Artificial Intervertebral Disc: Cervical Spine

Policy #  00229
Original Effective Date:  02/20/2008
Current Effective Date:  03/16/2016

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).

Degenerative disc disease 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 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.

Anterior cervical discectomy and fusion 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.
Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unrelenting 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., CT, 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.

The Prestige® LP artificial cervical disc was approved by FDA in 2014. The Prestige LP differs from the original Prestige cervical disc in terms of material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has 2 rails that press-fit into holes created during the surgical procedure.

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
Artificial Intervertebral Disc: Cervical Spine

Policy # 00229
Original Effective Date: 02/20/2008
Current Effective Date: 03/16/2016

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.

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® (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 polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C is 3 piece semi-constrained 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.

### Table 1. Cervical Disc Prostheses Under Investigation in the United States

<table>
<thead>
<tr>
<th>Prosthesis (Manufacturer)</th>
<th>Implant Composition</th>
<th>Articulation Design</th>
<th>Bearing Surface</th>
<th>Bearing Constraint</th>
<th>Fixation</th>
<th>FDA Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kineflex C®‡ Cervical Artificial Disc Implant (Spinal Motion)</td>
<td>Cobalt-chromium-molybdenum</td>
<td>3-piece, metal core</td>
<td>MoM</td>
<td>Unconstrained</td>
<td>Primary: central keel Secondary: endplate ingrowth</td>
<td>FDA IDE trial complete</td>
</tr>
<tr>
<td>Discover (DePuy)</td>
<td>Titanium-on-polyethylene</td>
<td>3-piece, polyethylene core</td>
<td>MoP</td>
<td>Unconstrained</td>
<td>Primary: spike fixation Secondary: endplate ingrowth</td>
<td>FDA IDE trial enrollment complete</td>
</tr>
<tr>
<td>NeoDisc™‡ (NuVasive)</td>
<td>Titanium-on-polyethylene</td>
<td>3-piece, polyethylene core</td>
<td>MoP</td>
<td>Unconstrained</td>
<td>Primary: spike fixation Secondary: endplate ingrowth</td>
<td>FDA IDE trial complete</td>
</tr>
<tr>
<td>Freedom® Cervical Disc (AxioMed)</td>
<td>Titanium on polymer core</td>
<td>7-piece, with endplates, nucleus, fibrous annulus, and sheath</td>
<td>MoM</td>
<td>Metal-on-metal</td>
<td>FDA IDE trial recruiting</td>
<td></td>
</tr>
</tbody>
</table>

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption; MoM: metal-on-metal; MoP: metal-on-polyethylene.
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

Policy History
Original Effective Date: 02/20/2008
Current Effective Date: 03/16/2016
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
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.

©2016 Blue Cross and Blue Shield of Louisiana
An independent licensee of the Blue Cross and Blue Shield Association
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Page 5 of 7
Artificial Intervertebral Disc: Cervical Spine

Policy # 00229
Original Effective Date: 02/20/2008
Current Effective Date: 03/16/2016

03/05/2015 Medical Policy Committee review
03/20/2015 Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/03/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 03/2017

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2015 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0095T, 0098T, 0375T, 22856, 22858, 22861, 22864</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*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. 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.

† Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.