Medical Policy

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Title: Artificial Intervertebral Disc: Cervical Spine

Related Policy:	▪ *Artificial Intervertebral Disc: Lumbar Spine*

Professional	**Institutional**
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Populations	Interventions	Comparators	Outcomes
Individuals: • With cervical radicular pain or myelopathy	Interventions of interest are: • Single-level cervical spine arthroplasty	Comparators of interest are: • Anterior cervical discectomy and fusion	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With cervical radicular pain or myelopathy	Interventions of interest are: • Two-level cervical spine arthroplasty	Comparators of interest are: • Anterior cervical discectomy and fusion	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity

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 patients with symptomatic cervical degenerative disc disease.

OBJECTIVE

The objective of this evidence review is to determine whether cervical disc arthroplasty improves the net health outcome compared with anterior cervical discectomy and fusion in patients who have degenerative disc disease.

BACKGROUND

Cervical Degenerative Disc Disease

Cervical degenerative disc disease is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical degenerative disc disease include arm pain, weakness, and paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and, in severe cases, leads to weakness in the arms or legs and numbness of the arms or hands. The prevalence of degenerative disc disease secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical degenerative disc disease. By age 65, 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 degenerative disc disease of the cervical spine. The goals of anterior cervical discectomy and fusion are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurologic symptoms may be expected in 80% to 100% of anterior cervical discectomy and fusion patients. Anterior cervical discectomy and fusion involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and

reduce the need for prolonged postoperative brace application that is needed following anterior cervical discectomy and fusion without an anterior plate. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90% to 100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent-segment kinematics following fusion may lead to adjacent-level degenerative disc disease and the need for secondary surgery.

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

REGULATORY STATUS

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy. The device is implanted using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least 1 of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (e.g., magnetic resonance imaging, computed tomography, x-rays): herniated disc and/or osteophyte formation. The FDA required Medtronic (the Prestige disc manufacturer) to conduct a 7-year post approval clinical study of the safety and function of the device and a 5 year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

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

More recently, continued FDA approval requires the completion of 2 post approval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10 year enhanced surveillance of adverse event data. Continued approval is

contingent on the submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, other serious device-related complications, and analysis of all explanted discs.

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®	Centinal 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 [porous-coated motion] Cervical Disc®	NuVasive	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P100012	2012
SECURE®-C	Globus Medical	Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert	P100003	2012
Mobi-C®	Zimmer Biomet (previously LDR Spine)	Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert; approved for both 1 and 2- levels	P110002/P110009	2013
Prestige LP™	Medtronic Sofamor Danek	Titanium-ceramic composite with a metal-on-metal bearing; approved for both 1- and 2-levels	P090029	2014/2016
M6®-C	Orthofix (previously Spinal Kinetics)	Ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates	P170036	2019
Simplify® Cervical Artificial Disc	NuVasive (previously Simplify Medical)	PEEK endplates and a mobile ceramic core; MRI compatible	P200022	2020

FDA: U.S. Food and Drug Administration; MRI: magnetic resonance imaging.

POLICY

A. Cervical disc arthroplasty may be considered **medically necessary** when **ALL** of the following criteria are met:

1. The device is approved by the U. S. Food and Drug Administration (FDA)
   AND
2. The patient is skeletally mature
   AND
3. The patient has intractable cervical radicular pain or myelopathy
   a. which has failed at least 6 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. if the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment.
   AND
4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography
   AND
5. Cervical degenerative disc disease is from C3 through C7
   AND
6. The patient is free from contraindication to cervical disc arthroplasty

B. 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).

C. Subsequent cervical disc arthroplasty at an adjacent level may be considered **medically necessary** when all of the following are met:

1. Criteria A 1 to A 6 above are met
   AND
2. The device is FDA-approved for 2 levels
   AND
3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement
   AND
4. Clinical documentation that the initial cervical disc arthroplasty is fully healed.

D. Cervical disc arthroplasty is considered **experimental / investigational** for all other indications, including, but not limited to, the following:
   1. Disc implantation at more than 2 levels
   2. Combined use of an artificial cervical disc and fusion
   3. Prior surgery at the treated level
   4. Previous fusion at another cervical level
   5. Translational instability
   6. Anatomical deformity (e.g., ankylosing spondylitis)
   7. Rheumatoid arthritis or other autoimmune disease
   8. Presence of facet arthritis
   9. Active infection
   10. Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
   11. Malignancy

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RATIONALE

This evidence review was created with searches of the PubMed database. The most recent literature update was performed through March 1, 2022.

