Cohere Medical Policy - Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)

Clinical Guidelines for Medical Necessity Review

Version: 3
Effective Date: December 19, 2024

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Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medical Policy - Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)

Date of last literature review: 9/22/2023
Document last updated: 12/19/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

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

Recommended Clinical Approach

Thermal ablation of the intraosseous basivertebral nerve (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°Cto 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]

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 of age); **AND**
- ◆ Chronic lumbar back pain lasting 6 months or more in duration that causes functional deficit measured on pain or disability scale[1,10]; **AND**
- ◆ Documentation of moderate to severe pain; **AND**
- ◆ Failure of conservative management for greater than 6 months, including **ALL** of the following:
  - Anti-inflammatory medications, analgesics, or prescription medications (e.g., oral steroids, narcotics, neuropathic pain medications) if not contraindicated; **AND**
  - Physical therapy; **AND**
- ◆ Magnetic resonance imaging (MRI) demonstrates Modic change in one or more vertebrae from the third lumbar (L3) to the first sacral (S1), as shown by **ANY** of the following[1]:
  - Inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized

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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**
- The patient has undergone careful screening, evaluation (including psychological), and diagnosis by a multidisciplinary team[1]; **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 are 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) (neuro compression [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 that correlates with nerve compression on imaging); **OR**
- Previous lumbar or lumbosacral spine surgery at intended treatment level (except discectomy/laminectomy if performed greater than 6 months before 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**

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- 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**
- Imaging shows **ANY** of the following is **TRUE**:
    - MRI evidence of Modic changes, Type I or Type II at greater than 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 greater than or equal to 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 from an imaging study (MRI) suggests 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 in the same study; **OR**
    - Other obvious etiology of low back pain on imaging); **OR**
- The patient with body mass index (BMI) greater than 40; **OR**
- Advanced generalized systemic disease that limits quality-of-life improvements and there is no statement of the objective of treatment; **OR**
- Underlying mental health conditions/issues (e.g., depression, substance abuse, alcohol abuse) as a major contributor to chronic back pain; **OR**

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- The patient is being treated with radiation, chemotherapy, immunosuppression, or chronic high dose steroid therapy (e.g., prednisone use up to 5 mg/day); **OR**
- The 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 generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety.
- Non-vertebrogenic pathology that could explain the source of the 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 (CPT/HCPCS)

CPT/HCPCS 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)

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Medical Evidence

Fischgrund et al. (2018) report on an U.S. Food and Drug Administration-approved Investigational Device Exemption randomized control trial (RCT). A total of 225 patients with chronic lower back pain (CLBP) were included with a mean age of 47 years (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 2 and 6 weeks - postoperative evaluation was performed at 3, 6, and 12 months. Improvement in ODI at 3 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 an RCT of 117 patients who had positive long-term outcomes following BVN ablation. At a 5-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 greater than 50%; 47% report a greater than 75% reduction; and 34% report complete pain resolution.[5]

De Vivo et al. (2021) evaluated the effectiveness of computed tomography (CT) guided radiofrequency ablation (RFA) of the basivertebral nerve (BVN) in the treatment of 56 patients with chronic vertebrogenic lower back pain, in a prospective experimental uncontrolled trial. Pre- and post-procedure pain and disability levels were measured using the visual analog scale (VAS) and ODI. At follow-up (3 and 12 months), VAS and ODI scores decreased significantly compared to baseline. Clinical success was reached in 96.5% of patients with pain and disability. CT-assisted targeting of the ablation zone was successful in all patients. No immediate or delayed complications were detected.[14]

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]

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The International Society for the Advancement of Spine Surgery (ISASS) recommends BVN ablation for the treatment of chronic low back pain based on clinical research and MRI results. This includes two RCTs that indicate a significant improvement in pain and function for at least 24 months. Ablation reduces the need for opioids and provides 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]

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Clinical Guideline Revision History/Information

Original Date: September 22, 2023		
Review History		
Version 2	7/30/2024	Updated the conservative care section within the indications section.
Version 3	12/19/2024	• Annual review • Updated indications/non-indications • Updated medical evidence • Updated references • Verified CPT codes and descriptions

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