MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Artificial Lumbar Intervertebral Disc**
Policy Number	**7.01.63**
Category	**Technology Assessment**
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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, 04/15/21, 04/21/22, 05/18/23, 10/17/24**
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Product Disclaimer	• *Services are contract dependent; 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

Initial Procedure

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 patient is aged 18 to 60 years;
   B. 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;
   C. No planned simultaneous fusion (hybrid surgery) at an adjacent lumbar level;
   D. The planned implant will be used in the reconstruction of a single-level lumbar disc at only one of the following lumbar levels: L3-4, L4-5, or L5-S1;
   E. Absence of facet ankylosis or severe facet degeneration at the operative level;
   F. Plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI) confirm **ALL** of the following:
      1. Presence of moderate to severe single-level disc degeneration at the operative level (between L3-4, L4-5, L5-S1);
      2. Absence of degenerative disc disease at more than one level (between L3-4, L4-5, L5-S1); **and**
      3. Absence of degenerative disc disease above L3-L4;
   G. Subjective symptoms concordant with single-level lumbar degenerative disc disease (DDD) include:
      1. Significant level of pain on a daily basis, defined as Clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.);
   H. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living;
   I. 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; **and**
3. less than clinically meaningful improvement with **BOTH** of the following for at least six (6) consecutive months, unless contraindicated:
   a. prescription-strength analgesics, steroids, gabapentinoids or NSAIDs; **and**
   b. provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician;

J. Absence 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. Documentation of nicotine-free status including **EITHER** of the following (unless this is an urgent/emergent request for fusion/ disc arthroplasty or when myelopathy is present):
   1. Individual is a never smoker; **or**
   2. Individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

II. For lumbar fusion (with or without decompression) following failed lumbar total disc arthroplasty surgery (Refer to policy #7.01.90 Lumbar Fusion for Adults).

III. Based upon our criteria and assessment of the peer reviewed literature, lumbar total disc arthroplasty is considered not medically necessary when performed for **ANY** of the following:
   A. Lumbar partial disc prosthetics;
   B. As an adjunct to the treatment of primary-central or far-lateral disc herniation.

IV. 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 contraindications:
   A. Performed for the revision of a failed lumbar artificial total disc arthroplasty;
   B. Individual with osteopenia or osteoporosis (T-score less than -1.0);
   C. There is 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. Presence of tumor or active infection at the site of implantation;
      8. Lumbar nerve root compression or bony spinal stenosis;
      9. Preoperative remaining disc height of less than 3 mm; **or**
      10. Mid-sagittal stenosis of less than 8 mm by MRI;
   D. History of ankylosing spondylitis, rheumatoid arthritis, lupus, or other autoimmune disorder;
   E. Allergy or sensitivity to implant materials;
   F. Isolated radicular compression syndromes, especially due to lumbar disc herniation;
   G. Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width;
   H. 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

Urgent/Emergent Conditions

I. All individuals being evaluated for spine surgery should be screened for the presence of urgent/emergent indications/conditions that warrant definitive surgical treatment imaging findings noted in the applicable procedure section(s) are required.
   A. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
      1. Provider-directed non-surgical management;
      2. Proof or smoking cessation;
      3. Absence of unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorders, chronic pain syndrome, secondary pain, opioid and alcohol use disorders);
      4. Time frame for repeat procedure.

II. An urgent/emergent request is based on the 2019 NCQA standards for utilization management and is as follows:
   A. A request for medical care or services where application of the time frame for making routine or non-life-threatening care determinations:
      1. Could seriously jeopardize the life or health of the individual or the individual's ability to regain maximum function, based on a prudent layperson's judgment, or
      2. Could seriously jeopardize the life, health, or safety of the individual or others, due to the individual's psychological state, or
      3. In the opinion of a practitioner with knowledge of the individual's medical or behavioral condition, would subject the individual to adverse health consequences without the care or treatment that is the subject of the request.

III. Minimum documentation requirements needed to complete a spinal surgery prior authorization request include **ALL** of the following:
   A. CPT codes, ICD-10 codes, and disc levels or motion segments involved for planned surgery must be provided;
   B. Detailed documentation of the type, duration, and frequency of provider-directed non-surgical treatment (e.g., interventional pain management, physical therapy, chiropractic care, or provider-directed active exercise program, etc.) that includes response to each treatment:
      1. Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated (if applicable);
      2. Detailed documentation of less than clinically meaningful improvement for each treatment;
   C. Written reports/interpretations of the most recent advanced diagnostic imaging reports (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI], or Myelography) performed, read, and interpreted by an independent radiologist. Clinically significant discrepancies in interpretation between the surgeon and the radiologist need to be reconciled prior to the documentation submission;
   D. The documentation for spinal fusion surgery requests must include flexion-extension plain x-rays based upon indications for instability and/or other plain x-rays that document failure of instrumentation, fusion, etc.; **and**
   E. Documentation of nicotine-free status including **EITHER** of the following (unless this is an urgent/emergent request for fusion/ disc arthroplasty or when myelopathy is present):
      1. Individual is a never smoker; **or**
      2. Individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

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 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.

Meyerding Classification Grade of Spondylolisthesis: determined by measuring the degree of slip using standing, neutral lateral radiographs of the lumbar spine. The classification system divides slip into five (5) grades:
Grade I- 0% to 25%
Grade II- 25% to 50%
Grade III- 50% to 75%
Grade IV- 75% to 100%
Grade V- greater than 100%

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)
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 (150.10). 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& accessed 09/25/24.