Back: Intradiscal Procedures for Low Back Pain

MEDICAL POLICY NUMBER: 20

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Thermal Intradiscal Procedures

I. Thermal intradiscal procedures are considered **not medically necessary** for the treatment of low back pain, including but not limited to, the following (A.-F.):

   A. Intradiscal Biacuplasty (IDB)
   B. Intradiscal electrothermal therapy (IDET), also known as intradiscal thermal annuloplasty (IDTA)
   C. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
   D. Percutaneous (or plasma) disc compression (PDD) or coblation
   E. Radiofrequency annuloplasty (RA)
   F. Targeted disc decompression (TDD)

Non-Thermal Intradiscal Procedures

II. Non-thermal intradiscal procedures are considered **not medically necessary** for the treatment of low back pain, including but not limited to, the following (A.-B.):

   A. Glucocorticoid intradiscal injections
   B. Methylene blue intradiscal injections

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Low Back Pain Treatments

Thermal Intradiscal Procedures

Initial treatment for discogenic low back pain entails conservative measures including pain medications, physical exercises, physical therapy (PT), back brace, intradiscal corticosteroid injections, and/or nerve blocks.

Surgical treatment is offered only if the pain is not responsive to conservative measures. Surgical procedures include disc excision, spinal fusion (arthroplasty), or total artificial disc replacement.

Percutaneous thermal intradiscal treatments, also known as thermal intradiscal procedures (TIPs), are proposed as minimally invasive alternatives to invasive surgical procedures.

Per the Centers for Medicare & Medicaid (CMS) NCD regarding thermal intradiscal procedures:[1]

"Thermal intradiscal procedures involve the insertion a catheter(s)/probe(s) into the spinal disc under fluoroscopic guidance in order to produce, or apply, heat and/or disruption within the disc to relieve low back pain."

This 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.

TIPs procedures performed within the annulus include intradiscal electrothermal therapy (IDET), intradiscal radiofrequency thermocoagulation (IRFT), intradiscal biacuplasty (IDB), and radiofrequency annuloplasty (RA). Procedures performed within the nucleus of the disc include percutaneous (or plasma) disc decompression (PDD) or ablation, and targeted disc decompression (TDD) procedures.

At times thermal intradiscal procedures are identified, or labeled, based on the name of the catheter(s)/probe(s) that are used (e.g., SpineCath, DiscTRODE, Spine Wand, Accutherm, or TransDiscal electrodes); and each technique or device has its own protocol for application of therapy."[1]

Non-Thermal Intradiscal Procedures

Non-thermal intradiscal procedures can include various combinations of injectable medications and substances such as steroids, normal saline, and anesthetics that may alleviate discogenic pain. Both steroids and non-steroidal anti-inflammatory drugs have been shown partially effective in treating pain due to inflammation. As a result, it is purported that intradiscal injections may improve pain by contracting tissues surrounding the disc and promoting spinal segment stabilization.[2] Recent studies primarily evaluate the efficacy of glucocorticoid and methylene blue intradiscal injections.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

There are a number of radiofrequency (RF) coagulation devices that have been cleared for marketing by the FDA through the 510(k) clearance process that may be used for disc nucleotomy. Examples of these devices include:

- Nucleotomy Catheter (Oratec Interventions, Inc.)
- SpineCATH™ Intradiscal Catheter (Oratec Interventions, Inc.)
- Radionics RF Disc Catheter Electrode System (Radionics Inc.)
- TransDiscal ™ System (Baylis Medical) for biacuplasty
- Spine Wand (ArthroCare, Corporation)

Note: Some of the devices listed above are no longer available but were identified during the evidence review.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of thermal and non-thermal intradiscal procedures for the treatment of low back pain. Below is a summary of the available evidence identified through April 2023. Due to the volume of literature, the evidence review on the various procedures is focused on systematic reviews.

