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| **Policy Number** | **SUR712.028** |
| **Policy Effective Date** | **5/7/2026** |

# Artificial Intervertebral Disc – Cervical

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| Related Policies (if applicable) |
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| None |
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## Disclaimer

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

## Coverage

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

1. The individual is skeletally mature; AND
2. The disc will be used for single-level reconstruction following cervical discectomy within the C3-C7 region; AND
3. The individual has intractable cervical radiculopathy and/or myelopathy due to herniated disc or osteophyte formation; AND

a) The individual has failed at least six weeks of conservative nonoperative treatment, including an active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources and physical therapy; **or**
b) The individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment; AND

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

Two Level

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

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

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

7. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

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

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

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

## Policy Guidelines

None.

## Description

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

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 DDD include arm pain, weakness, and paresthesia associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and in severe cases, leads to weakness in the arms or legs, and numbness of the arms or hands. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, 95% of men and 70% of women have at least 1 degenerative change evident at the radiographic examination. It is estimated that approximately 5 million adults in the United States are

disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

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

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

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

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

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

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

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

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

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

## Rationale

**Cervical Artificial Intervertebral Disc**

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.

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 six weeks, or if symptoms progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical DDD and no contraindications for the procedure.

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

Systematic Reviews

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

Latka et al. (2019) conducted a meta-analysis of RCTs on cervical disc arthroplasty to evaluate the safety and long-term efficacy for reducing adjacent segment degeneration. (12) The authors included 20 publications from 13 RCTs (N=3,656) that reported 24- to 60-

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

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

Single-Level Cervical Disc Arthroplasty

The pivotal trials of 9 artificial cervical discs are described in Table 3 (Kineflex is no longer marketed). All of the trials utilized a non-inferiority design that compared cervical disc arthroplasty to the standard of ACDF with an FDA-mandated composite clinical outcome. The studied populations included patients with cervical radiculopathy or myelopathy, and the composite outcome included improvements in disability and neurologic symptoms with an absence of serious adverse events or secondary surgery at the index level. At the 24-month follow-up, all of the trials met non-inferiority and 4 of the 8 trials achieved superiority compared to ACDF (Table 4). Five of the trials (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM) have reported follow-up at 3 to 10 years. At 3 to 7 years, trial results are consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and/or lower cumulative reoperation rates. The pivotal study of the Bryan cervical disc has the longest follow-up at 10 years, with 100 patients per group planned for the post-approval study. Overall success was 81.3% for cervical disc arthroplasty compared to 66.3% for ACDF (p=.005). There was a statistically significant difference in the improvement of the Neck Disability Index between the groups (cervical disc arthroplasty: -38.3; ACDF: -31.1; p=.01), but there was no significant difference in arm pain or neurologic success between the cervical disc arthroplasty and ACDF groups. There was not a statistical difference in secondary surgeries, with 9.7% of cervical disc arthroplasty patients and 15.8% of ACDF patients requiring secondary surgery at either the index or adjacent level (p=.146).

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

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

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

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

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

| **Study** | **Participants** | **Interventions** | |
|---|---|---|---|
| | | *CDA* | *ACDF* |
| **Mummaneni et al. (2007) (16)** | Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy | Prestige ST (n=276) | n=265 |
| **Gornet et al. (2015) (17)** | Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy | Prestige LP (n=280) | n=265 historical controls from the Prestige ST trial |
| **Murray et al. (2009) (18)** | Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy unresponsive to nonoperative treatment for at least 6 weeks | ProDisc-C (n=103) | n=106 |
| **Heller et al. (2009) (19)** | Patients with radiculopathy or myelopathy from single-level cervical disc disease secondary to disc herniation that had not responded to at least 6 weeks of nonoperative management | Bryan disc (n=242) | n=223 |
| **Hisey et al. (2014) (20); FDA SSED (21)** | Patients with discogenic neck and/or arm pain with degeneration of the disc with | Mobi-C (n=169) | n=87 |

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|---|---|---|---|
| | radiculopathy or myeloradiculopathy from C3 to C7 at 1 level without prior cervical fusion | | |
| **Phillips et al. (2013) (22)** | 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) (23); FDA SSED (24)** | Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7 | Secure C (n=151) | n=140 |
| **Phillips et al. (2021); FDA SSED: M6-C (25, 26)** | Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7 | M6-C (n=160) | n=189 propensity-matched controls selected from concurrent ACDF patients and a previous IDE study |
| **FDA SSED: Simplify Cervical Disk (27)** | Patients with intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain or myelopathy at 1 level from C3 to C7 | Simplify (n=150) | n=133 historical controls from a previous IDE study from 2005-2007 |

