

LUMBAR ARTIFICIAL DISC REPLACEMENT

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Overview

Degenerative disc disease is not truly a disease but a term used to describe changes to the intervertebral discs, which, in turn, may result in changes to the vertebrae and other structures of the spine. Degenerative disc disease most often occurs in the lumbar (lower back) and cervical (neck) regions of the spine.

Degenerative disc disease is treated conservatively with physical therapy and ice or heat on the affected area. Medication is integral to the treatment of lumbar degenerative disc disease with peripherally acting analgesics, such as nonsteroidal anti-inflammatory drugs and acetaminophen, being the mainstays of treatment. In most cases, symptoms associated with degenerative disc disease lessen over time. About 50% of people with a herniated lumbar disc will recover in 4 to 6 weeks, and 90% will recover within six months. Surgical intervention is reserved for those who fail to respond to conservative treatment for six months or more.

The most common surgical procedure for the treatment of chronic pain associated with lumbar degenerative disc disease is discectomy. Discectomy is the surgical removal of the part of the herniated disc that is pressing on the nerve root. Laminectomy or laminotomy may be performed alone or with discectomy when the spinal cord or nerve roots are being compressed. Spinal fusion (arthrodesis) is a surgical procedure that joins, or fuses, two or more vertebrae together with a bone graft. Spinal fusion is major surgery, usually done as a last resort after other surgeries have failed to relieve pain associated with degenerative disc disease. There are different methods of spinal fusion, including BAK® Interbody Fusion (Zimmer, Inc.) and 360 degree circumferential fusion. Spinal fusion has significant risks including loss of mobility in the fused section of the spine and premature degeneration at adjacent levels.

Lumbar artificial disc replacement, also known as total disc arthroplasty, has been proposed as an alternative to spinal fusion in the treatment of degenerative disc disease. Artificial (prosthetic) discs ostensibly avoid the complications associated with spinal fusion, i.e., loss of mobility and degeneration at adjacent levels. Artificial discs have been used for many years in Europe to replace damaged lumbar discs that are causing chronic low back pain. Two lumbar artificial discs have been approved for use in the U.S. The Charité™ Artificial Disc (DePuy Spine, Inc.) was FDA-approved in October 2004 and the ProDisc-L® (Synthes Spine) was approved in August 2006. Several other lumbar artificial discs are currently in various phases of development and clinical trials.

The evidence supporting the effectiveness of lumbar artificial disc replacement is limited. The clinical trial of the Charité™ artificial disc (Blumenthal et al., 2005) has several potential issues affecting the interpretation of its results. The analysis showed noninferiority compared to BAK fusion but not superiority. A noninferiority criterion usually implies some trade-off in the principal outcomes for some other trade-off.

However, there is no immediately evident advantage to the use of the artificial disc. The 57% success rate does not show the artificial disc to be a highly successful treatment. In addition, the long-term safety and effectiveness of the Charité™ artificial disc is unknown. The manufacturer has been required by the FDA to conduct a post-approval study following the original IDE trial patients for a total of 5 years post-implantation.

Similar problems regarding the interpretation of the Charité™ trial apply to the ProDisc®-L trial (Zigler et al., 2007). For a noninferiority comparison, the investigational treatment where the results are not inferior to another treatment is generally considered acceptable if there are other obvious advantages. For the lumbar artificial disc, the advantages are not obvious. Although the disc has been in use in Europe for over 10 years, the design promise of spinal mobility leading to improved outcomes over fusion remains unproven. The ProDisc®-L noninferiority trial has as a comparator 360 degree circumferential fusion. However, it is not clear that a trial designed to demonstrate noninferiority is valid given that the effectiveness of circumferential fusion in degenerative disc disease is not well-established in comparison to conservative treatment. The choice of a clinically relevant difference is crucial in noninferiority and equivalence trials (Gotzche, 2006) however; there is no justification for the noninferiority margin in the ProDisc®-L trial. Knowledge of the effectiveness of circumferential fusion is lacking.

The ProDisc®-L trial randomized 162 patients to the ProDisc®-L and 80 patients to circumferential fusion. The achieved success rates (63.5% achieved versus 85% planned) are significantly lower than the planned success rates. It is not clear why the achieved success rates were so far from the planned success rates, and calls into question if, in fact, noninferiority to fusion also means superiority to conservative treatment. In addition, the success rates were based on patients completing the trial rather than the full, randomized sample. The lack of documentation of missing data and subjects makes it difficult to determine which patients were ultimately included in the analysis.

Case series studies have shown that some patients with disabling degenerative lumbar disc disease may benefit from artificial disc replacement. Unfortunately, rather than confirm results of case series studies, the Charité™ and ProDisc®-L clinical trials created uncertainty. The clinical trials are suspect as valid noninferiority trials. It is not clear whether lumbar artificial disc replacement is as beneficial as the established alternative. All other arthroplasties have demonstrated a finite lifespan. Revision anterior surgery at the lower lumbar level is technically challenging. Long-term studies are needed to understand the implications of late implant failure due to wear or loosening.

Covered Services

Removal of an existing lumbar artificial disc requires preauthorization.

Lumbar artificial disc replacement, also known as total disc arthroplasty, is not covered. Lumbar artificial disc replacement does not meet FCHP's technology assessment

criteria. Specifically, currently available scientific evidence is insufficient to permit conclusions regarding the effect of the technology on health outcomes.¹

Revision including replacement of an existing failed lumbar artificial disc is not covered.

There are some possible complications that could necessitate removal of an existing artificial disc such as:

- Allergic reaction to the implant materials
- Material failure (e.g., implants that bend, break, loosen or move)
- Local and or systemic infection

FCHP will cover the removal of an existing lumbar artificial disc (and the necessary stabilization of the spine by conventional methods, such as fusion) when an FCHP Medical Director has determined that removal of the artificial disc is medically necessary.

Exclusions

1. Revision including replacement of an existing failed lumbar artificial disc. Revision surgery is not covered, even in a patient who has complications following lumbar artificial disc replacement.

Codes

Claims for total disc arthroplasty and revision including replacement of total disc arthroplasty will be denied with the following disposition: *Reject Not Covered – Vendor Liable*, leaving no member balance.

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

¹ Although FCHP’s Technology Assessment Committee has determined that cervical artificial disc replacement is experimental/investigational, the Federal Employees Health Benefits Program (FEHBP) requires coverage for all FDA-approved drugs, devices or biological products. Therefore, cervical artificial disc replacement and revision are covered for FEHBP members if an FCHP Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27).

Codes	Number	Description
	0164T	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar; each additional interspace

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

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Committee review dates:

Technology Assessment Subcommittee: 09/17/2008, 12/16/08

Technology Assessment Committee: 04/26/2005, 10/14/2008, 01/13/09

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.