Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Current Policy Effective Date: 1/1/25

Title: Artificial Intervertebral Disc: Cervical Spine

Description/Background

CERVICAL DEGENERATIVE DISC DISEASE

Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesia associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis or instability that compress the spinal cord result in myelopathy, which is manifested by subtle changes in gait or balance, weakness in the arms or legs, and numbness of the arms or hands, in severe cases. 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, some 95% of men and 70% of women have at least one degenerative change evident at radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Treatment

Anterior cervical discectomy and fusion (ACDF) is currently 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 neurological symptoms may be expected in more than 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and emplacement of either 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. The choice of bone material for interbody fusion in ACDF has important clinical implications. Allograft bone has several drawbacks, including a small (albeit, unproven) risk of infectious disease transmission; possible immunological reaction to the allograft, and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the

harvest site, generally the iliac crest. These morbidities include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies demonstrate similar rates of postoperative fusion (90–100%) and satisfactory outcomes for single-level, anterior-plated ACDF, using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material. Biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

Cervical disc arthroplasty (CDA) is an alternative to ACDF for patients with symptomatic cervical DDD. In CDA, an artificial disc device is secured in the prepared intervertebral space rather than bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomical disk 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 (DDD) above or below a fusion site has been the major rationale driving device development and use. Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in CDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis.

Medical Policy Statement

The safety and effectiveness of the insertion of cervical artificial intervertebral discs have been established. It is a useful therapeutic option for individuals meeting patient selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions:

A. Cervical disc replacement in a skeletally mature individual with an **FDA approved** device is considered medically necessary for **any** of the following indications:
   1. One or two contiguous level disc replacement from C3-C7 for **either** of the following:
      a. Symptomatic radiculopathy secondary to spondylotic osteophyte or herniated disc confirmed by appropriate imaging, regardless of presence of neck pain, which has failed to respond to at least 6 weeks of non-operative treatment or is clinically worsening.
      b. Symptomatic myeloradiculopathy or myelopathy secondary to spondylotic osteophyte or herniated disc confirmed by appropriate imaging, regardless of presence of neck pain, which has failed to respond to at least 6 weeks of non-operative treatment (or is clinically worsening).
   2. One level disc replacement from C3-C7 for symptomatic radiculopathy secondary to spondylotic osteophyte or herniated disc confirmed by appropriate imaging at one level in a patient with a previous one level cervical fusion at another level.

B. Revision disc arthroplasty is considered medically necessary for **any** of the following:

1. Persistent symptomatic central or foraminal stenosis
2. Imaging evidence of implant migration, subsidence, endplate failure, loosening, wear
3. Instability
4. Device failure
5. Loss of motion
6. Imaging evidence of implant malposition
7. Infection*

*The inclusion criteria for infection are for revision surgeries; if a previous disc arthroplasty becomes infected, a revision surgery would be needed.

****NOTE: Removal of an implanted cervical disc device may be considered established for patients who experience side effects or complications of the device of such severity as to disrupt the patient's normal quality of life.**

Exclusions:

- Symptomatic disease affecting three or more levels;
- Previous cervical fusion at two or more levels, or planned two-level disc replacement with any prior or planned fused cervical levels;
- Active infection at the surgical site or systemic infection;
- Presence of osteopenia or osteoporosis (T-score of less than -1.0);
- Instability indicated by **any** of the following:
  - Greater than 3 mm translation between lateral flexion-extension views at the symptomatic level;
  - 11° angular difference between lateral flexion-extension views at the symptomatic level;
- Known hypersensitivity to implant materials;
- Advanced spondylosis meeting **all** the following criteria:
  - Disc height loss of 50% or more;
  - Motion at the symptomatic site is absent on flexion-extension views;
  - Presence of bridging osteophytes;
- Radiographic evidence of moderate or severe and symptomatic (e.g., pain with extension of joints that is relieved temporarily with injections) facet joint degeneration or disease;
- Ankylosing spondylitis, inflammatory arthritis, ossification of posterior longitudinal ligament, or active malignancy in the cervical spine;
- Anatomical deformity due to previous fracture.

