



Intrasept™ Intraosseous Basivertebral Nerve Ablation

Spine, Pain, and Joint (SPJ)
Utilization Management Policy

Approval Date: 02/02/2026

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Policy Statement

The Intracept™ Intraosseous Basivertebral Nerve Ablation is considered medically necessary for the treatment of chronic low back pain (cLBP) when all of the following criteria are met (North American Spine Society, 2023):

- Patient is skeletally mature AND
- Patient has cLBP for at least 6 months and lower back pain is their main symptom AND
- Patient has failed to adequately improve despite attempts at nonsurgical management AND
- Patient has 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

Intracept™ Intraosseous Basivertebral Nerve Ablation is limited to the following (Noridian, 2024):

- No previous history of basivertebral nerve (BVN) ablation at the planned level of treatment
- No more than 1-2 vertebral bodies may be treated at a single session
- Treatment of no more than 4 vertebral bodies per patient lifetime
- Treatment is within the confines of L3-S1 vertebral bodies
- Retreatment of a single vertebral body with BVN ablation within the patient's lifetime is not considered reasonable and necessary
- Local anesthesia is considered appropriate for the region treated. Mild sedation may be administered by the performing physician or staff under his/her direction but should not be coded separately. Additional anesthesia services may not be billed separately without documentation of medical necessity

Intracept™ Intraosseous Basivertebral Nerve Ablation is not medically necessary in any of the following circumstances (North American Spine Society, 2023):

- Evidence on imaging (MRI, flexion/extension radiographs, etc.) suggests another obvious etiology for the patient's cLBP 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., HNP, stenosis), as primary symptoms
- Patient has severe cardiac or pulmonary compromise
- Patient has an implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety

Scope

All in and out of network programs where utilization review determinations are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum on the reporting of Intracept™ intraosseous basivertebral nerve ablation.

For Medicare beneficiaries, refer first to any relevant local coverage determinations (LCDs) and then to the [Medicare Benefit Policy Manual](#), section 16.20, for services considered not reasonable and necessary.

Background Information

Chronic low back pain (cLBP) is a highly prevalent and disabling condition, affecting an estimated 619 million people worldwide in 2020 with projections rising to 843 million by 2050. A distinct subtype—vertebrogenic cLBP—arises from nociceptive signaling within the vertebral endplates, transmitted through the basivertebral nerve (BVN). It is most reliably identified by the presence of Modic Type 1 and Type 2 changes on MRI—Type 1 reflecting bone marrow edema and inflammation, and Type 2 representing fatty marrow replacement—which serve as key imaging biomarkers strongly correlated with symptomatic vertebral endplate injury. Patients with vertebrogenic cLBP typically present with midline-dominant axial low back pain, sometimes radiating to the gluteal region, worsened by sitting, standing, or flexion but not generally by lumbar extension. These patients are more likely to experience long-standing, treatment-resistant pain due to previously unrecognized vertebral endplate pathology. Basivertebral nerve ablation (BVNA) directly targets this mechanism by disrupting intraosseous BVN pain transmission to relieve symptoms. (Ehsanian et al., 2025).

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 six months of conservative care and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI.” (U.S. Food and Drug Administration [FDA], 2017).

The INTRACEPT System technique “uses RF ablation of the basivertebral nerve for relief of chronic low back pain and involves a two-step process. First, utilizing the Access Instruments, based on a minimally invasive, “transpedicular or extrapedicular approach” a cannula is placed into the vertebral body to create a path or channel to the terminus of the basivertebral foramen. An RF Probe is then placed into this channel at the terminus of the basivertebral foramen, and controlled RF energy is delivered to destroy the basivertebral nerve. This nerve has been identified as a proprioceptive sensory nerve with enervation of the vertebral endplates.” (FDA, 2017).

