Artificial Disc Replacement

Policy Number: HS-046

Original Effective Date: 9/18/2008

Revised Date(s): 9/18/2009; 9/24/2010; 9/1/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Degenerative disc disease (DDD) of the lower back results from changes in the intervertebral discs in the lumbar region, and is characterized by chronic low back pain. An estimated 60% to 80% of adults in the United States have low back pain at some time in their lives with DDD being a major contributor. In most cases, low back pain can be relieved through rest and conservative therapy, but, for 5% to 10% of patients, it becomes chronic and disabling. It is a leading cause of physician visits, surgery, hospitalization, and disability. Chronic low back pain that is refractory to conservative therapies might require surgical therapy, mainly lumbar spinal fusion; over 200,000 of these surgeries are performed annually in the United States at a cost of more than $6 billion. An aging population and improvements in diagnosis, expanding surgical indications, and new instrumentation have led to a marked increase in the utilization of lumbar spinal fusion and an increase in hospital charges.

A new technique has been developed in which the diseased spinal disc is removed surgically and replaced with an artificial disc. Artificial discs for the cervical and lumbar sections of the spine are available. These devices are composed of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disk that is inserted between the metal endplates. The goal of this procedure is to reduce or eliminate back pain while maintaining spinal curvature, flexibility and load bearing. Discs are implanted through an anterior approach and are attached to vertebrae with screws, teeth, ridges, or fins. Several models have a rough or porous coating to encourage bone in growth around the disc. Current models use metal alloys, ultra-high molecular weight polyethylene, and ceramics.

The artificial disc was developed in response to these concerns. Designed to maintain the function of the natural spine, the artificial disc is hypothesized to prevent degeneration of adjacent discs, which is presumably caused by the increased movement required of these discs when the fused area becomes immobilized. Currently there are two artificial lumbar discs approved by the Food and Drug Administration (FDA) for use in the United States, the Charité® Artificial Disc (DePuy Spine Inc., a Johnson & Johnson Company) and ProDisc-L® Total Disc Replacement (Synthes Spine Inc.). Both discs are approved for use in adult patients with single-level DDD between L3 and S1. Other discs, such as the Maverick™ Total Disc Replacement (Medtronic Sofamor Danek Inc.) and FlexiCore® Lumber Intervertebral Disk Replacement (Stryker Spine), are not approved for use in the U.S.

The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed. Long-term follow-up results from randomized controlled studies are not yet available, and it is therefore not known how the long-term safety of LTDR compares with spinal fusion. Furthermore, patient selection criteria still need to be refined. The evidence was further limited by the absence of appropriate control conditions and blind assessments in some studies (from Hayes, 2007).

Hayes (2011) gives a rating of C (single level cervical total disc replacement) and D (multiple cervical disc disease).

POSITION STATEMENT

Artificial Disc Replacement in the lumbar and cervical spine is considered experimental and investigational.
ARTIFICIAL DISC REPLACEMENT
HS-046

CODING

Non-Covered CPT® Codes

22856  Cervical - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation includes osteophysectomy for nerve root or spinal cord decompression and microdissection, single interspace

22857  Lumbar - Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare Interspace other than for decompression, each additional interspace

Non-Covered CPT® Category II Codes

0092T+  Cervical - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation includes osteophysectomy for nerve root or spinal cord decompression and microdissection, each additional interspace,
  + Add on code List separately in addition to code for primary procedure 22856

0163T+  Lumbar - Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare Interspace other than for decompression, each additional interspace
  + Add on code List separately in addition to code for primary procedure 22856

Non-Covered ICD-9-CM Procedure Codes

84.62  Insertion of total spinal disc prosthesis, cervical
84.64  Insertion of partial spinal disc prosthesis, lumbosacral
84.65  Insertion of total spinal disc prosthesis, lumbosacral

HCPCS Level II © Codes  -  No applicable codes

Non-Covered ICD-9-CM Diagnosis Codes  –  This list may not be all inclusive

722.10  Displacement of cervical intervertebral disc without myelopathy
722.10  Displacement of Lumbar intervertebral disc without myelopathy
722.4  Degeneration of cervical intervertebral disc
722.52  Degeneration of lumbar or lumbosacral intervertebral disc


REFERENCES

Peer Reviewed


**Government Agencies, Professional and Medical Organizations**


**Other**


**HISTORY AND REVISIONS**

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