CPT/HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

22856	22861	22864	22858	0095T

*Other codes (investigational, not medically necessary, etc.):***

0098T	22899

Note: The following procedures may be covered by some contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

0098T

Regulatory Status:

The Prestige® ST Cervical Disc (Medtronic) received U.S. Food and Drug Administration (FDA) premarket application (PMA) approval as a Class III device on July 16, 2007. The Prestige® ST Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy. The device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least one 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 neurological deficit) and radiographic studies (e.g., computed tomography, magnetic resonance imaging, x-rays): herniated disc and/or osteophyte formation. The FDA has required 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 of the disc to characterize adverse events more fully in a broader patient population.

The Prestige® LP artificial cervical disc was approved by FDA in 2014. The Prestige® LP differs from the original Prestige cervical disc in terms of material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has two rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige® LP was approved by FDA for two adjacent levels. A post approval study will follow the IDE patients who received the Prestige LP at two contiguous levels for 10 years. This includes subsequent surgeries, heterotopic ossification, device malfunction, and other serious device-related complications.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in December 2007. As with the Prestige® ST Cervical Disc, the FDA approval of ProDisc-C® is conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial (discussed in Rationale section), 7-year follow-up on 99 continued access subjects, and a 5-year enhanced surveillance study to characterize adverse events when the device is used more fully under general conditions of use. The post-approval study reports are to be delivered to the FDA annually.

The Bryan® Cervical Disc (Medtronic Sofamor Danek) consists of 2 titanium-alloy shells encasing a polyurethane nucleus, and has been available outside of the United States since 2002. The Bryan® Cervical Disc was approved by the FDA in May 2009 for treatment using an anterior approach of single-level cervical DDD 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. Patients receiving the Bryan® cervical disc should have failed at least six weeks of non-operative treatment prior to

implantation of the Bryan cervical disc. As a condition for approval of this device, the FDA required the manufacturer to extend its follow-up of enrolled subjects to 10 years after surgery. The study will involve the investigational and control patients from the pivotal investigational device exemption (IDE) study arm, as well as the patients who received the device as part of the continued access study arm. In addition, the manufacturer must perform a 5-year enhanced surveillance study of the BRYAN® Cervical Disc to characterize adverse events when the device is used more fully in a broader patient population.

More recently, continued FDA approval requires 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 adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, or other serious device-related complications, and analysis of all explanted discs.

The following have received FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- Secure®-C (Globus Medical) was approved in 2012 (P100003). The Secure®-C is a 3-piece semi-constrained device with 2 metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is 3 piece semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for 1 (P110002) or 2 level (P110009) disc replacement.

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®	Centinal Spine	Two 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 two metal (cobalt-chromium alloy) endplates and a polyethylene insert.	P100012	2012
SECURE®-C	Globus Medical	Semi-constrained device with two 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: US Food and Drug administration; MRI: magnetic resonance imaging; PEEK polyethertherketone.

Rationale

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, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest are individuals with symptomatic cervical DDD.

Interventions

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

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

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

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

Review of Evidence

Systematic Reviews
In 2016, Hu et al published a meta-analysis of eight randomized controlled trials (RCTs; total N=2368 patients) reporting mid-term outcomes (at least 48 months) of artificial intervertebral disc arthroplasty (CDA) compared to 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 studies were rated as low risk of bias, despite lack of blinding. Only two studies reported on overall success[4,5] and three reported on Neck Disability Index (NDI) success.[4-6] Six studies reported neurologic success data with pooled data that favored the CDA group to a small degree (relative risk [RR], 1.04; 95% confidence interval [CI], 1.01 to 1.08; p=0.01). Pooled data showed a significant benefit of CDA 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), as well as at the adjacent level (5 studies[4,7,9-11], RR=0.42; 95% CI, 0.26 to 0.70; p<0.002). These studies are described in detail next.

Latka et al (2019) conducted a meta-analysis of RCTs on cervical disc arthroplasty to evaluate safety and long-term efficacy for reducing adjacent segment degeneration.[12] They included 20

publications from 13 RCTS (total of 3,656 patients) 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% confidence interval [-3.72; -0.87], P=0.002) along with the frequency of dysphagia/dysphonia (odds ratio [OR] =0.69, 95% confidence interval CI [0.49; 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% confidence interval [0.21; 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 (sample size ranged from 79 to 545 participants per study) 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.[15,] Follow-up ranged from 1 to 10 years and most studies included single-level cervical disc arthroplasty.

