Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: Radiofrequency Ablation of Basivertebral Nerve for Low Back Pain (i.e., Intracept)

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)."

Product codes: GXI and GXD

Medical Policy Statement

The safety and effectiveness of radiofrequency ablation of the basivertebral nerve has been established. It may be considered a useful therapeutic option when selection criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:
Basivertebral nerve ablation, with an FDA approved device, for one or more levels of L3 through S1 when **ALL** of the following are met:

- Individual is skeletally mature (≥ 18 years of age).
- Moderate to severe chronic low back pain that is primarily axial[a] in nature.
- Pain is refractory to at least 6 months of non-operative treatment[b] within the past year, including at least 6 weeks of detailed professional directed exercise program (i.e. Physical Therapy)
- 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.
    - Type 2 – changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyper-intensive signals.

[a] *Pain that is localized (e.g., lower back) and is **not** accompanied by motor or sensory dysfunction in the associated extremities (e.g. legs)*

[b] *Pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy.*

***Note**: When performing ablations for members with implanted electric devices (spinal cord stimulator, pacemaker/defibrillator, etc.), manufacturer guidelines should be followed regarding turning off or monitoring the device during the ablation procedure.*

Exclusions:

- 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
- Active, untreated substance/drug use disorder
- Uncontrolled moderate to severe depression, evaluated by psychiatric examination or by a validated depression screening test (e.g., Beck Depression Inventory, PHQ-9, etc.)
- 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
- Any current litigation related to back pain or injury
- 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 BVN ablation.
- Above criteria are not met.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

64628 64629

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Chou et al (2009) reported on a guideline that was developed by a multidisciplinary panel which was convened by the American Pain Society. Despite use of conservative treatment and surgical modalities, back pain may be persistent and become disabling. Back pain affects approximately 15% of the U.S. population and is a frequent cause of chronic pain and disability. Based on a systematic review of 161 RCTs, recommendations were made regarding the use of conservative treatments, interventional diagnostic tests and therapies, surgery and interdisciplinary rehabilitation. Conservative treatment modalities were reported to include pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy. If these measures are unsuccessful, a number of interventional techniques and procedures

may be considered that attempt to target specific structures or spinal abnormalities considered to be potential sources of pain, including back muscles and soft tissues, degenerated facet or sacroiliac joints, spinal canal stenosis, and degenerated or herniated intervertebral discs. It can often be difficult to determine the underlying cause of low back pain.

Becker et al (2017) assessed the efficacy of intraosseous basivertebral nerve ablation for the treatment of chronic lumbar back pain. Seventeen patients with chronic low back pain, lasting greater than 6 months, which was unresponsive to at least 3 months of conservative care were enrolled. Sixteen patients were treated successfully following screening using magnetic resonance imaging finding of Modic type I or II changes and positive confirmatory discography to determine the affected levels. The treated population consisted of 8 male and 8 female patients; the mean age was 48 years (34-66 years). Self-reported outcome measures were collected prospectively at each follow-up interval. Measures included the Oswestry Disability Index, visual analogue scale score VAS), and Medical Outcomes Trust 36-Item Short-Form Health Survey (SF-36). There was a significant decrease in the average Oswestry Disability Index (ODI) at 3 months postoperatively, which was maintained at 12 months. Significant improvement in the VAS scores and quality of life were also reported at the 3-month follow-up. Authors concluded that ablation of the basivertebral nerve for the treatment of chronic lumbar back pain significantly improved the subjects self-reported outcome early in the follow-up period. Limitations of the industry-sponsored study included a small sample size, lack of randomization and control and short-term follow-up.

Fischgrund et al (2018) evaluated the safety and efficacy of RFA of the basivertebral nerve for the treatment of chronic low back pain in the multi-center, randomized, double-blind, sham-controlled SMART trial which was sponsored by Relievant Medsystems, Inc. A total of 225 individuals diagnosed with chronic low back pain were randomized to treatment with the Intracept procedure (n=147) or sham therapy (n=78). All individuals had Type I or Type II Modic changes of the treated vertebral bodies. The primary endpoint was the comparative change in the ODI from baseline to 3 months. At 3 months, the average ODI in the treatment arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham arm. A responder analysis based on ODI decrease ≥ 10 points showed that 75.6% of patients in the treatment arm as compared to 55.3% in the sham control arm exhibited a clinically meaningful improvement at 3 months.

