Policy Number	SUR702.020
Policy Effective Date	12/01/2025

Intraosseous Radiofrequency Nerve Ablation of the Basivertebral Nerve for the Treatment of Low Back Pain

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Intraosseous radiofrequency ablation of the basivertebral nerve (L1-S1 vertebrae) (e.g., Intracept® system) **may be considered medically necessary** for the treatment of axial lower back pain that is of vertebrogenic nature when ALL of the following criteria are met:

- Skeletally mature patients (generally age >18 years); AND
- Chronic low back pain (CLBP) for at least 6 months, and lower back pain is the main symptom; AND
- Failure to adequately improve after six months of nonsurgical management (e.g., activity/lifestyle modification, physical therapy, medications [nonsteroidal anti-inflammatory drugs, nonnarcotic analgesics]); AND
- Modic Type 1 or Type 2 changes seen on MRI — endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving in the endplates between L3 and S1.

Intraosseous radiofrequency ablation of the basivertebral nerve (L3-S1 vertebrae) (e.g., Intracept® system) for the treatment of axial lower back pain that is of vertebrogenic nature **is considered not medically necessary** when ANY of the following are present:

- Evidence on imaging (MRI, flexion/extension radiographs, etc.) suggests another obvious etiology for the individual'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.
- Metabolic bone disease (e.g., osteoporosis), treatment of spine fragility fracture, trauma/ compression fracture, or spinal cancer.
- Spine infection or active systemic infection.
- Neurogenic claudication, lumbar radiculopathy, or radicular pain due to neurocompression (e.g., herniated nucleus pulposus (HNP), stenosis) as primary symptoms.
- Severe cardiac or pulmonary compromise.
- Individuals with implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety.
- Individual with BMI > 40.

Intraosseous radiofrequency ablation of the basivertebral nerve (L3-S1 vertebrae) (e.g., Intracept® system) for all other indications not mentioned above **are considered experimental, investigation and/or unproven.**

NOTE: This policy addresses radiofrequency neuroablation, which is the destruction of nerves using heat and should be distinguished from intradiscal electrothermal procedures.

Policy Guidelines

None.

Description

Lumbar axial back pain arising from degenerative disc disease is a challenging clinical problem whether treated with non-surgical management, local injection, or motion segment stabilization and fusion. (1) The intraosseous nerves reportedly found within the vertebrae, are referred to as basivertebral nerves and are present in the basivertebral foramen. When these surfaces undergo damage or degeneration, the nerve fibers at the endplates increase in density, demonstrating a role in the transmission of nerve impulses correlating with chronic back pain.

Treatment

Chronic, vertebrogenic, low back pain is often debilitating and difficult to treat. First-line treatments include nonpharmacologic and nonsurgical options, such as avoiding pain-aggravating activities, pain medication, lumbar exercises, physical therapy, chiropractic therapy,

acupuncture, and spinal injections. Physicians may recommend surgical intervention to patients who are refractory to the first line of treatment.

Interruption through destruction of the intraosseous basivertebral nerve has been proposed to block the nerve transmission pain signals from the vertebral body to the central nervous system.

The Intracept procedure, performed on an outpatient basis, uses fluoroscopic guidance to introduce a cannula through the pedicle. A curved cannula is employed to create a channel to the trunk of the basivertebral nerve. A radiofrequency probe is inserted and placed at the nerve, which is ablated using a radiofrequency generator. (2)

Regulatory Status

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." The U.S. Food and Drug Administration (FDA) reviewed the device and issued a substantially equivalent designation in August 2017 (K170827). (3) In March of 2022, the FDA issued another substantially equivalent designation for an additional Intracept Intraosseous Nerve Ablation System (Relievant Medsystems, Inc.; K213836). The prior device (K170827) is listed as the reference access instrument and the new indication adds a description of accompanying use case features, "...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)." (4) FDA product code: GXI.

Rationale

This policy is based on a review of relevant professional association recommendations.

International Society for the Advancement of Spine Surgery (ISASS) (1)

In 2022, the ISASS published updated guidelines on intraosseous basivertebral nerve ablation. The guideline was informed by a systematic review that included 2 RCTs and additional single-arm studies. The guideline authors concluded that intraosseous ablation of the basivertebral nerve from the L3 through S1 vertebrae may be considered medically for individuals with chronic low back pain (CLBP) when all of the following criteria are met:

- CLBP of at least 6 months duration.
- Failure to respond to at least 6 months of nonsurgical management.
- Magnetic resonance imaging demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1 (endplate changes, inflammation, edema, disruption, and/or fissuring).

- Fibrovascular bone marrow changes (hypointense signal for Modic type 1).
- Fatty bone marrow changes (hyperintense signal for Modic type 2).

