Medical Coverage Policy | Artificial Intervertebral Disc Insertion Lumbar Spine

EFFECTIVE DATE: 09|01|2005
POLICY LAST UPDATED: 04|21|2021

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

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see related policy section.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Artificial intervertebral discs of the lumbar spine are considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For Medicare Advantage Plans, see related policy section for the Medicare Advantage Plans National and Local Coverage Determinations policy.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
The most frequent cause of back pain requiring surgery, degenerative disc disease (DDD) is common with age or trauma. Spine imaging—such as magnetic resonance imaging (MRI), computed tomography, or plain radiography—shows that lumbar disc degeneration is widespread but for most people does not cause symptoms. 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. Patients who require procedures in addition to fusion (eg, laminectomy, decompression) are not candidates for the artificial disc.

When conservative treatment 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. Also, 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.

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
Three artificial lumbar disc devices (activL, Charité, ProDisc-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process). Production under the name Charité was stopped in 2010 and the device was withdrawn in 2012.

Because the long-term safety and effectiveness of these devices were not known when approved, approval was contingent on completion of postmarketing studies. The activL (Aesculap Implant Systems), and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. The activL device is approved for use at one level. Initial approval for ProDiscL was also limited to patients with disease at one level. In April 2020, the ProDiscL indication was expanded to include patients with disease at up to 2 consecutive levels.

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité®device with a change in name under the same premarket approval. 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™, scheduled in 2013, but was cancelled without explanation.

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) of artificial discs vs fusion with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement compared to.spinal fusion. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. No RCTs compared activL to spinal fusion or conservative care. RCTs were limited by a lack of blinding, insufficient followup to evaluate potential harms, and lack of comparison to the criterion standard for treatment of degenerative disc disease. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Commercial Products
The following services are considered not medically necessary:

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 (List separately in addition to code for primary procedure)

22862 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace

0165T Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace. (List separately in addition to code for primary procedure)

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations Policy
Preauthorization via Web-based tool for Procedures

PUBLISHED

Provider Update, June 2021
Provider Update, July 2020
Provider Update, July 2019
Provider Update, June 2018
Provider Update, August 2017

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