Single Level CDA

The pivotal trials of 9 artificial cervical discs are described in Table 2 (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 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 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 (Table 3). 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=0.005) There was a statistically significant difference in improvement of the neck disability index between the groups (cervical disc arthroplasty: -38.3, anterior cervical discectomy and fusion: -31.1, p=0.01), 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 a secondary surgery at either the index or adjacent level (p=0.146).

Table 2. Summary of Pivotal Study Characteristics of Cervical Artificial Intervertebral Discs

Study; Trial	Device	Design	Primary Outcome Measure	Participants	Interventions	
					CDA	ACDF
Mummaneni et al (2007)	Prestige ST	Multi-center non-inferiority RCT	Three 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=276)	n=265 in FDA SSED
Gornet et al (2015)	Prestige LP	Multi-center 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 andother 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 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 notresponded 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 from C3 toC7 at 1 level without prior cervical fusion	Mobi-C (n=169)	n=87
Phillips et al (2013)	Porous Coated Motion (PCM)	Multicenter non-inferiority RCT	Composite measure of overall success measured at 24-weeks post-operatively, defined	Patients with single-level symptomatic cervical spondylosis with radiculopathy and/or myelopathy	PCM (n=224)	n=192

			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	unresponsive to nonoperative treatment		
Vacarro et al	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 $\geq$ 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 one level from C3 – C7	M6-C (n=160)	189 propensity matched controls selected from concurrent ACDF patients and a previous IDE study
FDA SSED: Simplify Cervical Disk	Simplify Cervical Disc	Multicenter non-inferiority RCT	Improvement of NDI $\geq$ 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 one 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; NDI: neck disability index; RCT: randomized controlled trial.

Table 3. Summary of Pivotal RCT Results

Outcomes	**24 Months**			**36-48 Months**			**60 Months**			**84 Months**			**120 Months**		
	CDA	**ACDF**	**p**	**CDA**	**ACDF**	**p**	**CDA**	**ACDF**	**p**	**CDA**	**ACDF**		**CDA**	**ACDF**	**p**
Prestige ST	Mummaneni et al (2007)									Burkus et al (2014)					
N										212	183				
Overall Success			Superiority							72.6 %	60.0%	0.008			

NDI	81%	81%	Met non-inferiority							-37.5	-31.9		
Neurologic Success										88.2 %	79.7%	0.011	
Secondary Surgeries										4.8%	13.7%		
Prestige LP	Gornet et al (2015)												
N	272	223[a]											
Overall Success			Superiority										
Neurologic Success	93.5 %	83.5%	Superiority										
Secondary Surgeries													
ProDisc C	Murray et al (2009)			Delamarter et al (2010)			Zigler et al (2013) Delamarter et al (2013)			Janssen et al (2015)			
N	85%			75	67					152/209 (72.7%)			
Overall Success	72%	68%	Met non-inferiority										
NDI							50-60%		NS				
Neurologic Success										88%	89%	NS	
Secondary Surgeries							2.9%	14.5%		7%	18%	0.009	
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%	Superiority	85.1%	72.5%	0.004						81.3 %	66.3 %	0.005
NDI												-38.3	-31.1	0.01
Arm Pain				16.6	22.4	0.028						-58.9	-51.6	0.60
Neurologic Success						NS						92.1 %	95.1 %	0.82
Secondary Surgeries				7.8%	8.6%	NS						9.7%	15.8 %	0.146
Mobi-C (1 level)	Hisey et al (2014)			Hisey et al (2015)			Hisey et al (2016)			Radcliff et al (2017			
n	93%						85.5%	78.9%					
Overall Success	73.7 %	65.3%	Met non-inferiority				61.9%	52.2%	Met non inferiority	55.2%	50%	Met non-inferiority	
NDI			Met non-inferiority							3%	12.3%	<0.05	
Neurologic Success													
Secondary Surgeries	1.2%	6.2%					4.9%	17.3%	<0.01				
PCM	Phillips et al (2013)						Phillips et al (2015)[9]						
N	189	151	Per protocol				163 74.8%	130 70.3%					
Overall Success	75.1 %	64.9%	Superiority										
Arm Pain									NS				
Neurologic Success									NS				
Secondary Surgeries							8.1%	12.0%	NS				
Secure C	Vacarro et al (2013)												
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	2.5%	9.7%											

