

## Medical Policy



### Title: Artificial Intervertebral Disc: Cervical Spine

See also: *Artificial Intervertebral Disc: Lumbar Spine*

#### **Professional**

Original Effective Date: September 25, 2007  
 Revision Date(s): September 23, 2008  
 May 18, 2010; March 8, 2013;  
 January 1, 2015; August 5, 2015;  
 October 12, 2016; May 23, 2018  
 Current Effective Date: October 12, 2016

#### **Institutional**

Original Effective Date: October 23, 2008  
 Revision Date(s): December 15, 2009;  
 May 18, 2010; March 8, 2013;  
 January 1, 2015; August 5, 2015;  
 October 12, 2016; May 23, 2018  
 Current Effective Date: October 12, 2016

**State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).**

**The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.**

**The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.**

**If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.**

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With cervical radicular pain or myelopathy</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Single-level artificial intervertebral disc arthroplasty of the cervical spine</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Anterior cervical discectomy and fusion</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With cervical radicular pain or myelopathy</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Two-level artificial intervertebral disc arthroplasty of the cervical spine</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Anterior cervical discectomy and fusion</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>

## **DESCRIPTION**

Several prosthetic devices are currently available for artificial intervertebral disc arthroplasty (AIDA) of the cervical spine. AIDA is proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for patients with symptomatic cervical degenerative disc disease (DDD).

### **Objective**

The objective of this evidence review is to determine whether artificial intervertebral 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 (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, some 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**

Cervical DDD is initially treated conservatively using noninvasive measures (eg, rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve in 6 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.

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 neurologic symptoms may be expected in 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral

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

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In AIDA, 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. AIDA 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 AIDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis.

### **Outcome Measures**

The NDI is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life.<sup>1</sup> 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.

## 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 one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (eg, pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (eg, magnetic resonance imaging [MRI], computed tomography [CT], x-rays): herniated disc and/or osteophyte formation. FDA required Medtronic (the Prestige disc manufacturer) to conduct a 7-year postapproval 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.

In 2014, the Prestige® LP artificial cervical disc (Medtronic Sofamor Danek) was approved by FDA through the PMA process. The Prestige® LP differs from the original Prestige cervical disc regarding material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has 2 rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige® LP was approved by FDA for 2 adjacent levels. A postapproval study will follow the investigational device exemption (IDE) patients who received the Prestige® LP at 2 contiguous levels for 10 years. Medtronic will also submit to FDA adverse events, device failures, and complaint analysis 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) was approved by FDA through the premarket approval process in 2007. As with the Prestige® ST Cervical Disc, FDA approval of ProDisc-C® was made 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 more fully adverse events when the device is used under general conditions of use. Postapproval study reports are to be delivered to 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. In 2009, the Bryan® Cervical Disc was approved by FDA 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 neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using CT, myelography and CT, and/or MRI. Patients receiving the Bryan® Cervical Disc should have failed at least 6 weeks of

nonoperative treatment before implantation. As a condition for device approval, FDA has required Medtronic Sofamor Danek 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. Also, Medtronic Sofamor Danek must perform a 5-year enhanced surveillance study of the disc to characterize more fully AEs when the device is used in a broader patient population.

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

A number of other devices are under study in FDA IDE trials in the United States (Table 1).

**Table 1. Cervical-Disc Prostheses Under Investigation in the United States**

Prosthesis	Manufacturer	FDA Status
Kinflex/C®	Spinal Motion	FDA IDE trial complete; status known
Freedom®	AxioMed	FDA IDE trial recruiting
M6-C	Spinal Kinetics	FDA IDE trial recruiting complete

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption.

Updates on the regulatory status of these devices are available online using FDA product code MJO (available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> ).

**POLICY**

- 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 the 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 artificial intervertebral disc implantation
- 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 (ie, Mobi-C, Prestige LP).
- 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.

- D. 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 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 (eg, ankylosing spondylitis)
  7. Rheumatoid arthritis or other autoimmune disease
  8. Presence of facet arthritis
  9. Active infection
  10. Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)
  11. Malignancy

## **RATIONALE**

The most recent literature update was performed through February 5, 2018. This review was informed by TEC Assessments in 2007, 2009, 2011, and 2013.<sup>2-5</sup>

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 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.

### **Cervical Degenerative Disc Disease**

A number of systematic reviews have been published. Hu et al (2016) published a systematic review and meta-analysis of 8 RCTs (total N=2368 patients) reporting mid-term outcomes (at least 48 months) comparing artificial intervertebral disc arthroplasty (AIDA) with anterior cervical discectomy and fusion (ACDF).<sup>6</sup> All 8 trials were rated as low risk of bias, despite lack of blinding. Only 2 trials reported on overall success,<sup>7,8</sup> and three reported on Neck Disability Index (NDI) success.<sup>7-9</sup> Six trials reported neurologic success data; pooled data favored the AIDA group to a small degree (relative risk, 1.04; 95% confidence interval, 1.01 to 1.08; p=0.01). Pooled data

also showed a significant benefit of AIDA for secondary procedures at the index level (6 studies<sup>7,8,10-13</sup>; relative risk, 0.40; 95% confidence interval, 0.28 to 0.58;  $p < 0.001$ ) and at the adjacent level (5 studies<sup>7,10,12-14</sup>; relative risk, 0.42; 95% confidence interval, 0.26 to 0.70;  $p < 0.002$ ). These trials and outcome measures are detailed below.

