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

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Thermal Ablation of the Intraosseous Basivertebral Nerve (BVN)
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

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

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1,9,10]

- Local coverage determination (LCD): Thermal destruction of the intraosseous basivertebral nerve (BVN) for vertebrogenic lower back pain (L39420).
  - Billing and Coding: Thermal destruction of the intraosseous basivertebral nerve (BVN) for vertebrogenic lower back pain (A59205).
- Local Coverage Determination (LCD): Intraosseous basivertebral nerve ablation (L39644).
  - Billing and Coding: Intraosseous basivertebral nerve ablation (A59468).
- Local Coverage Determination (LCD): Intraosseous basivertebral nerve ablation (L39642).
  - Billing and Coding: Intraosseous basivertebral nerve ablation (A59466).

Description

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]

Medical Necessity Criteria

Indications

Thermal ablation of the intraosseous basivertebral nerve (BVN) is considered appropriate if **ALL** of the following are **TRUE**[1-7,9-12]:

- Skeletally mature patient (greater than or equal to 18 years of age)[1]; **AND**
- Chronic lower (lumbar) back pain lasting 6 months or more duration that causes functional deficit accompanied by pain categorized as moderate to severe by clinician assessment[1,9-13]; **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 3** of the following modalities (unless medically contraindicated)[1,13]:
  - 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 with image report with radiologic interpretation 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[1,9,10]; **AND**

- The patient/surgical candidate has undergone a behavioral health gap assessment/evaluation (formal or informal, recorded in medical records) intended to identify patient-related risk factors linked to unfavorable surgical results and provides details/resources on clinical interventions intended to reduce such risks.[1,16-17]; **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[9]; **AND**
- Thermal destruction of the intraosseous BVN is only be performed once per vertebral body from L3-S1 per lifetime[1]; **AND**
- No more than 4 vertebral bodies are treated during 1 procedure.[1]

Non-Indications

Thermal ablation of the intraosseous basivertebral nerve (BVN) is not considered appropriate if **ANY** of the following is **TRUE**[1-7,9-12]:

- Skeletally immature patient (less than 18 years of age)[9]; **OR**
- Severe cardiac or pulmonary compromise[9]; **OR**
- Active systemic or local infection at the intended treatment level[10]; **OR**
- Bleeding diathesis[1]; **OR**
- Pregnancy[1]; **OR**
- Neurogenic claudication, lumbar radiculopathy, radicular pain, nerve impingement or compression (e.g., NHP, stenosis), as primary symptoms[9]; **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)[1]; **OR**
- Radiographic evidence of **ANY** of the following that correlates with predominant physical complaints[1]:

    - Lumbar/lumbosacral disc extrusion or protrusion >5mm at levels L3-S1; **OR**
    - Lumbar/lumbosacral spondylolisthesis ≥ 2mm at any level; **OR**
    - Lumbar/lumbosacral spondylolysis at levels L3-S1; **OR**
    - Lumbar/lumbosacral facet arthrosis/effusion correlated with facet-mediated pain at levels L3-S1; **OR**
- Primary symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging)[1]; **OR**
- Diagnosed osteoporosis (T-score of -2.5 or less)[9]; **OR**
- Spine fragility fracture history[1]; **OR**
- Trauma or compression fracture at intended treatment level[1]; **OR**
- Spinal cancer[1]; **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 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 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[9]; **OR**
- Patient with body mass index greater than 40[1]; **OR**
- Advanced generalized systemic disease that limits quality-of-life improvements (without a statement of the objective of treatment)[1]; **OR**
- Active untreated substance abuse disorder[1]; **OR**
- Implantable pulse generator (e.g., pacemakers, defibrillators, or neurostimulators) or other electronic implants unless specific precautions are taken to maintain patient safety[9]; **OR**
- Thermal destruction of the intraosseous BVN must only be performed once per vertebral body from L3-S1 per lifetime[1]; **OR**

- No more than 4 vertebral bodies may be treated during 1 procedure[1]; **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.

Definitions

- Functional impairment: A physical, functional or physiologic impairment causing deviation from the normal function of a tissue, organ or body member, resulting in a significant limitation or impairment of the capacity to move, coordinate actions or perform physical activities, demonstrated by difficulty performing physical and motor tasks, independent movement or basic life functions.[9,10]
- Modic Changes (Magnetic Resonance Imaging): MRI features consistent with Type 1 or Type 2 Modic changes such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change). [9,10]
- Radicular pain or radiculopathy: pain radiating or identified in the path and distribution or dermatomal pattern of a named spinal nerve. Pain that is localized and does not travel in the distribution of an identified spinal nerve and remains axial in location is considered to have a non-radicular pattern.[9,10]
- Spinal stenosis: Narrowing of the central spinal canal and /or the foraminal openings through which nerve or neural tissue is located, causing compression and irritation of the involved neural structures. A wide range of symptoms may be present, contributing to back and extremity pain and dysfunction.[9,10]

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)

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

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS' required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for **thermal ablation of the intraosseous basivertebral nerve** may include:

- Adverse effects from delayed or denied treatment, to comply with the requirements that the patient/surgical candidate has undergone a behavioral health gap assessment/evaluation (formal or informal, recorded in medical records) intended to identify patient-related risk factors linked to unfavorable surgical results. Studies have shown that patient preoperative mental health is linked to significant poorer outcomes after surgery.[16-17]

The clinical benefits of using these criteria for **thermal ablation of the intraosseous basivertebral nerve** may include:

- Improved patient selection, resulting in better long-term outcomes. Ideal surgical candidates are patients that have preoperatively been evaluated for their mental health status. Studies have shown that patients with poor mental health who were seen by a mental health practitioner at least two times before surgery reported significantly better pain scores during the first six month postoperative period.[17]

Medical Evidence

Fischgrund et al. (2018) reported on a prospective randomized controlled trial (RCT) of patients treated with radiofrequency ablation to demonstrate safety and efficacy as part of an 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%).[11]

Fischgrund et al. (2020) reported 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.[6]

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 selected patients.[14] Correct diagnosis and selection of patients with primary vertebrogenic lower back pain symptoms are critical for the best outcomes.

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.[13]

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.[15]

In a comprehensive review of the literature, Smirniotopoulos et al. (2024) found that more than 90% of individuals receiving BVN ablation are anticipated to experience enhancements in pain relief and function within 3 to 12 months, while about 60% of patients can expect lasting improvement for up to 5 years following treatment.[8]

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer added.
Version 3	05/29/2025	Annual review. No changes to procedure codes. Added references to indications and non-indications. Reviewed Boolean logic. Clarified indication requiring the patient to undergo a behavioral health gap assessment/evaluation. Reviewed literature, including a recent comprehensive procedure review, and two references for the modified indication.