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: June 15, 2016
Next Review Date: June 2017

Related policies:
CP# 03.03.03 Spinal surgeries

ABOUT THIS POLICY: Arbor Health Plan has developed clinical policies to assist with making coverage determinations. Arbor Health Plan’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Arbor Health Plan when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Arbor Health Plan’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Arbor Health Plan’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Arbor Health Plan will update its clinical policies as necessary. Arbor Health Plan’s clinical policies are not guarantees of payment.

Coverage policy

Arbor Health Plan considers the use of cervical artificial total disc replacement (TDR) 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:

- All other reasonable sources of pain have been ruled out.
- There is presence of 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 total disc replacement (CTDR) 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 CTDR is more efficacious and safer than fusion or nonsurgical treatment. Initially, after two years of follow-up, studies demonstrated statistically significant noninferiority of CTDR 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 CTDR. Both technologies showed similar complication rates. No evidence is available for the comparison between CTDR and nonsurgical treatment.

However, in the period 2013 to 2016, six meta analyses involving thousands of subjects have been published in peer-reviewed medical journals. Each compared outcomes for different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF). 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**
Arbor Health Plan 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 May 17, 2016. 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 six meta analyses published from 2013 to 2016 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 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, total disc replacement is now regarded as a viable option for certain patients with disc disorders.
Policy updates:

The multiple systematic reviews conducted in the period since the policy was last reviewed (May 2015 to May 2016) documented superiority in multiple outcomes for patients receiving CTDR, compared to those undergoing fusion, over a longer postoperative time period. These findings have prompted researchers to conclude that CTDR is a viable option for treating degenerative disc disease.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</table>
| Hu Y, et al. (2016) | **Key points:**
|                     | A meta-analysis of:
|                     |   • Eight controlled trials comparing outcomes for total cervical disc arthroplasty (TDA) with anterior cervical disectomy/fusion (ACDF).
|                     |   • 1,317 and 1,051 subjects in each group, followed >48 months.
|                     |   • Fusion group had lower follow-up rate.
|                     |   • Cervical disc group had higher rates of overall success, Neck Disability Index (NDI), neurological success, and long-term functional outcomes, and lower rates of surgery-related adverse events/secondary procedures. |
| Zhang Y, et al. (2015) | **Key points:**
|                     | A meta-analysis of:
|                     |   • Nineteen controlled trials comparing outcomes for TDA with ACDF.
|                     |   • Total of 4,516 subjects, followed >24 months.
|                     |   • TDA 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, et al. (2015) | **Key points:**
|                     | A meta-analysis of:
|                     |   • Four controlled trials comparing outcomes for TDA and ACDF.
|                     |   • Total of 921 subjects (506 in TDA, 415 in ACDF), followed >48 months.
|                     |   • TDA 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 total disc replacement (TDR) and fusion:
|                     |   • TDR reduces the need for reoperation and incidence of dysphagia.
|                     |   • TDR reduces risk of new adjacent segment disease. |
| Rao MJ, et al. (2015) | **Key points:**  
A meta-analysis of:  
- Eighteen controlled trials comparing outcomes for cervical disc arthroplasty (CDA) and fusion.  
- Total of 4,061 subjects.  
- CDA 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.  
- CDA group had higher operative time. |
|----------------------|----------------------------------------------------------|
| Wei J, et al. (2013)  | **Key points:**  
A meta-analysis of:  
- Six controlled trials comparing outcomes for TDA and fusion.  
- Total of 1,603 subjects, followed 24 months.  
- TDA group had greater improvement for Owestry Disability Index (ODI), Visual Analog Scale (VAS) scores, and complication rate.  
- No significant differences between the two groups observed for intra-operative blood loss and reoperation rate. |
| Yu G, et al. (2013)   | **Key points:**  
A meta-analysis of:  
- Twenty-seven controlled trials comparing outcomes for TDA and ACDF.  
- Total of over 2,000 subjects, depending on type of analysis.  
- ACDF group had shorter operative time and less blood loss.  
- TDA group had lower neck/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. |

**Glossary**

**ACDF** — Anterior cervical disectomy and fusion.

**CDA** — Cervical disc arthroplasty.

**CTDR (cervical total disc replacement)** — 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.
Discectomy — A surgical procedure in which the central portion of a disc is removed.

Fusion — The joining of two bones together so that they no longer move.

Herniated disc — A disc that, due to use, injury, or disease, bulges outside its normal area, potentially causing pain and limiting function.

Heterotopic ossification — Unintended bone formation around or across the disc space between the spinal bones (vertebrae).

Osteopenia — A condition in which the bones are somewhat thin or weak, which may develop into osteoporosis.

Osteoporosis — A condition in which the bones are thin or weak and become brittle and fragile.

Radiculopathy — Disease of the nerves in or near the spine as a result of pressure from a disc, or irritation of the nerves due to disc or spinal joint disease.

Spondylosis — A degenerative disease in which the vertebral joints of the spine become stiff and then fused.

Synthetic spacer — Implant made of an artificial material (such as metal or plastic) that is commonly used in fusion surgeries to hold open the disc space.

TDR — Total disc replacement.

Related policies:

Arbor Health Plan Utilization Management program description.

References

Professional society guidelines/other:


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on May 20, 2016, using term “disc replacement.” Thirty two studies found, three relevant.


Clinical Outcome After Anterior Cervical Decompression and Fusion and Cervical Total Disc Replacement. Clinicaltrials.gov website.


**CMS National Coverage Determinations (NCDs):**
No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

CPT codes not covered in this policy are listed in Non-covered Services (L29288), Florida-.


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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<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>Each additional interspace.</td>
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<td>0375T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyteectomy 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 osteophyteectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.</td>
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<td>22858</td>
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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.)](image-url)
**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.

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