



Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN) – Single Service

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: September 22, 2023

Important Notices

Notices & Disclaimers:

GUIDELINES 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 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.

©2023 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS® and CPT® copyright 2022 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)

Guideline Name: Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN) - Single Service

Literature review current through: 9/22/2023

Document last updated: 9/22/2023

Type: Adult (18+ yo) Pediatric (0-17yo)

Table of Contents

Important Notices	2
Table of Contents	3
Medical Necessity Criteria	3
Service: Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN) Somatic Nerves	3
General Guidelines	3
Medical Necessity Criteria	4
Indications	4
Non-Indications	5
Level of Care Criteria	7
Procedure Codes (HCPCS/CPT)	7
Medical Evidence	7
References	8
Clinical Guideline Revision History/Information	10

Medical Necessity Criteria

Service: Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)

General Guidelines

- **Units, Frequency, & Duration:** Thermal destruction of the intraosseous Basivertebral Nerve (BVN) must only be performed once per vertebral body from L3-S1 per lifetime. Up to 4 vertebral bodies may be treated during 1 procedure.¹
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Thermal ablation of the intraosseous BVN is a therapeutic, interventional surgical procedure used to treat chronic lower back pain of vertebrogenic origin. The procedure is performed using fluoroscopic imaging under moderate/conscious sedation or general anesthesia. Radiofrequency energy is applied for 15 minutes at 85 degrees Celsius to produce a lesion to destroy the BVN within the vertebral body. At a minimum, the BVN is ablated in at least 1 vertebral body.¹
- **Exclusions:** Radicular pain, prior lumbar spine surgery, symptomatic spinal stenosis, diagnosed osteoporosis ($T < -2.5$), disc extrusion or protrusion > 5 mm, spondylolisthesis > 2 mm at any level, 3 or more Waddell's signs, Beck Depression Inventory > 24 , or currently taking extended release narcotics.²

Medical Necessity Criteria

Indications

- **Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)** is considered appropriate if **ALL** of the following are TRUE:¹⁻⁹
- ◆ Skeletally mature patient (greater than or equal to 18 years old);
AND
 - ◆ Chronic lumbar back pain lasting 6 months or more duration that causes functional deficit measured on pain or disability scale^{1,10};
AND
 - ◆ Documentation of moderate to severe pain; **AND**
 - ◆ No significant improvement in pain or disability level due to symptoms, despite receiving non-surgical management interventions for more than six (6) weeks, including **ALL** of the following (unless medically contraindicated):
 - Physical therapy including home exercise program; **AND**

- Anti-inflammatory medications or oral steroids^{1,10}; **AND**
- ◆ MRI demonstrates Modic change in one or more vertebrae from L3 to S1, as evidence by **ANY** of the following:¹
 - Inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, or hypointense signals (Type 1); **OR**
 - Changes to vertebral body marrow, including replacement of normal bone marrow by fat or hyperintense signals (type 2); **AND**
- ◆ Patient has undergone careful screening, evaluation (including psychological), and diagnosis by multidisciplinary team¹; **AND**
- ◆ Frequency limitations including **ALL** of the following:¹
 - One intraosseous BVN per vertebral body (from L3 to S1) per lifetime; **AND**
 - Up to 4 vertebral bodies treated during one procedure.

Non-Indications

- **Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)** is not considered appropriate if **ANY** of the following is **TRUE**:¹⁻⁹
- ◆ Skeletally immature patient (less than 18 years old); **OR**
 - ◆ Severe cardiac or pulmonary compromise; **OR**
 - ◆ Active systemic or local infection at the intended treatment level; **OR**
 - ◆ Bleeding diathesis; **OR**
 - ◆ Pregnancy; **OR**
 - ◆ Leg pain or numbness that occurs with walking (neurogenic claudication), severe pain that radiates from the back into the hip and outer side of the leg (lumbar radiculopathy), or radicular pain due to pinched nerve(s) (neurocompression [e.g., herniated nucleus pulposus, stenosis]), or posterior-spinal column pain as primary symptoms; **OR**
 - ◆ Primary radicular pain into the lower extremities (defined as nerve pain following dermatomal distribution and that correlates with nerve compression on imaging); **OR**
 - ◆ Previous lumbar or lumbosacral spine surgery at intended treatment level (with the exception of discectomy/laminectomy if performed greater than 6 months prior to BVN nerve ablation and radicular pain resolved); **OR**