## Single-Level AIDA

### *Prestige ST*

The Prestige ST Cervical Disc received Food and Drug Administration (FDA) marketing approval in 2007 based on a nonblinded randomized noninferiority trial that compared AIDA ( $n = 137$ ) with ACDF ( $n = 148$ ) for patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy.<sup>15,16</sup> The patients reported in the premarket approval application represented about half of the total population (276 and 265, respectively), while the peer-reviewed article reported on about 75% of cases. Three primary outcome variables were used in the Prestige pivotal trial: a 15-point improvement in NDI score, neurologic status, and functional spinal unit (FSU) height. Both groups in the Prestige disc trial showed equivalent results for NDI scores (81%) and FSU height, demonstrating noninferiority to fusion but not superiority. Neurologic status showed noninferiority and statistical superiority for the disc. This contributed to the overall success composite end point demonstrating superiority for the disc compared with fusion. While maintained or improved neurologic status was more frequent following AIDA, it was unclear whether examiners were blinded. Most secondary outcome measures for the disc were deemed noninferior to ACDF. Perioperative results and adverse events were similar in both groups, with very few serious complications.

Five- and 7-year follow-ups of participants in this clinical trial were reported by Burkus et al (2010, 2014).<sup>7,17</sup> All participants were followed in this FDA-regulated postapproval study. Outcomes at 60 months were reported on approximately half of the original RCT participants. Patients who had not yet reached that point in their follow-up for the 2010 publication were included in the 2014 report. Follow-up at 84 months was obtained in 73% of study participants (212 AIDA, 183 ACDF). Overall success rates at 78 months were 72.6% for the Prestige disc and 60.0% for ACDF ( $p = 0.008$ ), NDI scores improved by 37.5 points for the Prestige disc compared with 31.9 points for ACDF ( $p = 0.002$ ), and neurologic success was greater in the Prestige disc group (88.2% vs 79.7%,  $p = 0.011$ ). There was no significant difference between groups in NDI success rates at 84 months ( $p = 0.109$ ) or in work status. The rate of secondary surgeries at the index level was lower for Prestige (4.8%) than for ACDF (13.7%;  $p < 0.001$ ), but there was no significant difference in the rate of adjacent-level surgeries (3.9% vs 5.4%).

### *Prestige LP*

Twenty-four-month results from the pivotal trial for the Prestige LP disc were published by Gornet et al (2015).<sup>18</sup> This multicenter noninferiority trial compared 280 patients who received the Prestige LP disc with 265 historical ACDF controls from the Prestige investigational device exemption (IDE) study described above. Primary outcomes were a neurologic success, individual success, and overall success. Blood loss and hospital stay were similar between groups, but median return-to-work time was significantly shorter for the Prestige LP group (40 days) than for the ACDF group (60 days;  $p = 0.020$ ). With a follow-up rate at 24 months of 97.1% for the Prestige LP group and 84.0% for controls (excluding radiographic assessment of disc height), noninferiority was demonstrated. Neurologic success was superior in the Prestige LP group (93.5%) compared with the control group (83.5%), with a Bayesian probability of about 1.00. Superiority on the composite measure of overall success was supported with a Bayesian

probability of 0.994. In addition to statistical analysis by the study sponsor, raw data were provided to Vanderbilt University for independent confirmation of results.

### ***ProDisc-C***

Murrey et al (2009) reported on 2-year results from the pivotal FDA randomized noninferiority trial to determine the safety and efficacy of ProDisc-C compared with ACDF.<sup>19</sup> In this trial, 103 patients received the ProDisc-C implant, and 106 were treated with fusion; participants were blinded to intervention until after surgery. Follow-up between 6 weeks and 2 years was reported to be 85% in the summary of safety and effectiveness data presented to FDA.<sup>20</sup> Noninferiority was achieved for the FDA-defined combined end point, with 72% of ProDisc-C and 68% of fusion patients achieving success in all 4 component end points.

Four-year interim follow-up of participants in this clinical trial was reported by Delamater et al (2010),<sup>21</sup> and 5-year results of this trial were published by Delamater and colleagues (2013), with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF.<sup>22,23</sup> Outcomes on the NDI were similar (50%-60% improved), along with visual analog scale (VAS) scores for arm pain (18 for both groups) and 36-Item Short-Form Health Survey (SF-36) scores. VAS scores for neck pain were modestly improved with ProDisc-C (21/100) compared with ACDF (30/100), although the proportion of patients who achieved a clinically significant improvement in neck pain was not reported. Fewer patients with ProDisc-C (2.9%) than with ACDF (14.5%) had secondary surgery at either the index or adjacent level.

Seven-year follow-up on 72.7% (152/209) of patients was reported by Janssen et al (2015).<sup>13</sup> Between 2 and 7 years, there were no significant differences between ProDisc-C and ACDF patients for a change in pain or function. Neurologic status was improved or maintained in a similar percentage of patients in both groups (ProDisc-C, 88% vs ACDF, 89%). Secondary surgical procedures were significantly higher in the ACDF group (18%) than in the ProDisc-C group (7%;  $p=0.009$ ), with an acceleration of secondary surgical procedures after 5 years in the ACDF group.

