDisc II vs Conservative Treatment NCT00394732	Hellum et al (2011)	Norway	5	2 y	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)			2 y	Adjacent-level degeneration and facet arthropathy results	ProDisc II n=59	Multidisciplinary rehabilitation n=57
	Furunes et al (2017)			8 y	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 9: Summary of Key RCTOutcomes 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)	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)										
Number analyzed	219	193	220	177	220	176	217	177	161	193
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)	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	45.1 %	50.0%	39.8 (24.3) -	34.5 (24.5) -	43.3 (31.6) -	40.0 (32.1)	38.8 (11.3)	40.1 (13.6)	28.6% (4.0%	5/56 (9.0%)

			37.8 (36.0)	47.4 (34.7)	42.4 (42.9)	- 47.5 (43.8)	29.8 (40.9)	29.9 (43.7)	required surgery)	
P inferiority	<0.01	0.024								
P superiority	0.044	0.7438	0.055	0.455	0.134	0.567	0.036	0.168	0.004	NR
Delamarter et al. (2011)										
Number analyzed	203									
ProDisc-L	58.8 %	NR	52.4% improvement	NR	-43.3	NR	54.2% (54.6)	NR	NR	NR
Fusion	47.8 %	NR	40.9% improvement	NR	-36.7	NR	36.2% (44.9)	NR	NR	NR
P noninferiority	0.0008									
P superiority	0.09		0.03		0.118		0.014		0.047	
Garcia et al. (2015) Yue et al. (2019)										
Number analyzed			324	324						
activ-L	NR (graph only)	NR (graph only)	% with ≥15 point improvement: 75.2% Mean improve	% with ≥15 point improvement 82.7%	Improvement from baseline 74%	Decrease from baseline (mm) -64	≥15% improvement: 88%	≥15% improvement: 87%	1%	5%

			ment: 67%							
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%	Decrease from baseline (mm) -62	≥15% improvement: 81%	≥15% improvement: 82%	6%	10%
P noninferiority	<0.001	NR; activL noninferior to control group								
P superiority	0.02	NR	0.09	0.10	NR	NR	NR	0.24	*0.01*	0.07
Hellum et al. (2011, 2012) and Furunes (2017)										
Number analyzed	173	151 (8 years)		151 (8 years)		151 (8 years)			8 years	173 (8 years)
ProDisc II	51 (70%)	19.8 (16.7)	20.0 (16.4 to 23.6)		35.4		NR	NR	34%	12/86 (14%)
Rehab	31 (47%)	26.7 (14.5)	14.4 (10.7 to 18.1)		49.7		NR	NR	4%	21/87 (24%)
p	0.006			0.02	0.009	0.04			<0.001	NR
	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= 9.9 (0.6-19.2)				

CI: confidence interval; MD: mean difference; NNT: number needed to treat; MD: mean difference; NNT: number needed to treat; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; Rehab: multidisciplinary rehabilitation; SD: standard deviation; SF-36: 36-Item Short Form Health Surve; VAS: visual analog score.

Study Limitations

The tables below 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 10: 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]
ProDiscL IDE Study Zigler et al. (2007, 2012)				Outcome changed from protocol	
ProDiscL 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. 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 US		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.
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. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11: 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]
ProDiscL 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)		
ProDiscL 2-level Delamarter et al. (2011)		1, 2. Not blinded				
ActivL IDE study Garcia et al. Yue et al. (2019)		1, 2. Outcome assessment not blinded, patients blinded at 2 y but not 5 y		1. high loss to follow-up at 5 years		
ProDiscL vs conservative care Hellum et al.				1. high and differential loss to follow-up		

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.

Lumbar Artificial Intervertebral Disc: 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 the tables below.

Siepe et al (2014) reported on a minimum 5-year follow-up for 181 patients implanted with the ProDisc II at their institution. 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. 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.

