

## Medical Policy



An Independent Licensee of the  
Blue Cross and Blue Shield Association

### **Title: Artificial Intervertebral Disc: Lumbar Spine**

*See also: Artificial Intervertebral Disc: Cervical Spine*

#### **Professional**

Original Effective Date: August 9, 2005  
Revision Date(s): June 14, 2006;  
January 1, 2007; July 24, 2007;  
September 25 2007  
Current Effective Date: September 23, 2008

#### **Institutional**

Original Effective Date: August 9, 2005  
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### **DESCRIPTION**

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae. Two artificial intervertebral disc devices, the CHARITÉ® and PRODISC®-L devices, have received FDA approval. The study protocol for the CHARITÉ device consisted of a randomized clinical trial comparing the artificial intervertebral disc to a spinal fusion using a threaded fusion cage with autologous bone graft. The study completed accrual in 2001, with a 24-month follow-up.

Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in which fusion is indicated. Patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for the artificial disc.

### **POLICY**

Artificial intervertebral discs of the lumbar spine are considered **investigational**.

**RATIONALE**

Several case series have been published describing the international experience with the SB Charité device. (1, 2)

In February 2005, TEC completed an assessment of artificial disc replacement, focusing on the Charité device. (3) The TEC Assessment concluded that current evidence supporting the effectiveness of artificial vertebral discs in terms of pain relief and restoration of function among patients with chronic discogenic low back pain, compared with fusion or other treatments, is insufficient. Case series evidence is inadequate to establish efficacy. There was only 1 completed randomized clinical trial evaluating the Charité artificial disc compared to BAK fusion cage for the treatment of single-level degenerative disc disease (4). The Charité artificial disc had a success rate of 63% compared to a success rate of 53% for BAK fusion, using a composite measure of outcomes that incorporated improvement of symptoms and absence of complications. The Charité trial had several potential issues affecting a straightforward interpretation of its results. The analysis showed non inferiority compared to BAK fusion using the composite measure of success, but did not show statistically significant superiority in most outcome measures. The point estimate of 63% success does not show the artificial disc to be a highly successful treatment. The assumptions underlying the validity of a non inferiority trial are not met for this study. Finally, the long-term effectiveness and health outcomes for artificial vertebral discs are uncertain.

The PRODISC-L, was approved by the FDA in August 2006. Approval was based largely on a single randomized clinical trial of 242 patients followed up for 24 months. (5) Using a composite measure of outcome requested by the FDA that incorporated symptom improvement and absence of complications, the PRODISC-L had a success rate of 53.4% and fusion had a success rate of 40.8%. However, the complete analysis is only available in brief form from the "Summary of Safety and Effectiveness Data." (6) The calculations are based on between 88% and 91% of randomized patients — how or which patients have been censored is not mentioned. The assumptions underlying the validity of a non inferiority trial are not met for this study. There is limited published evidence regarding the long-term outcomes of this device. One study followed up 55 patients for an average of 8.7 years after disc replacement. (7) Although 60% of patients report an excellent result, it is not possible, based on case series data, to compare results to other treatments. This study has now been published. (9) However, the same concerns still exist about this study as were noted above. All of the additional publications identified report on case series including patients who received artificial discs at 2 levels in the lumbar spine. (10) A study from Asia comparing the CHARITE with the PRODISC reported that clinical outcomes of both 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. (11)

On May 16, 2006, Medicare issued a national noncoverage determination for LADR (lumbar artificial disc replacement) with the Charité lumbar artificial disc for the Medicare

population over sixty years of age. For Medicare beneficiaries sixty years of age and under, there is no national coverage determination, leaving such determinations to be made on a local basis." (13)

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

### **CPT/HCPCS**

22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace
0164T	Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
0165T	Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace

## **REVISIONS**

08-09-2005	In Policy section: <ul style="list-style-type: none"> <li>▪ Added "Removal or revision of artificial disc(s) is a non-covered service."</li> </ul>
06-14-2006	Removed code 22851
01-01-2007	Replaced codes 0091T, 0094T, and 0097T with 22857, 22865, and 22862 respectively.
07-24-2007	Added codes 0163T, 0164T, 0165T
09-25-2007	Changed policy title from "Artificial Disc (i.e. CHARITE)" to "Artificial Intervertebral Disc: Lumbar Spine".
	In Description section: <ul style="list-style-type: none"> <li>▪ Revised wording in its entirety to reflect broader perspective.</li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-9 Procedure codes 84.65, 84.68</li> <li>Added Diagnosis codes 722 (intervertebral disc disorders code range)</li> </ul>

09-23-2008	In Description section:
	▪ Updated wording
	In Policy section:
	▪ Removed "Removal or revision of artificial disc(s) is a non-covered service."
In Coding section:	
▪ Removed CPT codes 0090T, 0092T, 0093T, 0095T, 0096T, 0098T	
Added Rationale section	

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