### ***Bryan Cervical Disc***

Two- (2009) and 4-year (2011) results have been published from the IDE trial for the Bryan disc.<sup>8,24</sup> A total of 582 patients were randomized and treated with the Bryan disc ( $n=242$ ) or ACDF ( $n=223$ ). After 2-year follow-up, data were available for 230 (95%) patients from the AIDA group and 194 (87%) who underwent ACDF. The overall success outcome was achieved more often after AIDA (82.6% vs 72.7%), with a mean 4.1-point greater improvement in NDI scores. As measured by the composite end point (success on all of the following:  $\geq 15$ -point improvement in NDI score, neurologic improvement, no serious adverse events related the implant or subsequent surgical procedure, and no subsequent surgery or intervention that would be classified as treatment failure), AIDA was superior to ACDF. At 24 months, neck pain scores were lower following AIDA, while other secondary outcomes were similar.

In 2011, 4-year follow-up from the IDE trial was reported for 181 (75%) of 242 patients who received the Bryan disc and 138 (62%) of 223 patients who underwent ACDF.<sup>8</sup> It was reported that 25% of AIDA and 38% of ACDF patients failed to return for follow-up at 48 months, due in part to requirements by FDA and the institutional review board for additional patient consent for the continuation study. Four-year overall success rates were significantly higher in the Bryan group (85.1%) than in the ACDF group (72.5%). Neurologic success rates did not differ between

groups. Arm pain was reduced from a baseline of 71.2 in both groups to 16.6 for the Bryan disc, and 22.4 for ACDF, the between-group difference being statistically significant. Reduction in neck pain scores was also significantly larger in the Bryan disc group (from 75.4 to 20.7) than in the fusion group (from 74.8 to 30.6). Improvement in the SF-36 Physical Component Summary score was also significantly greater in the AIDA group (15.8 vs 13.1). There was no significant difference in the percentage of additional surgical procedures at either the index (3.7% Bryan vs 4.5% ACDF) or adjacent (4.1% Bryan vs 4.1% ACDF) levels. FDA-required follow-up will continue for 10 years after the index surgery.

### ***Kineflex/C***

Coric et al (2011) reported on the 24-month pivotal multicenter randomized IDE trial of the metal-on-metal Kineflex/C artificial disc (n=136) compared with ACDF performed with allograft and anterior plate (n=133).<sup>25</sup> There were no significant differences between the Kineflex/C and ACDF groups for an operative time, blood loss, hospital length of stay, or reoperation rate at the index level. The overall success rate was significantly higher in the Kineflex/C group (85%) than in the ACDF group (71%). There were 6 (5%) index-level reoperations in the Kineflex/C group, including one of metal sensitivity and two for device migrations. There were 7 (7.6%) index-level surgeries in the ACDF group, including three for pseudarthrosis and four for instrumentation failure (removal or revision of the original anterior plate and screw construct). There were no significant differences between groups in VAS pain or NDI scores. Although fewer Kineflex/C patients showed severe adjacent-level radiographic changes (9% vs 24.8%), the between-group difference was not significant for the adjacent-level reoperation rate (7.6% for the Kineflex/C group vs 6.1% for the ACDF group) at short-term follow-up. Current status of this device is unknown.

### ***Mobi-C***

Mobi-C is the only artificial disc approved for 1- or 2-level cervical disc disease. The 1-level Mobi-C noninferiority trial randomized 169 patients to AIDA and 87 to ACDF.<sup>26</sup> Patient characteristics were generally similar to the other trials. At 24 months, the follow-up rate was 93%. Noninferiority criteria were met for mean NDI improvement, percent NDI success ( $\geq 15$ -point improvement), and overall success. The overall protocol-specified success rate was higher in the Mobi-C group (73.7%) than in the ACDF group (65.3%), which met noninferiority criteria but not superiority criteria. There were fewer cumulative subsequent surgical interventions at the index level in the AIDA group (1.2%) than in the ACDF group (6.2%).

Hisey et al (2014, 2015, 2016) published 2-, 4-, and 5-year results from the single-level Mobi-C trial, with follow-up rates of 85.5% for the Mobi-C group and 78.9% for ACDF at 5 years.<sup>12,27,28</sup> Overall success in the Mobi-C group was noninferior to the ACDF group, but was not superior, with a success rate of 61.9% for Mobi-C and 52.2% for ACDF. Range of motion was preserved with Mobi-C through 5 years, even though grade 4 heterotopic ossification was observed in 8.5% of Mobi-C patients. Adjacent-segment degeneration was significantly lower with Mobi-C, but radiographically determined adjacent-segment degeneration remained above 30% at 5-year follow-up in this group. Throughout the 5-year follow-up, Mobi-C patients had a lower incidence of subsequent surgeries (Mobi-C, 4.9%; ACDF, 17.3%;  $p < 0.01$ ).

Similar results were reported in an independently funded multicenter RCT (2014) from Asia of single-level arthroplasty with the Mobi-C device compared with ACDF (N=111).<sup>14</sup> Outcomes for pain and function were similar for the Mobi-C and ACDF groups at 48-month follow-up. There

was significantly more radiographically determined adjacent-level degeneration and a higher incidence of secondary surgery with ACDF (1 Mobi-C patient vs 3 ACDF patients).

### ***Porous Coated Motion Cervical Disc***

Results of the 2-year FDA-regulated multicenter randomized noninferiority trial of the PCM (Porous Coated Motion) Cervical Disc were reported by Phillips et al (2013).<sup>29</sup> Five- and 7-year follow-ups were reported by Phillips et al (2015).<sup>9</sup> Of the 416 patients randomized (224 to PCM, 192 to ACDF), 340 (82% [189 to PCM, 151 to ACDF]) were per protocol for the 24-month primary end point of overall success. At 24 months, overall success was 75.1% in the PCM group and 64.9% in the ACDF group, which met both the noninferiority and superiority criteria.

