Artificial Intervertebral Disc: Lumbar Spine

Policy # 00145
Original Effective Date: 01/31/2005
Current Effective Date: 09/04/2018

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: Cervical Spine is addressed in medical policy number 00229.

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 lumbar artificial intervertebral disc replacement to be **eligible for coverage.**

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

- Age 18 to 60 years old; AND
- Primary complaint of axial pain to be of discogenic origin; AND
- Symptoms for at least one year, which have not responded to a multifaceted program of conservative treatment over that period of time; AND
- Presence of single level, advanced disc disease at L4-5 or L5-S1, as documented by magnetic resonance imaging (MRI) and plain radiographs demonstrating moderate to severe degeneration of the disc with Modic changes (peridiscal bone signal above and below the disc space in question); AND
- Absence of disease at all other lumbar levels, as documented by normal radiographs, and MRI showing no abnormalities or mild degenerative changes; AND
- Absence of contraindications listed below.

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

Note: 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 cauda equine syndrome or conus medullaris syndrome is present, and urgent intervention is indicated.

Contraindications to lumbar artificial disc replacement (LADR) are:

- Significant facet arthropathy at the operated level;
- Disease above L4-L5;
- Bony lumbar spinal stenosis;

- Pars defect;
- Clinically compromised vertebral bodies at affected level due to current or past trauma;
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1;
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium);
- Presence of infection or tumor;
- Osteopenia or osteoporosis (defined as dual-energy x-ray absorptiometry **[DEXA]** bone density measured T-score less than -1.0).

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

The use of lumbar artificial intervertebral disc replacement when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers lumbar artificial intervertebral disc replacement to be **investigational***, including but not limited to the following:

- Disc replacement at more than one spinal level; OR
- Arthroplasty below, or in combination with, spinal fusion or other stabilizing-type procedure; OR
- Isolated radicular compression syndromes, especially due to disc herniation; OR
- Hybrid lumbar total disc arthroscopy (TDA)/Lumbar Fusion (lumbar TDA at one level at the same time as lumbar fusion at a different level); OR
- Arthroplasty using devices other than those which are U.S. Food and Drug Administration (FDA) approved, or use of an FDA-approved device in a manner which does not meet FDA requirements.

Background/Overview

Lumbar disc arthroplasty, also known as lumbar artificial disc surgery or TDA, was developed as an alternative to lumbar fusion for treatment of back pain due to severe degenerative disc disease.

The procedure is similar to lumbar interbody fusion, in that an anterior approach is required. Unlike fusion, motion at the level of disc replacement is maintained, which would seem to be advantageous in terms of preventing secondary degenerative changes and preserving spine mechanics.

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following:

- Prescription strength anti-inflammatory medications and analgesics;
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants;
- Physician-supervised therapeutic exercise program or physical therapy;
- Manual therapy or spinal manipulation;
- Alternative therapies such as acupuncture;
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders.

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

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Three artificial lumbar disc devices (activL®, Charité®, ProDisc®-L)‡ have been approved by the U.S. FDA through the premarket approval process. Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of postmarketing studies. The activL (Aesculap Implant Systems), Charité (DePuy), and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disk disease (DDD) at 1 level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. Production under the name Charité was stopped in 2010.

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION®‡ lumbar artificial disc (DePuy Spine) is a modification of the Charité device with a change in name under the same premarket approval. The INMOTION is not currently marketed in the United States.
- The Maverick™‡ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation.
- The metal-on-metal FlexiCore®‡ artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access.
- Kineflex-L™‡ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L, scheduled in 2013, but was canceled without explanation.

FDA product code: MJO.

Centers for Medicare and Medicaid Services (CMS)

Effective for services performed on or after August 14, 2007, Centers for Medicare & Medicaid Services (CMS) found “that LADR is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries older than 60 years of age.” “For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination (NCD) for LADR, leaving such determinations to be made by the local contractors.”

The NCD was revised in September 2007 to reflect a change from noncoverage for a specific implant (the Charité), to noncoverage for the LADR procedure for the Medicare population older than 60 years of age. CMS provided this explanation,

> "The original NCD for LADR was focused on a specific lumbar artificial disc implant (Charite) because it was the only one with FDA approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc-L, received FDA approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture's implant."

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. Jacobs W, Van der Gaag NA, Tuschel A, et al. Total disc replacement for chronic back pain in the presence of disc degeneration. The Cochrane database of systematic reviews. 2012(9):Cd008326.
2. National Institute for Health and Care Excellence, Low back pain and sciatica in over 16s: assessment and management, (2016) London UK,
3. Nie H, Chen G, Wang X, et al. Comparison of Total Disc Replacement with lumbar fusion: a meta-analysis of randomized controlled trials. Journal of the College of Physicians and Surgeons--Pakistan : JCPSP. 2015;25(1):60-7.
4. Skold C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. Eur Spine J. 2013;22(10):2288-95.
5. North American Spine Society, Coverage Policy Recommendations, "Lumbar Artificial Disc Replacement", May 2014.
6. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Artificial Intervertebral Disc: Lumbar Spine", 7.01.87, 4:2018.
7. AIM Specialty Health, AIM Musculoskeletal Program Guidelines for Spine Surgery, "Lumbar Disc Arthroplasty", July 1, 2018. Last reviewed December 12, 2017.

Policy History

Original Effective Date:	01/31/2005
Current Effective Date:	09/04/2018
12/07/2004	Medical Director review
12/21/2004	Medical Policy Committee review
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. Format revision. No change to policy statement.
01/01/2007	Medical Director review
01/17/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
02/13/2008	Medical Director review

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02/20/2008	Medical Policy Committee approval
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage.
02/04/2010	Medical Director review
02/17/2010	Medical Policy 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.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. No change to coverage.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. No change to coverage
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. No change to coverage.
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage with criteria to adopt AIM guidelines. Adopted criterion “Age 18 to 60 years old” for lumbar artificial intervertebral disc replacement from the North American Spine Society (NASS) Coverage Policy Recommendations.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Added two *Notes* after the Patient Selection Criteria from AIM’s 2018 Guidelines for Spine Surgery.

Next Scheduled Review Date: 07/2019

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 2017 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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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:

Code Type	Code
CPT	0163T, 0164T, 0165T, 22857, 22862, 22865
HCPCS	No codes
ICD-10 Diagnosis	M46.46-M46.47, M51.06, M51.26-M51.27, M51.34-M51.37, M51.46-M51.47, M51.86- M51.87, M51.9, M96.1

*****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.

‡ 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.