Clinical Policy Title: Cervical artificial total disc replacement

Clinical Policy Number: 03.03.09

Effective Date: October 1, 2014
Initial Review Date: June 18, 2014
Most Recent Review Date: May 1, 2018
Next Review Date: May 2019

Related policies:

- CP# 03.03.03 Spinal surgeries
- CP# 03.03.01 Spinal cord stimulators for chronic pain
- CP# 03.02.02 Radiofrequency ablation treatment for spine pain
- CP# 03.03.04 Spine pain — epidural injections
- CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
- CP# 03.02.07 Spine pain — facet joint injections
- CP# 03.03.05 Spine pain — trigger point injections

Coverage policy

AmeriHealth Caritas considers the use of cervical artificial total disc replacement to be medically necessary for the treatment of skeletally mature persons with symptomatic cervical degenerative disc disease or herniated disc at one level from C3 to C7, when all of the following criteria are met (Wu 2017, Hu 2016, Tashani 2015, Zhang 2015, Wu 2015, Hayes 2015, Rao 2015, Wei 2013, Yu 2013):

- All other reasonable sources of pain have been ruled out.
- There is neck or cervico-brachial pain with findings of weakness, myelopathy, or sensory deficit.
- Imaging studies indicate nerve root or spinal cord compression at the level corresponding with the clinical findings.
• Member has failed at least six weeks of conservative therapy (unless there is evidence of cervical cord compression, which requires urgent intervention).
• Member has physical and neurological abnormalities confirming the historical findings of nerve root or spinal cord compression at or below the level of the lesion and may have gait or sphincter disturbance (evidence of cervical radiculopathy or myelopathy).
• Member's activities of daily living are limited by persistent neck or cervico-brachial pain.

Limitations:

All other uses of artificial cervical disc replacements are considered not medically necessary.

Alternative covered services:

• Analgesic medication.
• Corticosteroid.
• Physical therapy.
• Anterior cervical fusion.
• Anterior cervical fusion with bone grafting.
• Decompression of nerve roots or the spinal cord by cervical discectomy, with or without vertebral body fusion using a bone graft or cage.

Background

Degenerative cervical disc disease may present with symptoms of pain and stiffness in the neck, and pain, paresthesia, numbness, or weakness of the limbs. Conservative treatment options include rest, analgesic medication, physical therapy, and local injections. In patients who are refractory to conservative treatment or at risk of permanent neurological damage, decompression of nerve roots or the spinal cord by cervical discectomy may be offered, with or without vertebral body fusion using a bone graft or cage.

Prosthetic intervertebral discs are implants that can be inserted between the vertebrae as an alternative to fusion using bone grafts or cages. They are designed with the aim of preserving the mobility of the diseased intervertebral segment, and therefore reducing the risk of adjacent segment degeneration in the long term. With the patient under general anesthesia and in the supine position, the anterior cervical spine is exposed. After standard decompression of the neural elements, and partial or full removal of the damaged disc, the artificial disc prosthesis is placed into the intervertebral space. More than one disc can be replaced during the same procedure. Various devices can be used for this procedure.

Cervical artificial total disc replacement has been increasingly used as an alternative to fusion surgery in patients with pain or neurological symptoms in the cervical spine who do not respond to nonsurgical treatment. A systematic literature review has been conducted to evaluate whether cervical artificial total disc replacement is more efficacious and safer than fusion or nonsurgical treatment. Initially, after two years of follow-up, studies demonstrated statistically significant noninferiority of cervical artificial total
disc replacement versus fusion with respect to the composite outcome “overall success.” Single patient relevant endpoints such as pain, disability, or quality of life improved in both groups with no superiority of cervical artificial total disc replacement. Both technologies showed similar complication rates. No evidence is available for the comparison between replacement and nonsurgical treatment.

However, from 2013 to 2016, seven meta analyses involving thousands of subjects were published in peer-reviewed medical journals. Each compared outcomes for different types of artificial cervical discs with anterior cervical discectomy and fusion. Two of these studies assessed outcomes for a period of 48 months or greater, the longest follow-up to date. Results are discussed in the Findings section.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on March 19, 2018. Search terms were: “artificial disc” and “cervical degenerative disc disease.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The seven meta-analyses published from 2013 to 2017 followed patients for at least 24 months postoperatively, with two of these for 48 months or more. Results show that, in general, the group that received disc replacement had superior outcomes, including:

- Greater overall success.
- Higher Neck Disability Index (NDI) scores.
- Greater neurological success.
- Better long-term functional outcomes.
- Lower rates of surgery-related adverse events.
- Lower rates of subsequent secondary procedures.
• Higher visual analog scores of neck and arm pain.
• Improved work status.
• Fewer complications from surgery.