- ◆ Primary symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging); **OR**
- ◆ Diagnosed osteoporosis (T-score of -2.5 or less); **OR**
- ◆ Spine fragility fracture history; **OR**
- ◆ Trauma or compression fracture at intended treatment level; **OR**
- ◆ Spinal cancer; **OR**
- ◆ MRI evidence of Modic changes, Type I or Type II at greater than three (3) vertebral bodies; **OR**
- ◆ Radiographic evidence that correlates with predominant physical complaints, as indicated by **ANY** of the following:
 - Lumbar or lumbosacral disc extrusion or protrusion greater than 5 mm at levels L3 to S1; **OR**
 - Lumbar or lumbosacral spondylolisthesis \geq 2 mm at any level; **OR**
 - Lumbar or lumbosacral spondylolysis at levels L3 to S1; **OR**
 - Lumbar or lumbosacral facet arthrosis or effusion correlated with facet-mediated pain at levels L3 to S1; **OR**
- ◆ Evidence on an imaging study (MRI) suggesting another obvious cause for low back pain, including but not limited to ANY of the following:
 - Lumbar stenosis; **OR**
 - Facet arthropathy; **OR**
 - Nerve root compression; **OR**
 - Free fragment disc extrusion; **OR**
 - Disc protrusion greater than five (5) mm; **OR**
 - Disc height loss greater than 50% compared to normal levels on the same study; **OR**
 - Other obvious etiology of low back pain on imaging); **OR**
- ◆ Patient with BMI greater than 40; **OR**
- ◆ Advanced generalized systemic disease that limits quality-of-life improvements (without statement of objective of treatment); **OR**
- ◆ Active untreated substance abuse disorder; **OR**
- ◆ Patient is being treated with radiation, chemotherapy, immunosuppression, or chronic steroid therapy (prednisone use up to 5 mg/qd or its equivalent is allowed); **OR**
- ◆ Patient is taking extended release narcotics (e.g., Fentanyl Patch, MS Contin, Oxycontin); **OR**
- ◆ Presence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia); **OR**

- ◆ Implantable pulse generator (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety.
- ◆ Non-vertebrogenic pathology that could explain source of patient's pain (e.g., fracture, tumor, infection, stenosis, facet mediated pain, significant deformity), as indicated by **ANY** of the following:¹
 - Clinical assessment; **OR**
 - Imaging study

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

Medical Evidence

Fischgrund et al. (2018) report on a Food and Drug Administration approved Investigational Device Exemption randomized control trial (RCT). A total of 225 patients with CLBP were included with a mean age of 47 (range 25–69). The baseline Oswestry Disability Index (ODI) was 42; patients had either Type I or Type II Modic changes of the vertebral bodies. Preoperative evaluation took place at two and six weeks – postoperative evaluation was performed at three, six, and 12 months. Improvement in ODI at three months following surgery was noted in 75.6% of patients as compared to sham treated controls (55.3%).³

Fischgrund et al. (2020) report on a RCT of 117 patients that had positive long-term outcomes following BVN ablation. At five year follow-up, the mean ODI score decreased by 25.95 points (42.81 to 16.86). A total of 66% of patients report a reduction in pain of >50%; 47% report a >75% reduction; and 34% report complete pain resolution.⁵

National and Professional Organizations

The **American Society of Pain and Neuroscience (ASPN)** published *Best Practice Guidelines on the Diagnosis and Treatment of Vertebrogenic Pain with Basivertebral Nerve Ablation*. Research supports the use of ablation for improvement in pain and function in some patients.¹¹

