MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**ARTIFICIAL CERVICAL INTERVERTEBRAL DISC**
Policy Number	**7.01.80**
Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and assessment of peer-reviewed literature, an initial/primary total artificial cervical intervertebral disc implant has been proven to be medically effective and, therefore, is considered **medically appropriate** when **ALL** the following criteria are met:
   A. The patient has degenerative disc disease (DDD) with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation;
   B. The patient is skeletally mature;
   C. The device is FDA-approved and is used in accordance with FDA labeling, namely:
      1. **ANY** of the following for single-level cervical disc arthroplasty:
         a. PRESTIGE ST™ / PRESTIGE LP® / PRESTIGE® Cervical Disc
         b. ProDisc®™-C;
         c. BRYAN® Cervical Disc;
         d. SECURE-C® Cervical Artificial Disc;
         e. Mobi-C®;
         f. PCM Cervical Disc; or
         g. M6-C™ Artificial Cervical Disc.
      2. **EITHER** of the following for two-level cervical disc arthroplasty:
         a. Mobi-C®; or
         b. PRESTIGE LP®;
   D. No previous surgeries have been performed on the disc(s) involved;
   E. The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy;
   F. The patient is a candidate for single-level or two-level anterior cervical decompression(s) and interbody fusion(s);
   G. The patient has no unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, or drug or alcohol abuse);
   H. No clinically significant cervical instability on neutral resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g., greater than 3.5 mm subluxation/translation or greater than 11 degrees angulation/rotational difference) from that of either adjacent spinal level;
   I. Performed for **EITHER** radiculopathy or myelopathy, as follows:
      1. Radiculopathy, when **ALL** of the following are met:
         a. Subjective symptoms, including **BOTH** of the following:
            i. Significant level of pain on a daily basis defined as either of the following:

a) Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven; or
b) Severe, disabling, crippling, or incapacitating pain; and

ii. Unremitting, radicular pain to shoulder girdle and/or upper extremity, resulting in a disability; and

b. Objective physical examination findings, including any of the following:
i. Dermatomal sensory deficit;
ii. Motor deficit (e.g., biceps, triceps weakness);
iii. Reflex changes;
iv. Shoulder Abduction Relief Sign;
v. Nerve root tension sign (e.g., Spurlings maneuver); or
vi. Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings; and

c. Less than clinically meaningful improvement with at least TWO of the following, unless contraindicated:
i. Prescription strength analgesics, steroids, and/or NSAIDs for six weeks;
ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician for six weeks; and/or
iii. Epidural steroid injections/selective nerve root block.

d. MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that correlates with the patient's symptoms or physical findings.

2. Myelopathy, when **ALL** of the following are met:
a. Subjective symptoms consistent with any of the following:
i. Upper/lower extremity weakness, numbness or pain;
ii. Fine motor dysfunction with tasks such as buttoning, handwriting, or clumsiness of hands);
iii. Urinary urgency;
iv. New-onset bowel or bladder dysfunction due to a neurocompressive pathology; or
v. Frequent falls;

b. Objective physical examination findings (any TWO of the following):
i. Grip and release test;
ii. Ataxic gait;
iii. Hyperreflexia;
iv. Hoffman sign;
v. Pathologic Babinski sign;
vi. Tandem, walking test;
vii. Inverted brachial radial reflex;
viii. Increased muscle tone and spasticity;
ix. Clonus; or
x. Myelopathic hand;

c. MRI/CT findings that correlate with the patient's symptoms or physical findings, including EITHER of the following:
i. MRI/CT demonstrates cervical spinal cord compression; or
ii. MRI/CT identifies cervical spinal stenosis.

J. Patient is a nonsmoker or has refrained from smoking for at least six weeks prior to planned surgery (see Guidelines sections I and III).

II. Based upon our criteria and assessment of peer-reviewed literature, *revision of a failed cervical total disc arthroplasty* is considered **medically appropriate** when the patient is a candidate for single-level or two-level anterior cervical decompression(s) and interbody fusion(s) for EITHER of the following:
A. Post-operative imaging studies of the cervical spine, including flexion/extension lateral views demonstrating failure of a cervical disc arthroplasty implant (i.e., subsidence, loosening, dislocation/subluxation, vertebral body fracture without instability, dislodgement); or
B. Performed for ANY of the following conditions:
1. Unremitting neck pain when ALL of the following are met:

a. Significant level of pain on a daily basis, defined as either of the following:
   i. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven; or
   ii. Severe, disabling, crippling, or incapacitating pain; and
b. More than six months have elapsed since prior cervical disc arthroplasty procedure; and
c. The patient has no unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug or alcohol abuse); and
d. Less than clinically meaningful improvement with prescription strength analgesics, steroids, and/or NSAIDs for six weeks, unless contraindicated; and
e. Post-operative MRI/CT findings that are consistent with the patient's symptoms or physical examination findings.