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of artificial intervertebral disc arthroplasty of the cervical spine in patients 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 question addressed in this evidence review is: Does artificial intervertebral disc arthroplasty of the cervical spine improve the net health outcome in patients with symptomatic cervical degenerative disc disease?

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

Populations
The relevant population of interest is individuals with symptomatic cervical degenerative disc disease.

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 degenerative disc disease is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve within 6 weeks, or if symptoms progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical degenerative disc disease and no contraindications for the procedure.

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

The Neck Disability Index is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life.[1,] It is a modification of the Oswestry Disability Index, based on responses to 10 questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Response options to each question range from 1 to 5, with a lower numeric score representing a better pain and disability status for that variable. A total Neck Disability Index score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, Neck Disability Index scores range from 0% to 100%, with a lower percentage indicating less pain and disability. Neurologic status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge whether patients are within normative parameters for those categories based on physiologic measurement. The anterior functional spinal unit height is a radiographic measure of interdiscal space. Comparison of the immediate postoperative functional spinal unit height with the 6-week postoperative value shows whether the disc space has decreased, which indicates that graft or device subsidence has occurred. Other outcome measures may include the 36-Item Short-Form Health Survey Mental and Physical Component Summary scores, neck and arm pain status, patient satisfaction, patient global perceived effect, gait assessment, foraminal compression test, adjacent-level stability and measurements, return to work, and physician's perception.

REVIEW OF EVIDENCE

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 with anterior cervical discectomy and fusion.[2,] This meta-analysis had the highest AMSTAR rating out of 14 meta-analyses published between 2011 and 2017.[3,] All 8 trials included in Hu et al were rated as low risk of bias, despite lack of blinding. Only 2 trials reported on overall success,[4,5,] and 3 reported on Neck Disability Index success.[4,5,6,] 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=.01). Pooled data also showed a significant benefit of cervical disc arthroplasty for secondary procedures at the index level (6 studies) [4,5,7,8,9,10,]; (RR, 0.40; 95% CI, 0.28 to 0.58; p<.001) and at the adjacent level (5 studies) [4,7,9,10,11,]; (RR, 0.42; 95% CI, 0.26 to 0.70; p<.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 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, -2.30; 95% CI,- 3.72 to -0.87, p=.002) along with the frequency of dysphagia/dysphonia (odds ratio [OR], 0.69; 95% CI, 0.49 to 0.98; p=.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=.0001)

Similar findings were reported by Deng et al (2020) in a meta-analysis of 9 studies with 48 to 120 months of follow-up.[13,] Symptomatic adjacent-level disease requiring surgery was significantly lower following cervical disc arthroplasty compared to anterior cervical discectomy and fusion.

Single-Level Cervical Disc Arthroplasty

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 a Food and Drug Administration (FDA)-mandated composite clinical outcome. The studied populations included patients with cervical radiculopathy or myelopathy, and the composite outcome included improvements in disability and neurologic symptoms with an absence of serious adverse events or secondary surgery at the index level. At the 24 month follow-up, all of the trials met non-inferiority and 4 of the 8 trials achieved superiority compared to anterior cervical discectomy and fusion (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=.005) There was a statistically significant difference in the improvement of the neck disability index between the groups (cervical disc arthroplasty: -38.3, anterior cervical discectomy and fusion: -31.1, p=.01), but there was no significant difference in arm pain or neurologic success between the cervical disc arthroplasty and anterior cervical discectomy and fusion groups. There was not a statistical difference in secondary surgeries, with 9.7% of cervical disc arthroplasty patients and

15.8% of anterior cervical discectomy and fusion patients requiring secondary surgery at either the index or adjacent level (p=.146).

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

Study; Trial	Device	Design	Primary Outcome Measure	Participants	Interventions	
				Patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy	CDA	ACDF
Mummaneni et al (2007)[14,]	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.		Prestige ST (n=137)	n=148 in FDA SSED
Gornet et al (2015)[15,]	Prestige LP	Multicenter non-inferiority RCT	Primary outcomes were neurologic success, individual success, and overall success.		Prestige LP (n=280)	n=265 historical controls from the Prestige ST trial
Murray et al (2009)[16,]	ProDisc-C	Multicenter non-inferiority RCT			ProDisc-C (n=103)	n=106
Heller et al (2009) [17,]	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.		Bryan disc (n=242)	n=223
Hisey et al (2014)[9,] FDA SSED [18,]	Mobi-C Single level	Multicenter non-inferiority RCT			Mobi-C (n=169)	n=87
Phillips et al (2013) [19,]	Porous Coated	Multicenter non-			PCM (n=224)	n=192

