BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Artificial Intervertebral Disc: Cervical Spine

Policy # 00229
Original Effective Date: 02/20/2008
Current Effective Date: 12/18/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: *Artificial Intervertebral Disc: Lumbar Spine is addressed in medical policy number 00145.*

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider artificial intervertebral cervical discs to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility will be considered when all of the following criteria are met:

- The device is approved by the U.S. Food and Drug Administration (FDA); and
- Replacement is performed at either one level or two contiguous levels from C3-C7; and
- Patient has failed at least six weeks of non-surgical therapy; and
- Patient has intractable radiculopathy and/or myelopathy due to herniated disc or osteophyte formation with symptomatic nerve root and/or spinal cord compression documented by ALL the following:
    - Neck and/or arm pain; and
    - Functional and/or neurological deficit; and
    - Radiographic imaging (e.g., computed tomography (CT), magnetic resonance imaging (MRI), x-rays).

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of artificial intervertebral cervical discs when patient selection criteria are not met is considered to be **investigational.***

Background/Overview

Several prosthetic devices are currently available for artificial intervertebral disc arthroplasty (AIDA) of the cervical spine. AIDA is proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for patients with symptomatic cervical degenerative disc disease (DDD).

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

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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 five 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. Cervical DDD is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve after six weeks or more, or if they progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical DDD and no contraindications for the procedure.

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 neurologic symptoms may be expected in 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. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate. The choice of bone material for interbody fusion in ACDF has important clinical implications. Allograft bone has several drawbacks, including a small (albeit, unproven) risk of infectious disease transmission; possible immunologic reaction to the allograft, and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. These morbidities include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies demonstrate similar rates of postoperative fusion (90–100%) and satisfactory outcomes for single-level, anterior-plated ACDF, using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material. Biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD; however, the clinical relevance of these changes has not been established.

AIDA is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In AIDA, an artificial disc device is secured in the prepared intervertebral space rather than in 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 DDD above or below a fusion site has been the major rationale driving device development and use.

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Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in AIDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis. Patients with advanced spondylosis or hard disc herniations have a separate pathologic condition and require a different surgical approach.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Prestige®‡ ST Cervical Disc (Medtronic) received U.S. FDA premarket application (PMA) approval as a Class III device on July 16, 2007. The Prestige ST Cervical Disc is composed of stainless steel and 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. Intractable radiculopathy and/or myelopathy should be present, with at least one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (e.g., computed tomography [CT], magnetic resonance imaging [MRI], x-rays): herniated disc and/or osteophyte formation. The FDA has required the Prestige disc manufacturer to conduct a 7-year post-approval clinical study of the safety and function of the device and a 5-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population.

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 (discussed in Rationale section), 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) consists of 2 titanium-alloy shells encasing a polyurethane nucleus and has been available outside of the United States since 2002. The Bryan Cervical Disc was approved by the FDA in May 2009 for treatment using an anterior approach of single-level cervical DDD defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using CT, myelography and CT, and/or MRI. Patients receiving the Bryan cervical disc should have failed at least 6 weeks of non-operative treatment prior to implantation of the Bryan cervical disc. 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.

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In more recent years, continued FDA approval requires completion of 2 post-approval studies. One study provides extended follow-up of the pre-market pivotal cohort out to 7 years. The second study provides 10-year enhanced surveillance of adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, or other serious device-related complications, and analysis of all explanted discs. The following have received FDA approval:

- The PCM [porous-coated motion] Cervical Disc®‡ (NuVasive) received FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- Secure®-C‡ (Globus Medical) was approved in 2012 (P100003). The Secure-C is a 3 piece semi-constrained device with 2 metal (cobalt chromium molybdenum alloy) endplates and a polyethelene insert.
- The Mobi-C®‡ (LDR Spine) received FDA approval in 2013. Mobi-C is 3 piece semiconstrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C is approved for 1 (P110002) or 2 level (P110009) disc replacement.

A number of other devices are under study in FDA IDE trials in the United States.

Cervical Disc Prostheses Under Investigation in the U.S.

Prosthesis (Manufacturer)	Implant Composition	Articulation Design	Bearing Surface	Bearing Constraint	Fixation	FDA Status
Prestige® LP (Medtronic)	Titanium-ceramic composite	Ellipsoid saucer	MoM	Semi-constrained	Primary – dual rails Secondary – endplate ingrowth	FDA IDE clinical trial enrollment 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 complete
CerviCore™ Intervertebral Disc (Stryker)	Cobalt-chromium-molybdenum	Saddle	MoM	Unconstrained	Primary – dual rails Secondary – endplate ingrowth	Status unknown

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Discover (DePuy)	Titanium-on-polyethelene	Three piece, polyethelene core	MoP	Unconstrained	Primary – Spike fixation Secondary – endplate ingrowth	FDA IDE clinical trial enrollment complete
NeoDisc™ (NuVasive)						FDA IDE clinical trial complete
Freedom® Cervical Disc (AxioMed)						FDA IDE trial Recruiting
M6-C (Spinal Kinetics)	Titanium endplates and polymer core	Seven-piece, with endplates and a nucleus, fibrous annulus and sheath				FDA IDE trial withdrawn prior to enrollment

Centers for Medicare and Medicaid Services (CMS)
A search of the Medicare National Database (http://www.cms.gov/mcd/search.asp?from2=search.asp&) identified a national coverage decision on artificial intervertebral discs for the lumbar spine. There is no national coverage decision on artificial intervertebral discs for the cervical spine.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Artificial Intervertebral Disc: Cervical Spine", 7.01.108, 12:2013.
2. Boselie TF, Willems PC, van Mameren H et al. Arthroplasty versus fusion in single-level cervical degenerative disc disease: a cochrane review. Spine (Phila Pa 1976) 2013; 38(17):E1096-107.
3. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. Summary of Safety and Effectiveness Data: Mobi-C. 2013. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002b.pdf. Last accessed November, 2013.
4. Davis RJ, Kim KD, Hisey MS et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial. J Neurosurg Spine 2013; 19(5):532-45.
5. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. Summary of Safety and Effectiveness Data: SECURE-C. 2012. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003b.pdf. Last accessed November, 2013.
6. Coric D, Kim PK, Clemente JD et al. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. J Neurosurg Spine 2013; 18(1):36-42.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines (BCBSLAMPCG) are obtained from Current Procedural Terminology (CPT®)‡, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0092T, 0095T, 0098T, 22856, 22861, 22864
HCPCS	No code
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	84.62, 84.66

Policy History

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02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage.
02/04/2009	Medical Policy Committee review
02/17/2009	Medical Policy Implementation Committee approval. No change to coverage.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. No change to coverage.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible with criteria.
12/12/2013	Medical Policy Committee review

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12/18/2013 Medical Policy Implementation Committee approval." Criteria revised to include two contiguous levels from C3 to C7 as eligible for coverage. FDA information updated.
Next Scheduled Review Date: 12/2014

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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