Artificial Intervertebral Disc: Cervical Spine

Policy # 00229
Original Effective Date: 02/20/2008
Current Effective Date: 05/30/2020

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 cervical artificial intervertebral disc replacement (CADR) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for cervical artificial intervertebral disc replacement for the following diagnoses and criteria:

- **Radiculopathy** related to nerve root compression caused by one or two-level degenerative disease at all levels from C3-4 through C6-7, with or without neck pain, when **BOTH** of the following criteria are met:
    - Objective neurologic findings which correlate with a cervical nerve root impingement, and/or unremitting radicular pain which has not responded to at least six (6) weeks of appropriate conservative management (see Policy Guidelines); **AND**
    - Imaging studies demonstrating nerve root compression due to herniated disc or spondylotic osteophyte correlating with the distribution of signs and symptoms;
- **Myelopathy** or **myeloradiculopathy** related to central spinal stenosis caused by one or two-level degenerative disease at all levels from C3-4 through C6-7, with or without neck pain, when **BOTH** of the following requirements are met:
    - Clinical signs and symptoms of myelopathy which may include: loss of dexterity, urinary urgency, new-onset bowel or bladder incontinence, frequent falls,

hyperreflexia, Hoffmann sign, increased tone or spasticity, gait abnormality or pathologic Babinski sign; **AND**
    - Imaging studies demonstrating cervical cord compression due to herniated nucleus pulposus or osteophyte formation;
- **Additional requirements for CADR** (radiculopathy and myelopathy):
    - The individual is skeletally mature as documented by growth plate closure; **AND**
    - A U.S. Food and Drug Administration (FDA)-approved cervical artificial intervertebral device is used in accordance with FDA labeling, and will be implanted using an anterior approach; **AND**
    - The individual lacks contraindications listed in section below;
- **Simultaneous CADR at two contiguous levels** requires that the above criteria be met for each disc level, and that the device being utilized is FDA-approved for two levels (i.e., Mobi-C®‡ or Prestige®‡ LP).

*Note: This document addresses cervical disc arthroplasty when performed as an **elective, non-emergent** procedure and not as part of the care of an acute or traumatic event.*

Contraindications to CADR are:

- Active systemic infection or infection localized to the site of implantation;
- Osteoporosis defined as dual energy X-ray absorptiometry (DEXA) bone density measured T-score of negative 2.5 or lower;
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs with greater than or equal to 3 mm translation or greater than 11 degrees of angular difference to either adjacent level;
- Clinically compromised vertebral bodies at the affected level due to current or past trauma, anatomic deformity or cervical spine malignancy;
- Focal kyphosis at the level of planned arthroplasty;
- Moderate or severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of greater than 50% of normal disc height, or severely limited range of motion (i.e., less than 2 degrees) at the affected level;
- Severe facet joint arthropathy;
- Ossification of the posterior longitudinal ligament (OPLL);
- Sensitivity or allergy to implant materials.

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When Services Are Considered Not Medically Necessary

The use of cervical artificial intervertebral disc replacement (CADR) when patient selection criteria are not met is considered to be **not medically necessary.****

Based on review of available data, the Company considers cervical artificial intervertebral disc replacement (CADR) to be **not medically necessary****, including but not limited to the following:

- Cervical total disc arthroplasty at more than two (2) levels or at two (2) non-contiguous levels; **OR**
- Hybrid constructs in a single procedure, involving cervical fusion with cervical total disc arthroplasty; **OR**
- Cervical total disc arthroplasty in an individual with a previous fusion at another cervical level.

Policy Guidelines

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including requirements for physical therapy AND at least ONE complementary conservative management strategy.

Physical therapy requirement includes **ANY** of the following:

- Physical therapy, **OR**
- Physician or physical therapist-supervised home treatment program which may include flexibility and muscle strengthening exercises; **OR**
- Exception to the physical therapy requirement in unusual circumstances (for instance intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record.

Complementary conservative management requirement includes **ANY** of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy; **OR**
- Anti-inflammatory medications and analgesics; **OR**
- Epidural corticosteroid injection(s).

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Reporting of symptom severity – Severity of pain and its impact on activities of daily living (ADLs) is a key factor in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refers to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Background/Overview

Cervical disc arthroplasty, also known as CADR, was developed as an alternative to cervical fusion for treatment of cervical radiculopathy due to severe degenerative disc disease (DDD).

For appropriately chosen indications, CADR has shown promising results in the available data, indicating at least equivalence to cervical fusion following adequate decompression.

