

07.01.104 Intraosseous Basivertebral Nerve Ablation (BVNA)*

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Related Policies:

- [07.01.87 Automated Percutaneous and Percutaneous Endoscopic Discectomy](#)
- [07.01.88 Decompression of the Intervertebral Disc Using Laser Energy \(Laser Discectomy\) or Radiofrequency-Coblation \(Nucleoplasty\)](#)
- [07.01.90 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty and Biacuplasty](#)

Summary

Description

Intraosseous basivertebral nerve ablation (BVNA) is a minimally invasive, percutaneous procedure to treat chronic low back pain (CLBP). It uses radiofrequency ablation (RFA) to interrupt pain signals in the nerves within the vertebral body on either side of a painful disc in the lumbar spine.

Summary of Evidence

For individuals who have vertebrogenic back pain who receive intraosseous ablation of basivertebral nerves (BVNA), the evidence includes 2 randomized controlled trials (RCTs) (the SMART and INTRACEPT trials) and a single-arm prospective study. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. The SMART trial did not find a difference in the Oswestry Disability Index (QDI) between individuals treated with BVNA or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of individuals in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. The INTRACEPT trial found a significant difference in the ODI and other pain scores between individuals treated with BVNA and standard care at 3 months. Comparative data at 6 months post randomization showed similar results. However, 92% of individuals initially assigned to standard care elected to cross over to receive early BVNA, thus, long-term comparative data beyond 6 months are not available. Additional limitations to this RCT include lack of a sham control. In a small (n=60), prospective, single-arm cohort, more than half of participants with vertebrogenic low back pain achieved at least a 30% improvement in ODI score 12 months after treatment with BVNA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. However, even though there is a paucity of peer-reviewed scientific evidence showing consistent long-term evidence regarding the effectiveness of intraosseous BVNA for individuals who have vertebrogenic back pain, BVNA will be considered medically necessary for certain carefully-selected individuals based on key inclusion and exclusion criteria from pivotal clinical trials, see [Policy](#).

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to evaluate whether intraosseous basivertebral nerve ablation (BVNA) improves the net health outcome in individuals with vertebrogenic back pain.

PRIOR APPROVAL

Prior approval is required.

POLICY

Medical Necessity

Intraosseous basivertebral nerve radiofrequency ablation (BVNA) (e.g., Intracept® System or ViaVerte™ System) of the lumbar L3-S1 may be considered **medically necessary** for the treatment of select chronic axial low back pain in individuals when **ALL** of the following criteria are met:

- Diagnosed with vertebrogenic axial lumbar back pain for at least 6 months
- BMI ≤40
- Absence of both of the following:
 - Lumbar radicular symptoms (nerve symptoms following a dermatomal distribution that correlates with nerve compression-abutment by imaging)

- Symptomatic spinal stenosis (the presence of neurogenic claudication that correlates with spinal stenosis confirmed by imaging)
- Skeletally mature patient (generally age >18 years)
- Minimum Visual Analog Score (VAS) score of ≥ 4 and Oswestry Disability Index (ODI) of ≥ 30
- Documented failure to respond to at least 6 consecutive months of continuous supervised non-surgical conservative management (see [Policy Guidelines](#))
- All other alternative pain generators have been reasonably excluded, including, but not limited to, fracture, tumor, infection, or significant spinal deformity
- Imaging studies confirm **BOTH** of the following:
 - Magnetic resonance imaging (MRI)-demonstrated Modic Type 1 or 2 changes in at least one vertebral endplate, at one or more levels from L3 to S1, including **EITHER** of the following:
 - Fibrovascular bone marrow changes are present (hypointense T1 signal; Modic Type 1)
 - Fatty bone marrow changes are present (hyperintense T1 and T2 signal; Modic Type 2)
 - Radiographic absence of **ALL** of the following:
 - Type 3 Modic changes (sclerotic)
 - Disc extrusion or protrusion > 5 mm at levels L3-S1
 - Spondylolisthesis > 2 mm at any level
 - Spondylolysis at any level
 - Facet arthrosis/effusion correlated with facet-mediated LBP at levels L3-S1

