



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, 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.

WellCare Health Plans of New Jersey, Inc.

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WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Intradiscal Electrothermal Therapy (IDET™)

Policy Number: HS-043

Original Effective Date: 9/4/2008

**Revised Date(s): 9/7/2009; 9/3/2010;
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

Subacute and chronic low back pain is a significant health problem that affects 60% to 80% of adults in the United States at some time in their lives. In most cases, low back pain is temporary and can be relieved by rest and conservative treatment; however, for 5% to 10% of patients, it becomes a chronic and disabling condition. IDET is a minimally invasive surgical procedure for patients with chronic lower back pain due to an internal disc disruption that does not respond to conservative medical therapy.

IDET™, also known as intradiscal electrothermal annuloplasty, is a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic discogenic low back pain. Following a provocative discogram, IDET™ is performed by inserting a catheter into the annulus and threading a flexible electrode through the catheter and around the inside of the disc, pressing against the posterior edge of the annulus. The electrode is then heated to a temperature of 90° F for up to 17 minutes. Analgesics and/or antibiotics are then injected and the catheter is withdrawn. The heating of the electrode denatures the collagen of the annulus and coagulates the nerve endings, with the ultimate goal of relieving back pain.

Clinical evidence does not support the use of IDET™ in the treatment of low back pain caused by a herniated intervertebral disc. The evidence base for this procedure remains limited. New studies report that some patients improve after IDET therapy; however randomized controlled trials have small populations and report varied results. The data do not support using IDET outside of a controlled clinical trial at this time because more substantial evidence and longer-term results, including comparison with other methods of treatment, are needed. Concerns include identification of appropriate candidates for the treatment, whether collagen shrinkage is permanent or if post-treatment collagen repair/formation results in improved mechanical function, and whether there is an increased risk of injury following IDET treatment.

Centers for Medicare and Medicaid Services Statement

The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that thermal intradiscal procedures do not improve health outcomes. Therefore, CMS has determined that thermal intradiscal procedures are not reasonable and necessary for the treatment of low back pain and we propose to issue a national non-coverage determination for TIPs.

POSITION STATEMENT

Intradiscal Electrothermal Therapy (IDET™) **is considered experimental and investigational.**

CODING

Non Covered CPT® Codes

22526 Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

22527+ Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels

+(Add on code; List separately in addition to code for primary procedure)

Non Covered ICD.9-CM Procedure Code

03.8 Operations on spinal cord and spinal canal structures; Injection of destructive agent into spinal cord
Electrothermal Therapy

Not Covered HCPCS® Codes - No applicable codes.

Non Covered ICD-9-CM Diagnosis Codes

722.10 Lumbar intervertebral disc without myelopathy; Lumbago or sciatica due to displacement of intervertebral disc; Neuritis or radiculitis due to displacement or rupture of lumbar intervertebral disc

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Boswell, M.V., Rino, V.S., Everett, C.R., Sehgal, N., McKenzie-Brown, A.M., Abdi, S., et al. (2005). Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician*, 8, 1-47.
2. Hayes Directory. (2010, February 9). Intradiscal electrothermal therapy (IDET). Retrieved from <http://www.hayesinc.com>
3. Lavelle, W.F., Lavelle, E.D., & Smith, H.S.(2008). Interventional techniques for back pain. *Clinics in Geriatric Medicine*, 24(2), 345-368.

Government Agencies, Professional and Medical Organizations

1. American Academy of Orthopaedic Surgeons. (2003). Use of thermal modalities (lasers and radiofrequency devices) in orthopaedic surgery.
2. Centers for Medicare and Medicaid Services. (2008, September 29). National coverage determination for thermal intradiscal procedures (150.11).
3. Centers for Medicare and Medicaid Services. (2008, July 15). Proposed decision memo for thermal intradiscal procedures (CAG-00387). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
9/1/2011	• Approved by MPC.