2. Radiculopathy, when **ALL** of the following are met:
   a. More than six months have elapsed since the prior cervical disc arthroplasty procedure; and
   b. The patient has no unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug or alcohol abuse); and
   c. Subjective symptoms, including BOTH of the following:
      i. Significant level of pain on a daily basis, defined as either of the following:
         a) Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven; or
         b) Severe, disabling, crippling, or incapacitating pain; and
      ii. Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability.
   d. Objective physical examination findings, including ANY of the following:
      i. Dermatomal sensory deficit;
      ii. Motor deficit (e.g., biceps, triceps weakness);
      iii. Reflex changes;
      iv. Shoulder Abduction Relief Sign;
      v. Nerve root tension sign (e.g., Spurlings maneuver); or
      vi. Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings.
   e. Less than clinically meaningful improvement with at least TWO of the following, unless contraindicated:
      i. Prescription strength analgesics, steroids, and/or NSAIDs for six weeks;
      ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician for six weeks; and/or
      iii. Epidural steroid injections/selective nerve root block.
   f. Post-operative MRI/CT findings that are consistent with the patient's symptoms or physical examination findings.

3. Myelopathy, when **ALL** of the following are met:
   a. More than six months have elapsed since the prior cervical disc arthroplasty procedure; and
   b. The patient has no unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug or alcohol abuse); and
   c. Subjective symptoms, including ANY of the following:
      i. Upper/lower extremity weakness, numbness or pain;
      ii. Fine motor dysfunction (buttoning, handwriting, clumsiness of hands);
      iii. New-onset bowel or bladder dysfunction due to a neurocompressive pathology; or
      iv. Frequent falls.
   d. Objective physical examination findings, including at least TWO of the following:
      i. Grip and release test;
      ii. Ataxic gait;
      iii. Hyperreflexia;
      iv. Hoffmann sign;
      v. Pathologic Babinski sign;
      vi. Tandem walking test;
      vii. Inverted brachial radial reflex;

viii. Increased muscle tone or spasticity;
ix. Clonus; and/or
x. Myelopathic hand.

e. Post-operative MRI/CT findings that are consistent with the patient's symptoms or physical examination findings including EITHER of the following:
i. MRI/CT demonstrates cervical spinal cord compression; or
ii. MRI/CT identifies cervical spinal stenosis.

III. Based upon our criteria and assessment of peer-reviewed literature, cervical total disc arthroplasty for adjacent segment disease secondary to cervical total disc arthroplasty is considered **medically appropriate** when **ALL** of the following criteria are met:

A. Imaging studies of the cervical spine, including flexion/extension lateral views, demonstrate successful cervical total disc arthroplasty at the adjacent level;
B. No previous surgeries have been performed on the disc(s) involved;
C. The patient has no unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, or drug or alcohol abuse;
D. The patient has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation;
E. The patient is skeletally mature;
F. An FDA-approved implant is used for two-level cervical disc arthroplasty in accordance with FDA labeling, namely:
1. Mobi-C®, or
2. PRESTIGE LP®
G. The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy;
H. The prior total disc arthroplasty procedure at an adjacent level was performed at least six months prior;
I. Performed for EITHER of the following conditions, as follows:
1. Radiculopathy, when ALL of the following are met:
a. Subjective symptoms, including BOTH of the following:
i. Significant level of pain on a daily basis, defined as either of the following:
a) Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven; or
b) Severe, disabling, crippling, or incapacitating pain; and
ii. Unremitting radicular pain to shoulder girdle and/or upper extremity, resulting in disability.
b. Objective physical examination findings, including ANY of the following:
i. Dermatomal sensory deficit;
ii. Motor deficit (e.g., biceps, triceps weakness);
iii. Reflex changes;
iv. Shoulder Abduction Relief Sign;
v. Nerve root tension sign (e.g., Spurlings maneuver); or
vi. Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings.
c. Less than clinically meaningful improvement with at least TWO of the following, unless contraindicated:
i. Prescription strength analgesics, steroids, and/or NSAIDs for six weeks;
ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician for six weeks; and/or
iii. Epidural steroid injections/selective nerve root block.
d. MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is consistent with the patient's symptoms and physical examination findings.
2. Myelopathy, when **ALL** of the following are met:
a. Subjective symptoms, including ANY of the following:
i. Upper/lower extremity weakness, numbness or pain;
ii. Fine motor dysfunction (buttoning, handwriting, clumsiness of hands);