Investigational

Intraosseous basivertebral nerve radiofrequency ablation (BVNA) (e.g., Intracept® System or ViaVerte™ System) of the L3-S1 vertebrae for the treatment of chronic axial lower back pain that is of vertebrogenic nature is considered **investigational** when **ANY** of the following are present:

- Skeletally immature patients (generally <18 years of age)
- Concurrent vertebral augmentation procedures at the intended levels of BVNA
- Implantable pulse generator
- Previous lumbar spine surgery at the intended treatment level (discectomy/laminectomy allowed if > 6 months prior to baseline and radicular pain resolved)
- Diagnosed osteoporosis (T-score of -2.5 or less), metabolic bone disease, spine fragility fracture history, or trauma/compression fracture at intended treatment level
- Spine tumor or metastatic disease
- Spine infection, active systemic infection, bleeding diathesis
- Active, untreated substance abuse disorder or addiction behavior
- Pregnant or lactating women
- Three or more Waddell's signs on physical examination
- Repeat BVNA at the same level of a prior BVNA
- BVN ablation may not be combined with any other spine procedure on the same day

Intraosseous basivertebral nerve radiofrequency ablation (BVNA) (e.g., Intracept® System or ViaVerte™ System) of the L3-S1 vertebrae for all other indications not cited above is considered **investigational** because evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

Conservative Management

Conservative Management Failure: Acceptable 6-month continuous conservative management include but are not limited to:

- Avoidance activities that aggravate pain
- Physical therapy
- Pharmacologic management (NSAIDs, non-narcotic analgesics, muscle relaxants, neuropathic agents, etc.)
- Chiropractic or osteopathic manipulation therapy
- Acupuncture
- Epidural steroid injections or other spinal injections

Required Documentation:

1. Clinical notes documenting chronic axial low back pain (CLBP) ≥ 6 months
2. Failure of ≥ 6 months of continuous conservative management (specify treatments attempted and outcomes)
3. MRI report confirming Type 1 and/or Type 2 Modic changes at L3-S1 at proposed treatment level(s)
4. Imaging confirms absence of another etiology for the individual's symptoms (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain).
5. Documented VAS score ≥ 4 , Oswestry Disability Index (ODI) of ≥ 30 , and number of Waddell's signs.
6. Physical examination findings ruling out radicular etiology and/or other primary pain generators.
7. BMI documentation.
8. Bone density results if osteoporosis is clinically suspected.

Waddell Signs

Waddell signs include:

- **Superficial tenderness:** The patient's skin over a wide area of the lumbar skin is tender to light touch or pinch.
- **Non-anatomical tenderness:** The patient experiences deep tenderness over a wide area that is not localized to one structure and crosses over non-anatomical boundaries.
- **Axial loading:** Downward pressure on the top of the patient's head elicits lumbar pain.
- **Acetabular rotation:** Lumbar pain is elicited while the provider passively and simultaneously externally rotates the patient's shoulder and pelvis together in the same plane as the patient stands. It is considered a positive test if pain occurs within the first 30 degrees of rotation.
- **Distracted straight leg raise discrepancy:** The patient complains of pain during a straight leg raise during formal testing, such as when supine, but does not on distraction when the examiner extends the knee with the patient in a seated position.
- **Regional sensory disturbance:** The patient experiences decreased sensation fitting a stocking-like distribution rather than a dermatomal pattern.
- **Regional weakness:** Weakness, cogwheeling, or the giving way of many muscle groups that are not explained on a neuroanatomical basis.

- **Overreaction:** A disproportionate and exaggerated painful response to a stimulus that is not reproduced when the same provocation is given later. These responses can include verbalization, facial expression, muscle tension, or tremor.