Study; Trial	Device	Design	Primary Outcome Measure	Participants	Interventions	
	Motion (PCM)	inferiority RCT				
Vacarro et al (2013)[20,]FDA SSED[21,]	Secure C	Multicenter non-inferiority RCT			Secure C (n=151)	n=140
Phillips et al (2021);FDA SSED: M6-C[22,23,]	M6-C	Multicenter non-randomized pragmatic trial	Improvement of NDI >15 pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures.	Patients with intractable degenerative cervical radiculopathy (arm pain and/or a neurological deficit) at 1 level from C3 to C7	M6-C (n=160)	189 propensity matched controls selected from concurrent ACDF patients and a previous IDE study
FDA SSED: Simplify Cervical Disk[24,]	Simplify Cervical Disc	Multicenter non-inferiority RCT	Improvement of NDI >15 pts, maintenance or improvement in neurologic function, and no serious adverse events or supplemental surgical procedures.	Patients with intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain or myelopathy at 1 level from C3 to C7	Simplify (n=150)	n=133 historical controls from a previous IDE study from 2005-2007

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA 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 to 48 Months			60 Months			84 Months			120 Months		
	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p	CDA	ACDF	p
Prestige ST	Mummaneni et al (2007)[14,]									Burkus et al (2014)[25,]					
n										212	183				
Overall Success			Superiority							72.6%	60.0%	.008			
NDI	81%	81%	Met non-							-37.5	-31.9				

Outcomes	**24 Months**			**36 to 48 Months**			**60 Months**			**84 Months**			**120 Months**		
			Inferiority												
Neurologic Success										88.2%	79.7%	.011			
Secondary Surgeries										4.8%	13.7%				
Prestige LP	Gornet et al (2015)[15],														
n	272	223[a]													
Overall Success			Superiority												
NDI															
Neurologic Success	93.5%	83.5%	Superiority												
Secondary Surgeries															
ProDisc C	Murray et al (2009)[16],			Delamarter et al (2010)[26],			Zigler et al (2013) Delamarter et al (2013)[27,28],			Janssen et al (2015)[10],					
n	85%			75	67					152/209 (72.7%)					
Overall Success	72%	68%	Met non-inferiority												
NDI							50% to 60%		NS						
Neurologic Success										88%	89%	NS			
Secondary Surgeries							2.9%	14.5%		7%	18%	.009			
Bryan Cervical Disc	Heller et al (2009)[17],			Sasso et al (2011)[5],									Lavelle et al (2018)[29],		

Outcomes	**24 Months**			**36 to 48 Months**			**60 Months**			**84 Months**			**120 Months**		
n	230 (95 %)	194 (87 %)		181 (75 %)	138 (62 %)								128[b]	104	
Overall Success	82.6 %	72.7 %	Superiority	85.1 %	72.5 %	.004							81.3 %	66.3 %	.005
NDI													-38.3	-31.1	.01
Arm Pain				16.6	22.4	.028							-58.9	-51.6	.60
Neurologic Success						NS							92.1 %	95.1 %	.82
Secondary Surgeries				7.8 %	8.6 %	NS							9.7 %	15.8 %	.146
Mobi-C (1 level)	Hisey et al (2014)[9], FDA SSED[18],			Hisey et al (2015) [30],			Hisey et al (2016)[31],			Radcliff et al (2017)[32],					
n	93%						85.5 %	78.9 %							
Overall Success	73.7 %	65.3 %	Met non-inferiority				61.9 %	52.2 %	Met non-inferiority	55.2 %	50.0 %	Met non-inferiority			
NDI			Met non-inferiority									Met non-inferiority			
Secondary Surgeries	1.2 %	6.2 %					4.9%	17.3 %	<.01	3%	12.3 %	<.05			
PCM	Phillips et al (2013)[19],						Phillips et al (2015)[6],								
n	189	151	Per protocol				163 (74.8 %)	130 (70.3 %)							
Overall Success	75.1 %	64.9 %	Superiority				85%	74.2 %							
Arm Pain									NS						

Outcomes	**24 Months**			**36 to 48 Months**			**60 Months**			**84 Months**			**120 Months**		
Neurologic Success									NS						
Secondary Surgeries							8.1%	12.0%	NS						
Secure C	Vacarro et al (2013)[20], FDA SSED[21],														
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)[23], FDA SSED: M6-C[22],														
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	1.9%	4.8%													