iii. New-onset bowel or bladder dysfunction due to a neurocompressive pathology; or
iv. Frequent falls.

b. Objective physical examination findings, including at least TWO of the following:
i. Grip and release test;
ii. Ataxic gait;
iii. Hyperreflexia;
iv. Hoffmann sign;
v. Pathologic Babinski sign;
vi. Tandem walking test;
vii. Inverted brachial radial reflex;
viii. Increased muscle tone or spasticity;
ix. Clonus; and/or
x. Myelopathic hand.

c. MRI/CT findings that are consistent with the patient's symptoms or physical examination findings, including EITHER of the following:
i. MRI/CT demonstrates cervical spinal cord compression; or
ii. MRI/CT identifies cervical spinal stenosis.

IV. Based upon our criteria and assessment of peer-reviewed literature, an artificial cervical intervertebral disc implant has not been medically proven effective and is considered **investigational** in the following circumstances:

A. The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid construct)
B. Patient is under age 18 or over age 60;
C. The patient had a prior surgery at the treated level;
D. The patient had a previous fusion at an adjacent cervical level (hybrid construct);
E. The planned procedure will lead to cervical total disc arthroplasty at more than two (2) levels;
F. Decreased bone mineral density, defined by ANY of the following:
1. DEXA bone mineral T-score equal to or worse than -3.5; or
2. T-score equal to or worse than -2.5 with history of a vertebral compression fracture; or
3. DEXA bone mineral density T-score less than or equal to -1.0;
G. Allergy or sensitivity to titanium, aluminum or vanadium;
H. Chronic non-specific neck or arm pain of unknown etiology;
I. Absence of radiculopathy or myelopathy;
J. The patient has rheumatoid arthritis or other autoimmune disease;
K. Active systemic infection;
L. Revision of an infected cervical disc arthroplasty;
M. Paget's disease, osteomalacia or other metabolic bone disease;
N. Severe, poorly controlled diabetes mellitus requiring insulin treatment; or
O. Radiological evidence of ANY of the following:
1. Clinically significant cervical instability on neutral resting or lateral or flexion/extension plain X-rays, such as kyphotic deformity/significant reversal of lordosis or spondylolisthesis (e.g., greater than 3.5 mm subluxation/translation or more than 11 degrees angulation/rotational difference) from that of either adjacent spinal level;
2. Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma);
3. Symptoms attributed to more than one cervical level (see criteria for two-level cervical disc replacement);
4. Spinal metastases;
5. Severe spondylosis at the level to be treated, characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space greater than 50% of its normal height;
6. Severe facet joint arthropathy; or
7. Ossification of the posterior longitudinal ligament (OPLL).

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.63 Artificial Lumbar Intervertebral Disc.

POLICY GUIDELINES

I. Minimum documentation requirements needed to complete a spinal surgery prior authorization request:
   A. CPT codes, disc level(s) or motion segments involved for planned surgery and ICD-10 codes;
   B. Detailed documentation of type, duration, and frequency of provider-directed conservative treatment (e.g., interventional pain management procedures/injections, medication, physical therapy, chiropractic, or other provider-directed active exercise program) and the response to each treatment:
      1. Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated if applicable;
      2. Detailed documentation of less than clinically meaningful improvement for each treatment;
   C. Most recent imaging reports performed, read and interpreted by an independent radiologist whose report shall supersede any discrepancies (when present) in interpretation;
   D. Documentation of nicotine-free status (see Tobacco Cessation criteria below, Guidelines III).

