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MEDICAL POLICY – 7.01.108

Artificial Intervertebral Disc: Cervical Spine

BCBSA Ref. Policy:	7.01.108
Effective Date:	July 1, 2024
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RELATED MEDICAL POLICIES:

7.01.87	Artificial Intervertebral Disc: Lumbar Spine
7.01.560	Cervical Spine Surgeries: Discectomy, Laminectomy, and Fusion in Adults
11.01.524	Site of Service: Select Surgical Procedures

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The bones that make up the neck are called cervical vertebrae. Between each of the vertebra is a disc, which acts as a shock absorber and prevents the bones from rubbing together. As a person ages, these discs may break down and become thinner because they lose water and the gel-like substance that's inside each disc. This is known as degenerative disc disease. Studies show that most adults over the age of forty have some degenerative disc disease when x-rays are done. However, for many people no treatment is needed because the neck continues to move normally without pain. In some people who have pain and severe degenerative disc disease is present, treatment may be helpful. An artificial disc is one type of treatment. The artificial disc replaces the damaged natural disc, with the goal being to keep the normal space between the bones and preserve the motion of the neck. This treatment may be considered when there is significant pain that has not responded to other types of treatments. This policy describes when an artificial disc replacement in the neck may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.**

Inpatient hospital/medical center	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):**
	• Anesthesia Risk
	  ○ ASA classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (>3 hours)
	• Cardiovascular Risk
	  ○ Uncompensated chronic heart failure (**NYHA class** III or IV)
	  ○ Recent history of myocardial infarction (MI) (<3 months)
	  ○ Poorly controlled, resistant hypertension*
	  ○ Recent history of cerebrovascular accident (< 3 months)

Site of Service for Elective Surgical Procedures	Medical Necessity
	○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days) ○ Symptomatic cardiac arrhythmia despite medication ○ Significant valvular heart disease • Liver Risk ○ Advance liver disease (MELD Score > 8)** • Pulmonary Risk ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) ○ Poorly controlled asthma (FEV1 <80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** • Renal Risk ○ End stage renal disease (on dialysis) • Other ○ Morbid obesity (BMI ≥ 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion]) ○ Anticipated need for transfusion(s) **Note:** * 3 or more drugs to control blood pressure ** **https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease** *** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
Inpatient hospital/medical center	**This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.**

Surgery	Medical Necessity

Artificial cervical intervertebral disc implantation	**Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met:**
	• The device is approved by the US Food and Drug Administration (FDA): (Examples, list may not be all inclusive)
	  ○ For <u>one level</u>:
	  ▪ Bryan Cervical Disc (Medtronic)
	  ▪ M6-C Artificial Cervical Disc (Orthofix)
	  ▪ Mobi-C Cervical Disc (Zimmer Biomet)
	  ▪ PCM (porous-coated motion) Cervical Disc (NuVasive)
	  ▪ PrestigeLP Cervical Disc (Medtronic)
	  ▪ Prestige Cervical Disc System (Medtronic)
	  ▪ ProDisc-C Total Disc Replacement (Centinel Spine)
	  ▪ SECURE-C Cervical Artificial Disc (Globus Medical)
	  ▪ Simplify Cervical Artificial Disc (NuVasive)
	  ○ For <u>two contiguous levels:</u>
	  ▪ Mobi-C Cervical Disc (Zimmer Biomet)
	  ▪ Prestige LP Cervical Disc (Medtronic)
	  ▪ SimplifyCervical Artificial Disc (NuVasive)
	• The individual is skeletally mature
	• The individual has intractable cervical radicular pain or myelopathy
	  a. Which has failed at least 6 weeks of conservative non-operative treatment including physical therapy and at least one of the following:
	  ▪ Acupuncture
	  ▪ Cervical collar
	  ▪ Corticosteroids
	  ▪ Exercise program
	  ▪ Medical treatment with NSAIDs or other analgesics
	  OR
	  b. The individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment.

