

Corporate Medical Policy

Artificial Intervertebral Disc

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Description of Procedure or Service

During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to spinal fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed, and to maintain the normal biomechanics of the adjacent vertebrae.

Lumbar

While artificial intervertebral discs in the lumbar spine have been used internationally for over 10 years, only two devices (Charité® and ProDisc®-L) have received approval from the U.S. Food and Drug Administration (FDA). Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of post-marketing studies. The Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level; Charité is approved for use in levels L4–S1, and the ProDisc-L is approved for use in levels L3–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Other devices are currently under investigation in this country as part of the FDA process of approval, including the FlexiCore (Stryker Spine) and Maverick (Medtronic) devices.

Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in which fusion is indicated. Patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for the artificial disc.

Cervical

Cervical degenerative disc disease (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 result in myelopathy, which is manifested by subtle changes in gait or balance, weakness in the arms or legs, and numbness of the arms or hands, in severe cases. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, some 95% of men and 70% of women have at least one degenerative change evident at radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

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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. Resolution of pain and neurological symptoms may be expected in more than 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and emplacement of either autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In artificial intervertebral disc arthroplasty (AIDA), an artificial disc device is secured in the prepared intervertebral space rather than bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomical disk space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level degenerative disc disease (DDD) above or below a fusion site has been the major rationale driving device development and use.

The Prestige ST Cervical Disc (Medtronic) received U.S. Food and Drug Administration (FDA) premarket application (PMA) approval as a Class III device on July 16, 2007. The Prestige ST Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy. The device is implanted via an open anterior approach. Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in December 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C is conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial, 7-year follow-up on 99 continued access subjects, and a 5-year enhanced surveillance study to more fully characterize adverse events when the device is used under general conditions of use. The post-approval study reports are to be delivered to the FDA annually.

The Bryan Cervical Disc (Medtronic Sofamor Danek) has been available outside of the United States since 2002. The Bryan Cervical Disc was deemed “approvable” by an FDA advisory committee on July 17, 2007, for treatment using an anterior approach of single-level cervical DDD. As a condition for approval of this device, the FDA required the manufacturer to extend its follow-up of enrolled subjects to 10 years after surgery. The study will involve the investigational and control patients from the pivotal investigational device exemption (IDE) study arm, as well as the patients who received the device as part of the continued access study arm. In addition the manufacturer must perform a 5-year enhanced surveillance study of the BRYAN® Cervical Disc to more fully characterize adverse events when the device is used in a broader patient population.

A number of other devices are under study in FDA Investigational Device Exemption (IDE) trials in the United States.

Cervical Disc Prostheses Under Investigation in the U.S.

Prosthesis	Implant	Articulation	Bearing	Bearing	Fixation	FDA Status
Manufacturer	Composition	Design	Surface	Constraint		
Prestige® LP (Medtronic)	Titanium-ceramic composite	Ellipsoid saucer	MoM	Semi-constrained	Primary – dual rails Secondary – endplate ingrowth	FDA IDE clinical trial enrollment complete
Porous Coated Motion (Nuvasive)	Cobalt-chromium-molybdenum	Ball and socket	MoP	Semi-	Primary – ridged metallic endplates	FDA IDE clinical trial enrollment

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	UHMWPE			constrained	Secondary – endplate ingrowth	complete
Kineflex C® Cervical Artificial Disc Implant (Spinal Motion)	Cobalt- chromium- molybdenum	Three piece, metal core	MoM	Unconstrained	Primary- central keel Secondary – endplate ingrowth	FDA IDE clinical trial enrollment complete
CerviCore™ Intervertebral Disc (Stryker)	Cobalt- chromium – molybdenum	Saddle	MoM	Unconstrained	Primary – dual rails Secondary – endplate ingrowth	Status unknown
Discover (DePuy)	Titanium-on- polyethelene	Three piece, polyethelene core	MoP	Unconstrained	Primary –Spike fixation Secondary – endplate ingrowth	FDA IDE clinical trial enrollment complete
Mobi-C (LDR spine)	Titanium and polyurethane					FDA IDE clinical trial enrollment complete
NeoDisc™ (NuVasive)						FDA IDE clinical trial enrollment complete
Secure®-C (Globus Medical)						Secure®-C (Globus Medical)

IDE: investigational device exemption; MoM: metal-on-metal; MoP: metal-on-polyethylene; PMA: premarket approval; SS: stainless steel; UHMWPE: ultra-high molecular weight polyethylene

No artificial cervical discs have received regulatory approval for greater than single level AIDA. Updates to the regulatory status of these devices can be viewed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> using the FDA product code “MJO”.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Artificial Intervertebral Disc is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design;

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therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Artificial Intervertebral Disc is covered

Not applicable.

When Artificial Intervertebral Disc is not covered

Artificial Intervertebral Disc is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

Lumbar

In 2009, the American Pain Society's (APS) practice guidelines provided a recommendation of "insufficient evidence" to adequately evaluate long-term benefits and harms of vertebral disc replacement. The guideline was based on a systematic review commissioned by APS and conducted by the Oregon Evidence-Based Practice Center.