Clinical Evidence

Ehsanian et al. (2025) reviewed the evidence on basivertebral nerve ablation (BVNA) for treating vertebrogenic chronic low back pain (cLBP). Findings show that BVNA is highly effective and provides durable relief for appropriately selected patients—those with chronic low back pain, Modic Type 1 or 2 changes on MRI, and prior failure of conservative care. Results from multiple randomized controlled trials (SMART (NCT00103181) and INTRACEPT (NCT03246061)) and prospective studies consistently demonstrate significant improvements in pain and function. For example, BVNA patients achieved mean reductions of 25–28 points on the Oswestry Disability Index (ODI) and 3.5–4.1 cm on the Visual Analog Scale (VAS) at 12–24 months, compared to minimal improvements in standard care groups. These benefits persisted for up to five years, with 65–75% of patients reporting clinically meaningful improvement at 6–12 months and stable outcomes at 60 months. Safety was favorable, with very few device-related adverse events; most complications were minor and transient. BVNA outperformed other interventions, such as intradiscal steroid injections and facet denervation, in both pain relief and functional gains. Additionally, BVNA significantly reduced healthcare utilization—opioid use dropped by 40% at one year and 62% at five years, while spinal injections decreased by over 80% at one year and remained low long term. Cost-effectiveness analyses indicate that BVNA is more economical than standard care alone for vertebrogenic cLBP. Limitations include strict trial criteria that limit generalizability and a lack of data for patients with complex spinal comorbidities. Future research should focus on refining imaging biomarkers, identifying predictors of response in broader populations, and comparing BVNA with emerging therapies.

A pooled 5-year analysis of three prospective clinical trials evaluating intraosseous basivertebral nerve ablation (BVNA) for vertebrogenic chronic low back pain demonstrates durable, clinically meaningful improvements in both pain and function (Khalil et al., 2024). Authors reported mean reductions of 4.32 points in numeric pain score and 28 points in Oswestry Disability Index at a mean 5.6-year follow-up;

nearly one-third of patients became pain-free, and substantial reductions in opioid use (65%) and spinal injection utilization (58.1%) were observed. Following BVNA, healthcare utilization, including additional lumbosacral interventions (13.2%) and fusion surgery (6%), remained low, and no serious device-related adverse events occurred, underscoring a favorable long-term safety profile. Limitations include the open-label design, industry sponsorship, lack of long-term comparator groups due to crossover in randomized trials, and a study population enriched with patients who had long-standing pain and prior treatments, which may limit generalizability. Overall, BVNA appears to be a safe, effective, and durable treatment for appropriately selected patients with vertebrogenic pain.

Nwosu et al. (2023) performed a systematic review to evaluate 11 recent studies (413 participants) on intraosseous basivertebral nerve ablation (BVNA) for non-radiating vertebrogenic chronic low back pain with Modic type 1 or 2 changes. Authors found consistent evidence that BVNA provides meaningful and durable improvements in pain, disability (ODI), and function, often outperforming sham procedures and standard care. Across randomized trials, 50–75% of treated patients achieved $\geq 50\%$ pain reduction, with many showing sustained benefit at 2–5 years, reduced opioid use, and improved quality of life. Adverse events were generally rare and transient, with no device-related serious complications reported. However, the evidence base is limited by narrow inclusion criteria, predominantly Caucasian samples, industry funding across most studies, lack of long-term non-industry trials, and exclusion of non-English or non-US/Canada studies, restricting generalizability. Authors conclude BVNA appears to be a safe, minimally invasive, and effective option for appropriately selected patients, though larger, independent, and more diverse trials are needed to confirm durability, safety, and broader applicability.

Conger et al. (2022) completed an updated systematic review and single-arm meta-analysis to evaluate the effectiveness of intraosseous basivertebral nerve (BVN) radiofrequency ablation (RFA) for treating chronic vertebrogenic low back pain associated with Modic type 1 or 2 changes. Across six unique study populations (414 participants), pooled success rates for clinically significant improvement were approximately 65% for pain reduction and 75% for functional improvement at both 6 and 12 months, with similar durability up to 5 years. Adverse events were generally minor and transient, most commonly leg pain due to pedicle breach. Limitations include the small number of randomized controlled trials, predominance of industry-funded studies, and potential risk of bias. According to the GRADE framework, evidence quality is moderate, indicating BVN RFA is effective for most appropriately selected patients, but further high-quality, independent trials are needed to confirm long-term efficacy and refine patient selection.

A systematic review conducted by Conger et al. (2021) evaluated the effectiveness of intraosseous basivertebral nerve radiofrequency neurotomy (BVN RFN) for chronic low back pain (CLBP) in adults with Modic type 1 or 2 changes. Seven studies involving 321 participants were analyzed. At three months, success rates for $\geq 50\%$ pain reduction ranged from 45% to 63%, and functional improvement (≥ 10 -point Oswestry Disability Index (ODI) improvement) ranged from 75% to 93%, with benefits sustained up to five years in observational cohorts. BVN RFN showed superiority over standard care and modest advantage over sham treatment. Limitations include small sample sizes, heterogeneity, lack of meta-analysis, selective reporting, inability to blind in pragmatic trials, and reliance on industry-funded studies, which raises concerns about bias and generalizability. Moderate-quality evidence supports BVN RFN as an effective treatment for reducing pain and disability in carefully selected patients with CLBP and Modic changes, but high-quality, non-industry-funded trials are needed to confirm these findings.