Table 12: Summary of Prospective Cohort Study Characteristics

Study	Country	Participants, N (% of total treated)	Treatment Delivery	Follow-Up (Range), Years
Siepe et al. (2014)	Germany	181 (90%)	ProDisc-II at 1 or 2 levels	7.4 (5.0-10.8)
Laugesen et al. (2017)	Denmark	57 (84%) with DDD	ProDisc-II at 1 or 2 levels	10.6 (8.1-12.6)

DDD: degenerative disc disease.

Table 13: Summary of Key Cohort Study Results

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

FU: follow-up; ODI: Oswestry Disability Index; PDQ: Dallas Pain Questionnaire; VAS: visual analog scale.

Section Summary: Lumbar Artificial Intervertebral Disc

A review of the randomized controlled trials (RCTs) of artificial discs versus fusion with 5-year outcomes and case series with longer term outcomes were identified reviewing for relevant outcomes such as 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.

Lumbar Artificial Intervertebral Disc: Hybrid Surgery for Lumbar Degenerative Disc Disease

Wemark did not identify any RCTs or systematic reviews of lumbar artificial intervertebral discs in a hybrid surgery for lumbar degenerative disc disease that reviewed for outcomes of interest, such as are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Section Summary: Lumbar Artificial Intervertebral Disc: Hybrid Surgery for Lumbar Degenerative Disc Disease

No studies were identified that have directly evaluated whether using of lumbar artificial intervertebral discs in a hybrid surgery for lumbar degenerative disc disease improves the health outcomes such as change in disease status and morbid events.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from 3 physician specialty societies and 2 academic medical centers while this policy was under review in 2015. There was agreement that cervical disc replacement may be medically necessary under specified conditions. Likewise, there was agreement that combined use of an artificial disc and fusion over two levels was investigational. Input was mixed on the medical necessity of 2-level artificial intervertebral disc arthroplasty.

2009 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. Input did not support the conclusion that artificial intervertebral disc arthroplasty is investigational.

2008 Input

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. The 4 reviewers disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational.

After considering the clinical input in 2008, it was concluded that, due to limitations of the available randomized controlled trials (described herein), combined with the marginal benefit compared with fusion, evidence was insufficient to determine whether artificial lumbar discs are beneficial in the short term. Also, serious questions remained about potential long-term complications with these implants.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Pain Society (APS)

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. The guidelines were based on a systematic review commissioned by the Society and conducted by the Oregon Evidence-Based Practice Center. 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.

International Society for the Advancement of Spine Surgery (IASS)

In 2021, the International Society for the Advancement of Spine Surgery issued a position statement on cervical and lumbar disc replacement. 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 [Food and Drug Administration], 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."

National Institute for Health and Care Excellence (NICE)

In 2010, NICE issued guidance on the artificial *cervical* disc, concluding:

- "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 the avoidance of revision surgery."

In 2009, NICE issued guidance on the safety and efficacy of prosthetic intervertebral disc replacement in the *lumbar* spine stating,

- Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar

spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.
- The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery.

The North American Spine Society (NASS)

In 2019, the North American Spine Society issued coverage recommendations for lumbar artificial disc replacement. The following recommendation was made:

Lumbar artificial disc replacement may be indicated for individuals with discogenic low back pain who meet ALL of the following criteria from the Lumbar Fusion Coverage Recommendations:

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

Lumbar Disc Arthroplasty is NOT indicated in 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 one level
3. Presence of spinal instability with spondylolisthesis greater than Grade I
4. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)
5. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
6. Poorly managed psychiatric disorder
7. Significant facet arthropathy at the index level
8. Age greater than 60 years or less than 18 years
9. Presence of infection or tumor