There were several other measures that showed equal (differences not statistically significant) outcomes for those undergoing disc replacement and those undergoing fusion.

Thus, while more and longer-term randomized controlled trials are merited, cervical disc replacement is now regarded as a viable option for certain patients with disc disorders.

**Policy updates:**

A meta-analysis (Wu 2017) compared anterior cervical discectomy and fusion versus artificial cervical disc replacement with regard to the rates of subsequent surgeries. Data showed that the pooled overall rate of subsequent surgery at the operated level and adjacent levels was lower in the latter group (7.4 percent) than in the former (16.8 percent) (P=0.0006). For subsequent surgery at the operated level, patients who received artificial cervical disc replacement had a lower rate of subsequent surgery than patients who received anterior cervical discectomy and fusion (P<0.0001). With respect to the adjacent level, artificial cervical disc replacement also had fewer subsequent surgeries compared with anterior cervical discectomy and fusion (P<0.0001).

The multiple systematic reviews conducted in the period since the policy was last reviewed documented superiority in multiple outcomes for patients receiving cervical artificial total disc replacement, compared to those undergoing fusion, over a longer postoperative time period. These findings have prompted researchers to conclude that cervical artificial total disc replacement is a viable option for treating degenerative disc disease; however, there is concern that more and better evidence is needed to unequivocally validate the data.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu (2017)</td>
<td>Key points:</td>
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<tr>
<td></td>
<td>• A meta-analysis compared anterior cervical discectomy and fusion versus artificial cervical disc replacement with regard to the rates of subsequent surgeries.</td>
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<td>Hu Y (2016)</td>
<td>Key points:</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| Mid- to long-term outcomes of cervical disc arthroplasty versus ACDF for treatment of symptomatic cervical disc disease | - A meta-analysis of eight controlled trials comparing outcomes for total cervical disc arthroplasty with anterior cervical discectomy and fusion. 1,317 and 1,051 subjects in each group, followed for > 48 months.  
- Fusion group had a lower follow-up rate.  
- Cervical disc group had higher rates of overall success, NDI, neurological success, and long-term functional outcomes, and lower rates of surgery-related adverse events and secondary procedures. |
| Tashani (2015) | **Key points:**  
- Cervical artificial disc replacement is now an alternative to anterior cervical discectomy and fusion.  
- The authors sought to evaluate the quality of systematic reviews and meta-analyses supporting this practice.  
- Only one study (a Cochrane review) was of "best quality" after critical review on a scoring rubric developed for this purpose.  
- Five studies scored below standard five, indicating low-quality reviews.  
- The most significant drawbacks of reviews of a score below five were inappropriate formulation of a conclusion, ignorance of publication bias, and failure to note excluded studies.  
- With a significant exception of a Cochrane review, the methodological quality of systematic reviews evaluating the evidence of cervical artificial disc replacement versus anterior cervical discectomy and fusion leaves much to be desired. |
| Zhang Y (2015) | **Key points:**  
A meta-analysis of:  
- 19 controlled trials comparing outcomes for arthroplasty with anterior cervical discectomy and fusion.  
- Total of 4,516 subjects, followed for > 24 months.  
- The arthroplasty group had higher NDI scores, neurological success, pain assessment, and secondary surgical rate.  
- No difference in Short Form 36 scores, or segmental motion at the adjacent level. |
| Wu A-M (2015) | **Key points:**  
A meta-analysis of:  
- Four controlled trials comparing outcomes for arthroplasty and anterior cervical discectomy and fusion.  
- Total of 921 subjects (506 in arthroplasty, 415 in anterior cervical discectomy and fusion), followed for > 48 months.  
- The arthroplasty group had higher scores for NDI and visual analog scores of neck and arm pain, higher SF-36 scores, overall success, neurological success, work status, implant-related complications, and secondary surgery events. |
| Hayes (2015) | **Key points:**  
A summary of findings of outcomes comparing cervical disc replacement and fusion:  
- Cervical disc replacement reduces the need for reoperation and incidence of dysphagia. |
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<tr>
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| degenerative disc disease    | • Cervical disc replacement reduces risk of new adjacent segment disease.  
• Cervical disc replacement may have higher rates of intraoperative and perioperative complications.  
• Growing evidence suggests that bilevel cervical disc replacement, but not single-level cervical disc replacement, may be as safe and efficacious as bilevel anterior cervical disectomy and fusion.  
• There is uncertainty for long-term efficacy of both single-level and bilevel cervical disc replacement.                                                                                                                   |
| Rao MJ (2015)                | **Key points:**  
A meta-analysis of:  
• 18 controlled trials comparing outcomes for cervical disc arthroplasty and fusion.  
• Total of 4,061 subjects.  
• Cervical disc arthroplasty group had better outcomes for neurological success, greater option preservation at the operative level, fewer secondary surgical procedures, and fewer adverse events.  
• No significant differences between the two groups in length of stay, blood loss, or neck/arm pain scores.  
• Cervical disc arthroplasty group had higher operative time.                                                                                                                   |
| Wei J (2013)                 | **Key points:**  
A meta-analysis of:  
• Six controlled trials comparing outcomes for cervical disc arthroplasty and fusion.  
• Total of 1,603 subjects, followed 24 months.  
• Cervical disc arthroplasty group had greater improvement for Oswestry Disability Index, Visual Analog Scale scores, and complication rate.  
• No significant differences between the two groups observed for intra-operative blood loss and reoperation rate.                                                                                              |
| Yu G (2013)                  | **Key points:**  
A meta-analysis of:  
• 27 controlled trials comparing outcomes for cervical disc arthroplasty and anterior cervical disectomy and fusion.  
• Total of over 2,000 subjects, depending on type of analysis.  
• Anterior cervical disectomy and fusion group had shorter operative time and less blood loss.  
• Cervical disc arthroplasty group had lower neck and arm pain scores, better neurological success, greater motion, fewer secondary surgical procedures, and fewer procedures involving supplemental fixation.  
• Two groups had similar lengths of stay, NDI scores, adverse events, removals, and reoperations.                                                                                                                  |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Jeon SH, Choi WG, Lee SH. Anterior revision of a dislocated ProDisc prosthesis at the L4-5 level. J Spinal

