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**POLICY LAST UPDATED:** 05|07|2020

## 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 BlueCHiP for Medicare, 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 the effects of the technology on health outcomes.

For BlueCHiP for Medicare, see related policy section for the BlueCHiP for Medicare 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), Charité® (DePuy), and ProDisc®-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs.

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 DDD. 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** 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

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, July 2020

Provider Update, July 2019

Provider Update, June 2018

Provider Update, August 2017

Provider Update, February 2017

Provider Update, July 2015

Provider Update, August 2013

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2. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: PRODISC-L Total Disc Replacement. 2006; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/P050010b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010b.pdf). Accessed March 9, 2020
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