MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Percutaneous Intradiscal Electrothermal Annuloplasty (IDET/IDTA, PIRFT, Biacuplasty) and Intradiscal Injections**
Policy Number	**7.01.17**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 11/15/01, 10/16/02, 10/15/03, 08/19/04, 06/16/05, 05/18/06, 05/17/07, 04/17/08**
Current Effective Date	**12/21/23**
Archived Date	**04/16/09**
Archive Review Date	**04/22/10, 04/21/11, 04/19/12, 04/18/13, 04/17/14, 03/19/15, 03/17/16, 03/16/17, 06/21/18, 04/18/19, 11/21/19, 12/17/20, 03/18/21, 12/22/22, 12/21/23**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty [IDET], percutaneous intradiscal radiofrequency thermocoagulation [PIRFT], or intradiscal biacuplasty [IBD]) has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of chronic discogenic back pain.

II. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous intradiscal injection using an allogeneic cellular or tissue-based product to replace or supplement the disc tissue (e.g., Via Disc) has not been medically proven to be effective and, therefore, is considered **investigational** for all indications, including degenerative disc disease.

Refer to Corporate Medical Policy #7.01.16 Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression

Refer to Corporate Medical Policy #7.01.62 Intervertebral Disc Decompression: Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

Refer to Corporate Medical Policy #7.01.35 Bioengineered Tissue Products for Wound Treatment and Surgical Interventions

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINE

This policy does not address disc nucleoplasty, which uses a bipolar radiofrequency device to provide heat treatment to the intervertebral disc, in order to remove tissue with minimal thermal damage to collateral tissue.

DESCRIPTION

Intradiscal annuloplasty therapies utilize radiofrequency energy to thermally treat discogenic low back pain arising from annular tears and other forms of internal disc derangement. In contrast with disc nucleoplasty, which ablates disc material, thermal annuloplasty techniques are designed to decrease pain arising from the annulus and enhance its structural integrity. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures, and that pain reduction may occur through the thermal coagulation of nocioceptors in the outer annulus.

Intradiscal electrothermal annuloplasty (IDET or IDTA) is a minimally invasive treatment for discogenic low back pain, intended to treat the protein wall of the disc and reduce the volume of disc material that causes nerve irritation. The procedure involves the insertion of a spinal catheter through a needle into the disc under fluoroscopy, then the use of indirect radiofrequency energy, heating the needle to 194 degrees Fahrenheit (90 degrees centigrade) for up to 20 minutes. The heat from which kills the invading nerves and tightens the surrounding ligaments, creating a new seal. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDET/IDTA include precise temperature feedback and control, as well as the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct radiofrequency needle.

IDET/IDTA is different from the direct application of radiofrequency energy, known as percutaneous intradiscal thermocoagulation (PIRFT) using the Radionics Disc Catheter System. In this procedure, the radiofrequency probe is placed into the center of the disc, rather than around the annulus, and the device is activated for only 90 seconds at a temperature of 70 degrees centigrade. The mechanism of action is not precisely understood, but it is thought to be related to reducing the nociceptive pain input from the free nerve ending in the outer annulus fibrosis. The Radionics Disc Catheter System is similar in concept to IDET/IDTA; however, the methods of delivering the thermal energy are distinctly different. The proposed advantages of the electrothermal delivery of energy (as with IDET/IDTA), compared to the use of a radiofrequency needle (as with PIRFT) are due to the fact that IDET/IDTA provides electrothermal coagulation to a broader tissue segment and allows precise temperature control and temperature feedback.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty, involves the use of two cooled radiofrequency electrodes that are placed on the posterolateral sides of the intervertebral annulus fibrosis. It is proposed that, by cooling the probes, a larger area may be treated than is possible with a regular needle probe.

Viable allograft supplemental disc regeneration (VAST), or Via Disc, is a therapeutic percutaneous injection of the lumbar spine using an allogeneic cellular or tissue-based product to replace or supplement the disc tissue. It repairs or reconstitutes a damaged intra-vertebral disc.

RATIONALE

The SpineCATH/Oratec Intradiscal Electrothermal Catheter received Section 510(k) premarket authorization from the United States Food and Drug Administration (FDA) in March 1998. The Radionics RF Disc Catheter Electrode System (Radionics, Inc., Burlington, MA) received Section 510(k) authorization in 2000. It is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Baylis Pain Management Cooled Probe, used for intradiscal biacuplasty (Baylis Medical, Inc., Montreal, Canada), received Section 510(k) authorization in 2005. It is intended for use “in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue.” The Baylis Transdiscal System received Section 510(k) authorization in 2006. This system, “[u]sed in combination with the Baylis Pain Management Generator is intended for the creation of radiofrequency (RF) lesions in nervous tissue including that which is situated in intervertebral disc material.”

