MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Artificial Cervical Intervertebral Disc**
Policy Number	**7.01.80**
Category	**Technology Assessment**
Original Effective Date	**03/20/08**
Committee Approval Date	**04/16/09, 03/18/10, 01/20/11, 01/19/12, 01/17/13, 01/16/14, 02/19/15, 01/21/16, 02/16/17, 12/21/17, 06/21/18, 12/20/18, 07/18/19, 01/16/20, 02/18/21, 02/17/22, 02/16/23, 05/18/23**
Current Effective Date	**09/15/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
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POLICY STATEMENT

I. Based upon our criteria and assessment of the 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 is skeletally mature.
B. The device has been approved by the U.S. Food and Drug Administration (FDA), for an FDA approved indication, and is used in accordance with FDA labeling.
C. No previous surgeries have been performed on the disc(s) involved
D. No prior fusion at an adjacent cervical level
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 planned implant(s) is/are for a single level or simultaneous two contiguous level replacement(s)
H. The patient has no unmanaged, significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, or opioid use or alcohol use disorder).
I. There is no clinically significant cervical instability on 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.
J. The procedure is performed for **EITHER** of the following conditions:
  1. Radiculopathy, when **ALL** of the following criteria are met:
    a. The patient has subjective symptoms that include **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 include **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. The patient has not experienced 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; and

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

2. Myelopathy, when **ALL** of the following criteria are met:
a. the following subjective symptoms:
i. upper/lower extremity weakness, numbness or pain;
ii. fine motor dysfunction with tasks such as buttoning or handwriting, or clumsiness of hands;
iii. urinary urgency;
iv. new-onset bowel or bladder dysfunction due to a neuro-compressive pathology; or
v. frequent falls; and

b. Objective physical examination findings include 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; and

c. Recent (within six months) MRI/CT identifies **EITHER** of the following, which correlates with the patient's symptoms or physical findings:
i. cervical spinal cord compression; or
ii. 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 the peer-reviewed literature, revision of a failed cervical total disc arthroplasty is considered **medically appropriate** for a patient who is a candidate for single-level or two-level anterior cervical decompression(s) and interbody fusion(s), when **EITHER** of the following criteria are present:

A. Recent (within six months) post-operative imaging studies of the cervical spine, including flexion/extension lateral views, demonstrate failure of a cervical disc arthroplasty implant (i.e., subsidence, loosening, dislocation/subluxation, vertebral body fracture without instability, dislodgement); or

B. The procedure is performed for **ANY** of the following conditions:
1. Unremitting neck pain, when **ALL** of the following criteria are met:
a. Significant level of pain on a daily basis, defined as either of the following:
i. VAS/NRS greater than or equal to seven; or

ii. severe, disabling, crippling, or incapacitating pain;

b. More than six months have elapsed since prior cervical disc arthroplasty procedure;
c. The patient has no unmanaged, significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorder);
d. The patient has not experienced clinically meaningful improvement with prescription strength analgesics, steroids, and/or NSAIDs for six weeks, unless contraindicated; and
e. Post-operative MRI/CT identifies findings that are consistent with the patient's symptoms or physical examination findings;

2. Radiculopathy, when **ALL** of the following criteria are met:
   a. More than six months have elapsed since the prior cervical disc arthroplasty procedure at the same level;
   b. The patient has no unmanaged, significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorder); and
   c. The patient has subjective symptoms that include **BOTH** of the following:
      i. Significant level of pain on a daily basis, defined as either of the following:
         a) VAS/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; and
   d. Objective physical examination findings include at least **ONE** 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. The patient has not experienced 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 performed at the same level(s) as the requested surgery; and
   f. Recent (within six months) post-operative MRI/CT identifies findings (e.g., nerve root impingement caused by herniated disc(s) or osteophytes**)** that are consistent with the patient's symptoms and physical examination findings; or

3. Myelopathy, when **ALL** of the following criteria are met:
   a. More than six months have elapsed since the prior cervical disc arthroplasty procedure;
   b. The patient has no unmanaged, significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorder);
   c. The patient has subjective symptoms that include **ANY** of the following:
      i. upper/lower extremity weakness, numbness or pain;
      ii. fine motor dysfunction (buttoning or handwriting, clumsiness of hands);
      iii. new-onset bowel or bladder dysfunction due to a neuro-compressive pathology; or
      iv. frequent falls;
   d. Objective physical examination findings include 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; and