Surgeries							
M6-C	FDA SSED						
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%					
Simplify Cervical Disc							
n	150	133					
Overall Success	93%	73.6%	<0.001				
NDI Success	98%	88%	0.009				
Neurologic Success	99%	94.7%					
Secondary Surgeries	2.9%	2.9%	0.979				
Pain Med	10.8 %	36.8%					

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 discarthroplasty 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 noninferiority 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, 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 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 4 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 5).[37]

In 2016, the Prestige LP™ received FDA approval for implantation at 2 levels.[38] Overall success was achieved in 81.4% of Prestige LP patients and 69.4% of anterior cervical discectomy and fusion controls, meeting both noninferiority and superiority margin, with a posterior probability of near 100% and 99.3%, respectively (Table 5). Table 5 provides data on patients 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).[8,34,39,40] Clinically relevant heterotopic ossification (grade III or IV) was observed in 29.7% of the Mobi-C patients but the Mobi-C patients had significantly less adjacent-segment degeneration (50.7%) than anterior cervical discectomy and fusion patients (90.5%; p<0.001).

Table 4. Summary of Pivotal RCT Characteristics of Cervical Disc Arthroplasty at Two Continuous Levels

Study; Trial	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 refractory radiculopathy and/or myelopathy	Simplify Cervical Disc (n=182)	n=170 historical controls from a previous IDE study from the mid-2000s
FDA SSED (2016)	Prestige LP	Multicenter Noninferiority Trial		Overall success[a]		Prestige LP at 2 contiguous levels (n=299)	n=188
Davis et al (2013)	Mobi-C			Overall Success		Mobi-C at 2 contiguous level (n=209)	n=188

CDA: artificial intervertebral disc; ACDF: anterior cervical discectomy and fusion; 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 5. 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)[35]**														
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												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%	Superiority
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%	75%				
Overall Success				66%	36%		61%	31%	<0.001	60%	35%	Superiority			
NDI Success				79.3%	53.4%	<0.001			significant	79%	59%	<0.05			
Neurologic Success															
Arm & Neck Pain									Not significant	Not significant					
Secondary Surgeries				4.0%	15.2%		7.1%	21%	<0.001	4.4%	16%	<0.05			

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA: SSED: US Food and Drug Administration Summary of Safety and Effectiveness; NS: not significantly different

[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 (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 (2-4 levels, n=56) cervical disc arthroplasty with the Mobi-C device in a prospective multicenter study from Europe.[44] 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 two-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 two years has been maintained at 10 years. Secondary outcome measures showed superiority of CDA over ACDF.

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.

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 anterior cervical discectomy and fusion. The mean group differences on a 10 point scale for both pain measures was 0.6 points in post-operative 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=NS), 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 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.[46] 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% confidence interval -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 CDA, but there is no evidence of a large impact on clinical outcomes. A 2012 meta-analysis of heterotopic ossification (McAfee grade 3-4) after CDA included 8 studies (total N=617 patients).[47] The pooled prevalence of any heterotopic ossification was 58.2% at 24 months after CDA 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 one-level and 225 two-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.

SUMMARY OF EVIDENCE

For individuals who have cervical radicular pain or myelopathy who receive CDA of the cervical spine, 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 noninferiority criteria as measured by the Neck Disability Index and overall success composite outcome. Mid-term outcomes have been reported on five devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [Porous Coated Motion]). At 4-5 years, the trial results are consistent with continued noninferiority of CDA for clinical outcomes and lower cumulative reoperation rates. Seven -year follow-up of the Prestige and ProDisc-C pivotal trials continues to show lower secondary surgery rates, although this is not a consistent finding in other reports. 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 ACDF. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level CDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for Neck Disability Index (NDI) scores, NDI success rates, reoperation rates, and overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level CDA for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared to 2-level ACDF patients. FDA approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at 2 years. The increase in overall success rates at 2 years has been maintained for those patients who have reached the 5- and 7-year follow-ups. Based on this evidence, it can be concluded that 2-level CDA with either 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 a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05691231[a]	Long-Term Assessment of the Safety and Performance of the NuVasive Simplify Disc at Two Levels	158	May 2029
NCT05740176[a]	The Synergy Disc for the Treatment of 2 Level Cervical Degenerative Disc Disease Compared With Cervical Fusion Surgery	200	Dec 2025
NCT05489822[a]	PMCF Study to Evaluate the VERTICALE® Cervical System in Spine Surgery According to Its Intended Use.	20	Apr 2026
NCT02403453[a]	RHINE™ cervical disc clinical study	166	Dec 2028
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	270	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	Oct 2025
NCT03367052	Clinical and Radiological Outcomes of a 7-year Follow-up, Multi-center, Prospective, Randomized, Controlled Trial: Two-level Cervical ProDisc-C Vivo Versus Hybrid Construct.	542	Dec 2025
NCT04469231[a]	A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing The Safety And Effectiveness Of The Synergy Disc To Anterior Cervical Discectomy And Fusion In Patients With One-Level Symptomatic Cervical Degenerative Disc Disease (DDD)	190	Jan 2026
Unpublished			
NCT03123549[a]	Clinical Study Protocol for the Investigation Of The Two	200	Aug 2021