II. URGENT/EMERGENT CONDITIONS: All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment in lieu of conservative pain management treatment. Severe neck pain associated with any of the following will still need confirmatory imaging, such as a CT or MRI scan. An urgent/emergent care request for medical care or services includes any of the following.
   A. Where application of the timeframe for making routine or non-life threatening care determinations:
      1. Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment; or
      2. Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state; or
      3. In the opinion of a practitioner with knowledge of the member's medical or behavioral health condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request; or
   B. Myelopathy;
   C. Central cord syndrome;
   D. Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated;
   E. Severe or rapidly progressive symptoms of motor loss or of bowel or bladder dysfunction due to neurocompressive pathology;
   F. Documented progressive neurological deficit on two separate physical exams.

III. Documentation of Nicotine Free Status:
   A. Patient is a non-tobacco user, or
   B. If patient is a documented tobacco user, then patient must have abstained from tobacco use for at least six weeks prior to the planned spinal fusion surgery, as evidenced by lab results (cotinine level) documenting nicotine-free status. Note: In order to complete the prior authorization process for spinal fusion surgery, planning should allow for enough time to submit lab results performed after the six-week tobacco abstinence period.

IV. Patients with discogenic pain must be screened by their physician for major psychopathology. All patients who have current symptoms that concern the physician, or who have had a psychiatric hospitalization, must have a psychiatric evaluation. A psychiatrist or clinical psychologist who is providing ongoing care for the patient may provide this evaluation. Psychological testing as a screening tool or as part of the psychological evaluation prior to surgery is considered **not medically necessary**.

V. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Cervical DDD (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. 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 an appropriate time frame of conservative therapy, 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. The ACDF procedure is believed to do relatively well in stabilizing the anterior column and relieving pain by eliminating motion. However, it is not physiologic, and it alters the stress distribution on the adjacent segments.

Replacement of the intervertebral disc with an artificial device (artificial intervertebral disc arthroplasty [AIDA]) is proposed as an alternative ACDF to treat symptomatic DDD. It is thought that an artificial disc would restore not only the anatomy but also normal mechanical function. Many designs have been proposed over the past 40 years, both total disc and disc nucleus (partial disc replacement or PDA) devices. A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate, and consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. Partial disc replacement is also referred to as a nucleus arthroplasty. Hybrid constructs or procedures that combine ACDF with cervical artificial disc replacement (C-ADR) in a single procedure are also being investigated. The intent of the hybrid construct is to avoid multilevel fusion and maintain cervical motion when the individual has more than one level of symptomatic cervical disc disease.

Definitions:

I. Acceptable imaging modalities are CT scan, MRI, and myelogram. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, interpretations by the radiologist will supersede. Discography results will not be used as a determining factor of medical necessity for any requested procedures. Use of discography is not endorsed.
II. Clinically meaningful improvement: Global assessment showing at least 50% improvement.

RATIONALE

Medtronic received FDA approval to market its Prestige® Cervical Disc System in July 2007 for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. Evidence for the Prestige Disc is available from the non-inferiority RCT presented to the FDA, comparing the Prestige disc with fusion and from a published report on 421 cases from the trial. Statistical non-inferiority was demonstrated on all outcome measures. Outcomes at two years were similar in both groups. Disc recipients improved more than the fusion group only on neurological status; however, the information provided about how this was evaluated is insufficient to understand its significance. Sixty-month follow-up of participants in this clinical trial were reported by Burkus *et al*. All participants were followed up in this FDA-regulated post-approval study. Outcomes at 60 months were reported on approximately half of the original randomized controlled trial (RCT) participants. The majority of the remaining patients had not yet reached that point in their follow-up, rather than being lost to follow-up. About 18% of all participants were actually lost to follow-up at 60 months. The NDI improved by 38.4 points for the Prestige disc compared to 34.1 for ACDF (p=0.022). For most other clinical outcomes, the Prestige disc was similar to ACDF, with no significant difference between groups in improvement in neck pain score (56.0 vs. 52.4) or arm pain score (52.5 vs. 47.7 – both, respectively). There was a trend for greater neurologic success in the Prestige disc group (95% vs. 89%, p=0.051). Need for additional surgery was similar between the two procedures, and there was no significant difference in the percentage of patients requiring adjacent-level surgery (2.9% vs. 4.9% for ACDF). No implant migration was observed at up to 60 months. Bridging bone was observed in 3 of 94 patients (3.2%) with the Prestige disc.

The Prestige® LP artificial disc was approved by the FDA in 2014. It differs from the original Prestige cervical disc in terms of material and fixation.