Surgery	Medical Necessity
	• Degeneration is documented by imaging within the prior 12 months (magnetic resonance imaging, computed tomography or myelography) • Cervical degenerative disc disease is from C3 through C7 • The individual is free from contraindication to artificial cervical intervertebral disc implantation
Subsequent artificial cervical intervertebral disc implantation	**Subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) 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) and the initial cervical artificial disc implantation is fully healed.**

Surgery	Investigational
Artificial cervical intervertebral disc implantation	**Cervical artificial intervertebral disc implantation is considered investigational for all other indications, including the following:** • Active infection • Anatomical deformity (e.g., ankylosing spondylitis) • Cervical artificial disc at one level combined simultaneously with cervical spinal fusion at another level (adjacent or nonadjacent; aka hybrid surgery) • Disc implantation at more than 2 levels • Malignancy • Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia) • Presence of facet arthritis • Previous fusion at another cervical level • Prior surgery at the treated level • Rheumatoid arthritis or other autoimmune disease • Translational instability

Documentation Requirements

The following information must be submitted to ensure an accurate, expeditious, and complete review for artificial intervertebral disc implantation:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes that include a current history and physical exam
- Detailed documentation of extent and response to non-operative conservative therapy, if applicable, including outcomes of any procedural interventions, medications used and physical therapy/physiatrist notes
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months.

Coding

Code	Description
CPT	
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace; cervical
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection; second level, cervical
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

Related Information

Definition of Terms

American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive

Cervical myelopathy: Loss of function in the upper and lower extremities due to compression of the spinal cord within the neck.

Cervical radiculopathy: Persistent neck pain that radiates into the shoulder/arm in a dermatomal/single nerve pattern, or progressive weakness caused by irritation or injury near the root of a spinal nerve in the neck. The North American Spine Society describes the most common clinical findings as arm pain, neck pain, scapular or periscapular pain, and paresthesias, numbness and sensory changes, weakness, or abnormal deep tendon reflexes in the arm.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Subsidence: Sinking or settling in bone, for example from a prosthetic component of an implant.

Evidence Review

Description

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

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 paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and, in severe cases, leads to weakness in the arms or legs and numbness of the arms or hands. The prevalence of 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 one degenerative change evident at the radiographic examination. It is estimated that approximately five million adults in the US are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Treatment

Anterior cervical discectomy and fusion (ACDF) has historically been considered the definitive surgical treatment for symptomatic DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurologic symptoms may be expected in 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft of 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 bone sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90% to 100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to ACDF for individuals 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.

Summary of Evidence

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At two-year follow-up, trials of all artificial cervical discs met noninferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on five devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At four to five years, the trial results have been consistent with the continued noninferiority 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. 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 US Food and Drug Administration (FDA) for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. FDA approval of Simplify Cervical Disc and Prestige LP for implantation at two levels was based on superiority to 2-level ACDF in overall success at two years. The increase in overall success rates at two years has been maintained for those individuals who have reached the 10-year follow-up. At two- and four-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 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 individuals compared with 2-level ACDF patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty 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 an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. 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
NCT04520776[a]	A Multicenter, Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of the BAGUERAC 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 BAGUERAC 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

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03367052	Clinical and Radiological Outcomes of a 7-year Follow-up, Multi-center, Prospective, Randomized, Controlled Trial: Two-level Cervical ProDisc-C Vivo Versus Hybrid Construct.	542	Dec 2025
NCT04469231[a]	A Multi-Center, Prospective, Historically Controlled Pivotal Trial Comparing The Safety And Effectiveness Of The Synergy Disc To Anterior Cervical Discectomy And Fusion In Patients With One-Level Symptomatic Cervical Degenerative Disc Disease (DDD)	175	Jan 2026
Unpublished			
NCT03123549[a]	Clinical Study Protocol for the Investigation Of The Two Level Simplify Cervical Artificial Disc	182	Mar 2022
NCT02667067[a]	Clinical Study Protocol for the Investigation Of The Simplify Cervical Artificial Disc	150	Jul 2021

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

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

2015 Input

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

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 in 2009. Input did not support the conclusion that artificial intervertebral disc arthroplasty is investigational.