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

**Table 4a. Summary of Pivotal RCT Results**

| **Outcomes** | **24 Months** | | | **36 to 48 Months** | | |
|---|---|---|---|---|---|---|
| | *CDA* | *ACDF* | *p* | *CDA* | *ACDF* | *p* |
| **Prestige ST** | **Mummaneni et al. (2007) (16)** | | | | | |
| n | 223 | 198 | | | | |
| Overall Success | 79.30% | 67.80% | .004 for superiority | | | |

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|---|---|---|---|---|---|---|
| NDI | mean improvement 36 points | mean improvement 33.6 points | Met non-inferiority | | | |
| Neurologic Success | 92.80% | 84.30% | 0.005 | | | |
| Secondary Surgeries | 1.10% | 3.40% | 0.0492 | | | |
| **Prestige LP** | **Gornet et al. (2015) (17)** | | | | | |
| n | 272 | 223 | | | | |
| Overall Success | mean difference, -0.111 (95% CrI, -0.196 to -0.026) | | Superiority | | | |
| NDI | | | | | | |
| Neurologic Success | 93.50% | 83.50% | Superiority | | | |
| Secondary Surgeries | 28.60% | 34% | | | | |
| **ProDisc C** | **Murray et al. (2009) (18)** | | | **Delamarter et al. (2010) (29)** | | |
| n | 101 | 101 | | 75 | 67 | |
| Overall Success | 72.3% | 68.3% | Met non-inferiority | | | |
| NDI | 21.4±20.2 points | 20.5±18.4 points | 1.0 | 20.3±18.6 | 21.2±14.9 | |
| Neurologic Success | 90.9% | 88% | 0.638 | 88.9% | 74.4% | 0.0665 |
| Secondary Surgeries | 1.8% | 8.5% | 0.003 | 2.9% | 11.3% | 0.0292 |
| **Bryan Cervical Disc** | **Heller et al. (2009) (19)** | | | **Sasso et al. (2011) (5)** | | |
| n | 230 (95%) | 194 (87%) | | 181 (75%) | 138 (62%) | |
| Overall Success | 82.6% | 72.7% | .010 for superiority | 85.1% | 72.5% | 0.004 |
| NDI Success | 86% | 78.9% | .035 for superiority | | | |
| Arm Pain Score | 19.1 | 21.5 | 0.194 | 16.6 | 22.4 | 0.028 |

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| Neurologic Success | 93.9% | 90.2% | Met non-inferiority | | | NS |
| Secondary Surgeries | | | | 7.8% | 8.6% | NS |
| **Mobi-C (1 level)** | **Hisey et al. (2014) (20) FDA SSED (21)** | | | **Hisey et al. (2015) (9)** | | |
| n | 164 | 81 | | | | |
| Overall Success | 73.7% | 65.3% | Met non-inferiority | 69.5% | 58.7% | Met non-inferiority |
| NDI | | | Met non-inferiority | | | |
| Secondary Surgeries | 1.2% | 6.2% | | 3% | 9.9% | <.05 |
| **PCM** | **Phillips et al. (2013) (22)** | | | | | |
| n | 189 | 151 | Per protocol | | | |
| Overall Success | 75.1% | 64.9% | Superiority | | | |
| NDI Success | 83.4% | 81.5% | 0.667 | | | |
| Neurologic Success | 94.7% | 89.5% | 0.100 | | | |
| Secondary Surgeries | 5.2% | 5.4% | | | | |
| **Secure C** | **Vacarro et al. (2013) (23) FDA SSED (24)** | | | | | |
| n | 87% | | | | | |
| Overall Success | 83.8% | 73.2% | Met non-inferiority | | | |
| NDI Success | 89.2% | 84.5% | Met non-inferiority | | | |
| Neurologic Success | 96.0% | 94.9% | Met non-inferiority | | | |
| Secondary Surgeries | 2.5% | 9.7% | | | | |
| **M6-C** | **Phillips et al. (2021) (26) FDA SSED: M6-C (25)** | | | | | |
| n | 160 | 189 | | | | |