JK Burkus and colleagues (2014) assessed the long-term safety and efficacy of cervical disc replacement with the Prestige Cervical Disc in a prospective, randomized, multicenter trial at seven years of follow-up. 541 patients with single-level cervical disc disease with radiculopathy were randomized to 1 of 2 treatment groups: 276 investigational group patients underwent anterior cervical discectomy and arthroplasty with the Prestige disc, and 265 control group patients underwent ACDF. Clinical outcomes included Neck Disability Index, the 36-Item Short-Form Health Survey, and neck and arm pain scores. Radiographs were assessed for angle of motion and fusion. Clinical and radiographic outcomes were evaluated preoperatively, intraoperatively, and at 1.5, 3, 6, 12, 24, 36, 60, and 84 months. Of the 541 patients treated, 395 patients (73%; 212 investigational and 183 control patients) completed seven years of clinical follow-up. Significant improvements achieved by 1.5 months in both groups were sustained at seven years. In the investigational group, mean Neck Disability Index improvements from preoperative scores were 38.2 and 37.5 at 60 and 84 months, respectively. In the control group, the corresponding means were 33.8 and 31.9. The differences between the investigational and control groups at the 60-month and 84-month periods were significant ($p = 0.014$ and 0.002, respectively). The overall rates of maintenance or improvement in neurological status in the investigational group were significantly higher: 92.2% and 88.2% at 60 months and 84 months, respectively, compared with 85.7% and 79.7% in the control group ($p = 0.017$ and 0.011, respectively). At 84 months, the percentage of working patients in the investigational group was 73.9%, and in the control group, 73.1%. Postoperatively, the implant effectively maintained average angular motion of 6.67° at 60 months and 6.75° at 84 months. Cumulative rates for surgery at the index level were lower ($p < 0.001$) in the investigational group (11 [4.8%] of 276) when compared with the control group (29 [13.7%] of 265) (based on life-table method), and there were statistical differences between the investigational and control groups with specific regard to the rate of subsequent revision and supplemental fixation surgical procedures. Rates for additional surgical procedures that involved adjacent levels were lower in the investigational group than in the control group (11 [4.6%] of 276 vs 24 [11.9%] of 265, respectively). The authors concluded the following: Cervical disc arthroplasty has the potential for preserving motion at the operated level while providing biomechanical stability and global neck mobility and may result in a reduction in adjacent-segment degeneration. The Prestige Cervical Disc maintains improved clinical outcomes and segmental motion after implantation at seven-year follow-up.

In December 2007, the ProDisc®-C received approval from the U.S. Food and Drug Administration (FDA) based on a premarket approval application (PMA). Murrey *et al*. (2008) reported the two-year follow-up of the pivotal FDA randomized non-inferiority trial to determine the safety and efficacy of ProDisc-C in comparison with ACDF. Clinical outcomes at 24-month follow-up were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88%, respectively), neck disability index (21.4 vs. 20.5 points), reduction in pain scores (e.g., 46 mm vs. 43 mm reduction in neck pain on a visual analog scale), and patient satisfaction (83 mm vs. 80 mm). Four-year interim follow-up of participants in this clinical trial were reported by Delamarter *et al*. All participants in the clinical trial were followed up in this FDA-regulated post-approval study. At 48 months, follow-up rates for ProDisc-C and ACDF were 63% and 46.2% respectively. It was not reported what proportion of these patients had not yet reached 48 months post-surgery or were truly lost to follow-up at that time point. Also included in this report was 24-month follow-up on 77% of 136 continued access patients who received the ProDisc-C after the clinical trial. Clinical outcomes were similar between the 3 groups, with point estimates in favor of ProDisc-C. The NDI at 48 months was 20.3 for ProDisc-C versus 21.2 for ACDF. Neurologic success was achieved in 88.9% of ProDisc-C patients in comparison with 74.4% of ACDF patients ($p=0.067$). There was a cumulative incidence of additional surgeries of 2.9% (3 patients) in the ProDisc-C group and 11.3% (12 patients) in the ACDF group. Two patients were converted to fusion with removal of the device; one patient had decompression with supplemental fixation without removal of the device. At 48 months, 5 ProDisc-C patients (7.7%) were found to have bridging bone. Five-year results of this trial were published in 2013 with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF by Zigler et al. and Delamarter, et al. Outcomes on the NDI were found to be similar (50-60% improved), along with VAS for arm pain (18 for both groups) and scores on the SF-36. VAS for neck pain was modestly improved with ProDisc-C compared to ACDF (21 vs. 30), although the proportion of patients who achieved a clinically significant improvement in neck pain was not reported. There was a lower percentage of patients with ProDisc-C who had secondary surgery at either the index or adjacent level (2.9% vs. 14.5%).