	Level Simplify® Cervical Artificial Disc		

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial

SUPPLEMENTAL INFORMATION

Clinical Input Received 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 three physician specialty societies and two academic medical centers while this policy was under review for July 2015. There was agreement that cervical disc replacement may be medically necessary under specified conditions. Input agreed that combined use of an artificial disc and fusion over two levels is investigational. Input was mixed regarding the medical necessity of 2-level artificial intervertebral disc arthroplasty (CDA).

2009 Input

In response to requests, input was received from two physician specialty societies and two academic medical centers while this policy was under review for March 2009. The clinical input obtained disagreed with the conclusion that CDA is investigational.

PRACTICE GUIDELINES AND POSITION STATEMENTS

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."

National Institute for Health and Care Excellence (NICE)

The U.K.'s National Institute for Health and Clinical Excellence (NICE) issued guidance on the artificial cervical disc in 2010.[50] NICE concluded that:

> "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. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
>
> 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."

Government Regulations

National:

There is no national coverage determination for artificial cervical discs. A search of the online Medicare National Database (http://www.cms.gov/mcd/search.asp?from2=search.asp&) identified a national coverage decision on artificial intervertebral discs for the lumbar spine only.[43]

Codes 22856, 22858, 22861 and 22864 have a fee schedule.

Local:

There is no local WPS coverage determination for artificial cervical discs.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Artificial Intervertebral Disc: Lumbar

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/12	12/13/11	1/31/12	Joint policy established; topic separated from former combined policy, “Artificial Intervertebral Discs.”
5/1/13	4/24/13	4/24/13	Policy status changed from experimental/investigational to established for patients meeting patient selection guidelines.
9/1/14	6/20/14	6/23/14	Policy status unchanged. Rationale and references updated.
11/1/15	8/18/15	9/14/15	Routine maintenance. Updated references and rationale. Deleted 0092T and added codes 0375T 22858 to policy. Policy status unchanged.
1/1/17	10/11/16	10/11/16	Routine policy maintenance. Inclusionary and Exclusionary changes made to mirror BCBSA. Rationale and references updated.
1/1/18	10/19/17	10/19/17	Routine policy maintenance. No change in policy status.
1/1/19	10/16/18	10/16/18	Routine policy maintenance. No change in policy status.
1/1/20	10/15/19		Routine policy maintenance. No change in policy status.
1/1/21	10/20/20		Rationale changed to tabular format. Change in terminology from “artificial Intervertebral Disc Arthroplasty of the Cervical Spine” to “cervical disc arthroplasty.” Code 0375T deleted, replaced with 22899.
1/1/22	10/19/21		Updated rationale, added references 43-45. No change in policy status.
1/1/23	10/18/22		Reorganized references, routine policy maintenance, no change in policy status.
1/1/24	10/17/23		Updated rationale, added references 13, 15 and 35. No change in policy status. Vendor managed: Turning point. (ds).
1/1/25	10/15/24		Inclusion/exclusion section reworded, some bullets added, one removed. Added Note: addressing removal of implanted cervical disc

			covered when there are complications. Code 0095T moved to established. Code 0092T removed from benefit page due to code deletion. Vendor managed: Turning Point. (ds)

Next Review Date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ARTIFICIAL INTERVERTEBRAL DISC: CERVICAL SPINE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply. All codes are payable except 0098T
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.