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|---|---|---|---|---|---|---|
| Overall Success | 86.8% | 79.3% | Met non-inferiority | | | |
| NDI Success | 90.5% | 85.1% | | | | |
| Neurologic Success | 93.3% | 87.2% | | | | |
| Secondary Surgeries | 1.9% | 4.8% | | | | |
| Pain Medication | 14% | 38.2% | <.001 | | | |
| **Simplify Cervical Disc** | **FDA SSED: Simplify Cervical Disc (2020) (27)** | | | | | |
| n | 150 | 133 | | | | |
| Overall Success | 93% | 73.6% | <.001 | | | |
| NDI Success | 97.9% | 88% | 0.009 | | | |
| Neurologic Success | 99.3% | 94.7% | | | | |
| Secondary Surgeries | 2.9% | 2.9% | 0.979 | | | |
| Pain Medication | 10.8% | 36.8% | | | | |

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

**Table 4b. Summary of Pivotal RCT Results**

| **Outcomes** | **60 Months** | | | **84 Months** | | |
|---|---|---|---|---|---|---|
| | *CDA* | *ACDF* | *p* | *CDA* | *ACDF* | *p* |
| **Prestige ST** | | | | **Burkus et al. (2014) (28)** | | |
| n | | | | 212 | 183 | |
| Overall Success | | | | 72.6% | 60.0% | 0.008 |
| NDI | | | | -37.5 | -31.9 | |
| Neurologic Success | | | | 88.2% | 79.7% | 0.011 |
| Secondary Surgeries | | | | 4.8% | 13.7% | |

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| **ProDisc C** | **Zigler et al. (2013) (30) Delamarter et al. (2013) (31)** | | | **Janssen et al. (2015) (10)** | | |
| n | 72 | 61 | | 152/209 (72.7%) | | |
| Overall Success | | | | | | |
| NDI | 50% to 60% | | NS | | | |
| Neurologic Success | 90.3% | 91.7% | NS | 88% | 89% | NS |
| Secondary Surgeries | 2.9% | 14.5% | 0.0079 | 7% | 18% | 0.009 |
| **Mobi-C (1 level)** | **Hisey et al. (2016) (33)** | | | **Radcliff et al. (2017) (34)** | | |
| n | 85.5% | 78.9% | | | | |
| Overall Success | 61.9% | 52.2% | Met non-inferiority | 55.2% | 50.0% | Met non-inferiority |
| NDI | | | | | | Met non-inferiority |
| Secondary Surgeries | 4.9% | 17.3% | <.01 | 3% | 12.3% | <.05 |
| **PCM** | **Phillips et al. (2015) (6)** | | | | | |
| n | 163 (74.8%) | 130 (70.3%) | | | | |
| Overall Success | | | | | | |
| NDI Success | 85% | 74.2% | 0.026 | | | |
| Neurologic Success | 92.4% | 87.5% | 0.229 | | | |
| Secondary Surgeries | 8.1% | 12.0% | NS | | | |

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

**Table 4c. Summary of Pivotal RCT Results**

| **Outcomes** | **120 Months** | | |
|---|---|---|---|
| | *CDA* | *ACDF* | *p* |
| **Bryan Cervical Disc** | **Lavelle et al. (2018) (32)** | | |

| | | | |
|---|---|---|---|
| n | 128 | 104 | |
| Overall Success | 81.3% | 66.3% | 0.005 |
| NDI Success | -38.3 | -31.1 | 0.01 |
| Arm Pain Score | -58.9 | -51.6 | 0.6 |
| Neurologic Success | 92.1% | 95.1% | 0.82 |
| Secondary Surgeries | 9.7% | 15.8% | 0.146 |

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

Most available products have efficacy and safety results published up to 10 years post-operative. The group originally studying the Bryan Cervical Disc recently published 20-year follow-up data. (35, 36) Forty-seven patients with single-level cervical radiculopathy were randomized to either Bryan cervical disc or anterior cervical discectomy and fusion for an FDA Investigational Device Exemption trial. At 20-years follow-up, both groups showed significantly better Neck Disability Index scores, and Visual Analog Scale arm and neck pain scores compared to preoperative scores. There was no significant difference between cervical disc arthroplasty and discectomy and fusion groups in Neck Disability Index scores or Visual Analog Scale pain scores. Reoperations since the first procedure were reported in 41.7% of patients who initially underwent discectomy and fusion and 10% of cervical disc arthroplasty patients (p=.039). These data continue to demonstrate the long-term benefits with cervical disc arthroplasty.