Five-year follow-up included 163 (74.8%) PCM and 130 (70.3%) ACDF patients.<sup>9</sup> At 5 years, NDI success was modestly better in the PCM group (85.0%) than in the ACDF group (74.2%), and dysphagia was slightly lower (VAS score, 8.8 vs 16.9; VAS range, 1-100). Success measured on VAS pain scores did not differ significantly between groups for neck pain or worst arm pain, and there were no significant differences between groups for neurologic success rates. There were also no significant differences between groups in subsequent secondary surgical interventions (PCM, 8.1% vs ACDF, 12.0%). Radiographically determined adjacent-level degeneration was more frequent after ACDF (50.9%) than after PCM (33.1%,  $p=0.006$ ). Six percent of patients in the PCM group showed grade IV heterotopic ossification with bony ankylosis, while 94.4% of patients in the ACDF group showed fusion.

### ***SECURE-C***

The FDA-regulated SECURE-C trial was a multicenter nonblinded noninferiority trial with 151 patients randomized to AIDA and 140 patients to ACDF.<sup>30,31</sup> An additional 89 nonrandomized patients were included in the published data (2013).<sup>31</sup> At 24 months, the follow-up rate was 87%. Noninferiority criteria (AIDA vs ACDF) were met for NDI mean improvement, rate of NDI success (89.2% vs 84.5%), neurologic success (96.0% vs 94.9%), and overall success (83.8% vs 73.2%), all respectively (posterior probability of 98.1% by Bayesian analysis). The overall success rate was higher in the SECURE-C group (90.1%) than in the ACDF group (71.1%), which met both noninferiority and superiority criteria (posterior probability of 100% by Bayesian analysis). Cumulative secondary surgical interventions at the treated level were lower in the AIDA group (2.5%) than in the ACDF group (9.7%).

### ***Section Summary: Single-Level AIDA***

At 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM). At 4 to 5 years, the trial results have been consistent with the continued noninferiority of AIDA 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. Longer term results for other discs are expected, given the FDA requirement for 7-year postapproval 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 AIDA

### *Two-Level Prestige LP*

In 2016, the Prestige LP received FDA approval for implantation at 2 levels. Approval was based on 24-month data from a noninferiority trial that randomized patients to AIDA (n=209) or ACDF (n=188) at 2 contiguous levels.<sup>32</sup> Data for FDA approval were collected until the last subject enrolled had completed 24-month follow-up. Additional prespecified evaluations are scheduled at 36, 60, 84, and 120 months. The primary outcome of the trial supporting FDA approval was an overall success, with a noninferiority margin of 10%. Complete overall success data at 24 months were available for 199 (95.2%) 2-level Prestige LP patients and 160 (88.9%) ACDF controls. Overall success was achieved in 81.4% of Prestige LP patients and 69.4% of ACDF controls, meeting both noninferiority and superiority margin, with a posterior probability of near 100% and 99.3%, respectively. The average difference in the chance of success between the 2-level Prestige LP group and the 2-level ACDF group at 24 months was 11.3%, with a 95% probability that this difference fell in the range of 2.2% to 20.1%. Based on Bayesian credible intervals, there were no statistical differences between the 2 treatment groups for adverse events. There were 12 (6.4%) severe device-related adverse events in the 2-level ACDF group compared with 5 (2.4%) in the Prestige LP group. More patients in the 2-level ACDF group underwent subsequent surgical procedures at the index level (8.0%) than in the Prestige LP group (2.4%) (posterior mean, -5.6%; 95% credible interval, -10.2% to -1.1%).

Table 2 provides data on patients who reached follow-ups at intervals up to 84 months and of those patients who have met criteria for overall success. The difference in success rates between the Prestige LP and ACDF patients achieved at 24 months was maintained through 7 years. However, there was a higher loss to follow-up in the 2-level ACDF group, which might have biased results. Secondary outcome measures were similar between groups at 24-month follow-up. Data on adjacent-level surgeries were not collected prospectively but assessed through adverse event documentation. At 24 months, reoperation rates at the adjacent level(s) were 2.4% for the 2-level Prestige LP group and 3.2% for the 2-level ACDF group. Follow-up continues.<sup>32</sup>

**Table 2. Follow-Up and Success Rates for 2-Level Prestige LP Compared With 2-Level ACDF**

Outcomes	24 Months		36 Months		60 Months		84 Months	
	AIDA	ACDF	AIDA	ACDF	AIDA	ACDF	AIDA	ACDF
Follow-up, n (%)	199 (95)	160 (86)	185 (89)	149 (80)	166 (80)	138 (74)	126 (67)	99 (58)
Cumulative withdrawal, n (%)	0 (0)	7 (3.7)	1 (0.5)	10 (5.3)	5 (2.3)	12 (6.3)	5 (2.3)	16 (8.5)
Overall success n/N (%)	162/199 (81.4)	111/160 (69.4)	151/185 (81.6)	105/149 (70.5)	132/166 (79.5)	91/138 (65.9)	99/126 (78.6)	62/99 (62.6)

AIDA: artificial intervertebral disc arthroplasty; ACDF: anterior cervical discectomy and fusion.