Outcomes	24 Months			36 to 48 Months			60 Months			84 Months			120 Months		
Surgeries															
Pain Medication	14 %	38.2 %	<.001												
Simplify Cervical Disc	[24,]														
n	150	133													
Overall Success	93 %	73.6 %	<.001												
NDI Success	97.9 %	88 %	.009												
Neurologic Success	99.3 %	94.7 %													
Secondary Surgeries	2.9 %	2.9 %	.979												
Pain Medication	10.8 %	36.8 %													

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

Section Summary: Single-Level Cervical Disc Arthroplasty

At 2 year follow-up, the pivotal trials of 9 artificial cervical discs met non-inferiority criteria, with 5 achieving statistical superiority compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on 5 devices. At 3 to 7 years, trial results have been consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and/or lower cumulative reoperation rates. Ten-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

In 2016, the Prestige LP received FDA approval for implantation at 2 levels.[33,] Overall success was achieved in 81.4% of Prestige LP patients and 69.4% of anterior cervical discectomy and fusion controls, meeting both non-inferiority and superiority margin, with a posterior probability

of near 100% and 99.3%, respectively (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).[8,34,35,32,]. Clinically relevant heterotopic ossification (grade III or IV) was observed in 29.7% of the Mobi-C patients at 5 years, but the Mobi-C patients had significantly less adjacent-segment degeneration (50.7%) than anterior cervical discectomy and fusion patients (90.5%; p<.001).

Table 4. Summary of Pivotal RCT Characteristics of Cervical Disc Arthroplasty at 2 Continuous Levels

Study; Trial	Device	Design	Blinding	Primary Outcome Measure	Participants	Interventions	
						CDA	ACDF
FDA SSED (2016)	Prestige LP	Multicenter non-inferiority 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 levels (n=209)	n=188

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; 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
Prestige LP	FDA SSED[36,]												Gornet et al (2019)[a37,]		
n (%)	199 (95)	160 (86)		185 (89)	149 (80)		166 (80)	138 (74)		126 (67)	99 (58)		148 (86 %a)	118 (85 %)	
Overall success	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

Outcomes	**24 Months**			**48 Months**			**60 Months**			**84 Months**			**120 Months**		
s n/N (%)															
NDI Success	87.9 %	79.2 %	Superiority	89.7 %	82.3 %	Superiority	89.2 %	77.8 %	Superiority	87.0 %	75.6 %	Superiority	88.4 %	76.5%	Superiority
Neurologic Success	91.5 %	86.2 %	NS	90.3 %	83.8 %	Superiority	90.4 %	87.5 %	NS	91.6 %	82.1 %	Superiority	92.6 %	86.1%	Superiority
Secondary Surgeries	2.4 %	3.2 %											13.7 %	35.5%	Significant
Mobi-C	Davis et al (2013)[8,]			Davis et al (2015)[34,]			Radcliff et al (2016)[35,]			Radcliff et al (2017)[32,]					
n	225	105		89.0 %	81.2 %		90.7 %	86.7 %		84.4%	75 %				
Overall success				66.0 %	36.0 %		61 %	31 %	<.001	60.8%	34.6%	Superiority			
NDI Success				79.3 %	53.4 %	<.001			Significant	79.0%	58.9%	<.05			
Arm and Neck Pain									Not Significant			Not Significant			
Secondary Surgeries				4.0 %	15.2 %		7.1 %	21.0 %	<.001	4.4 %	16.2%	<.05			

ACDF: anterior cervical discectomy and fusion; CDA: cervical disc arthroplasty; FDA: SSED: US Food and Drug Administration Summary of Safety and Effectiveness; 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).[38,] The comparison showed no significant differences between 1- and 2-level cervical disc arthroplasty on clinical outcomes (Neck Disability Index, Visual Analog Scale and 12-Item Short-Form Health Survey scores), major complication rates (4.3% for 1-level cervical disc arthroplasty vs 4.0% for 2-level cervical disc arthroplasty), or subsequent surgery rates (3.0% of 1-level vs 4.0% of 2-level). Clinically relevant heterotopic ossification was observed in 23.8% of 1-level patients and 25.7% of 2-level patients. Huppert et al (2011) compared outcomes between single-

level (n=175) and multilevel (2 to 4 levels, n=56) cervical disc arthroplasty with the Mobi-C device in a prospective multicenter study from Europe.[39,] 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 for the Prestige LP disc at 2 levels was based on superiority to 2-level anterior cervical discectomy and fusion at 2-year follow-up. At present, over 80% of patients have reached 3-year follow-up, and 85% of expected patients have reached 10-year follow-up. The difference in overall success rates at 2 years has been maintained at 10 years. Secondary outcome measures showed the superiority of cervical disc arthroplasty over anterior cervical discectomy and fusion.

