Medical Coverage Policy | Artificial Intervertebral Disc Insertion Lumbar Spine

EFFECTIVE DATE: 02|01|2017
POLICY LAST UPDATED: 12|20|2016

OVERVIEW
Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling degenerative disc disease.

This policy is applicable to Commercial Products only. For BlueCHiP for Medicare, see related policy section.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Artificial intervertebral disc replacement of the lumbar spine is considered not medically necessary due to the lack of peer-reviewed literature that demonstrates that the procedure is effective.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
When conservative treatment of degenerative disc disease (DDD) fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. In addition, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and normal biomechanics of the adjacent vertebrae.

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

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, pseudotumor formation).

Regulatory Status
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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. 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 Maverick™ artificial disc (Medtronic) is not marketed in the United States due to patent infringement litigation. The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access. Kineflex-L™ (Spinal Motion) is a 3-piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L was scheduled for July 2013, but was cancelled without explanation.

The evidence for the lumbar artificial intervertebral disc in individuals who have lumbar degenerative disc disease includes randomized controlled trials (RCTs) with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The Charité disc has been withdrawn from the U.S. market, and its successor, the INMOTION, is not marketed in the United States. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. Superiority of ProDisc-L with circumferential fusion was achieved at 2 but not 5 years in this unblinded trial. At this time, the potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. In addition, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Some randomized trials have concluded that this technology is noninferior to fusion, but outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. Therefore, this service is considered not medically necessary for Commercial products as the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Commercial Products
The following services are considered not medically necessary:
22857 0163T
22862 0165T

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy
Preauthorization via Web-based tool for Procedures
Removal of Not Medically Necessary Implanted Devices

PUBLISHED

Provider Update, February 2017
Provider Update, July 2015
Provider Update, August 2013
Provider Update, January 2013
Provider Update, February 2012
Provider Update, December 2010
Provider Update, December 2009

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