### *Two-Level Mobi-C*

Two- and 4-year results from the 2-level Mobi-C IDE trial were reported by Davis et al (2013, 2015).<sup>11,33</sup> In this noninferiority trial, 225 patients received the Mobi-C device at 2 contiguous levels, and 105 patients received 2-level ACDF. At 48 months, the follow-up rate was 89.0% for AIDA and 81.2% for ACDF. Both groups showed significant improvements in NDI, VAS neck pain, and VAS arm pain scores from baseline to each follow-up point, with Mobi-C meeting the noninferiority margin. However, AIDA patients had significantly greater improvements than ACDF

patients in NDI scores and had higher NDI success rates (eg, at 48 month, 79.3% vs 53.4%;  $p < 0.000$ ) and overall success rates (eg, at 48 months, 66.0% vs 36.0%) at all time points, respectively. Neck pain and arm pain scores did not differ between groups at 48 months. The Mobi-C group also had a lower reoperation rate (4.0%) than the ACDF group (15.2%;  $p < 0.001$ ). At 48 months, adjacent-level degeneration was observed in 41.5% of AIDA patients and 85.9% of ACDF patients with available radiographs, while 25.6% of AIDA patients showed clinically relevant heterotopic ossification.

Radcliff et al (2016) published 5-year results from the Mobi-C 2-level IDE trial.<sup>34</sup> Follow-up rates were 82.7% of patients for the Mobi-C group (8.9% study failures) and 68.6% for the ACDF group (21.0% study failures). Excluding patients who dropped from the trial due to death or device failures, follow-up rates were 90.7% for the Mobi-C group and 86.7% for the ACDF group. Improvement in the Mobi-C group was significantly better than in the ACDF group for the NDI and SF-12 Physical Component Summary scores. There were no significant differences between groups for VAS neck and arm pain scores, neurologic status, or for SF-36 Mental Component Summary scores. The FDA-defined composite measure of success (similar to that described in the trial of the Bryan disc, above) was significantly better for the Mobi-C group (61%) than for the ACDF group (31%;  $p < 0.001$ ). There were also significantly fewer secondary surgeries in the Mobi-C group (7.1%) compared with the ACDF group (21%;  $p < 0.001$ ), due to fewer index-level reoperations (4.3% vs 16.2%,  $p < 0.001$ ) and adjacent-level reoperations (3.1% vs 11.4%) with the Mobi-C devices. 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 ACDF patients (90.5%;  $p < 0.001$ ).

Post hoc analysis of data from the pivotal 1- and 2-level Mobi-C trials was reported by Bae et al (2015).<sup>35</sup> The comparison showed no significant differences between 1- and 2-level AIDA on clinical outcomes (NDI, VAS, and SF-12 scores), major complication rates (4.3% for 1-level AIDA vs 4.0% for 2-level AIDA), 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,  $n=56$ ) AIDA with the Mobi-C device in a prospective multicenter study from Europe.<sup>36</sup> At 2 years, there were no significant differences between groups for overall success, radicular and cervical VAS scores, NDI scores, and range of motion. There was a trend for more patients in the single-level group than in the 2-level group to return to work (70% vs 46%) and for the return to work to occur sooner (4.8 months vs 7.5 months), respectively.

### ***Section Summary: Two-Level AIDA***

FDA approval for the Prestige LP disc at 2 levels was based on superiority to 2-level ACDF at 2-year follow-up. Outcome assessments will continue through 10 years. At present, over 80% of patients have reached 3-year follow-up, and over 50% of patients have reached 7-year follow-up. The difference in success rates at 2 years has been maintained over the follow-up period. Secondary outcome measures and adjacent-level reoperations were similar for the AIDA and the ACDF groups at 2-year follow-up. Continued follow-up will provide important data on longer term safety of the 2-level construct and comparison with ACDF for secondary outcome measures and adjacent-level reoperations.

At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2-levels (Mobi-C) was found to be noninferior to ACDF in the IDE trial. Superiority to ACDF was achieved for NDI

scores, NDI success rates, and overall success composite outcome. Reoperation rates were significantly lower in the Mobi-C group. At 5 years, trial results were consistent with the continued superiority of 2-level AIDA for clinical outcomes and lower cumulative reoperation rates. Although a third of patients who received the Mobi-C had clinically significant heterotopic ossification, adjacent-segment degeneration with Mobi-C was found in a lower percentage of patients than in ACDF patients.

### Registry Data

Staub et al (2016) evaluated the clinical effectiveness of AIDA for 987 patients in the Spine Tango registry.<sup>37</sup> The primary outcome measures were the neck and arm pain relief and the Core Outcome Measures Index (COMI). 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 AIDA and ACDF. The mean group differences on a 10-point scale for both pain measures was 0.6 points in postoperative neck pain ( $p=0.04$ ) and 0.7 points in arm pain ( $p=0.02$ ); mean COMI score difference was 0.8 points ( $p=0.01$ ). Change scores did not differ significantly. The probability of being a responder (2-point change) was significantly better in the AIDA group than in the ACDF group for arm pain relief (78.4% vs 67.4%,  $p=0.02$ ) and COMI score (81.6% vs 67.9%,  $p<0.01$ ), but not neck pain relief (62.1% vs 57.9%,  $p=NS$ ), 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 AIDA and ACDF. A third analysis compared outcomes of AIDA with ACDF in patients who had a follow-up of more than 2 years (mean, 55.0 months; range, 27.0-76.5 months). After controlling for patient age, patients treated with AIDA had significantly higher responder rates for arm pain relief (80.0%) compared with patients treated with ACDF (64.9%;  $p=0.05$ ), with no significant difference in responder rates between groups for neck pain relief or COMI. Rates of adjacent-level degeneration and secondary surgeries were not assessed.