The first artificial cervical disc approved for 2 levels (Mobi-C) was found to be noninferior to anterior cervical discectomy and fusion in the investigational device exemption trial. Superiority to anterior cervical discectomy and fusion was achieved for Neck Disability Index scores, Neck Disability Index success rates, and 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 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.[40,] The primary outcome measures were neck and arm pain relief and the Core Outcome Measures Index. One analysis evaluated outcomes from a matched pair of patients (190 pairs) who met the selection criteria of published RCTs. With an average follow-up of 17 months, there were small but statistically significant differences in outcomes between cervical disc arthroplasty and anterior cervical discectomy and fusion. The mean group differences on a 10 point scale for both pain measures were 0.6 points in postoperative neck pain (p=.04) and 0.7 points in arm pain (p=.02); the mean Core Outcome Measures Index score difference was 0.8 points (p=.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=.02) and Core Outcome Measures Index score (81.6% vs. 67.9%, p<.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 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 to 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=.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.[41,] Using propensity matching, the investigators identified 185 patients in each group who had cervical degenerative disc disease and radiculopathy. The primary outcome was the Neck Disability Index, with a minimum clinically important difference of >15%. Scores on the Neck Disability Index were halved in both groups, but there was no significant difference (3.0%; 95% CI, -8.4 to 2.4; p=.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).[42,] 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.[43,] Heterotopic ossification was radiographically graded for 164 1-level and 225 2-level cervical disc arthroplasty patients from the Mobi-C pivotal trials and correlated with clinical outcomes. At 7 years, clinically relevant (grade 3 or 4) heterotopic ossification that affects range of motion was present in 28.7% of 1-level patients and 37.4% of 2-level patients. Patients were divided into non-clinically relevant heterotopic ossification and clinically relevant (motion restricting) heterotopic ossification. Arm pain and 12-Item Short Form Health Survey scores were not significantly different between the groups. There was an interaction between heterotopic ossification and time for the Neck Disability Index (p=.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 single-level cervical disc arthroplasty, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met non-inferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [Porous Coated Motion]). At 4 to 5 years, the trial results have been consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige, ProDisc-C, and Mobi-C pivotal trials continue to show lower secondary surgery rates, although this is not a consistent finding in other reports. 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 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 for the Prestige LP™ was based on superiority to 2-level anterior cervical discectomy and fusion 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 10-year follow-up. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to anterior cervical discectomy and fusion for Neck Disability Index scores, Neck Disability Index success rates, reoperation rates, and the overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared with 2-level anterior cervical discectomy and fusion patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty with 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.

SUPPLEMENTAL INFORMATION

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

2015 Input

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

2009 Input

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US

representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[44,] 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 2015, the guidelines from the North American Spine Society indicated that: [45,]
"Cervical artificial disc replacement, (also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Radiculopathy related to nerve root compression from one or 2 level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2-level degenerative disc disease from C3-4 to C6-7 with or without neck pain."

National Institute for Health and Care Excellence
In 2010, the National Institute for Health and Care Excellence (NICE) issued guidance on the artificial cervical disc, concluding that:[46,]

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

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02403453[a]	RHINE™ Cervical Disc Clinical Study	166	Dec 2028
NCT02667067[a]	Clinical Study Protocol for the Investigation Of The Simplify® Cervical Artificial Disc	150	Jan 2023
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	Sep 2024
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	Sep 2024
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 Level Simplify® Cervical Artificial Disc	200	Aug 2021

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

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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 (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22899	Unlisted procedure, spine
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

ICD-10 DIAGNOSES	
M47.12	Other spondylosis with myelopathy, cervical region
M47.22	Other spondylosis with radiculopathy, cervical region
M47.812	Spondylosis without myelopathy or radiculopathy, cervical region
M47.892	Other spondylosis, cervical region
M50.00-M50.023	Cervical disc disorder with myelopathy
M50.11-M50.123	Cervical disc disorder with radiculopathy
M50.21	Other cervical disc displacement, high cervical region
M50.221	Other cervical disc displacement at C4-C5 level
M50.222	Other cervical disc displacement at C5-C6 level
M50.223	Other cervical disc displacement at C6-C7 level
M50.31	Other cervical disc degeneration, high cervical region
M50.321	Other cervical disc degeneration at C4-C5 level
M50.322	Other cervical disc degeneration at C5-C6 level
M50.323	Other cervical disc degeneration at C6-C7 level

