MEDICAL POLICY

Excellus

MEDICAL POLICY DETAILS	
Medical Policy Title	**ARTIFICIAL LUMBAR INTERVERTEBRAL DISC**
Policy Number	**7.01.63**
Category	**Technology Assessment**
Effective Date	**03/18/04**
Revised 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**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based upon our criteria and assessment of 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** the following criteria are met:
   A. Use of an FDA approved implant in accordance with FDA requirements;
   B. Presence of chronic, unremitting, discogenic axial lower back pain and associated disability secondary to single-level degenerative lumbar disc disease (DDD) for at least one year;
   C. Age 18-60 years old;
   D. Significant level of pain on a daily basis defined as either of the following:
      1. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as greater than or equal to 7;
      2. Severe, disabling, crippling, or incapacitating pain;
   E. Clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing or essential job functions); and
   F. Absence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse);
   G. Structured physician-supervised, multi-modal, nonoperative 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 6 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, osteopathic or allopathic physician.
   H. Moderate to severe single-level disc degeneration at L4-L5 or L5-S1 has been confirmed on recent (within 6 months) plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI);
   I. Absence of significant facet arthropathy at the operative level.

II. Based upon our criteria and assessment of peer-reviewed literature, lumbar artificial total disc arthroplasty is considered **not medically necessary** for **ANY** of the following:
   A. The revision of a failed lumbar artificial total disc arthroplasty;
   B. The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid);
   C. Lumbar partial disc prosthetics;
   D. Simultaneous multi-level implantation;
   E. The implant will be inserted outside of the spinal motion segments approved by the FDA;

F. The patient has osteopenia or osteoporosis (T-score less than -1.0);
G. Above or below or in combination with a spinal fusion or other stabilizing type of surgical procedure;
H. A lumbar disc prosthesis not approved by the FDA or for an FDA approved indication;
I. Degenerative disc disease about L4-L5;
J. Presence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse;
K. Age less than 18 years or greater than 60 years;
L. As an adjunct to the treatment of primary central or far-lateral disc herniation;
M. There is any evidence on imaging studies of ANY of the following:
    1. Lytic or degenerative spondylolisthesis of Grade 2 or greater;
    2. Lumbar spinal stenosis;
    3. Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis;
    4. Scoliosis;
    5. Spinal fracture;
    6. Infection;
    7. Multi-level degenerative disc disease (2 or more levels) on a preoperative MRI and plain X-rays;
    8. Significant facet arthropathy at the operative level;
    9. Presence of tumor or active infection at the site of implantation; or
    10. Lumbar nerve root compression or bony spinal stenosis.
N. Allergy or sensitivity to implant materials;
O. Isolated radicular compression syndromes especially due to lumbar disc herniation;
P. Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width; or
Q. 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:
    A. Patient is a non-tobacco user, or
    B. If patient is a documented tobacco user, then patient must have 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 6-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 degenerative disc disease. Interbody fusion, with or without posterior instrumentation, has been the most common surgical treatment for anterior column instability caused by degenerative disc disease. 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 in the lumbar spine have been used internationally, only three devices (activL®, Charité®, ProDisc®-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. Because the long-term safety and effectiveness of these devices were not known, 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 (DDD) at 1 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 premarket approval. Production under the name Charité® was stopped in 2010. The INMOTION® is not currently marketed in the United States.

The US FDA Investigational Device Exemptions multicenter trial comparing single level discectomy and implantation of the Charité disc with interbody fusion with BAK cage and bone graft reported a success rate, using a composite measure of success, of 63% compared to 53% for BAK fusion for patients followed for up to 24 months, but did not show statistically significant superiority in most outcome measures. In 2008, Guyer and colleagues reported five-year follow-up of a subset of the patient cohort who had participated in the IDE trial of the Charité artificial disc. Of the initial 14 sites, 6 declined participation in the five-year continuation study, and an additional 8 patients were excluded from analysis, leaving 233 patients from the original randomized study. There were 133 cases included in the 5-year assessment (57% from the 8 sites). Based on a denominator of 375 patients originally enrolled in the IDE trial, this report represents 30% of the study population. Complications are emerging with longer-term follow-up. Shim, et al. (2007) reported that clinical outcomes of both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients regardless of the device used.

The FDA granted marketing approval for ProDisc in August 2006. The device is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L3-S1. Patients should have no more than grade 1 spondylolisthesis at the involved level and should have failed at least six months of conservative treatment prior to implantation. FDA approval of the ProDisc-L was based on a randomized controlled trial with 24 months 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 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). JE 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 70% (123 ProDisc and 43 controls) were included for radiographic outcomes 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.

A 2015 Medical Technology assessment evaluated seven randomized controlled trials (RCTs), one nonrandomized trial, and six uncontrolled studies with long-term (seven to 17 years) results published between 2002 through July 2015. A total of 2882 patients who underwent one or two level disc replacement treatment were included. The findings suggest that 1-level lumbar disc replacement (LDR) is comparable in efficacy and safety to fusion for the treatment of symptomatic degenerative disc disease in selected patients who have failed conservative treatment.

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.*

CPT Codes

Code	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	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
0163T	Total disc lumbar arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar
0164T	Removal of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar
0165T	Revision including replacement of total disc lumbar arthroplasty (artificial disc) , anterior approach, each additional interspace, lumbar

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&