### Adverse Events

Heterotopic ossification appears to be common with AIDA, 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 AIDA included 8 studies (total  $N=617$  patients).<sup>38</sup> The pooled prevalence of any heterotopic ossification was 58.2% at 24 months after AIDA and the pooled prevalence of advanced heterotopic ossification was 16.7% after 24 months.

Guyer et al (2011) reported on 4 cases of a lymphocytic reaction to a metal-on-metal artificial disc (1 Kineflex/C cervical disc and 3 lumbar) that required revision.<sup>39</sup> No hypersensitivity reactions have been reported from devices with a polyethylene/polyurethane insert or from Prestige stainless steel implants, however, periprosthetic tissue explanted after 1 to 7 years has commonly shown focal metallosis.<sup>40</sup> Extensive bone loss in the vertebral body, and device subsidence has been reported as a complication in some patients 4 and 6 years after cervical arthroplasty.<sup>41</sup>

### Summary of Evidence

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, 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 noninferiority criteria. 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 noninferiority of AIDA 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. There have been no safety signals with discs approved by FDA for single-level AIDA. The evidence is sufficient to determine 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 AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The Food and Drug Administration 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. 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 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 AIDA for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared with 2-level ACDF patients. Based on this evidence, it can be concluded that 2-level AIDA 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.

### **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

### North American Spine Society

The 2015 guidelines from the North American Spine Society indicated that<sup>42</sup>:

“Cervical artificial disc replacement ([CADR], 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

The National Institute for Health and Care Excellence issued guidance (2010) on the artificial cervical disc, concluding that<sup>43</sup>:

“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.”

### American Association of Neurological Surgeons

Guidelines from the American Association of Neurological Surgeons (2009) addressed anterior cervical discectomy and anterior cervical discectomy and fusion for the treatment of cervical degenerative radiculopathy and cervical spondylotic myelopathy.<sup>44,45</sup> Neither guideline addressed the artificial cervical disc.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Ongoing and Unpublished Clinical Trials

Some currently 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
<b>Ongoing</b>			
NCT01609374 <sup>a</sup>	Prospective, Concurrently Controlled, Multi-Center Study to Evaluate the Safety and Effectiveness of the Spinal Kinetics™ M6-C Artificial Cervical Disc Compared to Anterior Cervical Discectomy and Fusion (ACDF) for the Treatment of Symptomatic Cervical Radiculopathy	258	Jun 2018
NCT01763619 <sup>a</sup>	Freedom® Cervical Disc Use In The Treatment of Cervical Degenerative Disc Disease	50	Jul 2017 (ongoing)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT00637156 <sup>a</sup>	A Prospective, Randomized, Controlled, Multicenter Pivotal Clinical Trial of the Artificial Cervical Disc-LP at Two Levels for Symptomatic Cervical Disc Disease	397	Mar 2018 (ongoing)
NCT02403453 <sup>a</sup>	RHINE™ Cervical Disc Clinical Study	166	Jun 2021
<b>Unpublished</b>			
NCT00432159 <sup>a</sup>	A Multi-Center, Prospective, Randomized Controlled Trial Comparing Cervical Arthroplasty to Anterior Cervical Discectomy and Fusion for the Treatment of Cervical Degenerative Disc Disease (DISCOVER™ IDE Study)	500	May 2016 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. 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.**

### CPT/HCPCS

- |       |  |
|-------|--|
| 22856 | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy 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 osteophylectomy 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)   |
| 0375T | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels   |

- CPT category I codes for these procedures include: 22856, 22858, 22861, 22864.
- There are add-on CPT category III codes for these procedures in additional cervical interspaces: 0375T, 0095T, 0098T.

**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
M50.01	Cervical disc disorder with myelopathy, high cervical region
M50.021	Cervical disc disorder at C4-C5 level with myelopathy
M50.022	Cervical disc disorder at C5-C6 level with myelopathy
M50.023	Cervical disc disorder at C6-C7 level with myelopathy
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level 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
M54.12	Radiculopathy, cervical region

<b>REVISIONS</b>	
09-23-2008	In Description section: <ul style="list-style-type: none"> <li>Updated wording</li> </ul>
	In Policy section: <ul style="list-style-type: none"> <li>Removed "Removal or revision of artificial disc(s) is a non-covered service."</li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>Removed CPT codes 0096T, 0098T</li> </ul>
	Added Rationale section
05-18-2010	Updated Description Section
	In Coding Section: <ul style="list-style-type: none"> <li>Updated wording for the following CPT codes: 0092T, 0095T (effective 01-01-09)</li> <li>Added CPT codes: 22856, 22861, 22864, 0098T (effective 01-01-09)</li> <li>Deleted CPT codes: 0090T, 0093T (effective 01-01-09)</li> </ul>
	Updated Rationale and References Sections
03-08-2013	Description section updated
	Rational section updated
	In Coding section: <ul style="list-style-type: none"> <li>Coding notations added.</li> </ul>
	References updated
01-01-2015	In Coding section: <ul style="list-style-type: none"> <li>Added CPT Codes: 22858, 0375T (Effective January 1, 2015)</li> <li>Deleted CPT Code: 0092T (Effective January 1, 2015)</li> </ul>
	Description section updated
08-05-2015	In Policy section: <ul style="list-style-type: none"> <li>Revised policy from:</li> </ul>

