MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Artificial Lumbar Intervertebral Disc**
Policy Number	**7.01.63**
Category	**Technology Assessment**
Original Effective Date	**03/18/04**
Committee Approval Date	**03/17/05, 01/19/06, 01/18/07, 03/20/08, 02/19/09, 01/21/10, 01/20/11, 01/19/12, 01/17/13, 01/16/14, 12/18/14, 12/17/15, 12/15/16, 12/21/17, 06/21/18, 12/20/18, 07/18/19, 01/16/20, 02/18/21, 04/15/2, 04/21/22, 05/18/23**
Current Effective Date	**05/18/23**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, an initial primary lumbar total disc arthroplasty has been medically proven to be effective and, therefore, is considered **medically appropriate** when **ALL** of the following criteria are met:

A. The procedure will be performed using a lumbar disc prosthesis approved by the United States Food and Drug Administration (FDA), for an FDA-approved indication, and in accordance with FDA labeling.

B. The patient has had chronic, unremitting, discogenic, axial, lower back pain and associated disability secondary to single-level lumbar degenerative disc disease (DDD) for at least one year.

C. The patient is aged 18 to 60 years.

D. The patient has a significant level of pain on a daily basis, defined as either of the following:
1. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to 7; or
2. severe, disabling, crippling, or incapacitating pain.

E. The patient has clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing or essential job functions).

F. There are no unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorder).

G. There has been structured, physician-supervised, multi-modal, non-operative management of medical care with licensed healthcare professionals, which includes **ALL** of the following:
1. regularly scheduled appointments;
2. follow-up evaluation;
3. less than clinically meaningful improvement with **BOTH** of the following for at least six consecutive months, unless contraindicated:

a. prescription-strength analgesics, steroids, and/or NSAIDs; and
b. provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician.

H. There is moderate-to-severe, single-level disc degeneration at L3-4, L4-L5 or L5-S1, confirmed on plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI).

I. There is no facet ankylosis or severe facet degeneration at the operative level.

II. Based upon our criteria and assessment of the peer-reviewed literature, lumbar artificial total disc arthroplasty is considered **not medically necessary** for **ANY** of the following:

A. Revision of a failed lumbar artificial total disc arthroplasty;

B. Procedure that combines use of a prosthesis and spinal fusion (hybrid);

C. Lumbar partial disc prosthetics;

D. Simultaneous multi-level implantation;

E. Insertion of implant outside of the spinal motion segments approved by the FDA;

F. Patient with osteopenia or osteoporosis (T-score less than -1.0);

G. Procedure above, below, or in combination with a spinal fusion or other stabilizing type of surgical procedure;

H. Lumbar disc prosthesis is not approved by the FDA or not used for an FDA-approved indication, or not used in accordance with FDA labeling;

I. Degenerative disc disease above L3-L4;

J. Presence of unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorder);

K. Patient younger than 18 years or older than 60 years;

L. As an adjunct to treatment of primary central or far-lateral disc herniation;

M. Presence of any evidence on imaging studies of **ANY** of the following:
1. Degenerative or lytic spondylolisthesis more than 3 mm;
2. Lumbar spinal stenosis;
3. Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis;
4. Lumbar scoliosis of more than 11 degrees of sagittal plane deformity;
5. Spinal fracture;
6. Infection;
7. Multi-level DDD (two or more levels) on a pre-operative MRI and plain X-rays;
8. Presence of facet ankylosis or severe facet degeneration at the operative level;
9. Presence of tumor or active infection at the site of implantation;
10. Lumbar nerve root compression or bony spinal stenosis;
11. Preoperative remaining disc height of less than 3 mm; or
12. Mid-sagittal stenosis of less than 8 mm by MRI;

N. History of ankylosing spondylitis, rheumatoid arthritis, lupus, or other autoimmune disorder;

O. Allergy or sensitivity to implant materials;

P. Isolated radicular compression syndromes, especially due to lumbar disc herniation;

Q. Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width; or

R. Clinically compromised vertebral bodies at the affected level due to current or past trauma.

Refer to Corporate Medical Policy #7.01.80 Artificial Cervical Intervertebral Disc.

Refer to Corporate Medical Policy #7.01.90 Lumbar Fusion for Adults.

POLICY GUIDELINES

I. URGENT/EMERGENT CONDITIONS: All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment in lieu of conservative pain management treatment.

II. Documentation of nicotine-free status is established when **EITHER** of the following applies:

   A. Patient is a non-tobacco user.

   B. Patient is a documented tobacco user, but has abstained from tobacco use for at least six weeks prior to the planned spinal fusion surgery, as evidenced by lab results (cotinine level) documenting nicotine-free status. Note: In order to complete the prior authorization process for spinal fusion surgery, planning should allow for enough time to submit lab results performed after the six-week tobacco abstinence period.