ICD-10 DIAGNOSES	
M54.12	Radiculopathy, cervical region

REVISIONS	
09-23-2008	In Description section: ▪ Updated wording
	In Policy section: ▪ Removed "Removal or revision of artificial disc(s) is a non-covered service."
	In Coding section: ▪ Removed CPT codes 0096T, 0098T
	Added Rationale section
05-18-2010	Updated Description Section
	In Coding Section: ▪ Updated wording for the following CPT codes: 0092T, 0095T (effective 01-01-09) ▪ Added CPT codes: 22856, 22861, 22864, 0098T (effective 01-01-09) ▪ Deleted CPT codes: 0090T, 0093T (effective 01-01-09)
	Updated Rationale and References Sections
03-08-2013	Description section updated
	Rational section updated
	In Coding section: ▪ Coding notations added.
	References updated
01-01-2015	In Coding section: ▪ Added CPT Codes: 22858, 0375T (Effective January 1, 2015) ▪ Deleted CPT Code: 0092T (Effective January 1, 2015)
08-05-2015	Description section updated
	In Policy section: ▪ Revised policy from: "Artificial intervertebral discs are considered experimental / investigational for treatment of disorders of the cervical spine, including degenerative disc disease." to: "A. Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met: 1. The device is approved by FDA AND 2. The patient is skeletally mature AND 3. The patient has intractable cervical radicular pain or myelopathy a. which has failed at least 6 weeks of conservative nonoperative treatment, including 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. if the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment. AND 4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography AND 5. Cervical degenerative disc disease is limited to a single level from C3-C7 AND 6. The patient is free from contraindication to cervical artificial intervertebral disc implantation B. Cervical artificial intervertebral disc implantation is considered experimental / investigational for all other indications, including, but not limited to, the following: 1. Disc implantation at more than 1 level 2. Combined use of an artificial cervical disc and fusion

REVISIONS	
	3. Prior surgery at the treated level 4. Previous fusion at another cervical level 5. Multilevel disc disease 6. Translational instability 7. Anatomical deformity (e.g., ankylosing spondylitis) 8. Rheumatoid arthritis or other autoimmune disease 9. Presence of facet arthritis 10. Active infection 11. Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia) 12. Malignancy"
	Rationale section updated
	In Coding section: ▪ ICD-9 and ICD-10 Codes added.
	References updated
10-12-2016	Description section updated
	In Policy section: ▪ In Item A 5 removed "limited to a single level" to read "Cervical degenerative disc disease is from C3-C7" ▪ Added medically necessary indications of: "B. Simultaneous cervical artificial intervertebral disc implantation 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 (i.e., Mobi-C, Prestige LP)." and "C. Subsequent cervical artificial intervertebral disc implantation at an adjacent level may be considered medically necessary when all of the following are met: 1. Criteria 1 to 6 above are met; AND 2. The device is FDA-approved for 2 levels; AND 3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; AND 4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed."
	Rationale section updated
	In Coding section: ▪ ICD-10 Codes Effective 10-01-2016: M50.021, M50.022, M50.023, M50.11, M50.121, M50.122, M50.123, M50.221, M50.222, M50.223, M50.321, M50.322, M50.323, M54.12 ▪ ICD-10 Codes Termed 09-30-2016: M50.02, M50.22, M50.32
	References updated
05-23-2018	Description section updated
	Rationale section updated
	References updated
07-17-2019	Description section updated
	Rationale section updated
	References updated
01-01-2020	In Coding section: ▪ Deleted CPT Code: 0375T
08-21-2020	Description section updated
	In Policy section: ▪ In Items A, A 6, B, C, C 4, and D revised "cervical artificial intervertebral disc implantation" to read "cervical disc arthroplasty". This is no change to the intent of the policy.

REVISIONS	
	▪ In Item C 1 added "A" to read "Criteria A 1 to A 6 above". This added location clarification and is no change to the intent of the policy.
	Rationale section updated
	In Coding section: ▪ Removed coding notations (no coding changes)
	References updated
06-03-2021	Description section updated
	Rationale section updated
	References updated
07-01-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Converted ICD-10 codes to ranges
	Updated References Section

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