

WellCare Health Plans, Inc.
The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.



WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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WellCare Health Plans of New Jersey, Inc.

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WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Artificial Disc Replacement

Guideline Number: HS-046

Original Effective Date: 9/18/2008

Revision Date: 9/18/2009

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.

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DISCLAIMER

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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.

CLINICAL COVERAGE GUIDELINE

Artificial Disc Replacement in the lumbar and cervical spine is considered experimental and investigational.

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).

CODING

CPT® Codes

No covered procedure codes

ICD-9-CM Procedure Codes

No covered procedure codes

HCPCS Codes

No covered HCPCS codes

ICD-9-CM Diagnosis Codes

No covered diagnoses

*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10).
2. Hayes Brief. Bryan® Cervical Disc System (Medtronic Sofamor Danek) for Degenerative Disc Disease. June 13, 2005.
3. Hayes Brief. CHARITÉ™ Artificial Disc (Depuy Spine Inc.) for Degenerative Disc Disease. January 30, 2006.
4. Hayes Brief. Prestige® Cervical Disc System (Medtronic Sofamor Danek) for Degenerative Disc Disease. October 28, 2007.
5. Hayes Search and Summary. ProDisc™-C Total Disc Replacement (Synthes® Spine Solutions). August 14, 2008.
6. Hayes Directory. Lumbar Total Disc Replacement for Degenerative Disc Disease September 10, 2007.
7. BlueCross BlueShield Association Technology Assessment. Artificial Lumbar Disc Replacement. June, 2007.
8. BlueCross BlueShield Technology Assessment. Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine. February, 2008.