GM Malham, e*t al*. (2014) evaluated the clinical and radiographic outcomes in cervical ADR patients using the ProDisc-C device with a five- to nine-year follow-up. Data were collected through a prospective registry, with retrospective analysis performed on 24 consecutive patients treated with cervical ADR by a single surgeon. All patients underwent single- or two-level ADR with the ProDisc-C device. Outcome measures included neck and arm pain (visual analogue scale), disability (neck disability index [NDI]), complications, and secondary surgery rates. Flexion-extension cervical radiographs were performed to assess range of motion (ROM) of the device and adjacent segment disease (ASD). Average follow-up was 7.7 years. Neck and arm pain improved 60% and 79%, respectively, and NDI had an improvement of 58%. There were no episodes of device migration or subsidence. Mean ROM of the device was 6.4°. Heterotopic ossification was present in seven patients (37%). Radiographic ASD below the device developed in four patients (21%) (one single-level and three two-level ADR). No patient required secondary surgery (repeat operations at the index level or adjacent levels). Fourteen out of 19 patients (74%) were able to return to employment, with a median return to work time of 1.3 months. The authors concluded that the ProDisc-C device for cervical ADR is a safe option for patients, providing excellent clinical outcomes, satisfactory return to work rates, and maintenance of segmental motion despite radiographic evidence of heterotopic ossification and ASD on long-term follow-up. The study is limited by being a small single-center study that was not randomized. Also, the follow-up rate was only 79%.

The Bryan® Cervical Disc System received FDA approval based on PMA clearance in May 2009. Based on the information provided from the manufacturer and the FDA premarket approval, the device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The BRYAN® device is implanted via an open anterior approach. Patients receiving the BRYAN® Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the device. Heller and colleagues published the results of a non-inferiority trial in 2009. This multicenter RCT investigated the safety and efficacy of the device in 242 patients compared to 221 patients undergoing an anterior cervical discectomy. At 24-month follow-up, both groups had similar improvements in clinical outcomes. Four-year follow-up from the IDE trial was reported for 181 patients (75% of 242) who received the Bryan disc and 138 patients (62% of 223) who underwent ACDF. (Sasso, et al.) It was reported that 25% of AIDA and 38% of the ACDF patients failed to return for follow-up at 48 months, due in part to FDA and institutional review board approvals and the need for additional patient consent for the continuation study. Overall success was defined as an improvement of equal to or greater than 15 points in the NDI, neurologic improvement, no serious adverse events related to the implant or surgical implantation procedure, and no subsequent surgery or intervention that would be classified as a treatment failure. The four-year overall success rates were significantly greater in the Bryan (85.1%) than the ACDF (72.5%) group. This finding was driven largely by differences in the NDI success (90.6% of arthroplasty and 79.0% of ACDF). Neurologic success rates were not different between the groups. Arm pain improved from a baseline of 71.2 in both groups to 16.6 for the Bryan disc and 22.4 for ACDF, the difference between groups was statistically significant. The improvement in neck pain scores was also significantly better in the Bryan disc group (from 75.4 to 20.7), compared to patients with fusion (from 74.8 to 30.6). Improvement in the SF-36 physical component score was also significantly greater in the arthroplasty group (15.8 vs. 13.1). There was no significant difference in additional surgical procedures at either the index (3.7% Bryan, 4.5% ACDF) or adjacent (4.1% Bryan, 4.1% ACDF) levels. FDA-required follow-up will continue for 10 years after the index surgery.

The PCM [porous coated motion] Cervical Disc® (NuVasive), which received five-year FDA approval in October 2012, is a semi-constrained device consisting of two metal (cobalt-chrome alloy) endplates and a polyethylene insert that fits between the endplates. Continued approval is contingent on the submission of annual reports, which should include the number of devices sold, analysis of all explanted discs, and seven-year follow-up of the pre-market cohort with an evaluation of overall success. In addition, NuVasive will conduct 10-year enhanced surveillance of device-related adverse events. Results of the two-year FDA-regulated multicenter randomized non-inferiority trial of the PCM Cervical Disc were reported by Phillips and colleagues in 2013. The investigator and surgical staff were not blinded to treatment assignment, and patients were informed of the treatment assignment after surgery. Out of the 416 patients who were randomized (224 PCM, 192 ACDF), 340 (82%, 189 PCM and 151 ACDF) were per protocol for the 24-month primary endpoint of overall success. Overall success was defined as at least 20% improvement in NDI; absence of reoperation, revision, or removal; maintenance or improvement in neurological status; and absence of radiographic or major complications during the 24-month follow-up period. At 24 months, overall success was 75.1% in the PCM group and 64.9% in the ACDF group, which was statistically non-inferior and superior for AIDA. There was a trend toward a

