



Louisiana

Cervical Disc Arthroplasty

Policy # 00229

Original Effective Date: 02/20/2008

Current Effective Date: 10/20/2024

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: Lumbar Disc Arthroplasty 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 disc arthroplasty to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for cervical disc arthroplasty 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 **ALL** of the following criteria are met:
 - Objective neurologic findings which correlate with a cervical nerve root impingement, progressive or severe neurologic deficits secondary to spinal cord or foraminal compression, and/or unremitting radicular pain which has not responded to at least six (6) weeks of appropriate conservative management (physical therapy optional); 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; **AND**
 - The individual is skeletally mature as documented by growth plate closure; **AND**
 - An 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.

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- **Myelopathy or myeloradiculopathy** related to central spinal stenosis caused by one or two-level degenerative disease between C3-4 through C6-7, with or without neck pain, when **ALL** of the following criteria 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; **AND**
 - The individual is skeletally mature as documented by growth plate closure; **AND**
 - An 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.
- **Failed cervical disc arthroplasty**
Revision or replacement of a cervical artificial disc at the index level when **EITHER** of the following criteria are met:
 - Evidence of implant/device failure is demonstrated on standard or advanced imaging showing malposition or other evidence of failure (e.g., subsidence, surrounding radiolucency, dislocation/subluxation, vertebral body fracture, or hardware breakage); **AND** Symptoms can be attributed to implant failure or other implant related mechanical complications
 - Clinical symptoms persist or recur in the absence of implant failure; **AND** criteria for cervical radiculopathy or myelopathy are met (as above)
- **Two-level cervical disc arthroplasty (simultaneously or subsequent to one previously performed)** when performed at two contiguous levels simultaneously or at a second contiguous level to a previously performed arthroplasty when the above criteria are met for each disc level, and the device being utilized is FDA-approved for two levels (e.g., Mobi-C^{®‡}, Prestige LP^{™‡}, and Simplify^{®‡} Disc).

*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 cervical disc arthroplasty are:

- Active systemic infection or infection localized to the site of implantation;

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- 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.

When Services Are Considered Not Medically Necessary

The use of cervical disc arthroplasty when patient selection criteria are not met is considered to be **not medically necessary**.**

Based on review of available data, the Company considers cervical disc arthroplasty to be **not medically necessary**** for all other indications, 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**
- Cervical total disc arthroplasty in an individual with a previous fusion at another cervical level; **OR**
- Hybrid constructs in a single procedure involving cervical fusion with cervical total disc arthroplasty.

Policy Guidelines

The terms in the section provide operational definitions when they are referenced as requirements in the guideline.

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Documentation supporting medical necessity and a clearly stated plan of care should be submitted at the time of the request and must include the following components:

Conservative management must include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND** at least **ONE** complementary conservative treatment strategy.

- **Physical therapy requirement** includes **ANY** of the following:
 - Physical therapy rendered by a qualified provider of physical therapy services; **OR**
 - Supervised home treatment program that includes **ALL** of the following:
 - Participation in a patient-specific or tailored program; **AND**
 - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises; **AND**
 - Compliance (documented or by clinician attestation on follow-up evaluation);

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 treatment requirement** includes **ANY** of the following:
 - Anti-inflammatory medications and analgesics¹; **OR**
 - Adjunctive medications such as nerve membrane stabilizers or muscle relaxants¹; **OR**
 - Epidural corticosteroid injection(s), in the absence of contraindications¹; **OR**
 - Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable.

¹ In the absence of contraindications

Clinical reevaluation

In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit. Clinical reevaluation must be done in reasonable

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proximity to the anticipated date of service such that the patient's condition would be unlikely to change by the date of service.

Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care; **AND**
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation; **AND**
- More invasive forms of therapy are being considered.

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate. *The requirement for a period of conservative treatment as a prerequisite to a surgical procedure is waived when there is evidence of progressive nerve or spinal cord compression resulting in a significant neurologic deficit, or when myelopathy, weakness, or bladder disturbance is present.*

Reporting of symptom severity – Severity of pain and its impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) 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 and/or IADLs.

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 cervical artificial disc replacement, was developed as an alternative to cervical fusion for treatment of cervical radiculopathy due to severe degenerative disc disease (DDD).

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

Tobacco cessation – Adherence to a tobacco cessation program resulting in abstinence from tobacco for at least 6 weeks prior to spinal surgery is strongly recommended to reduce the risk of pseudoarthrosis.

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 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 1 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 7-year postapproval clinical study of the safety and function of the device and a 5 year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C^{®‡} (Synthes Spine), was approved by the FDA through the premarket approval process in 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C was made conditional on the 7 year follow-up of the 209 subjects included in the non-inferiority trial (discussed in the 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. The ProDisc-C Vivo is currently marketed by Centinal Spine.

More recently, continued FDA approval requires the completion of 2 postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10 year enhanced surveillance of adverse event data. Continued approval is contingent on

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the 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.

Devices with FDA approval for use in the United States are described in Table 1. These devices are for 1 site or 2 contiguous sites, there are no devices approved for non-contiguous sites. FDA Product Code: MJO

Table 1. Cervical Disc Prostheses Approved for use in the United States

Prosthesis	Manufacturer	Characteristics	FDA Approval	Year
Prestige ST	Medtronic	Stainless steel	P060018	2007
ProDisc-C	Centinal Spine	2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P070001	2007
Bryan ^{®‡} Cervical Disc	Medtronic Sofamor Danek	2 titanium-alloy shells encasing a polyurethane nucleus	P060023	2009
PCM [porous-coated motion] Cervical Disc ^{®‡}	NuVasive	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P100012	2012
SECURE ^{®‡} -C	Globus Medical	Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert	P100003	2012
Mobi-C	Zimmer Biomet (previously LDR Spine)	Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene	P110002/P110009	2013

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		insert; approved for both 1 and 2- levels		
Prestige LP	Medtronic Sofamor Danek	Titanium-ceramic composite with a metal-on-metal bearing; approved for both 1- and 2- levels	P090029	2014/2016
M6 [®] †-C	Orthofix (previously Spinal Kinetics)	Ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates	P170036	2019
Simplify [®] † Cervical Artificial Disc	NuVasive (previously Simplify Medical)	PEEK endplates and a mobile ceramic core; MRI compatible	P200022/S003	2020/2021

FDA: U.S. Food and Drug Administration; MRI: magnetic resonance imaging; PEEK: polyetheretherketone.

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, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

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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.

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7. U.S. Food and Drug Administration. Summary of Safety and Effectiveness: M6-C Artificial Cervical Disc. 2019.
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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 |
| 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. |

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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
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 <i>Note</i> in the coverage section after the Patient Selection Criteria.
04/01/2021	Medical Policy Committee review

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- 04/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 08/05/2021 Medical Policy Committee review
- 08/11/2021 Medical Policy Implementation Committee approval. Added a “When Services Are Eligible for Coverage” section for revision or replacement of a cervical disc prosthesis. Policy Guidelines revised to track AIM Guidelines.
- 06/02/2022 Medical Policy Committee review
- 06/08/2022 Medical Policy Implementation Committee approval. Title changed from “Artificial Intervertebral Disc: Cervical Spine” to “Cervical Disc Arthroplasty”. Revisions track AIM Guidelines.
- 06/01/2023 Medical Policy Committee review
- 06/14/2023 Medical Policy Implementation Committee approval. Revised Coverage and Policy Guidelines sections to track Carelon updates.
- 06/06/2024 Medical Policy Committee review
- 06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2025

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 2023 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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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.

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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
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.

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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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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