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther. Sep 1991; 14(7): 409-15. PMID 1834753
2. Hu Y, Lv G, Ren S, et al. Mid- to Long-Term Outcomes of Cervical Disc Arthroplasty versus Anterior Cervical Discectomy and Fusion for Treatment of Symptomatic Cervical Disc Disease: A Systematic Review and Meta-Analysis of Eight Prospective Randomized Controlled Trials. PLoS One. 2016; 11(2): e0149312. PMID 26872258
3. Zhai S, Li A, Li X, et al. Total disc replacement compared with fusion for cervical degenerative disc disease: A systematic review of overlapping meta-analyses. Medicine (Baltimore). May 2020; 99(19): e20143. PMID 32384498

4. Burkus JK, Traynelis VC, Haid RW, et al. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. J Neurosurg Spine. Oct 2014; 21(4): 516-28. PMID 25036218

5. Sasso RC, Anderson PA, Riew KD, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. J Bone Joint Surg Am. Sep 21 2011; 93(18): 1684-92. PMID 21938372

6. Phillips FM, Geisler FH, Gilder KM, et al. Long-term Outcomes of the US FDA IDE Prospective, Randomized Controlled Clinical Trial Comparing PCM Cervical Disc Arthroplasty With Anterior Cervical Discectomy and Fusion. Spine (Phila Pa 1976). May 15 2015; 40(10): 674-83. PMID 25955086

7. Coric D, Kim PK, Clemente JD, et al. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. J Neurosurg Spine. Jan 2013; 18(1): 36-42. PMID 23140129

8. Davis RJ, Nunley PD, Kim KD, et al. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. J Neurosurg Spine. Jan 2015; 22(1): 15-25. PMID 25380538

9. Hisey MS, Bae HW, Davis RJ, et al. Prospective, Randomized Comparison of Cervical Total Disk Replacement Versus Anterior Cervical Fusion: Results at 48 Months Follow-up. J Spinal Disord Tech. May 2015; 28(4): E237-43. PMID 25310394

10. Janssen ME, Zigler JE, Spivak JM, et al. ProDisc-C Total Disc Replacement Versus Anterior Cervical Discectomy and Fusion for Single-Level Symptomatic Cervical Disc Disease: Seven-Year Follow-up of the Prospective Randomized U.S. Food and Drug Administration Investigational Device Exemption Study. J Bone Joint Surg Am. Nov 04 2015; 97(21): 1738-47. PMID 26537161

11. Zhang HX, Shao YD, Chen Y, et al. A prospective, randomised, controlled multicentre study comparing cervical disc replacement with anterior cervical decompression and fusion. Int Orthop. Dec 2014; 38(12): 2533-41. PMID 25209344

12. Latka D, Kozlowska K, Miekisiak G, et al. Safety and efficacy of cervical disc arthroplasty in preventing the adjacent segment disease: a meta-analysis of mid- to long-term outcomes in prospective, randomized, controlled multicenter studies. Ther Clin Risk Manag. 2019; 15: 531-539. PMID 30992666

13. Toci GR, Canseco JA, Patel PD, et al. The Incidence of Adjacent Segment Pathology After Cervical Disc Arthroplasty Compared with Anterior Cervical Discectomy and Fusion: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. World Neurosurg. Apr 2022; 160: e537-e548. PMID 35085804

14. Deng Y, Li G, Liu H, et al. Mid- to long-term rates of symptomatic adjacent-level disease requiring surgery after cervical total disc replacement compared with anterior cervical discectomy and fusion: a meta-analysis of prospective randomized clinical trials. J Orthop Surg Res. Oct 12 2020; 15(1): 468. PMID 33046082

15. Peng Z, Hong Y, Meng Y, et al. A meta-analysis comparing the short- and mid- to long-term outcomes of artificial cervical disc replacement(ACDR) with anterior cervical discectomy and fusion (ACDF) for the treatment of cervical degenerative disc disease. Int Orthop. Jul 2022; 46(7): 1609-1625. PMID 35113188

16. Mummaneni PV, Burkus JK, Haid RW, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine. Mar 2007; 6(3): 198-209. PMID 17355018

