Medical Policy Reference Manual
Medical Policy

7.01.101 Percutaneous Intervertebral Thermal Annuloplasty Procedures for Low Back Pain

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Description

Chronic low back pain is extremely common, accounting for lost workdays due to disabling pain, and reduced quality of life. Discogenic low back pain originates in the intervertebral discs, as the aging process along with past lifestyle and history of injury may combine to produce degenerative changes in the discs. They lose moisture, and the fibrous outer portion of the disc becomes more brittle and prone to tearing. The term "internal disc disruption" has been used to describe pain caused by structural changes and degenerative processes in the discs without clinical evidence of nerve root irritation, radicular pain or neurological deficits. If the outer, annulus fibrosis layer of the disc sustains a tear, there may be a leakage of the gel-like nucleus pulposus layer into the annulus, irritating the tiny sinuvertebral nerves within the annulus, resulting in discogenic pain. This type of pain thus originates from within the disc rather than from pressure exerted on spinal nerves. As the degenerative process advances, the disc bulges even further, putting pressure on spinal nerves, eventually resulting in neurogenic signs.

Most cases of discogenic low back pain are successfully treated conservatively, using medications, physical therapy, and lifestyle changes. For patients who do not respond to conservative measures, surgical interventions are aimed at removing disc material to relieve pressure. The intervertebral disc annuloplasty techniques have been proposed as minimally invasive procedures designed to shrink the fibrous annulus portion of the disc, closing annular tears and relieving pain. Two main approaches have been developed: Intradiscal electrothermal therapy (IDET), also known as intradiscal electrothermal annuloplasty (IDEA), and percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). With the intradiscal electrothermal annuloplasty (IDEA) procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect radiofrequency energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90 degrees Celsius; the disc material is heated for up to 20 minutes. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of radiofrequency energy. With PIRFT, the radiofrequency probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70 degrees Celsius.

Policy

Intradiscal electrothermal therapy / annuloplasty (IDET / IDEA) is considered **experimental / investigational** as it does not meet TEC criteria # 2 - 5.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) nucleoplasty is considered **experimental / investigational** as it does not meet TEC criteria # 2 - 5.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association (BCBSA) Medical Policy Services (MPS) Assessment Criteria (formerly known as the TEC Criteria or “Technology Evaluation Center” criteria are deemed to be experimental/investigational):

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* Technology includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

IDET is performed using the Oratec® SpineCATH™ system, which has been approved by FDA for marketing under the 510(k) process since 1999. DiscTRODE™ (Radionics, Inc.) and Perc-D® Spinewand® (Arthrocare, Inc.) are examples of radiofrequency catheter systems for use in spinal discs, which have also been cleared under the 510(k) process.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

Intradiscal electrothermal therapy / annuloplasty

There have been a number of small, uncontrolled studies reported in the literature, but although these studies reported patients' subjective symptomatic relief in the short term, the uncontrolled nature of these studies limits the ability to draw conclusions. Two randomized, controlled studies have been reported. Pauza and colleagues (2004) randomized 64 selected patients to treatment of chronic discogenic low back pain with IDET (n=37) or sham treatment (n=27). The investigators reported significant improvements in the IDET group over the sham group in terms of pain scores and Oswestry disability questionnaires, but both groups exhibited improvement. Only five patients reported a 75% relief of pain, and 40% achieved greater than 50% pain relief. Half of the patients reported no appreciable benefit from treatment. The authors concluded that efficacy of IDET could not be attributable to placebo effect. The small size of the study, the short-term (6-month) follow-up period, and the fact that this was a single-center study limit the ability to draw conclusions from the results. Another randomized, double-blind, placebo-controlled study published by Freeman and colleagues (2005) randomized 57 patients with chronic discogenic low back pain to IDET (n=38) or a sham procedure (n=19). Multiple outcomes measures were utilized at baseline and 6 months post-treatment. The authors reported that no subject in either arm met criteria for a successful outcome after 6 months and concluded that the study demonstrated no significant benefit from IDET over placebo. A retrospective study of a group of 60 patients contacted one-year after their IDET procedures was reported by Davis et al in 2004. 44 of the 60 responded to the survey questions. The results were described as "disappointing", with 97% of respondents reporting continuing low back pain, 29% stating their pain was worse than before the procedure, and another 29% reporting no change as a result of the treatment. At one-year post-IDET, half of the patients stated they were dissatisfied with their outcome. A review of the evidence by Freeman (2006) concluded that "The evidence for efficacy of IDET remains weak and has not passed the standard of scientific proof."