Fischgrund et al. (2020) evaluated the durability of basivertebral nerve (BVN) ablation for vertebrogenic chronic low back pain (CLBP) in patients with Modic Type 1 or 2 changes. Among 117 U.S. patients treated, 100 (85%) were followed for a mean of 6.4 years. Outcomes showed significant and sustained improvements: mean Oswestry Disability Index (ODI) decreased by 25.95 points (from 42.81 to 16.86), and Visual Analog Scale (VAS) pain scores dropped by 4.38 points (from 6.74), both $p < 0.001$. At 5 years, 66% reported $>50\%$ pain reduction, 47% $>75\%$, and 34% complete pain resolution. Opioid use and injection rates declined markedly, and patient satisfaction was high (79% would repeat the procedure). Limitations include lack of a control group beyond 12 months due to crossover, U.S.-only population, and industry funding. Evidence suggests that BVN ablation is a safe, minimally invasive, and

durable treatment for a specific subgroup of CLBP patients, maintaining clinically meaningful improvements in pain and function beyond 5 years.

Fischgrund et al. (2019) reported two-year outcomes of a randomized controlled trial evaluating radiofrequency ablation of the basivertebral nerve (BVN) for chronic low back pain (CLBP) in patients with Modic type 1 or 2 changes. Among 147 treated patients, significant and durable improvements were observed: mean Oswestry Disability Index (ODI) improved by 23.4 points (53.7%), and Visual Analog Scale (VAS) pain scores improved by 3.59 cm (52.9%) at 24 months. Responder rates remained high, with 76.4% achieving ≥ 10 -point ODI improvement and 70.2% achieving ≥ 1.5 cm VAS reduction. Safety outcomes were favorable, with no device-related serious adverse events and minimal complications. Limitations include high crossover from the sham group (73%), preventing long-term between-group comparisons, and potential bias from patient attrition (17% at 24 months). Authors concluded that BVN ablation is a safe, minimally invasive, and durable treatment option for CLBP in patients with Modic changes, though further studies are needed to confirm generalizability and long-term comparative effectiveness.

The ECRI Evidence Analysis of the Intracept basivertebral nerve ablation system finds that the procedure appears generally safe and can reduce chronic vertebrogenic low-back pain, improve function, and enhance physical quality of life for many patients, with 65–80% experiencing sustained benefit up to five years. However, the strength of evidence is very low due to substantial limitations: only one high-quality randomized controlled trial used a blinded sham comparison, and while it showed statistically significant improvements, the magnitude of difference between Intracept and sham was small and of uncertain clinical significance. Other studies—including an RCT comparing Intracept with standard care and multiple before-and-after studies—had high risks of bias stemming from unblinded designs, heterogeneous control treatments, small sample sizes, and lack of comparators, limiting confidence in effectiveness estimates. Overall, Intracept may offer meaningful pain and functional improvement for select patients, but more rigorous, multicenter, blinded comparative trials are needed to determine its true clinical value versus other minimally invasive back pain interventions. (ECRI, 2025).

A Hayes Health Technology Assessment concludes that overall low-quality evidence suggests the Intracept intraosseous basivertebral nerve ablation system is reasonably safe and consistently improves pain and function relative to baseline and continued conservative therapy in adults with chronic vertebrogenic low back pain. However, the treatment offers no clinically meaningful advantage over sham treatment and has not been compared with other minimally invasive pain interventions. Across six included studies—mostly poor-quality pre/post designs and only two randomized controlled trials—the body of evidence is limited by methodological weaknesses such as lack of blinding, small sample sizes, short follow-up for comparative analyses, and the presence of only one sham-controlled trial showing minimal between-group differences. Safety findings indicate mostly mild adverse events, including pain, neuropathy, paresthesia, and foot drop, and no treatment-related deaths in published studies. The Hayes report concludes that substantial uncertainty remains regarding long-term and comparative effectiveness, and additional rigorous, controlled trials are needed to define patient selection criteria and establish the true clinical value of Intracept therapy. (Hayes, 2025).

Coding Information

Note: The Current Procedural Terminology (CPT) codes (2026) listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

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)

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Review and Approval History

Date	Description
02/02/2026	Approved by Optum UM Quality Oversight Committee (QOC).
02/10/2026	Optum Clinical Guideline Advisory Committee notified of new policy.