DESCRIPTION

Replacement of the intervertebral disc or the disc nucleus with an artificial device is proposed as an alternative to interbody fusion to treat symptomatic DDD. Interbody fusion, with or without posterior instrumentation, has been the most common surgical treatment for anterior column instability caused by DDD. The procedure is believed to do relatively well in stabilizing the anterior column and relieving pain by eliminating motion. However, it is not physiologic, and it alters the stress distribution on the adjacent segments. The issue of whether this stress alteration leads to symptomatic degeneration is still debated. It is proposed that a more functional device, an artificial disc, would restore not only the anatomy but also normal mechanical function. Many designs have been proposed over the past 40 years, both total disc and disc nucleus (partial disc replacement or PDA) devices. A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate, and consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. This device consists of a hydrogel core that can absorb fluid and expand when implanted. Partial disc replacement is also referred to as a nucleus arthroplasty.

RATIONALE

While a number of artificial intervertebral discs have been used internationally in the lumbar spine, only three devices (activL, Charité, ProDisc-L) have been approved by the FDA through the pre-market approval (PMA) process. Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of post-marketing studies. The activL (Aesculap Implant Systems), Charité (DePuy), and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at one level; activL and Charité are approved for use in levels L4-S1; and ProDisc-L is approved for use in levels L3-S1. The INMOTION lumbar artificial disc (DePuy Spine) is a modification of the Charité device, with a change in name under the same PMA. Production under the name Charité was discontinued in 2010. The INMOTION is not currently marketed in the United States.

Another device, called the Maverick artificial disc (Medtronic), is not marketed in the United States due to patent infringement litigation.

The FDA granted marketing approval for ProDisc in August 2006. In April 2020, the device indications were expanded to include spinal arthroplasty in skeletally mature patients with DDD at one or two intervertebral levels from L3-S1. Patients should have no more than grade 1 spondylolisthesis at the involved level(s) and should have failed at least six months of conservative treatment prior to implantation. The original FDA approval of the ProDisc-L was based on a randomized, controlled trial (RCT) with 24-month follow-up, comparing disc replacement with spinal fusion. Both treatment groups improved on all outcome measures; by study definitions of improvement on Oswestry Disability Index (ODI) and range of motion, 64% of ProDisc subjects and 45% of the fusion group achieved overall success (53% and 41%, respectively, by the FDA's definitions). J.E. Zigler et. al. (2012) reported five-year follow-up data of this pivotal trial. Out of an original 236 patients randomized, 186 (79%) were included in the follow-up of clinical outcomes (134 ProDisc and 52 controls)

and 166 (70%) were included for radiographic outcomes (123 ProDisc and 43 controls). Results showed non-inferiority but not superiority of artificial disc replacement, with 53.7% of the ProDisc patients and 50% of the fusion patients achieving overall success at five years.

The FDA granted PMA for activL in 2015. Yue et al. (2019) completed a five-year, non-inferiority trial that compared activL with control total disc replacement systems (TDR), Pro-Disc-L or Charité, in the treatment of patients with symptomatic, single-level lumbar DDD. Originally, 324 patients were randomly allocated (2:1) to treatment with activL (n=218) or control TDR (n=106). At five-year follow-up, 261 patients (176 activL and 85 control) were available for analysis (76.5%). The primary composite endpoint demonstrated non-inferiority at five years for activL, compared to control TDR. Reductions in back pain severity and improvements in ODI were maintained for both the activL and Control TDR groups through five years. Freedom from a serious adverse event through five years was 64% in activL patients, 47% in control patients. The authors concluded that the activL artificial disc is safe and effective for the treatment of symptomatic lumbar DDD through five years. This trial's exclusion criteria (NCT00589797) included pre-operative remaining disc height less than 3mm, mid-sagittal stenosis of less than 8mm (by MRI), degenerative or lytic spondylolisthesis greater than 3mm, lumbar scoliosis (greater than 11 degrees of sagittal plane deformity), facet ankylosis or severe facet degeneration, history of rheumatoid arthritis, lupus, or other autoimmune disorder, and ankylosing spondylitis (Yue and Mo, 2010).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure) *(effective 1/1/2023)*
22862 **(NMN)**	Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace, lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar
0164T	Removal of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar
0165T **(NMN)**	Revision including replacement of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
Multiple diagnosis codes	

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*Key Article

KEY WORDS

ActivL, Bryan, Charité, Disc, ProDisc-L

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for lumbar artificial disc replacement. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&