Clinical Policy: Intradiscal Electrothermal Therapy; Percutaneous Intradiscal Radiofrequency Thermocoagulation

Reference Number: HNCA.CP.MP.48
Effective Date: 10/03
Last Review Date: 8/19

Coding Implications

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Multiple treatment options for subacute and chronic low back pain are currently available. Several minimally invasive catheter–based techniques have been investigated to treat chronic discogenic low back pain, including intradiscal electrothermal therapy (IDET), also referred to as intradiscal electrothermal annuloplasty (IEA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), also known as percutaneous radiofrequency thermomodulation, and intervertebral disc biacuplasty (e.g. TransDiscal System).

Policy/Criteria
I. It is the policy of Health Net of California that intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation, and intervertebral disc biacuplasty are considered investigational for the treatment of back pain. These treatments continue to be evaluated in clinical studies, however, current peer review literature is inconclusive at this time.

Background
Subacute low back pain is commonly defined as back pain lasting between 4 and 12 weeks and chronic low back pain as pain that persists for 12 or more weeks. Multiple treatment options for subacute and chronic low back pain are currently available. Electrothermal therapies and radiofrequency thermocoagulation have been proposed as minimally invasive treatment of back pain in individuals who have failed to respond to conservative treatment.

Intradiscal electrothermal therapy
Intradiscal electrothermal therapy (IDET), also known as intradiscal electrothermal annuloplasty, is a technique designed to thermocoagulate and destroy nerves in the intravertebral disc of individuals presumed to have discogenic low back pain. A catheter or electrode, placed into the intervertebral disc, is slowly heated and kept at a predetermined temperature for a predetermined time to coagulate and shrink adjacent tissues. Randomized placebo-controlled trials have been conducted on IDET in patients with chronic back pain and positive responses to provocative discography. One such trial (Pauza et al) reported patients randomized to IDET experienced moderate improvements in pain scores compared with sham IDET, but experienced no improvements in functional status. Another trial, reported the IDET procedure appeared to be safe, but noted no significant benefit from IDET over placebo were demonstrated (Freeman et al). A small study of 50 patients with lumbar discogenic pain who underwent IDET treatment, reported at 24 months, there was an average 68 and 66% improvement in back pain and function, respectively, between pretreatment and 24 months after treatment.
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_Percutaneous intradiscal radiofrequency thermocoagulation_

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) is similar to IDET, but heat is generated in surrounding tissues by an alternating radiofrequency current. There is minimal published data on PIRFT. One small study of 28 individuals with chronic low back pain showed that PIRFT was not effective in reducing chronic discogenic low back pain. Patients were assigned to two treatment groups, one with radiofrequency current and one without. Improvement after eight weeks was noted in two patients in the control group and only one patient treated with PIRFT (Barendse et al). Another small RCT of 20 individuals with chronic low back pain and a positive provocation discography were randomized to either intra-annular PIRFT or intra-annular sham treatment. After 12 months the overall reduction from baseline pain had reached statistical significance, but there was no significant difference between the groups (Kvarstein et al.) A systematic review assessing the benefits and harms of nonsurgical interventional therapies for low back and radicular pain reported good or fair evidence that percutaneous intradiscal radiofrequency thermocoagulation is not effective. Insufficient evidence exists to reliably evaluate other interventional therapies. The review concluded that few surgical interventional therapies for low back pain have been shown to be effective in randomized, placebo-controlled trials. (Chou et al)

**Intervertebral disc biacuplasty**

Intervertebral disc biacuplasty (e.g. TransDiscal System) using a bipolar approach in conjunction with internally water-cooled radiofrequency (RF) probes to coagulate while decompressing disc material has been proposed to treat individuals suffering from chronic discogenic back pain originating from annular fissures or contained disc herniations who have attempted pain relief with medications and injections without adequate attenuation of pain. During biacuplasty, two TransDiscal Introducers are placed within the disc in a bilateral approach. A TransDiscal Probe is inserted through each introducer, placing them into contralateral sides of the posterior intervertebral disc. Once in place, RF energy is delivered between the two electrodes in the disc, heating the area between and immediately around the electrodes. RF energy heats the tissue and the internally circulating water cools the tissue in close proximity to the electrodes. This combination creates an ideal heating profile across the posterior disc without excessive heating, lesioning the disc's nociceptors in a controlled fashion.

Peer review literature evaluating intradiscal biacuplasty is limited. Randomized controlled trials have reported short-term positive effects of intradiscal biacuplasty versus conventional medical management or sham treatment. However, these studies have only reported results up to 12 months and the studies have had limited number of participants. In addition, a highly selected subset of patients have been evaluated (e.g. 64 from a potential cohort of 1,894 subjects).

In an updated evidence-based guideline for interventional techniques in chronic spinal pain, Manchikanti et al (2013) reported for intradiscal procedures of the lumbar spine, the evidence for intradiscal electrothermal therapy (IDET) and biaculoplasty is limited to fair.

*Guideline Recommendations*
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The National Institute of Health and Care Evidence (NICE) states the current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is inconsistent and of poor quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Guidelines from the American Pain Society (APS) in 2013 state that there is “good or fair” evidence from randomized trials that PIRFT thermocoagulation is not effective and found insufficient (poor) evidence from randomized trials to reliably evaluate other interventional therapies, which include IDET. Issues with the studies include conflicting conclusions, lack of quality data and no randomization.

The California Technology Assessment Forum technology review of IDET in 2014 concluded that the procedure with the Radionics RF System did not meet the CTAF technology assessment criteria.

The American Society of Interventional Pain Physicians (ASIPP) updated evidence-based practice guideline in 2013, stating that the evidence for IDET and biaucuplasy for management of chronic spinal pain for thermal annular procedures is limited for discTRODE and also may be effective for a select group of patients with discogenic pain nonresponsive to conservative modalities including epidural injections.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only.

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<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level</td>
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<td>22527</td>
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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**Reviews, Revisions, and Approvals**

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**References**

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to
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Applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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**Note:** For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note:** For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at [http://www.cms.gov](http://www.cms.gov) for additional information.

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