



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

# Artificial Intervertebral Disc: Cervical Spine

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## **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Artificial Intervertebral Disc: Cervical Spine when it is determined to be medically necessary because the criteria shown below are met.

## **When Policy Topic is covered**

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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
2. The patient is skeletally mature
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.
4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography
5. Cervical degenerative disc disease is from C3-C7
6. The patient is free from contraindication to cervical artificial intervertebral disc implantation

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).

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.

### **When Policy Topic is not covered**

Cervical artificial intervertebral disc implantation is considered **investigational** for all other indications, including the following:

- Disc implantation at more than two levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Translational instability
- Anatomical deformity (eg, ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)
- Malignancy

### **Description of Procedure or Service**

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

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).

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index (NDI) and overall success composite outcome. 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 are consistent with 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 U.S. Food and Drug Administration (FDA) requirement for 7-year postapproval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to more fully characterize 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. 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 that have been approved by the FDA for single-level AIDA. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for 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 to 2-level ACDF patients. FDA approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at 2 years. The increase in overall success rates at 2 years has been maintained for those patients who have reached the 5- and 7-year follow-ups. Based on this evidence, it can be concluded that 2-level AIDA with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

## **Background**

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 one degenerative change evident at radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Cervical DDD is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do

not improve or resolve after 6 weeks or more, or if they 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 emplacement of either autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate. The choice of bone material for interbody fusion in ACDF has important clinical implications. Allograft bone has several drawbacks, including a small (albeit, unproven) risk of infectious disease transmission; possible immunologic reaction to the allograft, and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. These morbidities include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies demonstrate similar rates of postoperative fusion (90–100%) and satisfactory outcomes for single-level, anterior-plated ACDF, using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material. Biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

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 in bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomical disk space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level degenerative disc disease (DDD) above or below a fusion site has been the major rationale driving device development and use. Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in AIDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis. Patients with advanced spondylosis or hard disc herniations have a separate pathologic condition and require a different surgical approach.

## **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 (PMA) 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, computed tomography, 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 PMA 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 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. 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 computed tomography, myelography and computed tomography, and/or

magnetic resonance imaging results. 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 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 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 adverse events 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 adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, other serious device-related complications, and analysis of all explanted discs.

The following have received FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- Secure®-C (Globus Medical) was approved in 2012 (P100003). The Secure®-C is a 3 piece semi-constrained device with 2 metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is 3 piece semiconstrained 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. Cervical Disc Prostheses Under Investigation in the U.S.**

Prosthesis	Manufacturer	FDA Status
Kineflex/C®	Spinal Motion	FDA IDE trial complete
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 to the regulatory status of these devices can be viewed at online site: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>

## **Rationale**

This evidence review was created in October 2006 and has been updated regularly with searches of the MEDLINE database. 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
<b>Follow-up, n (%)</b>	199 (95)	160 (86)	185 (89)	149 (80)	166 (80)	138 (74)	126 (67)	99 (58)
<b>Cumulative withdrawal, n (%)</b>	0 (0)	7 (3.7)	1 (0.5)	10 (5.3)	5 (2.3)	12 (6.3)	5 (2.3)	16 (8.5)
<b>Overall success n/N (%)</b>	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.

## **Supplemental Information**

### **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.

### **Medicare National Coverage**

A search of the Medicare National Database identified a national coverage determination on artificial intervertebral discs for the lumbar spine, but not for the cervical spine.<sup>46</sup>

## 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>			
<b>NCT01609374<sup>a</sup></b>	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
<b>NCT01763619<sup>a</sup></b>	Freedom® Cervical Disc Use In The Treatment of Cervical Degenerative Disc Disease	50	Jul 2017 (ongoing)
<b>NCT00637156<sup>a</sup></b>	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)
<b>NCT02403453<sup>a</sup></b>	RHINE™ Cervical Disc Clinical Study	166	Jun 2021
<b>Unpublished</b>			
<b>NCT00432159<sup>a</sup></b>	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.

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## **Billing Coding/Physician Documentation Information**

- 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
- 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** Removal 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

### **ICD-10 Codes**

- M50.00-** Cervical disc disorder with myelopathy  
**M50.023**
- M50.10-** Cervical disc disorder with radiculopathy  
**M50.123**

## **M54.12** Radiculopathy, cervical region

Category III codes 0090T, 0093T and 0096T were deleted effective 12/31/2008. 0092T was deleted effective 12/31/2014.

CPT category I codes for these procedures were revised for 2015 to include coding for a second level:

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 ; 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

There are add-on CPT category III codes for these procedures in additional cervical interspaces:

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

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)

### **Additional Policy Key Words**

N/A

### **Policy Implementation/Update Information**

12/1/07 New policy; considered investigational.

2/1/08 Description and Rationale updated; procedure remains investigational.

12/1/08 No policy statement changes.

6/1/09 No policy statement changes.

12/1/09 No policy statement changes.

6/1/10 No policy statement changes.

12/1/10 No policy statement changes.

6/1/11 No policy statement changes.

12/1/11 No policy statement changes.

6/1/12 No policy statement changes.

- 12/1/12 No policy statement changes.
- 6/1/13 No policy statement changes.
- 12/1/13 No policy statement changes.
- 6/1/14 Updated FDA approvals and new trials in Regulatory status. No policy statement changes.
- 12/1/14 No policy statement changes.
- 6/1/15 No policy statement changes. Updated CPT codes.
- 8/1/15 Updated policy statement to include Medically Necessary indications. Considered medically necessary for single level cervical disc replacement. Updated investigational statement.
- 12/1/15 No policy statement changes.
- 6/1/16 No policy statement changes.
- 11/1/16 Policy statement revised regarding multiple level replacement. Considered medically necessary for 2-level cervical disc replacement with a device that is FDA-approved for 2-levels (ie, Mobi-C and Prestige LP). Added: Subsequent cervical artificial intervertebral disc implantation at an adjacent level may be considered medically necessary. Removed Multilevel disc disease from investigational statement.
- 5/1/17 No policy statement changes.
- 12/1/17 No policy statement changes.
- 5/1/18 No policy statement changes.
- 11/1/18 No policy statement changes.

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