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Intraosseous Basivertebral Nerve Ablation (i.e., Intracept® System) Corporate Medical Policy

File Name: Intraosseous Basivertebral Nerve Ablation
File Code: 10.99.VT88
Origination: 11/2025
Next Review: 11/2026
Effective Date: 03/01/2026

Description/Background

Radiofrequency ablation (RFA) is a minimally invasive, percutaneous treatment which uses heat to ablate or "burn" the nerve pathway that conducts a pain signal. The goal of RFA is to interrupt the pain pathway, by selectively destroying pain fiber networks, while reducing the likelihood of causing excessive sensory loss, motor dysfunction or other complications, ideally resulting in an overall decrease in low back pain.

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular signs and symptoms, in conjunction with radiologically confirmed degenerative disc disease.

The basivertebral nerve (BVN) is a branch of the sinuvertebral nerve responsible for carrying nociceptive information from damaged vertebral endplates. Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration.

Certain vertebral end-plate (Modic) changes seen on MRI-imaging are thought to be related to inflammatory vertebral endplate damage related to vertebral body and/or general disc degeneration. A intraosseous nerve-ablating procedure, known commercially as the Intracept® System was designed around the concept that some patients with axial back pain suffer from vertebrogenic pain (pain transmitted through the basivertebral nerve). The Intracept device uses RFA to target the basivertebral nerve (BVN) that is thought to innervate the vertebral endplate, which is the interface between the vertebral body and the disc. In this procedure, a probe is advanced under fluoroscopic guidance into the vertebral body where the basivertebral nerve is located. Bipolar energy is used to ablate the neurovascular

tissue with the intention of interrupting the transmission of pain signals from the superior and inferior endplates.

Back injury, genetic makeup, age, and other factors can cause degeneration of the spine, placing stress on the vertebral body endplates. The stress on the endplates can lead to microfractures. Microfractures in the vertebral body endplates add pressure to the basivertebral nerve (BNV). The basivertebral nerve, found within the vertebrae, extends to the upper and lower surfaces of the vertebrae and transmit pain from the vertebral body endplates. Radiofrequency energy, or heat ablates the basivertebral nerve with the expected outcome that the pathway has been destroyed and pain signals are no longer able to be transmitted between the end plates and the brain, thus reducing the individuals chronic low back pain. Radiofrequency ablation of the basivertebral nerve is proposed as an alternative to spinal fusion in individuals with chronic low back pain who do not have a spinal instability or scoliosis but show Modic changes on a MRI.

Regulatory Status

In 2011, the FDA issued an investigational device exemption for the Intracept System (Relievant Medsystems) to begin their SMART pivotal trial to evaluate the safety and effectiveness of the system for the treatment of chronic low back pain.

The Intracept Intraosseous Nerve Ablation System (radiofrequency lesion probe) received clearance through the FDA's 510(k) Premarket Notification Process on June 9, 2016 (K153272) indicating it was substantially equivalent to a predicate device approval. Further updates occurred on August 9, 2017 (K170827), September 14, 2018 (K180369), and March 11, 2022 (K213836). On October 26, 2022 (K222281) an update was granted which indicates:

- "The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypo-intensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyper-intensive signals (Type 2 Modic change)."

On May 3, 2019 (K190504) the following FDA 510(k) approval was granted:

- "The Relievant radiofrequency generator is intended to be used with the FDA cleared RF probes, as part of the Relievant Intracept Intraosseous Nerve Ablation System, in the ablation of basivertebral nerves of the L3 through S1 vertebrae; for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypo-intensive signals (Type 1 Modic change), and

changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyper-intensive signals (Type 2 Modic change)."

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I

Policy

When a service may be considered medically necessary

Radiofrequency ablation of the basivertebral nerve, with an FDA approved device, (i.e., Intracept® system), for one or more levels of L3 through S1, for the treatment of vertebrogenic back pain may be considered **medically necessary** when **ALL** of the following are met:

- Individual is skeletally mature (≥ 18 years of age); **AND**
- Moderate to severe chronic low back pain that is primarily axial *(definition below)* in nature; **AND**
- Pain is refractory to at least 6 months of non-operative treatment *(definition below)* within the past year, including at least 6 weeks of detailed professional directed exercise program (i.e. Physical Therapy); **AND**
- Type 1 or Type 2 Modic changes are noted at the vertebral body(ies) to be treated, on an MRI between L3 and S1.
    - Type 1 – inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypo-intensive signals; **OR**
    - Type 2 – changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyper-intensive signals.

*Definition of Axial Pain - Pain that is localized (e.g., lower back) and is **not** accompanied by motor or sensory dysfunction in the associated extremities (e.g. legs)*

Definition of Non-Operative Treatment - Pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy.

When a service is considered investigational

Radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of back pain is considered **investigational** when **ANY** of the following are present:

- Imaging suggests other etiologies for pain including:
    - Active or recurrent facet symptoms
    - Disc extrusion or protrusion (>5 mm)

    - Spondylolisthesis (>2 mm at any level)
    - Spondylolysis at any level
    - Lumbar scoliosis (> 10 degrees)
    - Modic changes at any level above L3-L4
- History of spine fragility fracture
- Osteoporosis (T-score < -2.5)
- Trauma/compression fracture
- Spinal cancer
- Imaging-confirmed spinal stenosis with neurogenic claudication (pain, numbness, and/or weakness into the buttocks, thighs, and/or calves, often brought on by standing or walking and relieved by flexion or sitting).
- Active or recurrent radicular pain (pain that travels along a dermatomal distribution into the lower extremity, which can be associated with numbness, weakness, and/or tingling).
- Any prior lumbar spine surgery, other than laminectomy or discectomy > 6 months prior with resolution of radiculopathy.
- Bed bound or other condition that prevent early mobility
- BMI > 40
- Presence of severe cardiac or pulmonary compromise
- Pregnancy, less than 12 months postpartum or current breast-feeding
- Active systemic infection, spine infection or bleeding diathesis
- Planned in conjunction with any other procedures, or within 6 weeks of any prior procedure
- Repeat basivertebral ablation at the same level as a previous basivertebral nerve ablation.
- In all other indications and/or when medical necessity criteria above are not met.

Summary of Evidence

Evidence in the peer-reviewed scientific literature evaluating basivertebral nerve ablation consists of a pilot studies, RCTs, meta-analyses, retrospective and prospective case series. Industry sponsored study outcomes for basivertebral nerve ablation for low back pain at 1 or more levels reveal favorable outcomes without significant adverse events. The evolving clinical literature and available studies suggest that BVN ablation for low back pain is safe, effective and comparable to other established interventions. Authors generally concurred that exploration of characteristics associated with vertebrogenic LBP (e.g. clinical, imaging) will identify the best population for positive outcomes. High quality, larger scale, non-biased studies with longer follow-up periods will be helpful in assisting providers to become comfortable with the effectiveness and parameters of BVN RFA for low back pain.

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Related Policies

N/A

Document Precedence

Blue Cross and Blue Shield of Vermont (Blue Cross VT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, Blue Cross VT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, Blue Cross VT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval may be required for services outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

11/2026	Input received from network providers. New Policy with medical necessity criteria for treatment of discogenic low back pain using radiofrequency ablation (i.e., Intracept® System.) Codes added to coding table: 64628 & 64629 require prior approval.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by Blue Cross VT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
CPT®	64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral	Prior Approval Required
CPT®	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)	Prior Approval Required