17. Gornet MF, Burkus JK, Shaffrey ME, et al. Cervical disc arthroplasty with PRESTIGE LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device exemption study. J Neurosurg Spine. Nov 2015; 23(5): 558-573. PMID 26230424

18. Murrey D, Janssen M, Delamarter R, et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. Apr 2009; 9(4): 275-86. PMID 18774751

19. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. Spine (Phila Pa 1976). Jan 15 2009; 34(2): 101-7. PMID 19112337

20. Hisey MS, Bae HW, Davis R, et al. Multi-center, prospective, randomized, controlled investigational device exemption clinical trial comparing Mobi-C Cervical Artificial Disc to anterior discectomy and fusion in the treatment of symptomatic degenerative disc disease in the cervical spine. Int J Spine Surg. 2014; 8. PMID 25694918

21. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): Mobi-C. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002b.pdf. Accessed February 18, 2025.

22. Phillips FM, Lee JY, Geisler FH, et al. A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. 2-year results from the US FDA IDE clinical trial. Spine (Phila Pa 1976). Jul 01 2013; 38(15): E907-18. PMID 23591659

23. Vaccaro A, Beutler W, Peppelman W, et al. Clinical outcomes with selectively constrained SECURE-C cervical disc arthroplasty: two-year results from a prospective, randomized, controlled, multicenter investigational device exemption study. Spine (Phila Pa 1976). Dec 15 2013; 38(26): 2227-39. PMID 24335629

24. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): SECURE-C. 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003b.pdf. Accessed February 17, 2025.

25. Burkus Cervical Disc. 2019. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170036. Accessed February 20, 2025.

26. Phillips FM, Coric D, Sasso R, et al. Prospective, multicenter clinical trial comparing M6-C compressible six degrees of freedom cervical disc with anterior cervical discectomy and fusion for the treatment of single-level degenerative cervical radiculopathy: 2-year results of an FDA investigational device exemption study. Spine J. Feb 2021; 21(2): 239-252. PMID 33096243

27. U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness: Simplify Cervical Artificial Disc. https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200022S003B.pdf. Accessed February 20, 2025.

28. Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. J Neurosurg Spine. Sep 2010; 13(3): 308-18. PMID 20809722

29. Delamarter RB, Murrey D, Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. SAS J. 2010; 4(4): 122-8. PMID 25802660

30. Zigler JE, Delamarter R, Murrey D, et al. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study. Spine (Phila Pa 1976). Feb 01 2013; 38(3): 203-9. PMID 23080427

31. Delamarter RB, Zigler J. Five-year reoperation rates, cervical total disc replacement versus fusion, results of a prospective randomized clinical trial. Spine (Phila Pa 1976). Apr 20 2013; 38(9): 711-7. PMID 23124255

32. Lavelle WF, Riew KD, Levi AD, et al. Ten-year Outcomes of Cervical Disc Replacement With the BRYAN Cervical Disc: Results From a Prospective, Randomized, Controlled Clinical Trial. Spine (Phila Pa 1976). May 01 2019; 44(9): 601-608. PMID 30325888

33. Hisey MS, Zigler JE, Jackson R, et al. Prospective, Randomized Comparison of One-level Mobi-C Cervical Total Disc Replacement vs. Anterior Cervical Discectomy and Fusion: Results at 5-year Follow-up. Int J Spine Surg. 2016; 10: 10. PMID 27162712

34. Radcliff K, Davis RJ, Hisey MS, et al. Long-term Evaluation of Cervical Disc Arthroplasty with the Mobi-C© Cervical Disc: A Randomized, Prospective, Multicenter Clinical Trial with Seven-Year Follow-up. Int J Spine Surg. 2017; 11(4): 31. PMID 29372135

35. Sasso WR, Ye J, Foley DP, et al. 20-year Clinical Outcomes of Cervical Disk Arthroplasty: A Prospective, Randomized, Controlled Trial. Spine (Phila Pa 1976). Jan 01 2024; 49(1): 1-6. PMID 37644726

