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

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

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

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

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

Benefit Category

Not applicable.

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 one vertebral body.[1]

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 BVN ablation procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in BVN ablation procedures can lead to increased symptoms and complications, especially in patients with chronic low back pain. Fischgrund et al. reported significant improvements in pain and function scores at 2 years following intraosseous basivertebral nerve ablation.[4] According to the CMS LCD for BVN ablation, inappropriate denials could result in prolonged patient suffering and functional decline.[1]
- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the

need for repeat or additional procedures due to complications. Long-term outcomes following intraosseous basivertebral nerve ablation showed significant pain relief and functional improvement at 5 years post-procedure.[8]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Khalil et al. noted that intraosseous basivertebral nerve ablation significantly reduced pain scores and improved function compared to controls.[6]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to BVN ablation procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Smuck et al. found that BVN ablation resulted in significant pain reduction and functional improvement at 12 months.[8]
- Enhanced diagnostic accuracy: This is crucial for complex pain conditions such as chronic low back pain. Koreckij et al. reported that patients treated with BVN ablation had significant improvements in pain and disability scores at 24 months.[9]
- Reduction in complications and adverse effects: Proper use of BVN ablation criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Fischgrund et al. demonstrated significant long-term benefits of BVN ablation with reduced pain and improved function.[7]
- Enhanced overall patient satisfaction: Ensuring that BVN ablation is used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. Truumees et al. reported significant improvements in pain and function scores at 12 months following BVN ablation.[10]

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

- ➔ **Thermal ablation of the intraosseous basivertebral nerve (BVN)** is considered appropriate if **ALL** of the following are **TRUE**[1-11]:
  - ◆ Skeletally mature patient (greater than or equal to 18 years old); **AND**
  - ◆ Chronic lower (lumbar) back pain lasting 6 months or more duration that causes functional deficit measured on pain or disability scale[1-3,12]; **AND**
  - ◆ No significant improvement in pain or disability level due to symptoms, despite receiving documented non-surgical management interventions for more than six (6) weeks, including at least three (3) or more of the following modalities (unless medically contraindicated)[1,12]:
    - Avoidance of activities that aggravate pain; **OR**
    - Physical therapy or a professionally directed therapeutic exercise program; **OR**
    - Chiropractic manipulation; **OR**
    - Cognitive therapy; **OR**
    - Pharmacotherapy, including narcotic and non-narcotic analgesics, muscle relaxants, neuroleptics, and anti-inflammatories; **OR**
    - Injection therapy of epidural or facet joint implicated pain sources in the region of concern; **AND**

- MRI demonstrates Modic change in one or more vertebrae from L3 to S1, as evidenced 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**
- Absence of additional vertebral pathology by physical, history, radiologic, or clinical assessment including, but not limited to, fracture, tumor, infection, deformity, trauma, or post-surgical change which could cause the patient's symptoms or complicate the procedure and outcome[1-3]; **AND**
- The patient has undergone careful screening, evaluation (including psychological), and diagnosis by 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 treated during one procedure; **AND**
- Local anesthesia is considered appropriate for the region treated. Mild sedation may be administered by the performing physician or staff under his direction but should not be coded separately. Additional anesthesia services may not be billed separately without documentation of medical necessity.

Non-Indications

➔ **Thermal ablation of the intraosseous basivertebral nerve (BVN)** is not considered appropriate if **ANY** of the following is **TRUE**[1-11]:

- 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**
- Neurogenic claudication, lumbar radiculopathy, radicular pain, nerve impingement or compression (e.g., NHP, stenosis), as primary symptoms; **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**
- Radiographic evidence that correlates with predominant physical complaints, as indicated by **ANY** of the following[1]:
    - Lumbar or lumbosacral disc extrusion or protrusion greater than 5 mm at levels L3 to S1; **OR**
    - Lumbar or lumbosacral spondylolisthesis ≥ 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 imaging (MRI, flexion/extension radiographs, etc.) suggests another obvious etiology for the patient's LBP symptoms, including but not limited to lumbar stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis or facet arthropathy or effusion with clinically suspected facet joint pain; **OR**
- Patient with BMI greater than 40[1]; **OR**
- Advanced generalized systemic disease that limits quality-of-life improvements (without a statement of objective of treatment); **OR**
- Active untreated substance abuse disorder[1]; **OR**
- Implantable pulse generator (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety; **OR**
- 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)

Medical Evidence

Fischgrund et al. (2018) report on a randomized control trial (RCT) that received Investigational Device Exemption approval from the United States Food and Drug Administration (FDA). A total of 225 patients with chronic low back pain 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 compared to sham-treated controls (55.3%).[5]

Fischgrund et al. (2020) report on an RCT of 117 patients who had positive long-term outcomes following basivertebral nerve (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 greater than 50%; 47% report a greater than 75% reduction; and 34% report complete pain resolution.[7]

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.[13]

The International Society for the Advancement of Spine Surgery (ISASS) recommends BVN for the treatment of chronic low back pain based on clinical research and MRI results. Two RCTs indicate a significant improvement in pain and function for at least 24 months. Ablation reduces the need for opioids and is an option for patients who are not responsive to non-surgical treatment.[12]

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.[14]

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Clinical Guideline Revision History/Information

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