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

III. Based upon our criteria and assessment of the 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, opioid use or alcohol use disorder);
D. Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11)
E. The patient is skeletally mature.
F. The procedure will be performed using a cervical disc prosthesis approved by the FDA, for an FDA-approved indication, and in accordance with FDA labeling.
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. The procedure is performed for **EITHER** of the following conditions:
1. Radiculopathy, when **ALL** of the following criteria are met:
a. The patient has subjective symptoms that include **BOTH** of the following:
i. significant level of pain on a daily basis, defined as **EITHER** of the following:
a) VAS/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 include at least **ONE** 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. The patient has not experienced 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; and
d. Recent (within six months) 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 criteria are met:
a. The patient has subjective symptoms that include at least **ONE** of the following:
i. upper/lower extremity weakness, numbness or pain;

ii. fine motor dysfunction (buttoning or handwriting, clumsiness of hands);
iii. new-onset bowel or bladder dysfunction due to a neuro-compressive pathology; or
iv. frequent falls;

b. Objective physical examination findings include 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 demonstrating ataxia;
vii. inverted brachial radial reflex;
viii. increased muscle tone or spasticity;
ix. clonus; and/or
x. myelopathic hand;

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

IV. Cervical total disc arthroplasty for degenerative disc disease as the sole indication is considered **not medically necessary**

V. Cervical total disc arthroplasty following a failed cervical total disc arthroplasty at the same level is considered **not medically necessary**

VI. Cervical total disc arthroplasty without meeting the requirements listed in the policy guidelines is considered **not medically necessary**

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

A. The planned procedure includes the combined use of a prosthesis and spinal fusion, or the patient had a prior fusion at an adjacent cervical level (hybrid construct).
B. The patient is under age 18 or over age 60.
C. The patient has had prior surgery at the treated level.
D. The planned procedure will lead to cervical total disc arthroplasty at more than two levels.
E. The patient has decreased bone mineral density, defined by a T-score less than (worse than) -1.5 on a previous dual energy X-ray absorptiometry (DEXA) scan.
F. The patient is allergic or sensitive to titanium, aluminum or vanadium.
G. The patient has chronic, non-specific neck or arm pain of unknown etiology.
H. There is no radiculopathy or myelopathy.
I. The patient has rheumatoid arthritis or other autoimmune disease.
J. An active systemic infection is present.
K. The proposed procedure is a revision of an infected cervical disc arthroplasty.
L. The patient has Paget's disease, osteomalacia or other metabolic bone disease.
M. The patient has severe, poorly controlled diabetes mellitus requiring insulin treatment.
N. A prior fusion at an adjacent cervical level
O. The planned procedure involves two or more levels that are not contiguous
P. There is radiological evidence of **ANY** of the following:
1. clinically significant cervical instability on 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. spinal metastases;
4. 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;
5. severe facet joint arthropathy; or
6. 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. The minimum documentation required to complete a spinal surgery prior authorization request is as follows:

A. CPT codes, disc level(s) or motion segments involved, and ICD-10 codes for planned surgery;
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, including an explanation of:
   1. the reason(s) that a sufficient trial of non-surgical treatment was contraindicated, if applicable; and
   2. the less than clinically meaningful improvement experienced by the patient for each treatment;
C. Most recent imaging reports (e.g. CT, MRI, myelography) performed, read and interpreted by an independent radiologist whose report shall supersede any discrepancies (when present) in interpretation;
   1. Acceptable imaging modalities are: CT, MRI, and myelography;
   2. Discography or magnetic resonance (MR) spectroscopy results will not be used as a determining factor of medical necessity; and
D. Documentation of nicotine-free status (see Tobacco Cessation criteria below, Guideline III).

II. URGENT/EMERGENT CONDITIONS:

A. The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:

   1. Provider-directed non-surgical management
   2. Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)

B. Urgent/emergent conditions for cervical total disc arthroplasty include **ANY** of the following:

1. Myelopathy or Cord signal changes on MRI due to cord compression
2. Central cord syndrome
3. Documentation of progressive neurological deficit on two separate physical examinations
4. ANY of the following due to a neurocompressive pathology
   a. Motor weakness of grade 3/5 or less of specified muscle(s)
   b. Rapidly progressive symptoms of motor loss
   c. Bowel incontinence
   d. Bladder incontinence/retention
5. Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

III. Documentation of nicotine-free status is established when **EITHER** of the following applies:

A. Patient is a non-tobacco user.
B. Patient is a documented tobacco user, but has abstained from tobacco use for at least six weeks prior to the planned surgery, as evidenced by lab results (cotinine level of 10 ng/mL or less) documenting nicotine-free status.

Note: In order to complete the prior authorization process for surgery, planning should allow for enough time to submit lab results performed after the six-week tobacco abstinence period.

DESCRIPTION

Cervical 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. Radiculopathy, for the purpose of this policy, is defined as the presence of pain, dysesthesia(s), or paresthesia(s) reported by the individual in a level-specific referral pattern of an involved named spinal root(s) causing significant functional limitations, (i.e., diminished quality of life and impaired age-appropriate activities of daily living).
II. Spinal stenosis refers to the narrowing of the spinal canal usually due to spinal degeneration that occurs with aging. It may also be the result of spinal disc herniation, osteoarthritis, or a tumor.
III. Clinically meaningful improvement is defined as a global assessment showing at least 50% improvement.