Fischguard et al (2019) reported 2-year clinical outcomes in a total of 147 patients who were treated with RF ablation of the BVN in a randomized controlled trial as part of a Food and Drug Administration-Investigational Device Exemption trial (SMART trial). Participants randomized to the sham control arm were allowed to cross to RFA at 12 months: 73% of patients elected to cross to treatment, thus preventing an adequate control sample and a lack of statistical power for future between group comparisons Due to a high rate of crossover, RFA treated participants acted as their own control in a comparison to baseline for the 24-month outcomes. The mean percent improvements in ODI and visual analogue scale (VAS) compared to baseline at 2 years were 53.7 and 52.9%, respectively. Responder rates for ODI and VAS were also maintained through 2 years with subjects showing clinically meaningful improvements in both: ODI ≥10-point improvement in 76.4% of subjects and ODI ≥20-point improvement in 57.5%; VAS ≥1.5 cm improvement in 70.2% of subjects. The 24 month follow-up results were reported for the active treatment group from the SMART trial. Of the per protocol population treated with ablation (treatment arm), 106 (83%) completed a 24-month

follow-up visit. A durable Oswestry Disability Index mean improvement was observed (23.4 points).

Fischguard et al (2020) examined the 5-year results of individuals who were treated with basivertebral nerve ablation in the SMART trial. Of the 117 US treated patients 100 (85%) were available for review with a mean follow-up of 6.4 years (5.4–7.8 years). Mean ODI score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points ($p < 0.001$). Mean reduction in VAS pain score was 4.38 points (baseline of 6.74, $p < 0.001$). In total, 66% of patients reported a > 50% reduction in pain, 47% reported a > 75% reduction in pain, and 34% of patients reported complete pain resolution. Composite responder rate using thresholds of ≥ 15-point ODI and ≥ 2-point VAS for function and pain at 5 years was 75%. CLBP patients treated with BVN ablation exhibited sustained clinical improvements in function and pain with high responder rates at a mean of 6.4 years following treatment. Authors determined that BVN ablation is a durable, minimally invasive treatment for vertebrogenic CLBP.

Khalil et al (2019) compared the effectiveness of intraosseous RF ablation of the BVN to standard care for the treatment of chronic LBP in a specific subgroup of individuals suspected to have vertebrogenic related symptomatology. In the industry sponsored trial, a total of 140 individuals with Modic Type I or II vertebral endplate changes between L3 and S1, who had chronic LBP for at least 6 months duration, were randomized 1:1 to undergo either RF ablation of the BVN or continue standard care. Subjects in the treatment arm received intraosseous RF ablation of the BVN using a unilateral transpedicular delivery system (Intracept System, Relievant Medsystems, Minneapolis, MN, USA). Treatment of up to 4 vertebrae in nonconsecutive levels from L3 to S1 was allowed. The procedure was performed under image guidance with moderate conscious sedation or general anesthesia, per investigator discretion, in an outpatient setting. Subjects randomized to standard care continued treatment, including, but not limited to, pain medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections. Standard care was provided in a shared decision-making process between the subject and the treating investigator, according to the investigator's medical judgment and the subjects clinical presentation and experiences with prior treatments. The primary endpoint of the study is collected at 3 months post-randomization (standard care) or post-treatment (RF ablation). In addition, all RF ablation subjects are followed at 6 weeks, and 3, 6, 9, 12, and 24 months. Standard care individuals are followed at 3, 6, 9, and 12 months. Opioid pain medications were used by 32% ($p=0.529$) of individuals at baseline and no significant difference in opioid reduction was observed between the 2 treatment arms at 3-months. The primary outcome was determined by changes in individual-reported function on the ODI and was strongly in favor of the RF ablation treatment group with a mean improvement of -25.3 points, and an adjusted difference between means of -20.9 points compared with the usual care group. Authors determined that common therapies aimed at chronic nonspecific low back pain are limited by small effect size leaving many individuals dissatisfied, which is in contrast with the satisfaction scores received for RFA. Seventy-four percent of the RFA population indicated they were satisfied with the treatment, 80% said they would have the procedure again for the same condition and 88% would recommend the procedure to a loved one. The comparisons within the study, reveal that BVN ablation is a highly effective treatment only for a specific subgroup of individuals with chronic low back pain characterized by the clinical and radiographic findings.