36. Foley DP, Sasso WR, Ye JY, et al. Twenty-Year Radiographic Outcomes Following Single-Level Cervical Disc Arthroplasty: Results From a Prospective Randomized Controlled Trial. Spine (Phila Pa 1976). Mar 01 2024; 49(5): 295-303. PMID 38018773

37. Coric D, Guyer RD, Bae H, et al. Prospective, multicenter study of 2-level cervical arthroplasty with a PEEK-on-ceramic artificial disc. J Neurosurg Spine. Apr 01 2022: 1-11. PMID 35364570

38. U.S. Food and Drug Administration. Summary of Safety and Effectiveness: Prestige LP Cervical Disc. PMA Number P090029/S003. 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090029s003b.pdf. Accessed February 16, 2025.

39. Davis RJ, Kim KD, Hisey MS, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial: clinical article. J Neurosurg Spine. Nov 2013; 19(5): 532-45. PMID 24010901

40. Radcliff K, Coric D, Albert T. Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. J Neurosurg Spine. Aug 2016; 25(2): 213-24. PMID 27015130

41. U.S. Food and Drug Administration (FDA). Report of United States Clinical Study Results (G010188) -- Prestige LP Cervical Disc System. 2014; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P090029. Accessed February 19, 2025.

42. Gornet MF, Lanman TH, Burkus JK, et al. Two-level cervical disc arthroplasty versus anterior cervical discectomy and fusion: 10-year outcomes of a prospective, randomized investigational device exemption clinical trial. J Neurosurg Spine. Jun 21 2019: 1-11. PMID 31226684

43. Bae HW, Kim KD, Nunley PD, et al. Comparison of Clinical Outcomes of 1- and 2-Level Total Disc Replacement: Four-Year Results From a Prospective, Randomized, Controlled, Multicenter IDE Clinical Trial. Spine (Phila Pa 1976). Jun 01 2015; 40(11): 759-66. PMID 25785955

44. Huppert J, Beaurain J, Steib JP, et al. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. Eur Spine J. Sep 2011; 20(9): 1417-26. PMID 21336970

45. Staub LP, Ryser C, Röder C, et al. Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials. Spine J. Feb 2016; 16(2): 136-45. PMID 26674445

46. MacDowall A, Skeppholm M, Lindhagen L, et al. Artificial disc replacement versus fusion in patients with cervical degenerative disc disease with radiculopathy: 5-year outcomes from the National Swedish Spine Register. J Neurosurg Spine. Nov 02 2018; 30(2): 159-167. PMID 30485205

47. Chen J, Wang X, Bai W, et al. Prevalence of heterotopic ossification after cervical total disc arthroplasty: a meta-analysis. Eur Spine J. Apr 2012; 21(4): 674-80. PMID 22134486

48. Nunley PD, Cavanaugh DA, Kerr EJ, et al. Heterotopic Ossification After Cervical Total Disc Replacement at 7 Years-Prevalence, Progression, Clinical Implications, and Risk Factors. Int J Spine Surg. Jun 2018; 12(3): 352-361. PMID 30276092

49. Schroeder GD, Vaccaro AR, Divi SN, et al. 2021 Position Statement From the International Society for the Advancement of Spine Surgery on Cervical and Lumbar Disc Replacement. Int J Spine Surg. Feb 2021; 15(1): 37-46. PMID 33900955

50. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine [IPG341]. 2010; https://www.nice.org.uk/guidance/ipg341. Accessed February 20, 2025.

51. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Lumbar Artificial DISC Replacement (LADR) (150.10). 2007; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=National&KeyWord=disc&KeyWordLookUp=Title&Key WordSearchType=And&from2=search.asp&bc=gAAAACAAAAAAAA%3d%3d&. Accessed February 20, 2025.

