Protocol

Artificial Intervertebral Disc: Lumbar Spine

(70187)

Medical Benefit		**Effective Date**: 01/01/08	**Next Review Date**: 01/19
Preauthorization	No	**Review Dates**: 06/07, 07/08, 05/09, 01/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With lumbar degenerative disc disease	Interventions of interest are: • Lumber artificial intervertebral disc	Comparators of interest are: • Conservative therapy • Lumbar spinal fusion	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Description

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

Summary of Evidence

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) with five 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. The superiority of ProDisc-L with circumferential fusion was achieved at two but not at five years in this unblinded trial. The potential benefits of the artificial disc (e.g., 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. 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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

Background

When conservative treatment of 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 to maintain the 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 (e.g., 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

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. 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 DDD at one level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. Production under the name Charité® was stopped in 2010.

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 three piece, modular, metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L, scheduled in 2013, but was cancelled without explanation.

FDA product code: MJO.

Related Protocol

Artificial Intervertebral Disc: Cervical Spine

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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