Thermal Intradiscal Procedures

Systematic reviews have been published on the following percutaneous thermal intradiscal procedures:

- Intradiscal biacuplasty (IDB)[3-6]
- Intradiscal electrothermal therapy (IDET), also known as Intradiscal thermal annuloplasty (IDTA)[3-13]
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)[6,12]
- Percutaneous (or plasma) disc compression (PDD) or coblation[14-17]
- Radiofrequency annuloplasty (RA)[3-5]
- Targeted disc decompression (TDD)[17]

Many of the systematic reviews suffered from one or more of the following limitations:

- Heterogeneous in the methods used to examine primary studies evaluating various percutaneous thermal intradiscal procedures:
    - included or focused entirely on nonrandomized studies due to a paucity of published randomized controlled trials (RCTs)
    - included a large number of retrospective studies
    - included studies with heterogeneous patient cohorts (e.g. low back pain due to various etiologies)
    - reviews that did include RCTs reported that study criteria used in these RCTs were inconsistent (specifically regarding inclusion/exclusion criteria on age, body mass index, duration of symptoms)
- Two of the reviews were industry sponsored.[7,8]

All reviews mentioned the need for larger, better-quality studies with longer-term follow-up. The majority of recent reviews were unable to draw definitive conclusions regarding the efficacy of any one procedure as a treatment for low back pain. Many of the reviews indicated that ideal patient selection for each procedure remains to be determined.

Overall, the body of evidence for any given procedure suffers from one or more of the following limitations:

- extremely limited number of randomized controlled trials (RCTs) reporting outcomes for any given procedure
- primary studies, including very small numbers of RCTS, were of low- to very-low quality of due to methodological limitations including:
    - small sample size (under 100 patients)
    - insufficient statistical power
    - lack of blinding
    - primary outcomes reported consisted mostly of subjective, patient-reported outcomes
- inadequate follow-up
- heterogeneity of:
    - comparator treatment
    - primary outcomes reported
- conflicting or no evidence of short-term or long-term reductions in pain and/or disability.

Non-Thermal Intradiscal Procedures

No systematic reviews have been published within the last five years examining the efficacy of the following non-thermal intradiscal therapies for the treatment of low back pain:

- Glucocorticoid intradiscal injections
- Methylene Blue intradiscal injections

Glucocorticoid Intradiscal Injections

In 2017, Nguyen and colleagues conducted a RCT evaluating the efficacy of a single glucocorticoid intradiscal injection (GC-IDI) for the treatment of chronic lower back pain (LBP) and active discopathy.[18] In total, 135 patients received a single GC-IDI during discography (n=67) or discography alone (n=68). The primary outcome of interest was the percentage of patients with LBP intensity rating less than 40 on a scale of 0 (no pain) to 100 (maximum pain) in ten point increments over the past 48 hours and 1 month. Secondary outcomes were LBP intensity at 12 months, spine-specific limitations in activities, health-related QOL (HRQL), anxiety and depression, employment status, and use of analgesics and non-steroidal anti-inflammatory drugs at 1 and 12 month follow-up periods. At one month follow-up, GC-IDI patients responded better than the control group. At 1 month after the intervention, the percentage of responders (LBP intensity less than 40) was higher in the GC-IDI group (36 of 65 [55.4 %]) than the control group (21 of 63 [33.3 %]) (ARD: 22.1 percentage points [95 % CI: 5.5 to 38.7 percentage points]; $p = 0.009$). However, groups did not differ in LBP intensity at 12 months and in most secondary outcomes at either 1 or 12 months. Authors concluded that a single GC-IDI reduced LBP at 1 month but not at 12 months.[18]

Methylene Blue Intradiscal Injections

Two meta-analyses were published on methylene blue for back pain.[19,20] Guo et al. reviewed non-randomized data from 5 studies on discogenic low back pain. A pooled analysis found that visual analog and numerical rating scale pain scores and disability scores were lowered among participants, but there were no comparison groups and therefore no conclusions can be drawn from the results. In the second meta-analysis, Yao et al reviewed 3 RCTS on general back pain and found that, compared to a control group, pain scores were reduced at 24-48 hours (standard mean difference: -1.69; 95% CI: -2.07 to -1.32; P< 0.001) and at 2-3 months (mean difference: -1.09; 95% CI: -1.62 to -0.56; P< 0.0001), but not at 6 months. All studies from both meta-analyses suffered from high levels of biases. Sample sizes were small, ranging from 8-52 participants. There was high heterogeneity in participant populations, outcome measures, and results. Both meta-analyses are of poor quality and do not offer substantial evidence for the use of methylene blue intradiscal injections for back pain.