52. U.S. Food & Drug Administration. The prodisc L Total Disc Replacement P050010/S020. April 10, 2020. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050010S020. Accessed February 20, 2025.

53. U.S. Food and Drug Administration. Draft: PRODISC-L Total Disc Replacement package insert. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010c.pdf. Accessed February 20, 2025.

54. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: PRODISC-L Total Disc Replacement. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010b.pdf. Accessed February 20, 2025.

55. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc

replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine (Phila Pa 1976). May 15 2007; 32(11): 1155-62; discussion 1163. PMID 17495770

56. Zigler JE, Delamarter RB. Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. J Neurosurg Spine. Dec 2012; 17(6): 493-501. PMID 23082846

57. Zigler JE, Glenn J, Delamarter RB. Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. J Neurosurg Spine. Dec 2012; 17(6): 504-11. PMID 23082849

58. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial lumbar disc arthroplasty. TEC Assessments. 2013;Volume 28:Tab 7.

59. Delamarter R, Zigler JE, Balderston RA, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. J Bone Joint Surg Am. Apr 20 2011; 93(8): 705-15. PMID 21398574

60. Schoenfeld AJ. Commentary on an article by Rick Delamarter, MD, et al.: "Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level degenerative lumbar disc disease. Results at twenty-four months". J Bone Joint Surg Am. Apr 20 2011; 93(8): e41. PMID 21398573

61. Hellum C, Johnsen LG, Storheim K, et al. Surgery with disc prosthesis versus rehabilitation in patients with low back pain and degenerative disc: two year follow-up of randomised study. BMJ. May 19 2011; 342: d2786. PMID 21596740

62. Hellum C, Berg L, Gjertsen Ø, et al. Adjacent level degeneration and facet arthropathy after disc prosthesis surgery or rehabilitation in patients with chronic low back pain and degenerative disc: second report of a randomized study. Spine (Phila Pa 1976). Dec 01 2012; 37(25): 2063-73. PMID 22706091

63. Furunes H, Storheim K, Brox JI, et al. Total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain and degenerative discs: 8-year follow-up of a randomized controlled multicenter trial. Spine J. Oct 2017; 17(10): 1480-1488. PMID 28583869

64. Garcia R, Yue JJ, Blumenthal S, et al. Lumbar Total Disc Replacement for Discogenic Low Back Pain: Two-year Outcomes of the activL Multicenter Randomized Controlled IDE Clinical Trial. Spine (Phila Pa 1976). Dec 2015; 40(24): 1873-81. PMID 26630435

65. Yue JJ, Garcia R, Blumenthal S, et al. Five-year Results of a Randomized Controlled Trial for Lumbar Artificial Discs in Single-level Degenerative Disc Disease. Spine (Phila Pa 1976). Dec 15 2019; 44(24): 1685-1696. PMID 31404055

66. Radcliff K, Zigler J, Braxton E, et al. Final Long-Term Reporting from a Randomized Controlled IDE Trial for Lumbar Artificial Discs in Single-Level Degenerative Disc Disease: 7-Year Results. Int J Spine Surg. Aug 2021; 15(4): 612-632. PMID 34266934

67. Siepe CJ, Heider F, Wiechert K, et al. Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. Spine J. Aug 01 2014; 14(8): 1417-31. PMID 24448028

68. Laugesen LA, Paulsen RT, Carreon L, et al. Patient-reported Outcomes and Revision Rates at a Mean Follow-up of 10 Years After Lumbar Total Disc Replacement. Spine (Phila Pa 1976). Nov 01 2017; 42(21): 1657-1663. PMID 28368983

69. Tropiano P, Huang RC, Girardi FP, et al. Lumbar total disc replacement. Seven to eleven-year follow-up. J Bone Joint Surg Am. Mar 2005; 87(3): 490-6. PMID 15741612

70. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). May 01 2009; 34(10): 1066-77. PMID 19363457

71. Chou R, Baisden J, Carragee EJ, et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. Spine (Phila Pa 1976). May 01 2009; 34(10): 1094-109. PMID 19363455

72. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine [IPG306]. 2009; https://www.nice.org.uk/guidance/IPG306. Accessed February 20, 2025.