The available evidence does not permit conclusions regarding the effect of IDET on health outcomes.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) nucleoplasty

There is a paucity of evidence in the literature addressing the outcomes of patients who have undergone PIRFT. Sharps and Isaac (2002) prospectively evaluated 49 consecutive patients who underwent percutaneous disc decompression using the Spinewand®, and concluded that 12-month results were promising, but that randomized, controlled studies with subgroup analysis were needed to delineate a role for the procedure. Reddy and colleagues (2005) reported on a retrospective evaluation of 49 patients who had undergone percutaneous nucleoplasty. The authors reported that significant pain relief, functional improvement, and decrease in medication use were achieved, and recommended the procedure in patients who fail conservative management but who are unwilling to undergo a more invasive surgical procedure. Yakovlev et al (2007) has also reported on a very small, retrospective, non-randomized case series (n=22). The authors reported that pain and medication use were significantly decreased, and functional status improved at 1, 3, 6, and 12 months following nucleoplasty. The authors concluded that though the procedure appears to be safe and effective, randomized, controlled studies were needed. A study by Barendse and colleagues (2001) randomized 28 patients with chronic discogenic low back pain to treatment with PIRFT (n=13) or sham treatment (n=15). Double blinding was employed, and the authors reported that at eight weeks post-treatment there was one patient in the treatment arm that met the criteria for success, and two in the sham group. The authors concluded that PIRFT was not effective in reducing chronic discogenic low back pain. Kapural et al (2005) reported on a small, match-controlled study (n=42) comparing results of patients treated with IDET (n=21) against those who were treated with PIRFT (n=21).

In this study, where neither treatment group involved a placebo control, the IDET group showed significantly lower mean pain scores than the PIRFT group.

3. The technology must improve the net health outcome:

The available evidence does not permit conclusions concerning the effect of the treatment on health outcomes.

4. The technology must be as effective as any established alternatives:

The evidence does not establish that either IDET or PIRFT improves net health outcomes. Although both procedures appear to be safe in the short term, durability of the relief over time has not been adequately documented, and the long-term effects of heat induced structural changes to the intervertebral disc are not known. Furthermore, there is conflicting evidence from the higher quality studies whether these percutaneous procedures are more effective than a placebo. The evidence-based practice guidelines developed by Boswell and colleagues (2007) assign an evidence rating of Level III ("moderate") to the IDET procedure, and Level IV-V ("limited" in the short term, "indeterminate" in the long term) to the PIRFT procedure. There have been no direct comparison studies done between IDET or PIRFT and spinal surgery procedures.

5. The improvement must be attainable outside the investigational settings:

A net health improvement has not been established in the investigational settings. It is therefore not possible to determine if improvement in outcomes can be expected outside of the investigational settings.

Update 2022:
A search of the peer-reviewed literature was performed for the period of February 2020 through September 2022. Findings in the recent literature do not change the conclusions regarding the use of percutaneous intervertebral thermal annuloplasty procedures for low back pain. Therefore, the policy remains experimental / investigational.

Update 2020:
A search of the peer-reviewed literature was performed from the period of January 2018 through January 2020. Findings in the recent literature do not change the conclusions regarding the use of IDET and PIRFT. Therefore, the policy remains experimental / investigational.

Update 2018:
A search of the peer-reviewed literature was performed for the period of November 2015 through December 2017. Findings in the recent literature do not change the conclusions regarding the use of IDET and PIRFT, therefore the policy remains experimental / investigational.

Update 2015:
A search of the peer-reviewed literature was performed for the period of October 2013 through October 2015. Findings in the recent literature do not change the conclusions regarding the use of IDET and PIRFT, therefore the policy remains experimental / investigational.

Update 2013:
A search of the peer-reviewed literature was performed for the period of September 2011 through September 2013. Findings in the recent literature do not change the conclusions regarding the use of IDET and PIRFT, therefore the policy remains experimental / investigational.

Update 2011:
A search of the peer-reviewed literature was performed for the period of September 2009 through August 2011. Findings in the recent literature do not change the conclusions regarding the use of IDET and PIRFT, therefore the policy remains experimental / investigational.

Update 2009:
A search of the peer-reviewed literature was performed for the period of October 2007 through August 2009. There is a scarcity of current peer-reviewed literature regarding the use of percutaneous intervertebral thermal annuloplasty procedures for low back pain. Therefore, the policy statements remain unchanged.

Benefit Applications

NOTE: For FEP business, check the member's contract for benefits.

Provider Guidelines

There are no Provider Guidelines for this Medical Policy.

Cross References to Related Policies and Procedures

7.01.091	Minimally Invasive Intervertebral Disc Decompression Procedures for Low Back Pain, Policy
7.01.049	Archived Percutaneous Intradiscal Electrothermal Therapy, Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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