

CERVICAL ARTIFICIAL DISC REPLACEMENT

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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 lumbar 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 FCHP.

Cervical artificial disc replacement, also known as total disc arthroplasty, is not covered. Cervical artificial disc replacement does not meet FCHP's technology assessment criteria. Specifically, currently available scientific evidence is insufficient to permit conclusions regarding the effect of the technology on health outcomes.¹

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:

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

FCHP 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 FCHP Medical Director has determined that removal of the artificial disc is medically necessary.

Exclusions

1. 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 – Vendor Liable*, leaving no member balance.

¹ Although FCHP'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 FCHP Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27).

Codes	Number	Description
CPT	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace; cervical
	0092T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression) cervical; each additional interspace (List separately in addition to code for primary procedure)
	22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, cervical; single interspace; cervical
	0098T	Revision of total disc arthroplasty, anterior approach cervical; each additional interspace (List separately in addition to code for primary procedure)
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
	0095T	Removal of total disc arthroplasty, anterior approach cervical; each additional interspace (List separately in addition to code for primary procedure)

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

References

1. Rousseau MA, Cottin P, Levante S, et al. In Vivo Kinematics of Two Types of Ball-and-Socket Cervical Disc Replacements in the Sagittal Plane. *Spine* 2008;33(1):E6-E9.
2. Murrey D, Janssen M, Delamarter R et al. Results of the Prospective, Randomized, Controlled Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc-C Total Disc Replacement Versus Anterior Discectomy and Fusion for the Treatment of 1-Level Symptomatic Cervical Disc Disease. *Spine J* 2008 Sep; Epub ahead of print.
3. Nabhan A, Ahlhelm F, Shariat K et al. The ProDisc-C Prosthesis. *Spine* 2007;32(18):1935-41.
4. Chang UK, Kim D, Lee MC et al. Range of Motion Change after Cervical Arthroplasty with ProDisc-C and Prestige Artificial Discs Compared with Anterior Cervical Discectomy and Fusion. *J Neurosurg Spine* 2007;7:40-6.

5. Anerson PA and Rouleau JP. Intervertebral Disc Arthroplasty. *Spine* 2004;29(23):2779-86.
6. Mummaneni PV, Burkus JK, Haid RW et al. Clinical and Radiographic Analysis of Cervical Disc Arthroplasty Compared with Allograft Fusion: A Randomized Controlled Clinical Trial. *J Neurosurg Spine* 2007;6:198-209.
7. BlueCross BlueShield Association Technology Evaluation Center. Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine. Volume 22, No. 12, February 2008.
8. Department of Health and Human Services, Food and Drug Administration. Center for Devices and Radiological Health. PRESTIGE® Cervical Disc System PMA. Available at: <http://www.fda.gov/cdrh/pdf6/p060018a.pdf>.
9. Department of Health and Human Services, Food and Drug Administration. Center for Devices and Radiological Health. ProDisc™-C Total Disc Replacement PMA. Available at: <http://www.fda.gov/cdrh/pdf7/p070001a.pdf>.
10. Hayes, Inc. Health Technology Brief. ProDisc™-C Total Cervical Disc Replacement (Synthes Spine Co.). October 31, 2008.

Committee review dates:

Technology Assessment Subcommittee: 12/16/2008

Technology Assessment Committee: 01/13/2009

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.