Truumees et al (2019), discussed an industry sponsored, prospective, open-label, single arm study of intraosseous basivertebral nerve ablation for the treatment of CLBP. Twenty-eight

consecutive individuals with CLBP of at least 6 months duration and with Modic Type 1 or 2 vertebral endplate changes between L3 and S1 were treated with RF ablation of the BVN in up to 4 vertebral bodies at 2 investigational sites in the United States. The primary inclusion criteria included skeletally mature subjects with Type 1 or Type 2 Modic changes on an MRI at 1 or more vertebral bodies from L3 through S1 and ≥ 6 months of conservative care for CLBP. Primary exclusion criteria included symptomatic spinal stenosis, disk protrusion > 5 mm, spondylolisthesis > 2 mm at any level, or radiculopathy. Exclusions were also applied to those individuals with radicular pain that correlated with nerve compression in imaging, metabolic bone disease, spine fragility fracture history, trauma/compression fractures, spinal cancer, infection, bleeding diathesis, compensated injury or litigation, addiction behaviors who are currently taking extended-release narcotics, BMI > 40, any neurological condition that prevents early mobility, and those who were bedbound.

Urits et al (2021) reviewed several studies in order to determine the safety, durability and efficacy of radiofrequency ablation of the basivertebral nerve. Authors noted that radiofrequency ablation of the basivertebral nerve has emerged as a possible minimally invasive procedure to treat low back pain based on the growing evidence supporting the vertebrogenic model that involves the basivertebral nerve. Authors concluded that several studies have supported the safety, durability, and efficacy of RF ablation of the BVN and that there is convincing evidence that BVN ablation is more beneficial than the current standard of care for the treatment of chronic low back pain (CLBP). Although they indicated that reproducible large RCTs are needed for clinicians to gain full confidence in utilizing this treatment in practice. They also advocated for future research on the anatomy of the vertebrae to optimize the method of treatment.

Loan et al (2021) evaluated the value of basivertebral nerve ablation for the treatment of chronic low back pain using a systematic review and meta-analysis. Inclusion criteria consisted of individuals with discogenic back pain of more than 3 months duration with modic type 1 or 2 change and successful disc block or discogram. Primary outcomes were VAS pain, ODI, EuroQol- 5 Dimension (EQ-5D) and SF-36 improvement. Secondary outcomes were complications. Six studies were included, all funded by Relievant Medsystem, Inc. All studies showed significant improvement in all scores over the first 3 months with evidence these would be maintained over the longer term. There was one reported compression fracture, but otherwise no significant adverse events. Authors indicated they did not have any conflicts of interest and determined that this study supports the conclusion that radiofrequency ablation of the basivertebral nerve is a safe and effective treatment for discogenic chronic low back pain.

Conger et al (2022) designed a systematic review with a single arm meta-analysis with an industry paid grant to determine the efficacy of BVN RFA in the treatment of vertebrogenic low back pain. The population consisted of individuals ≥ 18 years of age with chronic LBP for ≥ 6 months which was associated with type 1 or 2 Modic changes on MRI within at least 1 level of L3-S1. Intraosseous BVN RFA was completed in 414 with 496 total participants (2 RCTs and 4 single-group cohort studies). The remainder (n=82) were considered controls (sham, placebo procedure, active standard care). The primary outcome was considered successful when there was a ≥ 50% improvement in pain scores on a visual analog scale or numeric rating scale. The secondary outcome was considered a success with a ≥ 15 point improvement in Oswestry Disability Index score. A success rate of 65% (95% confidence interval [CI] 51–78%) and 64% (95% CI 43–82%) for ≥ 50% pain relief at 6 and 12 months, respectively was noted in the single-arm meta-analysis. Rates of ≥ 15-point Oswestry Disability Index score improvement

were 75% (95% CI 63–86%) and 75% (95% CI 63–85%) at 6 and 12 months. Authors concluded that there continues to be “moderate”-quality evidence that BVN RFA effectively reduces chronic LBP and associated disability in individuals with chronic vertebrogenic LBP associated with Modic 1 and Modic 2 changes in the L3 to S1 vertebral bodies. Further high-quality studies will improve the understanding of the effectiveness of this procedure.

Mekhail et al (2023) performed an industry funded meta-analysis to determine the relative efficacy and safety protocols of BVN RFA for chronic LBP. A systematic search was performed for randomized controlled trials published in the past 20 years reporting on radiofrequency ablation of the basivertebral, disk annulus and facet nerve structures, steroid injection of the disk, facet joint, and medial branch, biological therapies, and multifidus muscle stimulation. The outcomes evaluated included VAS pain scores, ODI scores, quality of life (SF-36 and EQ-5D) scores, and serious adverse event rates. Basivertebral nerve ablation was chosen as the subject of comparison. Twenty-seven studies were included. BVN ablation was found to provide statistically significant improvements in VAS and ODI scores for 6-, 12- and 24-month follow-up (P≤ 0.05). Biological therapy and multifidus muscle stimulation were the only 2 treatments with both VAS and ODI outcomes not significantly different from BVN ablation at 6-, 12-, and 24-month follow-up. All outcomes found to be statistically significant represented inferior results to those of BVN ablation. Insufficient data precluded meaningful comparisons of SF-36 and EQ-5D scores. The SAE rates for all therapies and all reported time points were not significantly different from BVN ablation except for biological therapy and multifidus muscle stimulation at the 6-month follow-up. BVN was found to be equivalent to biological therapy and multifidus stimulation for pain and disability improvements when compared to other interventions. BVN did not report any serious adverse events, therefor authors concluded that BVN has a significantly better outcome than other modalities.