RATIONALE

Medtronic received FDA approval to market its Prestige Cervical Disc System in July 2007 for use in skeletally mature patients, for reconstruction of the discs from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. Evidence for the Prestige Disc is available from the non-inferiority randomized, controlled trial (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 was reported by J.K. Burkus et al. All participants were followed up in this FDA-regulated, post-approval study, and outcomes at 60 months were reported on approximately half of the original 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 Neck Disability Index (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 three 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.

J.K. Burkus and colleagues (2014) assessed the long-term safety and efficacy of cervical disc replacement with the Prestige Cervical Disc in a prospective, randomized, multi-center trial at seven years of follow-up. The study included 541 patients with single-level cervical disc disease with radiculopathy who were randomized to one of two 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 NDI, 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 pre-operatively, intra-operatively, and at 1.5, 3, 6, 12, 24, 36, 60, and 84 months post-operatively. 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 NDI improvements from pre-operative 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%. Post-operatively, 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 achieved after implantation at seven-year follow-up.

In December 2007, the ProDisc-C received approval from the FDA based on a pre-market 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), NDI (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 was 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 three 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, compared to 74.4% of ACDF patients (p=0.067). There was a cumulative incidence of additional surgeries of 2.9% (three 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, five ProDisc-C patients (7.7%) were found to have bridging bone. Five-year results of this trial were published by Zigler et al. in 2013, with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF. 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%).

G.M. Malham et al. (2014) evaluated the clinical and radiographic outcomes in C-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 C-ADR by a single surgeon. All patients underwent single- or two-level C-ADR with the ProDisc-C device. Outcome measures included neck and arm pain (visual analogue scale), disability (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 C-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 C-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 discs 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 multi-center 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 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, which was a statistically significant difference between groups. 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 Cervical Disc (NuVasive), which received five-year FDA approval in October 2012, is a porous-coated motion (PCM) disc. It is a semi-constrained device consisting of two metal (cobalt-chrome alloy) endplates and a polyethylene insert that fits between the endplates. Continued FDA 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. Phillips and colleagues reported the results of the two-year, FDA-regulated, multi-center, randomized non-inferiority trial of the PCM Cervical Disc 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 post-operatively, the SECURE-C device is at least as effective as ACDF in terms of clinically significant improvement on the NDI and maintenance or improvement in neurological status, and is statistically superior to ACDF 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 for use 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 six weeks of conservative treatment, or demonstrated progressive signs or symptoms despite non-operative 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 post-operatively, 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 2015, respectively. In this non-inferiority 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 non-inferiority 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 post-operatively, 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 multi-level (2-4 levels, n=56) AIDA with the Mobi-C device in a prospective, multi-center study from Europe. The age of the patients was significantly higher, and the time since symptom onset was significantly longer in the multi-level 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 both the single-level group and multilevel group. There was a trend for more patients in the single-level group to return to work (70% versus 46%), and for the return to work to occur sooner (4.8 months versus 7.5 months). A similar percentage of patients underwent adjacent-level surgery (2.3% for single-level and 3.6% for multi-level).

After several years of follow-up, randomized trials of all of the artificial cervical discs met non-inferiority criteria, as measured by the NDI 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 non-inferiority of AIDA for all devices and lower cumulative reoperation rates at four to five years. Several recent meta-analyses and systematic reviews (Badhiwala et al., 2020; Deng et al., 2020; Gendreau et al., 2020; Goedmakers et al., 2020; Zhang et al., 2020) have concluded that, while longer-term follow-up is required, mid- to long-term results identify artificial cervical disc arthroplasty as a viable treatment option for patients suffering symptomatic disc degeneration, with similar outcome results to ACDF.

Ten year outcomes of one- and two- level Mobi-C trials was reported by Kim and colleagues in 2021. At 10 years, patients continued to have significant improvement over baseline Neck Disability Index (NDI), neck and arm pain, neurologic function, and segmental range of motion (ROM). NDI and pain outcomes at 10 year were significantly improved from seven year outcomes. Segmental and global range of motion (ROM) and sagittal alignment also were maintained from seven to 10 years. Clinically relevant adjacent segment pathology was not significantly different between seven and 10 year. The incidence of motion restricting heterotopic ossification at 10 year was not significantly different between seven year for one-level (30.7% vs. 29.6%) or two-level (41.7% vs. 39.2%) patients. Additionally, only two subsequent surgeries were reported after 7 years.

North American Spine Society (NASS) coverage policy recommendations from 2015 indicate that Cervical artificial disc replacement may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Radiculopathy related to nerve root compression from one- or two- 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 two-level degenerative disc disease from C3-4 to C6-7 with or without neck pain.

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 (Grasso et al., 2020; Scott-Young et al., 2020; Yang et al., 2020).

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 non-union. 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 of 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 their best physical condition prior to undergoing surgery.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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.