*Subsection Summary: Single-Level Cervical Disc Arthroplasty*

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

Two-Level Cervical Disc Arthroplasty

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

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

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

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

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

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

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

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

| Study | Primary Outcome Measure | Participants | Interventions | |
|---|---|---|---|---|
| | | | CDA | ACDF |
| Coric et al. (2022) (37) | Improvement of NDI ≥15 | Patients with 2-level, symptomatic | Simplify Cervical Disc (n=182) | n=170 historical controls from a |

| | | | | |
|---|---|---|---|---|
| | pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures | cervical disc disease with medically refractory radiculopathy and/or myelopathy | | previous IDE study from the mid-2000s |
| FDA SSED (2016) (41) | Overall Success[a] | Patients with 2-level, symptomatic cervical disc disease with medically refractory radiculopathy and/or myelopathy | Prestige LP at 2 contiguous levels (n=209) | n=188 |
| Davis et al. (2013) (39) | Overall Success[a] | Patients with 2-level, symptomatic cervical disc disease with medically refractory radiculopathy and/or myelopathy | Mobi-C at 2 contiguous levels (n=225) | n=105 |

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; IDE: investigational device exemption; FDA SSED: U.S. Food and Drug Administration Summary of Safety and Effectiveness; NDI: neck disability index; RCT: randomized controlled trial.
[a] Overall success was achieved if the postoperative score improvement in the NDI was ≥ 15 points, neurological status did not worsen, and no serious implant/surgical procedure–associated adverse event, or second surgery, which was deemed "failure," occurred.

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

| **Outcomes** | **24 Months** | | | **48 Months** | | |
|---|---|---|---|---|---|---|
| | **CDA** | **ACDF** | **p** | **CDA** | **ACDF** | **p** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Simplify Cervical Disc** | **Coric et al. (2022) (37)** | | | | | |
| n (%) | 182 (100%) | 170 (100%) | | | | |
| Overall success % | 86.7% | 77.1% | <.05 | | | |
| NDI Success n/N (%) | 156/168 (92.3%) | 106/127 (85.5%) | <.10 | | | |
| Neurologic Success | 168/168 (100%) | 125/128 (97.7%) | NA | | | |
| No additional surgery | 177/181 (97.8%) | 152/166 (91.6%) | <.10 | | | |
| No SAEs due to implant or procedure | 176/182 (96.3%) | 158/170 (94.7%) | >.50 | | | |
| **Prestige LP** | **FDA SSED (41)** | | | | | |
| n (%) | 199 (95) | 160 (86) | | 185 (89) | 149 (80) | |
| Overall Success n/N (%) | 162/199 (81.4%) | 111/160 (69.4%) | Superiority | 151/185 (81.6%) | 105/149 (70.5%) | |
| NDI Success | 87.9% | 79.2% | Superiority | 89.7% | 82.3% | Superiority |
| Neurologic Success | 91.5% | 86.2% | NS | 90.3% | 83.8% | Superiority |
| Secondary Surgeries | 2.4% | 3.2% | | | | |
| **Mobi-C** | **Davis et al. (2013) (39)** | | | **Davis et al. (2015) (8)** | | |
| n | 225 | 105 | | 89.0% | 81.2% | |
| Overall Success | 69.7% | 37.4% | <.0001 | 66.0% | 36.0% | |
| NDI Success | 78.2% | 61.8% | <.05 | 79.3% | 53.4% | <0.001 |
| Secondary Surgeries | 3.1% | 11.4% | | 4.0% | 15.2% | |

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

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

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

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

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

| **Outcomes** | **120 Months** | | |
|---|---|---|---|
| | **CDA** | **ACDF** | **P** |
| **Prestige LP** | **Gornet et al. (2019)[a] (42)** | | |
| n (%) | 148 (86%[a]) | 118 (85%) | |
| Overall Success n/N (%) | 80.4% | 62.2% | Superiority |

| | | | |
|---|---|---|---|
| NDI Success | 88.4% | 76.5% | Superiority |
| Neurologic Success | 92.6% | 86.1% | Superiority |
| Secondary Surgeries | 13.7% | 35.5% | Significant |

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

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

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

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

The first artificial cervical disc approved for 2 levels (Mobi-C) was found to be noninferior to ACDF in the investigational device exemption trial. Superiority to ACDF was achieved for NDI scores, NDI success rates, and the overall success composite outcome. Reoperation rates were significantly lower in the Mobi-C group. At 5 and 7 years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Although a third of patients who

received the Mobi-C had clinically significant heterotopic ossification, adjacent-segment degeneration with Mobi-C was found in a lower percentage of patients than in ACDF patients.