73. North American Spine Society (NASS). NASS coverage policy recommendations: Lumbar Artificial Disc Replacement. 2019; https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations. Accessed February 20, 2025.

74. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Lumbar Artificial Disk Replacement (LADR) (150.10). 2007; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=National&KeyWord=lumbar+artificial+disc&KeyWordLo okUp=Title&KeyWordSearchType=And&id=170&bc=gAAAABAAAAAA&. Accessed February 20, 2025.

75. Centers for Medicare & Medicaid Services (CMS). Medicare Learning Network Matters: Lumbar Artificial Disc Replacement (LADR). Change request 5727. 2007; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1340CP.pdf . Accessed February 20, 2025.

76. Hayes, Inc., Evidence Analysis Research Brief. Multilevel Cervical Artificial Disc Replacement for Treatment of Degenerative Disc Disease. May 23, 2023. Available at: www.hayesinc.com. Accessed May 2025.

77. Hayes, Inc., Health Technology Assessment. Comparative Effectiveness Review of Multilevel Artificial Disc Replacement for Cervical Degenerative Disc Disease. Hayes, Inc. October 3, 2017. Last reviewed November 18, 2021. Available at: www.hayes.com. Accessed May 2025.

78. Hayes, Inc., Health Technology Assessment. Comparative Effectiveness Review Of Single-Level Artificial Disc Replacement For Cervical Degenerative Disc Disease. Hayes, Inc. August 21, 2017. Last reviewed September 22, 2021. Available at: www.hayesinc.com. Accessed May 2025.

79. Hayes, Inc. Evidence Analysis Research Brief. Two-Level Total Disc Replacement for Degenerative Disc Disease. May 30th, 2024. Available at: www.hayesinc.com. Accessed May 2025.

80. Hayes Inc. Evolving Evidence Review. Hybrid Lumbar Disc Arthroplasty with Fusion for Treatment of Multilevel Degenerative Disc Disease. April 5, 2024. Last reviewed April 25, 2025. Available at: www.hayesinc.com. Accessed May 2025.

81. UptoDate. Kothari Milind KJ., Chuang K., Shefner JM, et al. Treatment and prognosis of cervical radiculopathy. Last updated April 1, 2025. Review current through April 2025. Available at: www.uptodate.com. Accessed May 2025.
82. UpToDate. Chou R., Atlas SJ., Law K. Subacute and chronic low back pain: Surgical treatment. Last updated September 27, 2023. Review current through April 2025. Available at: www.uptodate.com. Accessed May 2025.

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT	0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
	0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
	0164T	Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
	0165T	Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace
	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
	22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
	22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
	22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
	22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
	22862	Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace; lumbar

Codes	Number	Description
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
	22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
	22899	Unlisted procedure, spine
Type of Service	Surgical	
Place of Service	Outpatient/ Inpatient	

POLICY HISTORY

Date	Reason	Action
June 2025	Annual Review	Policy Renewed
June 2024	Annual Review	Policy Revised
June 2023	Annual Review	Policy Renewed
March 2023	Annual Review	Policy Revised
March 2022	Annual Review	Policy Revised
March 2021	Annual Review	Policy Revised
March 2020	Annual Review	Policy Revised
March 2019	Annual Review	Policy Revised
March 2018	Annual Review	Policy Revised
March 2017	Annual Review	Policy Revised
April 2016	Annual Review	Policy Revised
August 2015	Interim Review	Policy Revised
May 2015	Annual Review	Policy Revised
February 2015	Annual Review	Policy Revised
February 2014	Annual Review	Policy Renewed

Date	Reason	Action
March 2013	Annual Review	Policy Renewed
March 2012	Annual Review	Policy Renewed
April 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.