CERVICAL ARTIFICIAL DISC REPLACEMENT

Policy number: 200812-0001
Original effective date: 8/1/2013
Revision date: N/A

Overview:
Cervical artificial disc replacement, also known as total disc arthroplasty, has been proposed as an alternative to anterior cervical discectomy and fusion for the treatment of symptomatic cervical degenerative disc disease. Symptomatic cervical degenerative disc disease is defined as neck or arm (radicular) pain and or a functional or neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and or loss of disc height. Artificial (prosthetic) discs ostensibly ameliorate symptoms of cervical degenerative disc disease while avoiding the complications associated with spinal fusion, i.e., loss of mobility and degeneration at adjacent levels.

Two cervical artificial discs have been approved for use in the U.S. The Prestige® Cervical Disc System (Medtronic) was FDA-approved in July 2007. The Prestige Cervical Disc System is indicated for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. The ProDisc®-C (Synthes Spine, Inc.) was approved in December 2007. The ProDisc®-C is indicated for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease. Several other lumber artificial discs are currently in various phases of development and clinical trials.

The evidence supporting the effectiveness of cervical artificial disc replacement is limited. Cervical disc replacement is an innovative technology that has been shown to preserve motion at the instrumented level and will potentially improve load transfer to the adjacent levels compared with fusion. Clinical reports of success of cervical total disc replacement are encouraging but are also preliminary. Implant wear, fatigue, and failure have been reported in cases of large-joint arthroplasty, and research is underway to limit these problems in cervical arthroplasty. Twenty-four month follow-up does not permit conclusions about long-term device performance, durability and potential need for revision, and these are key considerations for patients who are likely to undergo artificial disc implantation in clinical practice.

Definitions:
Cervical spondylosis: Cervical spondylosis is a common degenerative condition of the cervical spine. It is most likely caused by age-related changes in the intervertebral discs. Disc degeneration is followed by bone spur (osteophyte) formation which in some cases encroaches on nervous tissue. Some degree of disc degeneration is normal with aging, although severe degenerative changes are not normal. A previous neck injury (which may have occurred several years prior) can predispose to spondylosis. As spondylosis progresses, many individuals will become symptomatic. Symptoms may result from compression of the spinal cord, the spinal nerve roots, or both. Typically, if
six months of conservative treatment is ineffective or the patient becomes unable to perform activities of daily living due to progression of pain or neurological symptoms in a shorter time frame, surgical intervention is indicated. Surgical indications for cervical spondylotic myelopathy remain somewhat controversial, but most clinicians recommend operative therapy over conservative therapy for moderate-to-severe myelopathy. Anterior cervical discectomy and fusion is currently considered definitive treatment for symptomatic cervical degenerative disc disease.

**Covered Services:**
Removal of an existing cervical artificial disc requires preauthorization by FTC.

Cervical artificial disc replacement, also known as total disc arthroplasty, is not covered. Cervical artificial disc replacement does not meet FTC’s technology assessment criteria. Specifically, currently available scientific evidence is insufficient to permit conclusions regarding the effect of the technology on health outcomes.

*Revision, including replacement of an existing failed cervical artificial disc, is not covered.*

There are some possible complications that could necessitate removal of an existing artificial disc such as:

1. Allergic reaction to the implant materials
2. Material failure (e.g., implants that bend, break, loosen or move)
3. Local and or systemic infection

FTC will cover the removal of an existing cervical artificial disc (and the necessary stabilization of the spine by conventional methods, such as fusion) when an FTC Medical Director has determined that removal of the artificial disc is medically necessary.

**Exclusions:**
Revision including replacement of an existing failed cervical artificial disc. Revision surgery is not covered, even in a patient who has complications following cervical artificial disc replacement.

**Codes:**
Claims for total disc arthroplasty and revision including replacement of total disc arthroplasty will be denied with the following disposition: *Reject Not Covered &endash; Vendor Liable*, leaving no member balance.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyteotomy for nerve root or spinal cord decompression and microdissection), single interspace; cervical</td>
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References:
Although FTC’s Technology Assessment Committee has determined that cervical artificial disc replacement is experimental/investigational, the Federal Employees Health Benefits Program (FEHBP) requires coverage for all FDA-approved drugs, devices or biological products. Therefore, cervical artificial disc replacement and revision are covered for FEHBP members if an FTC Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27).