The **International Society for the Advancement of Spine Surgery (ISASS)** recommend BVN for the treatment of chronic low back pain based on clinical research and MRI results. This includes two randomized control trials (RCTs) that indicate a significant improvement in pain and function for at least 24 months. Ablation reduces the need for opioids and as an option for patients who are not responsive to non-surgical treatment.¹⁰

The ISASS also published the *ISASS Policy Statement 2022: Literature Review of Intraosseous Basivertebral Nerve Ablation*. The statement notes the addition of two Current Procedural Terminology (CPT) category I codes – 64628 and 64629 – for basivertebral nerve ablation based on the need to specify various types of low back pain.¹²

References

1. Center for Medicare and Medicaid Services (CMS). Local coverage determination: Thermal destruction of the intraosseous basivertebral nerve (BVN) for vertebrogenic lower back pain (L39420). Effective Date March 5, 2023. Accessed September 12, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
2. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. *Int J Spine Surg*. 2019 Apr 30;13(2):110-119. doi: 10.14444/6015. PMID: 31131209; PMCID: PMC6510180.
3. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: A prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J*. 2018 May;27(5):1146-1156. doi: 10.1007/s00586-018-5496-1. PMID: 29423885.
4. Khalil JG, Smuck M, Koreckij T, et al. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. *Spine J*. 2019 Oct;19(10):1620-1632. doi: 10.1016/j.spinee.2019.05.598. PMID: 31229663.
5. Fischgrund JS, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J*. 2020 Aug;29(8):1925-1934. doi: 10.1007/s00586-020-06448-x. PMID: 32451777.
6. Smuck M, Khalil J, INTRACEPT Trial Investigators Collaborators, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *Reg Anesth Pain Med*. 2021 Aug;46(8):683-693. doi: 10.1136/rapm-2020-102259. PMID: 34031220; PMCID: PMC8311085.
7. Koreckij T, Kreiner S, INTRACEPT Trial Investigators, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results. *N Am Spine Soc J*. 2021 Oct 26;8:100089. doi: 10.1016/j.xnsj.2021.100089. PMID: 35141653; PMCID: PMC8820067.
8. Truumees E, Macadaeg K, Pena E, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. *Eur Spine J*. 2019 Jul;28(7):1594-1602. doi: 10.1007/s00586-019-05995-2. PMID: 31115683.
9. Macadaeg K, Truumees E, Boody B, et al. A prospective, single arm study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *NASSJ*. 2020;3:100030-100037. PMID: 35141598; PMCID: PMC8819913.

10. Lorio M, Clerk-Lamallice O, Beall DP, et al. International Society for the Advancement of Spine Surgery Guideline–Intraosseous ablation of the basivertebral nerve for the relief of chronic low back pain. *Int J Spine Surg.* 2020 Feb 29;14(1):18–25. doi: 10.14444/7002. PMID: 32128298; PMCID: PMC7043835.
11. Sayed D, Naidu RK, Patel KV, et al. Best practice guidelines on the diagnosis and treatment of vertebrogenic pain with basivertebral nerve ablation from the American Society of Pain and Neuroscience. *J Pain Res.* 2022 Sep 14;15:2801–2819. doi: 10.2147/JPR.S378544. PMID: 36128549; PMCID: PMC9482788.
12. Lorio M, Clerk-Lamallice O, Rivera M, et al. ISASS policy statement 2022: Literature review of intraosseous basivertebral nerve ablation. *Int J Spine Surg.* 2022 Dec;16(6):1084–1094. doi: 10.14444/8362. PMID: 36266051; PMCID: PMC9807041.
13. ClinicalTrials.gov. SMART clinical study: Surgical multi-center assessment of RF ablation for the treatment of vertebrogenic back pain (SMART). Updated October 31, 2016. Accessed September 21, 2023. <https://clinicaltrials.gov/ct2/show/NCT01446419>.

Clinical Guideline Revision History/Information

Original Date: 9/22/2023	
Review History	