Ongoing Trials

Table 1. Ongoing Clinical Studies

NCT	Title	Participants	Completion Date
NCT05207813	A Prospective, Open-Label, Single-Arm Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain Long-term Follow Up	42	March 2024
NCT03246061	INTRACEPT: Prospective, Randomized, Multi-center Study Intraosseous Basivertebral Nerve Ablation for Treatment of CLBP	140	Sept 2024
NCT05660512	Intracept Intraosseous Basivertebral Nerve Ablation	50	Dec 2026

NCT: National Clinical Trial

Summary

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.

Supplemental Information

POSITION STATEMENTS

American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine
ASA clinical practice guidelines (2010) review the evidence for chronic pain management techniques in adults with noncancer neuropathic, somatic (e.g., myofascial), or visceral pain syndromes. The recommendation indicates that other treatment modalities should be attempted before consideration of the use of ablative techniques.

American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN)
In June 2022, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves published a personal communication in response to the North American Spine Society (NASS) request for comment on basivertebral ablation. AANS, CNS and DSPN indicated they cannot support a basivertebral nerve ablation coverage policy. Rationale included citations of contradictions in the arguments for support of the procedure and the clinical data. The 3 societies felt that the current indication of chronic low back pain for at least 6 months that failed attempts of nonsurgical treatment and showed Type 1 or Type 2 Modic changes on MRI are overly broad and would easily encompass anyone with chronic low back pain - ranging from chronic lumbar strain to lumbar stenosis, degenerative scoliosis, facet arthroplasty and disc disease. They pointed out that Modic changes on MRIs are an asymptomatic finding in the aging population. They recommended further work-up to elucidate the underlying cause of the pain along with a recommendation to clarify what other management options should be provided and for how long before undergoing BVN ablation. Some of the exclusionary contraindications were interpreted as a disclaimer versus a treatment plan.

(Stroink, AR., Bambakidis, NC., Kanter, AS. Personal Communication. 2022. Available at: https://www.aans.org/-/media/Files/AANS/Advocacy/2022-news/AANS-CNS_Comments_Regarding_NASS_Basivertebral_Nerve_Ablation_Coverage_Policy_060122.ashx.)

American Society of Pain and Neuroscience
The American Society of Pain and Neuroscience (Dec 2022) recommends BVN ablation at L3-S1 vertebrae when there is chronic axial LBP for greater than 6 months, the pain is refractory to conservative nonsurgical treatment for a least 6 months, and there is evidence of vertebral endplate changes on an MRI. The recommendation for basivertebral nerve ablation is Grade A (high certainty that the net benefit is substantial) with Level of Certainty 1a based upon 4 RCTs.

International Society for the Advancement of Spine Surgery
The International Society for the Advancement of Spine Surgery (2022) updated consensus guidelines for intraosseous ablation of the basivertebral nerve from L3 through the S1

vertebrae. Authors concluded that BVN ablation for chronic low back pain (CLBP) may be considered medically indicated for individuals when all of the following 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).

BVNA 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 Relievant requests for Designation.

Government Regulations

National:

No National Determination found regarding basivertebral nerve ablation or radiofrequency ablation for low back pain.

Local:

No Local Determination found regarding basivertebral nerve ablation or radiofrequency ablation for low back pain.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated

and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Spinal Surgery: Automated Percutaneous and Endoscopic Discectomy
- Spinal Surgery: Percutaneous Disc Decompression Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
- Spinal Surgery: Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 24, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/21	12/15/20		Joint policy established
3/1/22	12/14/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance
1/1/24	10/25/23		• Routine maintenance (slp) • Vendor managed: Turning Point (Changed status to EST on 10/1/23) • Stance changed to EST • Replacing IMP – RFA of Basivertebral nerve for LBP (i.e., Intracept) • 64628-64629 changed to EST • NOC removed

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RADIOFREQUENCY ABLATION OF BASIVERTEBRAL NERVE FOR LOW BACK PAIN (I.E. INTRACEPT)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.