Visual Analog Score (VAS)

VAS Score	Pain Severity
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

Oswestry Disability Index (ODI)

The Oswestry Disability Index (ODI) consists of 10 patient-completed questions in which response options are presented as 6-point Likert Scales. Scores range from 0% (no disability) to 100% (most severe disability).

ODI Score	Disability Index
0-20 percent	Minimal disability
21-40 percent	Moderate disability
41-60 percent	Severe disability
61-80 percent	Disability that severely restricts daily activities
81-100 percent	Bed bound or symptoms may be exaggerated

Coding

See the [Codes](#) table for details.

BACKGROUND

Vertebrogenic Low Back Pain

The basivertebral nerve 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.

Intraosseous Basivertebral Nerve Ablation

Certain vertebral endplate (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. An intraosseous nerve-ablating procedure, known commercially as the Intracept® System, was designed around the concept that some individuals with axial back pain suffer from vertebrogenic pain (pain transmitted through the basivertebral nerve). The Intracept® device uses radiofrequency ablation (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 signal from the superior and inferior endplates.

Intraosseous BVNA is proposed as an alternative to spinal fusion in individuals with chronic axial low back pain who have had alternative pain generators reasonably excluded, including, but not limited to, fracture, tumor, infection, or significant spinal deformity and show Modic Type 1 or 2 changes on MRI in at least one vertebral endplate, at one or more levels from L3 to S1.

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”. FDA reviewed the device and issued a substantially equivalent designation in August 2017 (K170827). In March of 2022, FDA issued a 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).”¹, FDA product code: GXI.

The ViaVerte™ Basivertebral Nerve Ablation (BVNA) System (Merit Medical, distributed by Medtronic Inc.) was approved by the FDA on February 13, 2026 (K251802). “The ViaVerte system is indicated for ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain (CLBP) of at least 6 months duration that has not responded to at least six months of conservative care and accompanied by either Type 1 or Type 2 Modic changes visible on an MRI.” Product Code. GXI

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar radiofrequency device (Coblation®; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar radiofrequency device is used to provide lower energy treatment to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. Disc nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered in the policy on [07.01.88 Decompression of the Intervertebral Disc Using Laser Energy \(Laser Discectomy\) or Radiofrequency-Coblation \(Nucleoplasty\)](#).

RATIONALE

This evidence review was created in October 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important

to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Intraosseous Basivertebral Nerve Ablation

Clinical Context and Therapy Purpose

The purpose of intraosseous basivertebral nerve ablation (BVNA) in individuals who have vertebrogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with vertebrogenic back pain.

Interventions

The therapy being considered is intraosseous BVNA.

Comparators

Relevant comparators are conservative management and surgical spinal decompression.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Fischgrund and colleagues (2018) conducted a randomized, double-blind, sham controlled study (SMART trial) of basivertebral nerve ablation using the Intracept system in 225 participants from the U.S. and Europe. Patients had chronic isolated lumbar pain that had not responded to at least 6 months of nonoperative management. Additional study inclusion criteria were a minimum Oswestry Disability Index of 30 points (on a 100-point scale), a minimum visual analog scale of 4, and Modic type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. Treatment was limited to a minimum of 2 and a maximum of 3 consecutive vertebral levels from L3 to S1. The active treatment group (n=147) received radiofrequency and the sham group (n=78) underwent the same protocol for the same overall duration as the treatment group; however, the radiofrequency treatment was simulated. Patients were blinded to the group assignment for 1 year, at which time those in the sham arm were allowed to cross over, 57 (73%) of whom elected to do so and receive the Intracept treatment. The primary endpoint of the original study was comparative change in Oswestry Disability Index from baseline to 3 months, and in the intent-to-treat analysis there was no statistically significant difference in this outcome between groups at this time point. There was a difference between groups in the 3-month per protocol analysis (mean Oswestry Disability Index improved 20.5 and 15.2 points in the treatment and sham arms, respectively; $p=.019$). However, at the 12 month per protocol analysis, the difference in mean Oswestry Disability Index between groups was no longer statistically significant. Pain severity, measured by visual analog scale, was not significantly different between groups at 3 months ($p=.083$) but there was significantly greater improvement in the treatment group at 6 and 12 months.

