INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Noridian Medicare Local Coverage Decision (LCD) Q+A
Basivertebral Nerve Ablation - Policy #L39642

When is the policy effective and what are the coverage criteria?
Noridian's LCD for the Intracept™ Procedure became effective January 28, 2024. It is important to review this policy for coverage criteria as well as Noridian's Billing and Coding Article.

Are there coverage criteria that should be closely reviewed and adhered to?
All criteria within the policy, including limitations and contraindications, must be adhered to and can be found in the policy linked above. Please refer to the LCD and the criteria checklist for a full list of criteria.

Some of the key requirements we want to highlight:

- No previous history of BVN ablation at the planned level of treatment
- No more than one to two (1-2) vertebral bodies may be treated at a single session
- Treatment of no more than four (4) vertebral bodies per patient lifetime
- 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.
- Individual is skeletally mature and has had CLBP for at least 6 months, with lower back pain as the dominant symptom
- Has failed to adequately improve despite documented non-surgical management, to include **at least 3 or more of the following modalities**:
    - Avoidance of activities that aggravate pain
    - Course of physical therapy or professionally directed therapeutic exercise program
    - Chiropractic manipulation
    - Cognitive therapy
    - Pharmacotherapy, including narcotic and non-narcotic analgesics, muscle relaxants, neuroleptics, and anti-inflammatories
    - Injection therapy of epidural or facet joint implicated pain sources in the region of concern
- Type 1 or Type 2 Modic changes on MRI: Endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving the endplates between L3 and S1
- 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
- Physical and psychological assessment of patient's ability to tolerate and benefit from BVN ablation

What can I do if I have questions or concerns about the anesthetic requirements for basivertebral nerve ablation (BVNA) as listed in the LCD?
If you have questions about this specific requirement or any others, you can reach out to the Carrier Medical Director for your jursidication or submit the question/concern to MedicalPolicy@Noridian.com.

Dr. Capehart, Carrier Medical Director, indicated that "the use of MAC or GA is at the discretion of the provider, and specifically that of the rendering provider. It would not be expected that a physician performing the actual procedure would also render or oversee MAC or GA as he would not be able to respond appropriately to related adverse events. The use of GA or MAC is based on the need of the patient and the Local Determinations addressing anesthesia list many, many allowed diagnoses for its coverage. But it would not be expected to be bundled into the performance of BVN ablation by a single physician. Subsequently, if the patient warrants more than local anesthesia and mild sedation, it is appropriately rendered by a qualified provider capable of meeting the patient's needs and requirements for safety."

Dr. Capehart further commented, "MAC anesthesia or GA is not documented to meet the medically necessary criteria for a healthy patient undergoing the Intracept [P]rocedure but is allowed for any procedure with documentation of need. BVNA is not a procedure allowing an assistant at surgery or team surgery, so anesthesia for the procedure requiring the monitoring of MAC or GA would be done by a separate qualified provider in the appropriate setting to ensure the safety of the beneficiary, who would also document the criteria for coverage."

Should Noridian patients be entered into the Intracept Procedure prior authorization portal?
No. Now that there is an LCD, and Medicare does not perform a prior authorization for the Intracept Procedure, Noridian requires providers review, follow and document the LCD requirements.

Given the critieria that 1-2 vetebral bodies can be treated in a single session (represented by CPT code 64628), would additional levels (represented by CPT code 64629) be covered?
Please refer to Noridian's Billing and Coding article, titled A59466. The statement in the billing and coding companion article allows for 1-2 vertebral bodies per session as CPT 64828 signifies and coverage/reimbursement of 64829 (a third level) with documentation of necessity. Noridian has indicated that it's possible use of 64629 may trigger review with request for additional documentation, as based on data.

What resources are available to me?
- This customer Q+A document
- Policy criteria checklist
- Noridian LCD and Billing and Coding Article

- Reimbursement Business Manager (RBM) – Please reach out to your local Territory Manager who can put you in contact with the RBM in your area.

What influence does this policy have on commercial payers?
It is significant when a Medicare establishes positive coverage however, each payer will establish their own coverage criteria. For Medicare Advantage plans, the Medicare provider manual indicates that Medicare Advantage plans must follow the least restrictive coverage policy – their policy or the local Medicare carrier's policy.

Disclaimer: Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label.

Indications for Use: 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 six months duration that has not responded to at least six 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, 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). Contraindications - Use of the Intracept Intraosseous Nerve Ablation System is contraindicated in: Patients with severe cardiac or pulmonary compromise, patients with active implantable pulse generators (e.g. pacemakers, defibrillators), patients where the targeted ablation zone is < 10 mm away from a sensitive structure not intended to be ablated, including the vertebral foramen (spinal canal), patients with active systemic infection or local infection in the area to be treated, patients who are pregnant, and/or skeletally immature patients (generally ≤ 18 years of age). Refer to the Instructions for Use provided with the Intracept Procedure or www.relievant.com/intracept/ for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.