The ISASS guidelines go on to state that on intraosseous basivertebral nerve ablation is NOT indicated in the following:

- Patients with severe cardiac or pulmonary compromise.
- Presence of implanted pulse generator(s) (e.g., pacemaker and defibrillator)/electronic implants except for circumstances where a specific patient safety precaution may be implemented.
- Co-existence of other obvious radiographic etiology for patient's axial CLBP requiring a medically necessary surgical intervention.
- Active or chronic infection-systemic or local.
- Patients who are pregnant.
- Skeletally immature patients (generally age <18 years).
- Current or post-trauma, tumor, infection, or poor bone quality compromising vertebral pedicle/body.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.
- Radiographic confirmation of gross spinal instability including angular or translatory instability (grade 2 or greater spondylolisthesis) at index level(s).
- Morbid obesity precluding satisfactory procedural imaging.
- Targeted ablation zone is <10 mm away from a sensitive structure not intended for ablation.
- Situation where unintended tissue damage may result based on the clinical assessment by the physician.
- Application with electrosurgical instruments NOT tested and specified for use with the current US Food and Drug Administration clearance for the relevant Requests for Designation.

Physician Qualifications include:

- Intraosseous basivertebral nerve ablation (BVNA) is a surgical procedure that may be performed by physicians with spinal expertise and advanced training in pedicular access.
- Such spinal specialists have successfully completed a residency/fellowship in their specialty and have participated in a specialized training course under the supervision of a physician experienced in the procedure using specimens that permit hands-on experience with the surgical technique.
- At this time, the procedure should be performed in either the hospital outpatient setting or ambulatory surgical center where either general anesthesia or moderate conscious sedation is available.

North American Spine Society (NASS) (5)

In February 2023, NASS recommended:

"Radiofrequency ablation of the basivertebral nerve (BVN) via a percutaneous interosseous approach has emerged as a possible interventional therapy for this condition. Current BVN

ablation evidence demonstrates consistent short- to intermediate-term improvements in function and pain. In addition to two prospective single-arm studies reporting clinically significant improvements in Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) from baseline, two Level 1 randomized controlled trials (RCTs) have demonstrated superiority over standard care at 3 months and 12 months and over sham control at 12 months.

BVN ablation is indicated when:

- Patients are skeletally mature and have CLBP for at least 6 months, and lower back pain is the main symptom.
- Patients have failed to adequately improve despite attempts at nonsurgical management.
- Patients have 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 in the endplates between L3 and S1.

BVN ablation is NOT indicated in ANY of the following scenarios:

- 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.
- Metabolic bone disease (e.g., osteoporosis), treatment of spine fragility fracture, trauma/ compression fracture, or spinal cancer.
- Spine infection or active systemic infection.
- Neurogenic claudication, lumbar radiculopathy, or radicular pain due to neurocompression (e.g., herniated nucleus pulposus (HNP), stenosis) as primary symptoms.
- Patients with severe cardiac or pulmonary compromise.
- Patients with implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety."

American Society of Pain and Neuroscience (6)

In 2022, the American Society of Pain and Neuroscience released guidelines on interventional treatments for low back pain. Basivertebral nerve ablation at the L3 to S1 vertebrae is indicated when patients meet the following criteria:

- Chronic axial LBP (greater than 6 months in duration).
- Pain refractory to conservative nonsurgical treatment for at least 6 months of duration.
- Evidence of vertebral endplate changes on MRU as below:
    - Modic Type I and/or Modic Type II changes.
    - Vertebral endplate changes with inflammation, edema, disruption and/or fissuring.
    - Fibrovascular bone marrow changes (hypointensive signal for Modic type I changes).
    - Fatty bone marrow replacement (hyperintensive signal for Modic type II changes).

Basivertebral nerve ablation is clinically indicated using an Food and Drug Administration (FDA)-cleared device for the procedure when the above criteria are met.

The Society recommends basivertebral nerve ablation (Grade A with Level of Certainty 1a) for patients with axial lower back pain of vertebrogenic nature.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	64628, 64629, 64999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. Lorio M, Clerk-Lamalice O, Rivera M, et al. International Society for the Advancement of Spine Surgery (ISASS) Policy Statement 2022: Literature Review of Intraosseous Basivertebral Nerve Ablation. Int J Spine Surg. 2022; 16(6):1084-1094. PMID 36266051
2. Intracept/Basivertebral Nerve Ablation. Available at <https://www.miamispine.com> (accessed May 5, 2025).
3. US Food & Drug Administration (FDA). 510(k) summary: K190504 Intracept Intraosseous Nerve Ablation System. July 9, 2016. Available at <https://www.accessdata.fda.gov> (accessed May 5, 2025).
4. U.S. Food & Drug Administration. 510(k) summary: K213836 Intracept Intraosseous Nerve Ablation System. 2022. Available at <https://www.accessdata.fda.gov> (accessed May 5, 2025).
5. North American Spine Society. Basivertebral Nerve Ablation. February 2023. Available at <https://www.spine.org> (accessed May 5, 2025).
6. Sayed D, Grider J, Strand N, et al. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022; 15:3729-3832. PMID 36510616

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/01/2025	Document updated. Coverage for basivertebral nerve ablation changed from experimental, investigation and/or unproved to conditional medically necessary. Reference 6 added; others removed. Reference 6 added; others removed.
07/15/2024	Document updated with literature review. Coverage unchanged. References 15-17 added; others updated.
09/01/2023	Document updated with literature review. Coverage unchanged. References 4, 10, 11, 13 and 14 added; others updated.
08/15/2022	Reviewed. No changes.
09/01/2021	New medical document. Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept procedure) is considered experimental, investigational and or unproven for all indications.