The 24-month follow-up results were reported for the active treatment group from the SMART trial (Fischgrund et al 2020). 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). Data for Oswestry Disability Index outcomes were not available for the sham group because of the high crossover rate. Therefore, long-term comparative outcomes are not available.

Five-year results were reported for the 100 U.S. patients from the treatment arm from the original SMART trial who were available for follow-up (Fischgrund et al 2020). Mean Oswestry Disability Index scores improved from 42.8 to 16.9 at 5 years, a reduction of 25.9 points. Mean reduction in visual analog scale score was 4.4 points (baseline 6.7, $p<.001$).

The INTRACEPT trial was an open-label RCT conducted at 20 U.S. sites (Khalil et al 2019). A total of 140 patients with lower back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized to undergo radiofrequency ablation of the basivertebral nerve or continue standard care. Standard care consisted of pain medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections; the specific treatment(s) administered were determined by the treating investigator in conjunction with the patient. Treatment of up to 4 vertebrae in non-consecutive levels from L3 to S1 was allowed. The primary study endpoint was change in Oswestry Disability Index at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3-month follow-up (n=51 in the treatment group and n=53 in the standard care group), and reported statistically significant differences between groups on all patient-reported outcome measures, favoring the treatment group. The study was halted, and the individuals were allowed to cross over to the treatment arm. Study limitations include short term follow-up, lack of a sham group, and allowance of crossover at 3 months.

Twelve-month follow-up results were reported from the INTRACEPT trial; after a median of 175 days post randomization, 92% of patients initially randomized to the standard care arm elected to receive early treatment with basivertebral nerve ablation (Smuck et al 2021). Six-month results for the Oswestry Disability Index were significantly improved with basivertebral nerve ablation (n=66) compared to standard care (n=74) (least squares mean difference between groups, -24.5; 95% CI, -29.4 to -19.6; p=.0001). Improvements in the Oswestry Disability index and mean visual analog scale that were reported among patients initially treated with basivertebral nerve ablation were maintained throughout the 12-month study period, with reported reductions of -25.7±18.5 points, and -3.8±2.6 cm, respectively (p<.001 for both comparisons to baseline). Improvements in pain, function, and quality of life were reported at 24 months; however, these results were also not comparative (Koreckij et al 2021). The lack of comparative data beyond 6 months due to the high rate of crossover is a limitation of this trial.

Details of the SMART and INTRACEPT trials can be found below in Table 1 and Table 2.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Fischgrund et al (2018); SMART	US, Germany	15	2011-2014	Skeletally mature patients with ≥6 months of isolated lumbar pain unresponsive to ≥6 months nonoperative management	BVN ablation (n=147)	Sham control (n=78)
Khalil et al (2019); INTRACEPT	US	20	2017-2019	Skeletally mature patients with ≥6 months of isolated lumbar pain unresponsive to ≥6 months nonoperative management	BVN ablation (n=51)	Standard care (n=53)

BVN: basivertebral nerve; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results^a

Study		Oswestry Disability Index, LS mean change from baseline	Visual Analog Scale score, LS mean change from baseline	SF-36 PCS score, LS mean change from baseline
Fischgrund et al (2018)	n			
BVN ablation	147	-19.0	-2.76 cm ^b	9.17 ^b
Sham control	78	-15.4	-2.16 cm ^b	7.63 ^b
p value		.107	.038 ^b	NS ^b

Study		Oswestry Disability Index, LS mean change from baseline	Visual Analog Scale score, LS mean change from baseline	SF-36 PCS score, LS mean change from baseline
Khalil et al (2019); INTRACEPT				
BVN ablation	51	-25.3	-3.46	14.021
Standard care	53	-4.4	-1.02	2.114
Difference between arms, (95% CI)		-20.9 (-27.0 to -14.7)	-2.44 (-3.36 to -1.53)	11.907 (9.035 to 14.780)
p value		<.001	<.001	<.001

BVN: basivertebral nerve; CI: confidence interval; LS: least squares; NS: not significant; PCS: physical component summary; SF-36: 36-item short form health survey.

a Results displayed are for the intent-to-treat population at 3 months unless otherwise specified.

b Results are for the per protocol population at 12 months.

