

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 97</b>	<b>Date: December 9, 2008</b>
	<b>Change Request 6291</b>

**Subject: Thermal Intradiscal Procedures (TIPs)**

**I. SUMMARY OF CHANGES:** Upon completion of a national coverage analysis for TIPS, the decision was made that TIPs are non-covered for Medicare beneficiaries. The addition of § 150.11 of Pub.100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**New / Revised Material**

**Effective Date: September 29, 2008**

**Implementation Date: January 5, 2009**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>Chapter / Section / Subsection / Title</b>
<b>R</b>	1/Table of Contents
<b>N</b>	1/150/150.11/Thermal Intradiscal Procedures (TIPs) (Effective September 29, 2008)

**III. FUNDING:**

**SECTION A: For Fiscal Intermediaries and Carriers:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**SECTION B: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

#### **IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 97	Date: December 9, 2008	Change Request: 6291
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**SUBJECT: Thermal Intradiscal Procedures (TIPs)**

**Effective Date:** September 29, 2008

**Implementation Date:** January 5, 2009

## I. GENERAL INFORMATION

**A. Background:** This is a new national coverage determination (NCD). There is no existing NCD on thermal intradiscal procedures (TIPs).

On January 15, 2008, the Centers for Medicare and Medicaid Services (CMS) initiated a national coverage analysis (NCA) on (TIPs). The scope of this NCA on TIPs included percutaneous intradiscal techniques utilizing devices that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probes/catheters, which utilize a resistance coil or other thermal intradiscal technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction or the annulus. Although not meant to be a complete list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or ablation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter(s)/probe(s) that is used (e.g. SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). This change request (CR) communicates the findings and the NCD of this NCA.

While four CPT codes are identified for TIPs procedures performed within the annulus of the intervertebral disc (22526, 22527, 0062T and 0063T), the codes (codes 62287, 22899 and 64999) used for TIPs procedures performed within the nucleus of the disc (eg., PDD or TDD procedures) may also be used for procedures that are not within the scope of the TIPs NCD. The contractors may advise providers through a MLN Matters article to submit TIPs procedures performed within the nucleus under code 22899 or 64999 with a clear description of the procedure in the narrative section of the claim since these codes suspend for review. Contractors may also advise providers to submit the biacuplasty procedure under code 0062T (currently some providers are submitting this procedure under code 64999). This CR provides instructions on codes that shall be denied when submitted and for codes that shall be denied when identified as a TIP.

All TIPs procedures are performed with radiologic or fluoroscopic guidance. This service would be directly related to a noncovered service and, therefore, noncovered. This CR provides an instruction to deny claims for the radiologic or fluoroscopic guidance when performed in conjunction with a TIP.

This CR includes requirements for physicians and hospitals to provide appropriate liability notices to beneficiaries. Any provider who performs the service described in this instruction that is expected to be non-covered on the basis of this coverage decision should provide the beneficiary with the appropriate liability notice in advance of the procedure consistent with chapter 30, Pub 100-04, the Medicare Claims Processing.

**B. Policy:** Effective for services performed on or after September 29, 2008, CMS has concluded that the evidence does not demonstrate that TIPs improve health outcomes. Thus, CMS has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs are noncovered as identified in section 150.11 of Pub.100-03, the NCD Manual.

**II. BUSINESS REQUIREMENTS TABLE**

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MA C	D M E M A C	F I	C A R R I E R	D M E R C	R H H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
6291.1	Effective for dates of service on and after September 29, 2008, contractors shall deny claims submitted for TIPs. See Pub 100-04 business requirements for detailed claims processing instructions.	X		X	X							

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B  M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
6291.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin.	X		X	X							

**IV. SUPPORTING INFORMATION**

**A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

Use "Should" to denote a recommendation.

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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X-Ref Requirement Number	Recommendations or other supporting information:

**B. For all other recommendations and supporting information, use this space: N/A**

## V. CONTACTS

**Pre-Implementation Contact(s):** Deirdre O'Connor, (410) 786-3263, [Deirdre.oconnor@cms.hhs.gov](mailto:Deirdre.oconnor@cms.hhs.gov), (coverage); Pat Brocato-Simons, (410) 465-4790, [Patricia.brocatosimons@cms.hhs.gov](mailto:Patricia.brocatosimons@cms.hhs.gov), (coverage), Cynthia Glover, (410) 786-6289, [Cynthia.glover@cms.hhs.gov](mailto:Cynthia.glover@cms.hhs.gov), (carrier claims), Melissa E. Dehn, (410) 786-5721, [Melissa.dehn@cms.hhs.gov](mailto:Melissa.dehn@cms.hhs.gov) (institutional claims), Valeri Ritter, (410) 786-8652, [Valeri.ritter@cms.hhs.gov](mailto:Valeri.ritter@cms.hhs.gov), (institutional claims)

### **Post-Implementation Contact(s):**

Appropriate Regional Office or MAC Project Officer

## VI. FUNDING

### **Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

### **Section B: For *Medicare Administrative Contractors (MACs)*:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 2 (Sections 90 – 160.25)

### Coverage Determinations

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#### Table of Contents

*(Rev. 97, 12-09-08)*

*150.11 – Thermal Intradiscal Procedures (Effective September 29, 2008)*

**150.11 – Thermal Intradiscal Procedures (TIPs) (Effective September 29, 2008)  
(Rev. 97, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)**

**A. General**

*Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.*

*The scope of this national coverage determination on TIPs includes percutaneous intradiscal techniques that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probe(s)/catheter(s), which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction, or the annulus.*

*Although not intended to be an all inclusive list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy. Percutaneous disc decompression or nucleoplasty procedures that do not utilize a radiofrequency energy source or electrothermal energy (such as the disc decompressor procedure or laser procedure) are not within the scope of this NCD.*

**B. Nationally Covered Indications**

N/A

**C. Nationally Non-Covered Indications**

*Effective for services performed on or after September 29, 2008, the Centers for Medicare and Medicaid Services has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are **noncovered**.*

**D. Other**

N/A

*(This NCD last reviewed September 2008.)*