Lu Y, McAnany SJ, Hecht AC, Cho SK, Qureshi SA. Utilization trends of cervical artificial disc replacement
after FDA approval compared with anterior cervical fusion: adoption of new technology. Spine (Phila., PA

McDonald CP, Chang V, McDonald M, Ramo N, Bey MJ, Bartol S. Three-dimensional motion analysis of the
cervical spine for comparison of anterior cervical decompression and fusion versus artificial disc

Nunley PD, Jawahar A, Cavanaugh DA, Gordon CR, Kerr EJ 3rd, Utter PA. Symptomatic adjacent segment
disease after cervical total disc replacement: re-examining the clinical and radiological evidence with

Rao MJ, Nie SP, Xiao BW, Zhang GH, Gan XR, Cao SS. Cervical disc arthroplasty versus anterior discectomy
and fusion for treatment of symptomatic cervical disc disease: a meta analysis of randomized controlled

Riew KD, Schenk-Kisser JM, Skelly AC. Adjacent segment disease and C-ADR: promises fulfilled? Evidence-

Tashani OA, El-Tumi H, Aneiba K. Quality of systematic reviews: an example of studies comparing artificial

Wei J, Song Y, Sun L, Lv C. Comparison of artificial total disc replacement versus fusion for lumbar
25.

Wu A-M, Xu H, Mullinix KP, et al. Minimum 4-year outcomes of cervical total disc arthroplasty versus fusion:
A meta-analysis based on prospective randomized controlled trials. Medicine (Baltimore). 2015;94(15):
e665.


Wu Y, Yue Z, Xiuxin H, Cui C. A meta-analysis of artificial total disc replacement versus fusion for lumbar

Yin S, Yu X, Zhou S, Yin Z, Qiu Y. Is cervical disc arthroplasty superior to fusion for treatment of symptomatic


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>+0095T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure).</td>
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<tr>
<td>+0098T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)</td>
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<tr>
<td>0375T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytyectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels.</td>
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<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytyectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.</td>
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<td>+22858</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytyectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure).</td>
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### CPT Code

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<tr>
<td>22861</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
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<tr>
<td>22865</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
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### ICD-10 Code