Tobacco cessation – Due to risk of pseudoarthrosis, adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to spinal surgery is recommended.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2007, the Prestige®‡ ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy. The device is implanted using 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 (eg, pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (eg, magnetic resonance imaging,

computed tomography, x-rays): herniated disc and/or osteophyte formation. The FDA required Medtronic (the Prestige disc manufacturer) to conduct a seven-year postapproval clinical study of the safety and function of the device and a five-year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

In 2014, the Prestige LP artificial cervical disc (Medtronic Sofamor Danek) was approved by the FDA through the PMA process. The Prestige LP differs from the original Prestige cervical disc regarding material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has two rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige LP was approved by the FDA for 2 adjacent levels. A postapproval study will follow the investigational device exemption (IDE) patients who received the Prestige LP at two contiguous levels for ten years. Medtronic will also submit to the FDA adverse events, device failures, and complaint analysis for ten years. This includes subsequent surgeries, heterotopic ossification, device malfunction, and other serious device-related complications.

Another disc arthroplasty product, the ProDisc-C®‡ (Synthes Spine), was approved by the FDA through the PMA process in 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C was made conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial (discussed in Rationale section), 7-year follow-up of 99 continued-access subjects, and a 5-year enhanced surveillance study to characterize more fully adverse events when the device is used under general conditions of use. Postapproval 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. In 2009, the Bryan Cervical Disc was approved by the FDA 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 computed tomography, myelography and computed tomography, and/or magnetic resonance imaging results. Patients receiving the Bryan Cervical Disc should have failed at least six weeks of nonoperative treatment before implantation. As a condition for device approval, the FDA required Medtronic Sofamor Danek to extend its follow-up of enrolled subjects to ten years after surgery. The study will involve the investigational

and control patients from the pivotal IDE study arm, as well as the patients who received the device as part of the continued-access study arm. Also, Medtronic Sofamor Danek must perform a five-year enhanced surveillance study of the disc to characterize more fully adverse events when the device is used in a broader patient population.

More recently, continued FDA approval requires completion of two postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to seven years. The second study provides ten-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, other serious device-related complications, and analysis of all explanted discs.

The following have also received the FDA approval:

- The PCM [porous-coated motion] Cervical Disc®‡ (NuVasive) received the FDA approval in 2012 (P100012). The PCM is a semi-constrained device consisting of two 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 three-piece semi-constrained device with two metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C (LDR Spine) received the FDA approval in 2013. Mobi-C is three-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.

In 2019, the M6-C™‡ Artificial Cervical Disc (Spinal Kinetics LLC) was approved by the FDA through the PMA process. The M6-C is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3–C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (CT, MRI, x-rays). The M6-C Artificial Cervical Disc is implanted via an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or exhibit progressive neurological symptoms which could lead to permanent impairment prior to implantation of the M6-C Artificial Cervical Disc.

A number of other devices are in the FDA IDE trials in the United States (see Table 1).

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

Prosthesis	Manufacturer	FDA Status
Kineflex/C®‡	SpinalMotion	FDA IDE trial complete; status unknown
Freedom®‡	AxioMed	FDA IDE trial recruiting

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption.
Updates on the regulatory status of these devices are available online using FDA product code MJO (available at:https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration 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. AIM Specialty Health, Musculoskeletal Program Clinical Appropriateness Guidelines for Spine Surgery, "Cervical Disc Arthroplasty", February 9, 2020.
2. Bono CM, Ghiselli G, Gilbert TJ. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. The spine journal: official journal of the North American Spine Society. 2011;11(1):64-72.
3. McAfee PCR, C.; Gilder, K.; Eisermann, L.; Cunningham, B. A meta-analysis of comparative outcomes following cervical arthroplasty or anterior cervical fusion: Results from 4 prospective multicenter randomized clinical trials and up to 1226 patients. Spine. 2012;37(11):943-52.
4. Radcliff K, Kepler C, Hilibrand A, et al. Epidural steroid injections are associated with less improvement in patients with lumbar spinal stenosis: a subgroup analysis of the Spine Patient Outcomes Research Trial. Spine. 2013;38(4):279-91.
5. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Artificial Intervertebral Disc: Cervical Spine", 7.01.108, May 2019.

6. U.S. Food and Drug Administration (FDA), M6-Artificial Cervical Disc, Premarket Approval February 6, 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf17/p170036a.pdf

Policy History

Original Effective Date: 02/20/2008
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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
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.
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.
12/01/2016	Medical Policy Committee review

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12/21/2016	Medical Policy Implementation Committee approval. Revised existing criteria and coverage statements, added new statement for subsequent disc implantation. New investigational statement added.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Changed the coverage section to adopt AIM guidelines.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Replaced the investigational coverage with not medically necessary coverage to track AIM Guidelines Exclusions section. Updated the Conservative management information and moved it from the Background/Overview section to the Policy Guidelines section to track AIM Guidelines. Added Tobacco cessation information to the Background/Overview section to track AIM Guidelines. "This document addresses cervical disc arthroplasty when performed as an **elective, non-emergent** procedure and not as part of the care of an acute or traumatic event" was moved from the Background/Overview section as a *Note* in the coverage section after the Patient Selection Criteria.

Next Scheduled Review Date: 04/2021

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 2019 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	0095T, 0098T, 22856, 22858, 22861, 22864, 22899 Code deleted eff 1/1/2020: 0375T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

**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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.