Cohere Medicare Advantage Policy - Intradiscal Biacuplasty, PIRFT, or IDET

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 10, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Intradiscal Biacuplasty, PIRFT, or IDET

Date of last literature review: 6/10/2024
Document last updated: 6/10/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Intradiscal Biacuplasty, PIRFT, or IDET

Benefit Category
Physician's services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

Recommended Clinical Approach
This service is clinically unproven and not medically necessary.

Evaluation of Clinical Benefits and Potential Harms
Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Intradiscal Biacuplasty, Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), or Intradiscal Electrothermal Therapy (IDET). This process helps to prevent both incorrect denials and inappropriate approvals of medically unnecessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inadequate management of low back pain, leading to complications like progression of the condition, worsening pain, and reduced mobility. If the low back pain progresses, the patient may need more invasive procedures such as lumbar decompression. Intradiscal Biacuplasty has mixed results in studies and Lu et al concluded that there are doubts that any conclusions can be drawn from small randomized trials that are applicable to the broader patient population with discogenic pain.[3]
- Adverse effects from delayed or denied treatment, which can worsen patient outcomes, such as increased risk of chronic low back pain and disability. Patients with chronic low back pain may become opioid dependent. However, this procedure has not been shown to be effective in treating low back pain.

- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to necessary treatments for managing various spinal conditions. In this case this procedure has not been shown to have favorable outcomes. According to Helm et al one randomized controlled trial demonstrated efficacy while another one suggests no benefit for treatment of low back pain.[2] Due to the limited nature of studies proving benefit the procedure is currently not recommended for treatment of low back pain. By preventing this procedure, the patient can utilize proven therapies to manage their low back pain.
- Reduction in complications and adverse effects from unnecessary procedures. If the patient had an intradiscal biacuplasty they would likely continue to have pain and require additional procedures or medications despite an invasive procedure.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Intradiscal Biacuplasty, Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), or Intradiscal Electrothermal Therapy (IDET)** are considered appropriate if **ALL** of the following are **TRUE**:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- ➔ **Intradiscal Biacuplasty, Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), or Intradiscal Electrothermal Therapy (IDET)** may not be appropriate if **ALL** of the following are **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
22526	Bilateral percutaneous intradiscal electrothermal annuloplasty of a single level of spine using fluoroscopic guidance; Unilateral percutaneous intradiscal electrothermal annuloplasty of a single level of spine using fluoroscopic guidance
22527	Bilateral percutaneous intradiscal electrothermal annuloplasty of a single additional level using fluoroscopic guidance; Bilateral percutaneous intradiscal electrothermal annuloplasty of multiple additional levels using fluoroscopic guidance; Unilateral percutaneous intradiscal electrothermal annuloplasty of multiple additional levels using fluoroscopic guidance; Unilateral percutaneous intradiscal electrothermal annuloplasty of single additional level using fluoroscopic guidance
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

Disclaimer: S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Helm et al. (2017) conducted a systematic review of 49 studies to evaluate and update the effectiveness of thermal annular procedures (TAPs) in treating chronic refractory discogenic pain. The primary outcome measures were at least 40% pain relief and functional improvement. Two randomized controlled trials (RCTs) with positive results indicate strong evidence (Level I) supporting the efficacy of biacuplasty for treating chronic, refractory discogenic pain. For intradiscal electrothermal therapy (IDET), one high-quality RCT demonstrating efficacy and one moderate-quality RCT suggesting no benefit provide moderate evidence (Level III) for its use in this condition. Evidence supporting the use of discTRODE is limited, categorized as Level V. Percutaneous biacuplasty demonstrates strong evidence (Level I) for its effectiveness in treating chronic, refractory discogenic pain, suggesting it may be a first-line treatment option. In contrast, IDET shows moderate evidence (Level III) of efficacy for this condition. Evidence for the efficacy of discTRODE in treating chronic, refractory discogenic pain is limited (Level V).[2]

Lu et al. (2014) performed a systematic review of current non-surgical management for treating discogenic low back pain. Eleven RCTs focused on injections, ablative techniques, and traction therapy. Six clinical studies did not find significant differences between active therapies and sham/placebo treatments. Five studies that included intradiscal biacuplasty demonstrated significant differences in clinical outcomes favoring intervention over sham treatment. PIRFT did not demonstrate any advantages of the intervention over the sham control. Assessing the selection criteria for studies on intradiscal biacuplasty, along with a stratified analysis of results from RCTs on intradiscal electrothermal therapy (IDET), raises doubts about whether the conclusions from these RCTs are applicable to the broader patient population with discogenic pain. The authors conclude that additional research is needed to establish the efficacy of these treatments.[3]

References

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD): Thermal intradiscal procedures (TIPs)(150.11). Effective September 29, 2008. Accessed May 23, 2024. https://www.cms.gov/medicare-coverage-database/view.
2. Helm Ii S, Simopoulos TT, Stojanovic M, et al. Effectiveness of thermal annular procedures in treating discogenic low back pain. *Pain Physician*. 2017 Sep;20(6):447-470. PMID: 28934777.
3. Lu Y, Guzman JZ, Purmessur D, et al. Nonoperative management of discogenic back pain: A systematic review. Spine (Phila Pa 1976). 2014 Jul 15;39(16):1314-24. doi: 10.1097/BRS.0000000000000401. PMID: 24827515; PMCID: PMC4144979.

Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer Added