Registry Data

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

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

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

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

Adverse Events

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

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

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

**Summary of Evidence - Cervical Artificial Intervertebral Disc**

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, the evidence includes randomized controlled trials 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 for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs and a non-randomized

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

**Practice Guidelines and Position Statements - Cervical Disc Arthroplasty**

International Society for the Advancement of Spine Surgery

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

North American Spine Society

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

1. Radiculopathy related to nerve root compression from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3 to C7 in the following scenarios:
    a. Persistent symptoms despite at least 6 weeks of nonoperative management.
    b. Progressive or functionally limiting weakness correlating with the compressed nerve root.
    c. Inability to perform normal work duties or necessary activities of daily living because of severity of symptoms, despite nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-C7.
3. Use can be considered for radiculopathy or myeloradiculopathy due to multilevel degenerative disease (either herniated disc or spondylotic osteophyte) as part of a hybrid construct, i.e., in concert with an anterior cervical discectomy and fusion (ACDF)

for cervical levels that do not satisfy the stringent criteria for TDA. There remain strict indications as to whether an arthroplasty is indicated at a given level… Indication for ACDF is addressed in a separate coverage recommendation.

There is not significant evidence at this time to support its use for 3 or more levels, nor is there evidence for its use for isolated axial neck pain. Neck pain, in addition to radiculopathy/ myeloradiculopathy, is not an exclusionary criterion. There is early evidence for use in treatment of adjacent segment disease following an index fusion."

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

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

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

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

**Table 7. Summary of Key Trials**

| NCT Number | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT05691231[a] | Long-Term Assessment of the Safety and Performance of the NuVasive Simplify Disc at Two Levels | 158 | May 2029 |
| NCT05740176[a] | A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing the Safety and Effectiveness of the Synergy Disc to Anterior Cervical Discectomy and Fusion in Patients With Two-Level Symptomatic Cervical Degenerative Disc Disease (DDD) | 200 | Dec. 2026 |
| NCT05489822[a] | Sponsor-initiated, Prospective, Single-center, Non-interventional Clinical Observational Study to Evaluate the | 20 | Apr. 2026 |

| | | | |
|---|---|---|---|
| | VERTICALE® Cervical System in Spine Surgery According to Its Intended Use. | | |
| NCT04520776[a] | A Multicenter, Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of the BAGUERA®C Cervical Disc Prosthesis to the Mobi-C® Cervical Disc for the Treatment of Patients With Symptomatic Cervical Disc Disease at a Single Level | 284 | Feb. 2026 |
| NCT04564885[a] | A Multicenter, Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of the BAGUERA®C Cervical Disc Prosthesis to the Mobi-C® Cervical Disc for the Treatment of Patients With Symptomatic Cervical Disc Disease at Two Contiguous Levels | 300 | Apr. 2030 |
| NCT03367052 | Clinical and Radiological Outcomes of a 7-year Follow-up, Multi-center, Prospective, Randomized, Controlled Trial: Two-level Cervical ProDisc-C Vivo Versus Hybrid Construct. | 542 | Dec. 2025 |
| NCT04469231[a] | A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing The Safety And Effectiveness Of The Synergy Disc To Anterior Cervical Discectomy And Fusion In Patients With One-Level Symptomatic Cervical Degenerative Disc Disease | 175 | Jan. 2026 |
| NCT03123549[a] | Clinical Study Protocol for the Investigation Of The Two Level Simplify® Cervical Artificial Disc | 182 | Mar. 2022 |
| NCT02667067[a] | Clinical Study Protocol for the Investigation Of The Simplify® Cervical Artificial Disc | 150 | July 2021 |

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

## Coding

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

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

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

| | |
|---|---|
| **CPT Codes** | 22856, 22858, 22861, 22864, 0095T, 0098T |
| **HCPCS Codes** | None |

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| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 5/7/2026 | New medical document. Insertion of a single level cervical artificial intervertebral disc, using a disc approved by the U.S. Food and Drug Administration, may be considered medically necessary when all the criteria in Coverage are met. Simultaneous cervical disc arthroplasty at a second contiguous level may be considered medically necessary if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (e.g., Mobi-C®, Prestige LP™). Subsequent cervical artificial intervertebral disc arthroplasty at an adjacent level using a disc specifically approved for two levels by the U.S. FDA, may be considered medically necessary for the treatment of symptomatic degenerative disc disease when all the criteria in Coverage are met. Artificial intervertebral cervical disc implantation is considered experimental, investigational and/or unproven for all other indications. |