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<td>M50.00-M50.023</td>
<td>Cervical disc disorder with myelopathy</td>
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<tr>
<td>M50.30-M50.323</td>
<td>Other cervical disc degeneration</td>
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<tr>
<td>M50.80-M50.823</td>
<td>Other cervical disc disorders</td>
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<tr>
<td>M50.90-M50.93</td>
<td>Cervical disc disorder, unspecified</td>
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### HCPCS Level II Code

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<th>Description</th>
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**Informational only:**

**FDA-approved cervical devices**

**Prestige ST Cervical Disc System**: The Prestige ST Cervical Disc System (Medtronic Inc.) is a metal-on-metal cervical prosthesis consisting of two stainless steel components (see Figure 1). A domed upper component articulates with the ellipsoidal or trough-shaped lower components to form a semiconstrained mobile bearing surface that permits 10° of flex/extension, 10° maximum of lateral bending, and 2 millimeters (mm) of translational movement (Porchet and Metcalf, 2004; Smith et al., 2004). The anterior plates of the upper and lower components are contoured to fit adjacent vertebrae and are attached to each adjacent vertebral body with a locking screw mechanism (Porchet and Metcalf, 2004; Traynelis, 2004). The Prestige ST is available in four different heights (6 mm, 7 mm, 8 mm, and 9 mm) and two different depths (12 and 14 mm) (Traynelis, 2004).
Figure 1. The Prestige® ST Cervical Disc System
**ProDisc-C Total Cervical Disc Replacement:** The ProDisc-C artificial disc (Synthes Spine) for total cervical disc replacement was developed to simulate the motion of the natural spine and prevent adjacent disc degeneration. This device consists of three pieces including a sliding core made of ultra-high-molecular-weight polyethylene and two end plates made of cobalt chromium alloy (see Figure 2). The sliding core and the upper end plate allow rotation on all three axes. The device is designed to have a fixed center of rotation, which limits shear stress to the facet joints and, thus, theoretically prevents ASD. Securing the end plates to the vertebra occurs through a central keel, spikes, and porous coated surface. To optimize implant fit, the ProDisc-C comes in 18 sizes (Murrey et al., 2009; Darden, 2012; Synthes Spine, 2012).

![Figure 2. ProDisc™-C Artificial Cervical Disc](image)
**Bryan Cervical Disc System:** The Bryan Cervical Disc System (Medtronic Inc.) is cylindrical with two titanium alloy end plates on the top and bottom, a flexible tubular polyurethane outer sheath that connects the end plates, and a flexible, lubricated polyurethane inner core that lies between the end plates. Connective tissue cannot intrude, lubricant cannot leak out, and any debris that forms due to device wear remains contained. After complete removal of the damaged cervical disc, the titanium end plates are attached to the vertebrae using bone anchors and porous coated surfaces that lie directly against the vertebral bone. The porous coating enhances bone ingrowth for long-term device fixation (Anderson et al., 2004). To optimize device fit, the artificial disc comes in five different sizes (Goffin et al., 2003). Because implantation of the Bryan disc allows the annulus fibrosus, pre-existing facets, ligaments, and muscle tissue to remain intact, unconstrained rotational motions, with flexion, extension, lateral bending, and translation are possible following artificial disc replacement (Anderson and Rouleau, 2004).

![Figure 3. The Bryan® Cervical Disc System](image-url)
**KineflexIC Spinal System**: The KineflexIC Spinal System (SpinalMotion Inc.) consists of two end plates and a mobile center core within a retention ring. It is made of cobalt-chrome on cobalt-chrome alloy (see Figure 4). The artificial disc is surgically inserted as an assembled unit in a one-stage procedure (Conic et al., 2011).

*Figure 4. KineflexIC (SpinalMotion, Inc.)*
**SECURE®-C Cervical Artificial Disc:** The SECURE®-C Cervical Artificial Disc consists of two metallic end plates (cobalt chromium molybdenum alloy, CoCrMo) and a polyethylene (plastic) inner core. The materials used in the device are commonly used in orthopedic implants. The two end plates are secured to the top and bottom surfaces of the involved vertebrae (the bones in the spine) and the core fits between them. The implanted device is designed to allow motion at the treated level as the plastic core moves against the metallic end plates.

Specifically, SECURE®-C’s design is intended to allow the neck to move in flexion/extension (bending the neck forward and backward), lateral bending (bending the neck side to side), and axial rotation (turning the head side to side). SECURE®-C is intended to treat a disc in the cervical spine (neck) between the C3 and C7 vertebral bodies. The device is provided in different sizes to fit different patients.

*Figure 5. SECURE®-C Cervical Artificial Disc*