MEDICAL POLICY

SUBJECT: 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

• If the member’s subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
Based upon our criteria and assessment of the peer-reviewed literature, artificial lumbar disc replacements (total or partial) have not been medically proven to be effective and are considered investigational.

Refer to Corporate Medical Policy #7.01.80 Artificial Cervical Intervertebral Disc.
Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES:
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.

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:
The Charité Artificial Disc received FDA premarket approval in October 2004 for disc replacement for degenerative disc disease at one lumbar level. The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. It is not currently marketed in the U.S. Production under the name Charité® was stopped in 2010. 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. Given the limitations of the original randomized controlled trial and the 50%-70% loss to follow-up, the results from the 5-year follow-up cannot be interpreted. Complications are emerging with longer-term follow-up. Shim, et al. (2007) reported that clinical outcomes
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 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. This change in the overall success between 2 and 5 years in the ProDisc patients indicate a possible decrement in response over time with the artificial disc which was not observed in the fusion group. Several of the individual components of the primary outcome measures which were significantly better at 2 years in the ProDisc group were no longer significantly different at 5 years compared to the fusion group.

An updated BlueCross BlueShield Association TEC Assessment (Jan 2014) evaluated the 5-year follow-up from the pivotal trial of the ProDisc. The Assessment concluded that: 1) Additional study of ProDisc in an appropriately powered clinical trial with minimum 5-year follow-up is needed to confirm the results of the investigational device exemption (IDE) trial in patients with single-level chronic symptomatic DDD unresponsive to conservative management. 2) Questions remain about the durability of the disc, in particular the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue. 3) The main claim of the artificial disc - that it maintains range of motion and thereby reduces the risk of adjacent-level segment degeneration better than fusion - remains subject to debate.

In conclusion, in addition to short-to mid-term outcome data from studies that demonstrate only a marginal benefit of total intervertebral lumbar disc arthroplasty compared to fusion, the long-term impact of lumbar disc replacement including preservation of mobility and progression of degenerative processes at adjacent levels is not known. Serious questions remain about potential long-term complications with these implants.

Partial disc replacement systems are in the earliest stages of investigation. Partial disc replacement systems are considered investigational due to the lack of FDA approval and lack of long-term studies of these devices that demonstrate their safety and improvement on patient health outcomes over standard fusion procedures.

**CODES:**

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<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>22857 E/I</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar</td>
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<tr>
<td>22862 E/I</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace, lumbar</td>
</tr>
<tr>
<td>22865 E/I</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar</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).
0163T (E/I) Total disc lumbar arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar

0164T (E/I) Removal of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar

0165T (E/I) Revision including replacement of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar

HCPCS: No codes

ICD9: Multiple diagnosis codes

ICD10: Multiple diagnosis codes

REFERENCES:


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


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*Proprietary Information of YourCare Health Plan


* key article

**KEY WORDS:**

Bryan, Charité, Disc, ProDisc

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### CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS