### 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;
   B. Presence of chronic, unremitting, discogenic lower back pain and associated disability secondary to single-level degenerative disc disease (DDD) in a skeletally mature individual;
   C. Functional Limitation defined as a significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4; and
   D. Clinically significant functional impairment such as the inability to perform household chores, prolonged standing or essential job functions or failed 6 months of structured physician supervised conservative management, which includes ALL of the following:
      1. Less than clinically meaningful improvement from prescription strength analgesics, steroids, and/or NSAIDs; and
      2. Less than clinically meaningful improvement* from a physician directed program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician

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

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

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

### 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. If any of the following are part of the clinical presentation with a request for precertification of the CPT code, the request will go to medical review. Severe neck pain associated with any of the following will still need confirmatory imaging, such as a CT or MRI scan:

   A. Acute/Unstable Traumatic Spinal Fractures or Dislocations with or without neural compression;
   B. Infection (e.g. discitis, epidural abscess, osteomyelitis);
   C. Primary or metastatic tumor causing pathologic fracture, cord compression or instability;
   D. Severe or rapidly progressive symptoms of motor loss, bowel or bladder dysfunction;
   E. Documented progressive neurological deficit on two separate physical exams;
   F. Epidural hematoma;
   G. Hospitalization secondary to severe debilitating pain and/or dysfunction to the point of being incapacitated.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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III. 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 6 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 3 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 5-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 5-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 6 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

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fusion group achieved overall success (53% and 41% respectively by the FDA’s definitions). JE Zigler, et. al. (2012) reported 5-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 5 years.

A 2015 Medical Technology assessment evaluated 7 randomized controlled trials (RCTs), 1 nonrandomized trial, and 6 uncontrolled studies with long-term (7 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. However, longer-term studies are still needed.

CODES:

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<td>22865</td>
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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).

HCPCS: No codes

ICD9: Multiple diagnosis codes

ICD10: Multiple diagnosis codes

REFERENCES:


**SUBJECT:** ARTIFICIAL LUMBAR INTERVERTEBRAL DISC  
**POLICY NUMBER:** 7.01.63  
**CATEGORY:** Technology Assessment

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BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment Program. Artificial Lumbar Disc Arthroplasty. 2014 Jan;28(7).


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* key article

**KEY WORDS:**

ActivL®, Bryan, Charité, Disc, ProDisc-L

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS


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