Two recent non-randomized trials[21,22] examined the efficacy of methylene blue for the treatment of low back pain. Despite reporting statistically significant improvements, both studies suffered from small sample sizes (n=15-33), inadequate follow-up (6-12 months) and a lack of comparator groups.

CLINICAL PRACTICE GUIDELINES

Thermal Intradiscal Procedures

North American Spine Society (NASS)

In 2020, the NASS published clinical practice guidelines addressing the diagnosis and treatment of low back pain.[23] Investigators stated that intradiscal steroids are "suggested" to provide short-term improvement in pain and function in patients with Modic changes (Grade of Recommendation: B [Fair evidence, level II or III studies with consistent findings). The recommendation was based on a RCT and comparative cohort study involving subjects with Modic Type I and/or II changes on MRI, and outcomes which included VAS scores and disability scores. At 6-month follow-up, reported clinical outcomes demonstrated significant improvements in pain and function.

For patients with discogenic low back pain, NASS reported there is insufficient evidence to support intradiscal steroid injections provide improvements in pain and function (Grade of Recommendation: I [insufficient or conflicting evidence]).

National Institute for Health and Care Excellence (NICE)

In 2016, NICE published interventional procedural guidance (IPG) documents for a number of percutaneous thermal intradiscal procedures. NICE indicated that the following procedures, "should only be used with special arrangements for clinical governance, consent and audit or research."[24]

- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica (IPG544).
    - NICE stated that "the evidence on efficacy is inconsistent and of poor quality."
- Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain (IPG545).
    - NICE stated that "the evidence on its efficacy is limited in quantity and quality."

NICE also indicated that the evidence on efficacy of percutaneous coblation of the intervertebral disc for low back pain and sciatica was "adequate". (IPG543). However, this guidance was based on one systematic review that included three key studies (two RCTs and one large case series).

American Society of Interventional Pain Physicians (ASIPP)

In 2013, the ASIPP reaffirmed their guideline regarding interventional techniques for the treatment of chronic spinal pain.[25] ASIPP made the following statements regarding thermal annular procedures:

- "The evidence supporting the efficacy of IDET is limited to fair." (Based on evidence of two randomized trials and five observational studies.)
- "There is limited to fair evidence for the effectiveness of biacuplasty for treating low back pain, based on one randomized trial with modest results."

- "The evidence for various modes of percutaneous disc decompression (PDD) is limited to fair for nucleoplasty." (Based on one RCT and 15 observational studies.)

Non-Thermal Intradiscal Procedures

National Institute for Health and Care Excellence (NICE)

In 2016, NICE published a guideline for the assessment and management of low back pain and sciatica in patients over 16 years old. The guideline recommended against the use of spinal injections for managing low back pain.[24]

EVIDENCE SUMMARY

There is insufficient evidence that the use of percutaneous thermal and non-thermal intradiscal procedures are safe and effective compared to standard of care (surgical and non-surgical) treatments for low back pain. To prove clinical utility, additional, large well-designed randomized controlled trials with long-term follow-up are needed. In addition, no evidence-based clinical practice guidelines were identified that strongly support the use of these procedures. One guideline recommended intradiscal steroids for improvements in pain and function in patients with Modic changes, but results did not endure past the short-term. Therefore, percutaneous and non-thermal intradiscal procedures are considered not medically necessary.

BILLING GUIDELINES AND CODING

All intradiscal procedures are performed with radiologic or fluoroscopic guidance. Therefore, radiologic, or fluoroscopic guidance is also considered not covered as an ancillary service when performed in conjunction with intradiscal procedures.

Non-thermal intradiscal injections should *not be billed* with the following codes:

- 20610: Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance.
- 20611: Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.
- 62281: Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic.

CODES*		
CPT	22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
	22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
	22899	Unlisted procedure, spine

	64999	Unlisted procedure, nervous system

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
8/2023	Annual update. Changed denial from investigational to not medically necessary