<b>REVISIONS</b>	
	<p>"Artificial intervertebral discs are considered experimental / investigational for treatment of disorders of the cervical spine, including degenerative disc disease."</p> <p>to:</p> <p>"A. Cervical artificial intervertebral disc implantation may be considered medically necessary when ALL of the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. The device is approved by FDA AND</li> <li>2. The patient is skeletally mature AND</li> <li>3. The patient has intractable cervical radicular pain or myelopathy                             <ol style="list-style-type: none"> <li>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</li> <li>b. if the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment. AND</li> </ol> </li> <li>4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography AND</li> <li>5. Cervical degenerative disc disease is limited to a single level from C3-C7 AND</li> <li>6. The patient is free from contraindication to cervical artificial intervertebral disc implantation</li> </ol> <p>B. Cervical artificial intervertebral disc implantation is considered experimental / investigational for all other indications, including, but not limited to, the following:</p> <ol style="list-style-type: none"> <li>1. Disc implantation at more than 1 level</li> <li>2. Combined use of an artificial cervical disc and fusion</li> <li>3. Prior surgery at the treated level</li> <li>4. Previous fusion at another cervical level</li> <li>5. Multilevel disc disease</li> <li>6. Translational instability</li> <li>7. Anatomical deformity (eg, ankylosing spondylitis)</li> <li>8. Rheumatoid arthritis or other autoimmune disease</li> <li>9. Presence of facet arthritis</li> <li>10. Active infection</li> <li>11. Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)</li> <li>12. Malignancy" </li></ol>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ ICD-9 and ICD-10 Codes added.</li> </ul>
	References updated
10-12-2016	Description section updated
	<p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ In Item A 5 removed "limited to a single level" to read "Cervical degenerative disc disease is from C3-C7"</li> <li>▪ 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 (ie, 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 </li></ul>

<b>REVISIONS</b>	
	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: <ul style="list-style-type: none"> <li>▪ 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</li> <li>▪ ICD-10 Codes Termed 09-30-2016: M50.02, M50.22, M50.32</li> </ul>
	References updated
05-23-2018	Description section updated
	Rationale section updated
	References updated

## **REFERENCES**

1. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *J Manipulative Physiol Ther.* Sep 1991;14(7):409-415. PMID 1834753
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. *TEC Assessments.* 2007;Volume 22:Tab 12.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. *TEC Assessments.* 2009;Volume 24:Tab 3.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disease of the cervical spine. *TEC Assessments.* 2011;Volume 26:Tab 5.
5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. *TEC Assessments.* 2013;Volume 28:Tab 13.
6. Hu Y, Lv G, Ren S, et al. Mid- to long-term outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion for treatment of symptomatic cervical disc disease: a systematic review and meta-analysis of eight prospective randomized controlled trials. *PLoS One.* Feb 2016;11(2):e0149312. PMID 26872258
7. Burkus JK, Traynelis VC, Haid RW, Jr., et al. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. *J Neurosurg Spine.* Oct 2014;21(4):516-528. PMID 25036218
8. Sasso RC, Anderson PA, Riew KD, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg Am.* Sep 21 2011;93(18):1684-1692. PMID 21938372
9. Phillips FM, Geisler FH, Gilder KM, et al. Long-term outcomes of the US FDA IDE prospective, randomized controlled clinical trial comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. *Spine (Phila Pa 1976).* May 15 2015;40(10):674-683. PMID 25955086
10. Coric D, Kim PK, Clemente JD, et al. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. *J Neurosurg Spine.* Jan 2013;18(1):36-42. PMID 23140129
11. Davis RJ, Nunley PD, Kim KD, et al. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *J Neurosurg Spine.* Jan 2015;22(1):15-25. PMID 25380538

12. Hisey MS, Bae HW, Davis RJ, et al. Prospective, randomized comparison of cervical total disc replacement versus anterior cervical fusion: results at 48 months follow-up. *J Spinal Disord Tech*. May 2015;28(4):E237-243. PMID 25310394
13. Janssen ME, Zigler JE, Spivak JM, et al. ProDisc-C Total Disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease: seven-year follow-up of the prospective randomized U.S. Food and Drug Administration Investigational Device Exemption Study. *J Bone Joint Surg Am*. Nov 4 2015;97(21):1738-1747. PMID 26537161
14. Zhang HX, Shao YD, Chen Y, et al. A prospective, randomised, controlled multicentre study comparing cervical disc replacement with anterior cervical decompression and fusion. *Int Orthop*. Dec 2014;38(12):2533-2541. PMID 25209344
15. Mummaneni PV, Burkus JK, Haid RW, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine*. Mar 2007;6(3):198-209. PMID 17355018
16. U.S. Food and Drug Administration (FDA). Report of United States Clinical Study Results (G010188) - Prestige® Cervical Disc System. 2006; [https://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4243b1\\_02.pdf](https://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4243b1_02.pdf). Accessed March 9, 2018.
17. Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine*. Sep 2010;13(3):308-318. PMID 20809722
18. Gornet MF, Burkus JK, Shaffrey ME, et al. Cervical disc arthroplasty with PRESTIGE LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device exemption study. *J Neurosurg Spine*. Jul 31 2015:1-16. PMID 26230424
19. Murrey D, Janssen M, Delamarter R, et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J*. Apr 2009;9(4):275-286. PMID 18774751
20. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis. n.d.; <http://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/adolescent-idiopathic-scoliosis>. Accessed February 12, 2018.
21. Delamarter RB, Murrey D, Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. *SAS J*. Jan 2010;4(4):122-128. PMID 25802660
22. Zigler JE, Delamarter R, Murrey D, et al. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study. *Spine (Phila Pa 1976)*. Feb 1 2013;38(3):203-209. PMID 23080427
23. Delamarter RB, Zigler J. Five-year reoperation rates, cervical total disc replacement versus fusion, results of a prospective randomized clinical trial. *Spine (Phila Pa 1976)*. Nov 2 2013;38(9):711-717. PMID 23124255
24. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine (Phila Pa 1976)*. Jan 15 2009;34(2):101-107. PMID 19112337
25. Coric D, Nunley PD, Guyer RD, et al. Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex|C artificial disc investigational device exemption study with a minimum 2-year follow-up: clinical article. *J Neurosurg Spine*. Oct 2011;15(4):348-358. PMID 21699471
26. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): Mobi-C. 2013; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf11/P110002b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002b.pdf). Accessed March 9, 2018.
27. Hisey MS, Bae HW, Davis R, et al. Multi-center, prospective, randomized, controlled investigational device exemption clinical trial comparing Mobi-C Cervical Artificial Disc to anterior discectomy and fusion in the treatment of symptomatic degenerative disc disease in the cervical spine. *Int J Spine Surg*. Feb 2014;8. PMID 25694918