Two systematic reviews, published in 2010, concluded that high quality RCTs with a relevant control group and long-term follow-up are needed to evaluate the effectiveness and safety of artificial lumbar disc replacement.

Overall, the available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on net health outcomes. Evidence is insufficient to determine whether artificial lumbar discs are beneficial in the short term, and questions remain about potential long-term complications with these implants.

Cervical

At this time, there is limited published information about the impact of cervical arthroplasty devices on clinical outcomes over the long term (5 or more years). There are some trials that report 4-5 year outcomes, but they do not have sufficient follow-up rates.

Results from randomized controlled trials at 4-5 years indicate that cervical AIDA is no worse than ACDF. Evidence to date has not shown a beneficial effect of any cervical disc product on the development of adjacent level disease, whereas long-term complication rates with artificial discs remain unknown. Given the natural history of the disease, longer-term results are needed, in particular to assess any effect of the device on adjacent-level disc degeneration, device durability, adverse events, and revisability.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0092T, 0095T, 0098T, 0163T, 0164T, 0165T, 22856, 22857, 22861, 22862, 22864, 22865.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 4/29/03.

Specialty Matched Consultant Advisory Panel - 6/2004

ECRI's Health Technology Forecast. (2004, October). FDA approves first artificial disc to treat low back pain. Retrieved 12/28/04 from http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id==5516&q=artificial+intervertebral&anm=WynneB

ECRI TARGET Database Report #852. (2004, December). Artificial intervertebral disc replacement for degenerative disc disease. Retrieved on 12/28/04 from http://www.target.ecri.org/summary/detail.aspx?doc_id+4927&q=artificial+intervertebral&anm=WynneB

ECRI's Health Technology Forecast. (December, 2004). Artificial intervertebral disc replacement for degenerative disc disease. Retrieved 12/28/04 from http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id=5516&q=artificial+intervertebral&am=WynneB

BCBSA Technology Evaluation Center. (2005, April). Artificial vertebral disc replacement. Retrieved 5/13/2005 from http://www.bcbsa.com/tec/vol20/20_01.html

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 4/1/2005

Institute for Clinical Systems Improvement, (2005, December). Technology assessment report: Lumbar artificial intervertebral disc. TA #92. Retrieved 2/24/2006, from <http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=2372>.

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 1/10/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 12/13/2007

Specialty Matched Consultant Advisory Panel - 5/2008

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BCBSA Technology Evaluation Center. (2009). Artificial Intervertebral Disc: Cervical Spine. Retrieved 7/16/2010 from <http://www.bcbs.com/blueresources/tec/vols/24/artificial-intervertebral.html>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 10/6/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 4/24/2010

Medical Director – 8/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 6/10/2010

Medical Director – 10/2010

Specialty Matched Consultant Advisory Panel – 11/2010

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disease of the cervical spine. TEC Assessments 2011; (in press).

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 10/4/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 10/4/2011

Specialty Matched Consultant Advisory Panel – 11/2011

Policy Implementation/Update Information

- 7/29/04 New policy implemented. Artificial Intervertebral Disc is considered investigational. Reviewed by Specialty Matched Consultant Advisory Panel 6/22/04. Notification given 7/29/04. Effective date 10/14/04.
- 1/20/05 Removed the statement from the Description of Service or Procedure section that indicated; "No artificial intervertebral disc has received FDA approval as of May 2004." Added information related to the approval by FDA of the Charite disc in October of 2004. Rationale added to Policy Guidelines section. References added.
- 6/2/05 References added. Policy number added to Key Words section.
- 6/16/05 Date added to reference.
- 7/7/05 Added new CPT codes: 0090T, 0091T, 0092T, 0093T, 0094T, 0095T, 0096T, 0097T, 0098T
- 1/19/06 Added new 2005 CPT code 0091T to "Billing/Coding" section.
- 6/5/06 Specialty Matched Consultant Advisory Panel review 5/3/2006. No changes to policy statement. Updated date of literature search in "Policy Guidelines" section. References added.

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- 1/3/07 Added the following new 2007 CPT codes: 0163T, 0164T, 0165T, 22857, 22862, and 22865 from "Billing/Coding" section. Removed deleted CPT codes, 0091T, 0094T, and 0097T.
- 6/30/08 Specialty Matched Consultant Advisory Panel review 5/29/08. No changes to policy statement. References added.
- 1/5/09 Added CPT codes 22856, 22861, and 22864 to the "Billing/Coding" section. Removed deleted CPT codes 0090T, 0093T, and 0096T. (btw).
- 6/22/10 Policy Number(s) removed. (amw)
- 12/21/10 Reviewed by Medical Director 8/14/2010. Description extensively revised. No change to policy statement. Rationale updated in "Guidelines" section. Specialty Matched Consultant Advisory Panel review 11/29/2010. References added.(btw)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/30/2011 Updated "Description" section. Updated "Policy Guidelines" section. No change to policy intent. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.