greater neurological success rate in the PCM group (94.7%), compared with ACDF (89.5%, p = 0.10). There was no significant difference between the groups for VAS pain scores, SF-36 component scores, or implant- or surgery-related adverse events (5.2% PCM vs. 5.4% ACDF). Patients with prior fusion were included in this study. Overall success for the two sub-groups in this analysis was similar (65.4% PCM and 64.3% ACDF).

On September 28, 2012, the FDA approved the SECURE-C Artificial Cervical Disc, which is intended to be used in skeletally mature patients to replace a cervical disc (from C3 to C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only one level. The approval was based on a prospective, multi-center, two-arm, randomized (1:1), unmasked, concurrently controlled, non-inferiority clinical study that compared the safety and effectiveness of the SECURE®-C Cervical Artificial Disc to the standard of care, ACDF using a plate (ASSURE® Anterior Cervical Plate System) and structural allograft in treating patients with intractable symptomatic cervical disc disease (SCDD) at one level between C3 and C7. Based on the FDA conclusion, the study data indicated that, at 24 months postoperatively, the SECURE®-C device is at least as effective as the ACDF control group in terms of clinically significant improvement on the Neck Disability Index and maintenance or improvement in neurological status and is statistically superior to the ACDF control group in terms of subsequent surgeries at the index level, device-related adverse event rates, and overall success according to both composite definitions analyzed.

The Mobi-C® Cervical Disc Prosthesis received FDA approval in August 2013. It is indicated in skeletally mature patients for reconstruction of the disc at either one or two levels level from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to diseased discs at one level or two adjacent levels. The Mobi-C® Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis. Data from a single level clinical study was the basis for the PMA approval decision. The study was a prospective, multi-center, two-arm, randomized (2:1), unmasked, concurrently controlled, non-inferiority clinical study to compare the safety and effectiveness of the Mobi-C® Cervical Disc Prosthesis to the standard of care, ACDF. The study data indicated that, at 24 months postoperatively, the Mobi-C® device is at least as effective as the control treatment (ACDF), for the patient population and indications studied in this investigation, in terms of the overall success according to the protocol-specified composite primary endpoint and alternative primary endpoint definitions analyzed.

Two- and four -year results from the two-level Mobi-C IDE trial were reported by Davis, *et al*. in 2013 and 2014, respectively. In this noninferiority trial, 225 patients received the Mobi-C device at two contiguous levels and 105 patients received two-level ACDF. At 24 months, the follow-up rate was 98.2% for the AIDA group and 94.3% for the ACDF group. At 48 months, the follow-up rate was 89.0% for AIDA and 81.2% for the ACDF group. Both groups showed significant improvement in NDI score, VAS neck pain, and VAS arm pain from baseline to each follow-up point, with Mobi-C meeting the noninferiority margin. Subsequent testing for superiority showed that AIDA patients had significantly greater improvement than ACDF patients in NDI and had higher NDI success rates (79.3% vs 53.4% at 48 months, $p<0.000$) and overall success rates (66.0% vs 36.0% at 48 months) at all time points. AIDA resulted in significantly greater improvement in VAS neck pain at three and six months postoperatively, but not at 12, 24, 36, or 48 months. Arm pain scores did not differ between the groups. The Mobi-C group had a lower reoperation rate (4.0% vs 15.2% $p<0.000$). 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.