28. Hisey MS, Zigler JE, Jackson R, et al. Prospective, randomized comparison of one-level Mobi-C Cervical Total Disc replacement vs. anterior cervical discectomy and fusion: results at 5-year follow-up. *Int J Spine Surg*. 2016;10:10. PMID 27162712
29. Phillips FM, Lee JY, Geisler FH, et al. A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion: 2-year results from the US FDA IDE clinical trial. *Spine (Phila Pa 1976)*. Jul 1 2013;38(15):E907-918. PMID 23591659
30. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): SECURE-C. 2012; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100003b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003b.pdf). Accessed March 9, 2018.
31. Vaccaro A, Beutler W, Peppelman W, et al. Clinical outcomes with selectively constrained SECURE-C cervical disc arthroplasty: two-year results from a prospective, randomized, controlled, multicenter investigational device exemption study. *Spine (Phila Pa 1976)*. Dec 15 2013;38(26):2227-2239. PMID 24335629
32. U.S. Food and Drug Administration. Summary of Safety and Effectiveness: Prestige LP Cervical Disc. PMA Number P090029/S003. 2016; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf9/p090029s003b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090029s003b.pdf). Accessed March 9, 2018.
33. Davis RJ, Kim KD, Hisey MS, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial. *J Neurosurg Spine*. Nov 2013;19(5):532-545. PMID 24010901
34. Radcliff K, Coric D, Albert T. Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *J Neurosurg Spine*. Aug 2016;25(2):213-224. PMID 27015130
35. Bae HW, Kim KD, Nunley PD, et al. Comparison of clinical outcomes of 1- and 2-level total disc replacement: four-year results from a prospective, randomized, controlled, multicenter IDE clinical trial. *Spine (Phila Pa 1976)*. Jun 1 2015;40(11):759-766. PMID 25785955
36. Huppert J, Beaurain J, Steib JP, et al. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. *Eur Spine J*. Sep 2011;20(9):1417-1426. PMID 21336970
37. Staub LP, Ryser C, Roder C, et al. Total disc arthroplasty versus anterior cervical interbody fusion: use of the Spine Tango registry to supplement the evidence from randomized control trials. *Spine J*. Feb 2016;16(2):136-145. PMID 26674445
38. Chen J, Wang X, Bai W, et al. Prevalence of heterotopic ossification after cervical total disc arthroplasty: a meta-analysis. *Eur Spine J*. Apr 2012;21(4):674-680. PMID 22134486
39. Guyer RD, Shellock J, MacLennan B, et al. Early failure of metal-on-metal artificial disc prostheses associated with lymphocytic reaction: diagnosis and treatment experience in four cases. *Spine (Phila Pa 1976)*. Apr 1 2011;36(7):E492-497. PMID 21252827
40. Kurtz SM, Toth JM, Siskey R, et al. The latest lessons learned from retrieval analyses of ultra-high molecular weight polyethylene, metal-on-metal, and alternative bearing total disc replacements. *Semin Spine Surg*. Mar 1 2012;24(1):57-70. PMID 22904606
41. Hacker FM, Babcock RM, Hacker RJ. Very late complications of cervical arthroplasty: results of 2 controlled randomized prospective studies from a single investigator site. *Spine (Phila Pa 1976)*. Dec 15 2013;38(26):2223-2226. PMID 24335628
42. North American Spine Society. NASS coverage policy recommendations: Cervical artificial disc replacement. 2015; <https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx>. Accessed March 9, 2018.
43. National Institute for Health and Care Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine [IPG341]. 2010; <https://www.nice.org.uk/guidance/ipg341>. Accessed March 9, 2018.

44. Matz PG, Holly LT, Groff MW, et al. Indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy. *J Neurosurg Spine*. Aug 2009;11(2):174-182. PMID 19769497
45. Mummaneni PV, Kaiser MG, Matz PG, et al. Cervical surgical techniques for the treatment of cervical spondylotic myelopathy. *J Neurosurg Spine*. Aug 2009;11(2):130-141. PMID 19769492
46. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Lumbar Artificial DISC Replacement (LADR) (150.10). 2007; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=National&Keyword=disc&KeywordLookUp=Title&KeywordSearchType=And&from2=search.asp&bc=gAAAAACAAAAAAAAA%3d%3d&>. Accessed March 9, 2018.