Protocol

Artificial Intervertebral Disc: Lumbar Spine

(70187)

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

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *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.*

Description

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 nonradicular low back pain.

Background

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease (DDD) and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of 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 non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in whom fusion is indicated. Patients who require procedures in addition to fusion, such as laminectomy and/or decompression, are not candidates for the artificial disc.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. These 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, and pseudotumor formation).

Regulatory Status

While artificial intervertebral discs in the lumbar spine have been used internationally for more than 10 years, only two devices (Charité® and ProDisc®-L) have received approval from the U.S. Food and Drug Administration (FDA). Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of postmarketing studies. The Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level; Charité is approved for use in levels L4–S1, and the 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 radiographic studies. The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in the name under the same premarket approval (PMA). Production under the name Charité® was stopped in 2010. The INMOTION® is not currently marketed in the U.S. The Maverick™ artificial disc (Medtronic) is not marketed in the U.S. die to patent infringement litigation. Other devices are currently under investigation in the U.S. as part of the FDA process of approval, including the FlexiCore® (Stryker Spine), Maverick (Medtronic), and Activ-L™ (Aesculap) devices. (Artificial intervertebral discs for treating the cervical spine are considered is a separate Protocol.)

Related Protocol

Artificial Intervertebral Disc: Cervical Spine

Policy (Formerly Corporate Medical Guideline)

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

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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