Limitations of the SMART and INTRACEPT trials are described in Table 3 and 4 below.

Table 3. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Fischgrund et al (2018)					
Khalil et al (2019)			1. Not clearly defined		2. Outcomes reported at 3 months

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 4. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Fischgrund et al (2018)				3. High number of crossovers 6. Per protocol analysis of secondary outcomes		

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Khalil et al (2019)		1,2. Open-label design				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers;

4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Prospective Observational Study

McCormick et al (2025) published a single-arm, prospective cohort study evaluating the effectiveness of basivertebral nerve radiofrequency ablation using the Intracept System in 60 adults with vertebrogenic low back pain lasting at least 6 months and associated with Type 1 or Type 2 Modic changes on lumbar MRI. Eligible participants had clinically suspected vertebrogenic low back pain unresponsive to at least 6 months of conservative care and underwent basivertebral nerve radiofrequency ablation at L2-S1 spinal levels exhibiting Modic changes. The primary outcome was mean improvement in Oswestry Disability Index score. Among 60 participants, mean Oswestry Disability Index score improvement was 13.9 ± 18.7 at 3 months and 14.0 ± 15.7 at 12 months. At 12 months, 52.8% achieved $\geq 30\%$ Oswestry Disability Index score improvement (95% CI, 39.7 to 65.6) and 39.6% achieved ≥ 15 -point improvement (95% CI, 27.6 to 53.1). Four procedure-related adverse events occurred, including one serious event (L5 radiculopathy with residual weakness).

Section Summary: Intraosseous Basivertebral Nerve Ablation

Two RCTs have been conducted to assess the efficacy of basivertebral nerve ablation for treatment of vertebrogenic back pain. One RCT did not find a difference in the Oswestry Disability Index between patients treated with basivertebral nerve ablation or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. A second RCT found a significant difference in the Oswestry Disability Index and other pain scores between patients treated with basivertebral nerve ablation and standard care at 3 months. Comparative data at 6 months post randomization showed similar results. However, 92% of patients initially assigned to standard care elected to cross over to receive early basivertebral nerve ablation, thus, long-term comparative data beyond 6 months are not available. Additional limitations to this RCT include lack of a sham control. In a small (n=60) prospective single-arm cohort, more than half of participants with vertebrogenic low back pain achieved at least a 30% improvement in Oswestry Disability Index score 12 months after treatment with basivertebral nerve radiofrequency ablation.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience (ASPN) released guidelines on interventional treatments for low back pain. Regarding basivertebral nerve ablation, the Society recommends basivertebral nerve ablation (Grade A with Level of Certainty 1a) for patients with axial lower back pain of vertebrogenic nature.

International Society for the Advancement of Spine Surgery

In 2022, the International Society for the Advancement of Spine Surgery published updated guidelines on intraosseous basivertebral nerve ablation. The guideline was informed by a systematic review which included 2 randomized controlled trials (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 indicated for individuals with chronic low back pain when all the following criteria are met:

- Chronic low back pain 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).

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. U.S. Food & Drug Administration. K213836 Intrasept Intraosseous Nerve Ablation System 510k Summary. 2022.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213836>
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2. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. May 2018; 27(5): 1146-1156. PMID 29423885

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	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)
HCPCS		
		None
Type of Service	Surgery	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
September 2026	Interim Review	Policy Revised – Content moved from medical policy “07.01.90 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty and Biacuplasty”

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
 Medical Policy Analyst
 PO Box 9232
 Des Moines, IA 50306-9232

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