Practice Guidelines and Position Statements

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

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

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

In 2010, the NICE issued guidance on the artificial cervical disc, concluding that[50]:

> "Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is at least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. …

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

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

Medicare National Coverage

A search of the Medicare National Database identified a national coverage determination on artificial intervertebral discs for the lumbar spine but not for the cervical spine.[51]

Regulatory Status

In 2007, the Prestige ST Cervical Disc (Medtronic) was approved by the FDA through the premarket approval (PMA) process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature individuals 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 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 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 seven-year post approval clinical study of the safety and function of the device and a five-year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C (Synthes Spine), was approved by the FDA through the premarket approval process in 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C was made conditional on seven-year follow-up of the 209 subjects included in the noninferiority trial, seven-year follow-up of 99 continued-access subjects, and a five-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 completion of two post-approval studies. One study provides extended follow-up of the premarket pivotal cohort out to seven years. The

second study provides ten-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, 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 2**. These devices are for one site or two contiguous sites, there are no devices approved for non-contiguous sites.

Product Code: MJO

Table 2. Cervical Disc Prostheses Approved for Use in the United States

Prosthesis	Manufacturer	Characteristics	FDA Approval	Year
Prestige ST	Medtronic	Stainless steel	P060018	2007
ProDisc-C	Centinel Spine	2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P070001	2007
Bryan Cervical Disc	Medtronic Sofamor Danek	2 titanium-alloy shells encasing a polyurethane nucleus	P060023	2009
PCM Cervical Disc	NuVasive	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P100012	2012
SECURE-C	Globus Medical	Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert	P100003	2012
Mobi-C	Zimmer Biomet (previously LDR Spine)	Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. Approved for both 1 and 2- levels.	P110002/P110009	2013
Prestige LP	Medtronic Sofamor Danek	Titanium-ceramic composite with a metal-on-metal bearing;	P090029	2014/2016

		approved for both 1- and 2-levels.		
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: polyetheretherketone.

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History

Date	Comments
08/11/15	New Policy. Replaces policy 7.01.537. Also added definitions of cervical myelopathy and cervical radiculopathy. ICD-9 procedure code 84.61 added.
01/08/16	Minor update. CPT code 0092T, deleted 12/31/14, removed from policy. No other changes.
10/01/16	Annual Review, approved September 13, 2016. New policy statement added that 2-level cervical disc replacement may be considered medically necessary when criteria are met. Policy updated with literature review through June 2016; references added, updated and/or removed. Policy statement added as noted.
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; Rationale revised, some references removed. Policy statements unchanged.
03/01/18	Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.
06/01/18	Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.

Date	Comments
07/01/18	Annual Review, approved June 12, 2018. Policy updated with literature review through February 2018; no references added. Medical necessity policy statement revised to include subsequent implantation of a second artificial cervical intervertebral disc at an adjacent level (contiguous to a previous placed artificial disc) when criteria are met. Investigational statements prior artificial disc placement and replacement at another cervical level removed. Prior artificial disc placement at another cervical level changed.
02/01/19	Minor update, updated title of related policy 7.01.560.
05/01/19	Minor update, clarified Site of Service requirements.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. M6-C Artificial Cervical Disc was added to the list of single level FDA approved devices. Otherwise, policy statements unchanged. Removed CPT code 22864.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
08/01/20	Annual Review, approved July 23, 2020. Policy updated with literature review through March, 2020; references added. Rationale changed to tabular format. Change in terminology from 'artificial intervertebral disc arthroplasty of the cervical spine' to 'cervical disc arthroplasty'.
01/01/21	Minor correction only made to Documentation Requirement section – no other changes.
02/01/21	Policy Criteria previously listed the PrestigeLP device as FDA approved for two contiguous levels only. Added PrestigeLP to FDA approved for level one to accurately reflect the device is FDA approved for both levels.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 11, 2021; references added. Policy statements unchanged. Removed CPT code 0375T termed 1/1/2020.
08/01/21	Interim Review, approved July 22, 2021. Clarified language regarding hybrid cervical artificial disc and fusion.
09/01/21	Interim Review, added Simplify to FDA approved list of cervical artificial discs; overlooked during annual review.
04/01/22	Interim Review, approved March 21, 2022. Minor edits to list of examples of one and two level cervical artificial discs. Removed CPT code 0095T.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 1, 2022; reference added. Policy statements unchanged.

Date	Comments
11/04/22	Minor update. Updated the manufacturer name listed in the policy statement from Spinal Kinetics LLC to its current name Orthofix for clarity. Intent unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 3, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 27, 2024; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.