Intradiscal Electrothermal Annuloplasty (IDET/IDTA)

Published clinical trials have not provided evidence to support the efficacy of IDET/IDTA. Published evidence consists mainly of case series. Results of two randomized, controlled trials (RCTs), each with methodological weaknesses, are inconsistent. Pauza et al. concluded that the treatment is effective; however, the researchers did not use an "intention to treat" analysis, and it is not clear that the reduction in reported pain is clinically significant. Freeman et al. conducted a randomized, sham-controlled study; no subject in either arm met criteria for successful outcome, and no significant benefit for IDET/IDTA over placebo was demonstrated.

Percutaneous Intradiscal Thermocoagulation (PIRFT)

There is little published clinical evidence regarding PIRFT. A 2001 double-blind trial randomized 28 patients with chronic low back pain to PIRFT or a sham control group. The primary outcome was the percentage of success at eight weeks, measured by changes in pain level, impairment, Oswestry disability scale, and analgesics taken. At the end of eight weeks, there were two treatment successes in the sham group, compared to one in the treatment group. The authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

A 2007 evidence-based practice guideline from the American Society of Interventional Pain Physicians on the management of chronic spinal pain, created to provide recommendations to clinicians in the U.S., concluded that evidence is moderate for IDET/IDTA in the management of chronic discogenic low back pain. Complications included catheter breakage, nerve root injuries, post-IDET/IDTA disc herniation, cauda equine syndrome, infection, epidural abscess, and spinal cord damage. The same guideline concluded that evidence for radiofrequency posterior annuloplasty (PIRFT) was limited, with complications similar to IDET/IDTA.

A systematic review of IDET/IDTA and PIRFT was conducted, following the criteria recommended by the Cochrane Back Review Group. Four randomized and two non-randomized studies, totaling 283 patients, were included in the review. The report concluded that the available evidence does not support the efficacy or effectiveness of IDET/IDTA and PIRFT, and that these procedures are associated with potentially serious side effects. Evidence-based guidelines from the American Society of Interventional Pain Physicians concluded that the evidence is moderate for management of chronic discogenic low back pain with IDET/IDTA. Complications include catheter breakage, nerve root injuries, post-IDET/IDTA disc herniation, cauda equine syndrome, infection, epidural abscess, and spinal cord damage. The evidence for PIRFT was reported to be limited, with complications similar to IDET/IDTA.

Intradiscal Biacuplasty

In an industry-sponsored, multi-center, RCT (Desai et al., 2016), 63 patients with lumbar discogenic pain were treated with intradiscal biacuplasty plus conservative medical management or with medical management alone. A significant effect was found for the primary outcome measure (mean reduction in visual analog scale score for pain at six months), but not the secondary outcome measures. Additional sham-controlled trials in a broader population of patients are needed, to confirm treatment efficacy.

The Viable Allograft Supplemented Disc Regeneration in the Treatment of Patients with Low Back Pain With or Without Disc Herniation (VAST) Trial was a prospective, randomized, parallel-arm, multi-center study approved to enroll up to 220 subjects at up to 15 clinical sites. The aim of the trial was to investigate the clinical relevance of treating painful intervertebral disc tissue by a supplementary transplantation of viable cellular allograft disc matrix and compare the cellular allograft with a saline placebo or continued treatment with sustained conservative care. This interim analysis enrolled 24 subjects who were randomized 3.5:1:1 to receive allograft (n=16) or saline (n=4) at either one or two levels or continue nonsurgical management (NSM) (n=4). Back pain with a visual analog scale (VAS) and disability by the Oswestry Disability Index (ODI) were assessed, as were adverse events. After three months, all subjects in the NSM cohort crossed over to allograft treatment. At 12 months, the VAS improved from 54.81, 55.25, and 62.255 in the allograft, saline, and NSM subjects, respectively, to 12.27 in the allograft group and 19.67 in the saline group. At 12 months, ODI improved from 53.73, 49.25, and 55.75 in the allograft, saline, and NSM subjects, respectively, to 15.67 in the allograft group and 9.33 in the saline group. Adverse events were transient and resolved in all cohorts.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
22526 **(E/I)**	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527 **(E/I)**	one or more additional levels (list separately in addition to code for primary procedure)
0627T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0629T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
0630T **(E/I)**	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
	No specific code(s)

ICD10 Codes

Code	Description
M51.36	Other Intervertebral disc degeneration, lumbar region
M51.37	Other Intervertebral disc degeneration, lumbosacral region

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KEY WORDS

IDET, IDTA, intradiscal electrothermotherapy, intradiscal biacuplasty, percutaneous intradiscal thermocoagulation, PIRFT, radiofrequency annuloplasty, thermal annuloplasty

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) (150.11) for thermal intradiscal procedures. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=324&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&] accessed 11/08/23.