

Policy # 00145

Original Effective Date: 01/31/2005 Current Effective Date: 06/25/2021

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:

- Primary complaint of axial pain determined to be of discogenic origin; AND
- Symptoms for at least six (6) months, which have not responded to a multifaceted program of conservative treatment over that period of time (see Policy Guidelines section for conservative management requirement); AND
- Presence of single level, advanced disc disease at L3-L4, L4-L5, or L5-Sl, 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
- At least moderate pain and disability ideally documented by a visual analog scale (VAS) pain score of 40 or higher (out of 100, or 4 out of 10) or with functional limitation of one or more Instrumental Activities of Daily Living (IADLs); **AND**
- Age between 18 and 60 years; AND
- Absence of symptomatic degenerative disc disease at all other lumbar levels, as documented by normal radiographs, and MRI showing no abnormalities or mild degenerative changes;
 AND

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- Use of an FDA-approved implant for the intended level; **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.

Note: See policy guidelines section for expanded description on ADL's and IADL's.

Contraindications to lumbar artificial disc replacement (LADR) are:

- Significant facet arthropathy at the operated level;
- Disease above L3-L4 or L4-L5 depending on FDA-approved levels;
- 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 Not Medically Necessary

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

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

• Disc replacement at more than one spinal level; OR

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- Arthroplasty below, or in combination with, spinal fusion or other stabilizing-type procedure; OR
- Prior spine surgery of any form at the target level; OR
- Isolated radicular compression syndromes, especially due to disc herniation; OR
- Hybrid lumbar total disc arthroscopy/lumbar fusion (lumbar total disc arthroscopy 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.

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;

AND;

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.

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Activities of Daily Living (ADLs) – These activities are the basic functions required for self-care of every-day life.

- Eating
- Bathing
- Grooming
- Dressing
- Transferring
- Toileting

Instrumental Activities of Daily Living (IADLs) -- These are the complex skills required to successfully live independently.

- Shopping
- Meal Preparation
- Management of Medications
- Transportation
- Housework
- Using communication devices
- Handling personal finances
- Laundry

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

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

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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.

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)

Three artificial lumbar disc devices (activL[®], Charité[®], ProDisc[®]-L)[‡] have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (Table 1). Production under the name Charité was stopped in 2010 and the device was withdrawn in 2012

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 disc disease at 1 level. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs.

Table 1. U.S. Food and Drug Administration-Approved Lumbar Artificial Disc Devices

Device	Manufacturer	Indication	PMA Number	Approval Date
activL	Aesculap Implant Systems, LLC	The activL Artificial Disc (activL) is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I	P120024	06/11/2015

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		spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.		
ProDisc-L	Synthes Spine	The PRODISC-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients	P050010	8/25/2006

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		receiving the PRODISC-L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the PRODISC-L Total Disc Replacement.		
Charite	Depuy Spine, Inc	The CHARITE Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S I. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than 3mm of spondylolisthesis at the involved level. Patients receiving the CHARITE Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the CHARITE Artificial Disc.	P040006	10/26/2004 Withdrawn 1/5/2012

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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.

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, Musculoskeletal Program, Appropriate Use Criteria: Spine Surgery, "Lumbar Disc Arthroplasty", March 14, 2021.
- 2. 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.
- 3. National Institute for Health and Care Excellence, Low back pain and sciatica in over 16s: assessment and management, (2016) London UK.

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- 4. 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.
- 5. 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.
- 6. Blue Cross and Blue Shield Association, <u>Medical Policy Reference Manual</u>, "Artificial Intervertebral Disc: Lumbar Spine", 7.01.87, May 2020.
- 7. Katz, S., & Akpom, C. A. (1976). 12. Index of ADL. Medical Care, 14 (5), 116–118.

Policy History

Original Effecti	ve Date: 01/31/2005
Current Effectiv	ve Date: 06/25/2021
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
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

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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.	
09/05/2019	Medical Policy Committee review	
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility	
	unchanged.	
11/07/2019	Medical Policy Committee review	
11/13/2019	Medical Policy Implementation Committee approval. Coverage revised to track	
	AIM Guidelines. Added a Policy Guidelines section taken from AIM GLs General	
	Requirements.	
04/02/2020	Medical Policy Committee review	
04/08/2020	Medical Policy Implementation Committee approval. Revised coverage section and	
	policy to track AIM Guidelines. All investigational statements are now not	
	medically necessary. Tobacco cessation moved from the Policy Guidelines section	
	to the Background/Overview section. Reporting of symptom severity paragraph	
	removed from the Policy Guidelines to avoid confusion with Patient Selection	
	Criteria regarding pain intensity and functioning.	
04/01/2021	Medical Policy Committee review	

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04/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

Next Scheduled Review Date: 04/2022

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 2020 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:

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,

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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.

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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.