Post hoc analysis of data from the pivotal one- and two-level Mobi-C trials was reported by Bae and colleagues in 2015. Comparison showed no significant difference between one- and two-level AIDA on clinical outcomes (NDI, VAS, SF-12), major complication rates (4.3% for one-level AIDA, 4.0% for two-level AIDA), or subsequent surgery rates (3.0% of one-level, 4.0% of two-level). Clinically relevant heterotopic ossification was observed in 23.8% of one-level patients and 25.7% of two-level patients. Huppert *et al*. compared outcomes between single- (n=175) and multilevel (2-4 levels, n=56) AIDA with the Mobi-C device in a prospective multicenter study from Europe.29 The age of the patients was significantly higher, and the time since symptom onset was significantly longer in the multilevel group. At two years, there was no significant difference between groups for the radicular VAS, cervical VAS, or NDI. Range of motion was similar in the

two groups. The overall success rate was 69% for the single-level group and 69% for the multilevel groups. There was a trend for more patients in the single-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). A similar percentage of patients underwent adjacent-level surgery (2.3% for single-level and 3.6% for multilevel).

Several other devices are under study in FDA Investigational Device Exemption (IDE) trials in the U.S., but final approval of those is not expected for several years. These include: Cervicore, Flexicore, Kineflex C, Discover, and NeoDisc.

After several years of follow-up, randomized trials of all the artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index and overall success composite outcome. Mid-term outcomes have been reported on four of the devices (Prestige ST, ProDisc-C, Mobi-C, Bryan discs). The trial results are consistent with continued noninferiority of artificial intervertebral disc arthroplasty for all devices and lower cumulative reoperation rates at four to five years. Longer term results are expected, given the FDA requirement for seven- to 10-year post-approval studies of the safety and function of the devices, and five- to 10-year enhanced surveillance study of these discs to more fully characterize adverse events in a broader patient population. Several recent meta-analyses and systematic reviews (Wu, *et al*. (2015); Mummaneni, *et al*. (2012); Luo, *et al*. (2015); Muheremu, *et al*. (2015); Zhao, *et al*. (2015)) have concluded that, while longer-term follow-up is required, midterm results identify artificial cervical disc arthroplasty as a viable treatment option for patients suffering disc degeneration with radiculopathy, with similar outcome results to ACDF.

NASS coverage policy recommendations from 2014 state that cervical arthroplasty may be indicated for radiculopathy, myelopathy or myeloradiculopathy related to a single-level degenerative disease. NASS recommends that cervical arthroplasty is not indicated for symptomatic multilevel disease or adjacent level disease, among other contraindications.

Currently, there is insufficient literature investigating the safety and efficacy of hybrid procedures. Larger sample populations and longer-term outcomes are necessary to determine the effect of this procedure on health outcomes.

Partial disc replacement systems are in the earliest stages of investigation. Partial disc replacement systems are considered **investigational** due to the lack of FDA approval and lack of long-term studies of these devices that demonstrate their safety and improvement on patient health outcomes over standard fusion procedures.

Tobacco use

Tobacco use is considered a risk factor for poor healing and is associated with nonunion. It is well-established that smoking is a preventable cause of morbidity and mortality. The American Academy of Orthopedic Surgeons (AAOS) strongly recommends avoiding use and exposure to tobacco products due to the severe and negative impact on the musculoskeletal system, including the bones, muscles, tendons, and ligaments (AAOS, 2010). In most situations, this is an elective surgery; it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. A policy statement published by the International Society of Advancement for Spine Surgery (ISASS, 2011) indicates that, while undergoing conservative care prior to surgery, smokers should be encouraged to stop smoking, as smoking aggravates low back pain, is a risk factor for multiple systemic health problems, and increases the risk from poor outcomes of spine surgery (ISASS, 2011). In addition, tobacco use has been associated with poorer clinical outcomes such as less pain relief, poorer functional rehabilitation, and less overall patient satisfaction (Vogt, *et al*., 2002).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace, cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, cervical
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical
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)

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
M50.00-M50.023	Cervical disc disorder with myelopathy (code range)
M50.10-M50.123	Cervical disc disorder with radiculopathy (code range)
M54.12	Radiculopathy, cervical region

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*Key Article

KEY WORDS

AIDA, Artificial intervertebral disc arthroplasty, Artificial Disc, Bryan, Mobi-C, PCM [porous coated motion] Cervical Disc® Prestige, ProDisc, SECURE-C

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, artificial cervical intervertebral disc is not addressed in National or Regional Medicare coverage determinations or policies. However, there is a Local Coverage Determination (LCD) which addresses Category III CPT codes. Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=98&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%

7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&KeyWord=category+III&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&

There is a Local Coverage Article which addresses billing and coding for Category III CPT codes. Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56195&ver=21&LCDId=33392&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&KeyWord=category+III&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACABAAAA&