Molina Clinical Policy
Intraosseous Basivertebral Nerve Ablation: Policy No. 452

Last Approval: 4/10/2024
Next Review Due By: April 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Chronic low back pain (CLBP), a leading cause of disability in the United States, is defined as persistent pain of the lower back lasting more than 12 consecutive weeks. Historically CLBP is diagnosed as “nonspecific” and managed with broad treatments that are often costly and ineffective in the long term. An increasing body of evidence has arisen highlighting the vertebral endplates as a significant source of CLBP. Pain fibers in the vertebral endplates trace back to the basivertebral nerve located within the vertebral body and proliferate with endplate damage, resulting in vertebrogenic CLBP, of which an estimated 15% of CLBP patients primarily suffer. Vertebrogenic CLBP can be diagnosed via MRI showing Type 1 or Type 2 Modic changes, which are associated with higher levels of disability and more severe CLBP (Lorio 2022).

Intraosseous Basivertebral Nerve Ablation (BVNA) is a minimally invasive procedure that targets the nocioreceptors in the vertebral endplates between L3 and S1 that send pain signals through the basivertebral nerve to the central nervous system, contributing to severe CLBP. BVNA is performed in the outpatient setting and is completed via cannula insertion under fluoroscopic guidance to the basivertebral nerve trunk, once the cannula reaches the destination a radiofrequency probe is inserted and heated until the appropriate ablation zone is achieved. This ablation is repeated at each vertebral body identified as a source of pain (Tieppo Francio and Sayed 2023). Currently the Intracept Intraosseous Nerve Ablation System is the only FDA approved system for this specific procedure. Per the FDA approval document the Intracept 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”.

Regulatory Status

While intraosseous BVNA is a procedure, and thus not FDA regulated, any instruments utilized in the procedure are regulated and must be approved. The Intracept Intraosseous Nerve Ablation System by Relievant Medsystems Inc. (Redwood City, CA) received FDA approval on July 9, 2016, through the 510(k) Premarket approval process under product code GXI and 510(k) number K153272. It is classified as a radiofrequency lesion probe.

COVERAGE POLICY

Intraosseous Basivertebral Nerve Ablation is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Nwosu et al. (2023) conducted a systematic review evaluating the effectiveness of intraosseous basivertebral nerve ablation (BVNA) in the treatment of non-radiating vertebrogenic chronic low back pain (CLBP). The authors analyzed 11 publications for a total of 413 patients, these publications were comprised of one systematic review, one meta-analysis, three prospective randomized double-blinded studies, three prospective randomized open-label studies, one prospective single-arm, one randomized single-blinded, and one narrative review. The key outcome analyzed was the percentage of patients with greater than or equal to 50% pain reduction, greater than or equal to 10-point improvement in function and disability measured by the Oswestry Disability Index (ODI), greater than or equal to two-point pain reduction in the visual analog scale (VAS) or numerical pain rating scale, and a decrease in opioid utilization by 10 morphine milligram equivalents. Among the quantifiable data, most of the participants reported greater than or equal to 10-point improvement in the ODI, and greater than or equal to two-point improvement in the VAS at the three month follow up. In all studies adverse events were rare, however the authors noted that more adverse events may be observed when BVNA becomes a standard procedure. The review noted that all studies except for one systematic review were industry sponsored, thus increasing the risk for reporting and publication bias. The review also comments on the lack of meta-analyses due to the scarcity of quality RCTs. The authors conclude that based on current evidence, the novel procedure of BVNA is a safe and effective treatment for vertebrogenic CLBP.

Conger et al. (2022) published an updated systematic review with single – arm meta-analysis evaluating the effectiveness of intraosseous BVNA for the treatment of vertebrogenic low back pain. The key outcome analyzed was a 50% or more improvement in VAS, with a secondary outcome analysis of a 15 point or greater improvement in ODI score. Twelve publications, for a total of 414 participants, were analyzed. Single-arm meta-analysis showed 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. Rates of ≥15-point ODI score improvement were 75% (95% CI 63–86%) and 75% (95% CI 63–85%) at 6 and 12 months, respectively. The authors concluded there is moderate evidence supporting the efficacy of BVNA in treating vertebrogenic CLBP; however, it is emphasized there is a small pool of data and that larger high quality RCTs are needed to further assess the safety and efficacy of this procedure.

Koreckij et al. (2021) published a prospective open label single arm randomized multicenter clinical study evaluating intraosseous BVNA with two year follow up results. One hundred and forty participants were randomized, 66 to BVNA and 74 to standard care. The primary endpoint was improvement in patient ODI score. VAS, and Short Form Health Survey (SF-36) scores were taken at baseline and in follow up as well. The secondary endpoint was to review target success of the procedure via an MRI at 6 weeks post BVNA procedure. At a retention rate of 88%, 58 BVNA participants completed the 24 month follow up. At baseline, 67% had back pain for >5 years, 36% were actively taking opioids, 50% had prior epidural steroid injections, and 12% had prior low back surgery. Improvements in ODI, VAS, and SF-36 were statistically significant at all timepoints through 2 years. Participants reported a mean improvement in ODI of 28.5 ± 16.2 points (from a paired baseline of 44.5 to 16.0; $p < 0.001$) and mean improvement in VAS of 4.1 ± 2.7 cm (from 6.6 to 2.5; $p < 0.001$) at 2 years post ablation. A 50% or greater reduction in pain was reported in 72.4% of patients, 31.0% were pain-free, and 62% fewer patients were actively taking opioids. Patient satisfaction results revealed 79% of BVNA patients reported improvement of their condition, 21% reported no change in their condition at 71% of the patients reported they had returned to the level of activity that they enjoyed prior to having low back pain, and 84% indicated they would have the procedure again. There were no serious device or device-procedure related adverse events reported at any point during the study period.

De Vivo et al. (2020) conducted a prospective experimental uncontrolled trial evaluating the efficacy of intraosseous BVNA in the treatment of vertebrogenic chronic low back pain. The primary end point was to evaluate pain and disability levels following BVNA, with a secondary endpoint of assessing the feasibility and safety of a percutaneous CT guided technique. Fifty-six percutaneous CT-guided BVNA procedures were performed utilizing an articulating bipolar radiofrequency electrode, with a mean operative time of 32 minutes. At one month post procedure an MRI was performed to evaluate the ablation area to assess the target success of the procedure, and at 3-months post procedure a CT study was performed to evaluate bone mineral density to exclude structural bone abnormalities that might have been induced by the treatment. Pre- and post-procedure pain and disability levels were measured using the VAS and ODI. At 3- and 12-month follow-up, VAS and ODI scores decreased significantly compared to baseline. Clinical success was reached in 54/56 patients (96.5%) for pain, defined as a 2-point improvement threshold; and 54/56 patients (96.5%) for disability, defined as a 10-point improvement threshold. CT-assisted targeting of the ablation zone

was determined successful in 100% of patients. There were no complications reported in the immediate post – operative or follow up phases. The results led authors to conclude that percutaneous CT guided BVNA is a safe and effective procedure treating vertebrogenic CLBP.

The SMART Trial
Fischgrund et al. (2018) conducted a prospective randomized double-blind sham controlled multi-center clinical trial to study intraosseous BVNA for the treatment of CLBP. The primary objective was to evaluate the safety and efficacy of using RF energy to ablate the BVN for the treatment of chronic axial low back pain. All participants had to be skeletally mature with CLBP of 6 or more months, isolated lumbar pain refractory to 6 months standard treatment, Type 1 or Type 2 Modic changes on MRI, and report a minimum ODI of 30 points (100-point scale) and a minimum VAS of 4 cm (10 cm scale). Two hundred and twenty-five patients were randomized in a 2:1 block, 78 to sham and 147 to treatment. To maintain blinding, the treating and follow-up physicians differed. At 1 year, patients in the sham arm were permitted to cross-over to the active treatment. Targeting, defined as overlap between the RF created ablation zone and the terminus of the BVN at each level treated observed on 6-week post procedure MRI, was successful in 129 of 145 patients (89.0%) or in 300 of 317 treated vertebral bodies (94.6%). At the 3-month follow up the treatment group exhibited a 20.5-point improvement in ODI compared to a 15.2-point improvement in the sham group ($p = 0.019$), and a 2.97 cm improvement in VAS scores compared to 2.36 in the sham group. The improvement in VAS in the treatment arm was 3.04, and 2.84 cm at 6, and 12 months, respectively; compared to 2.08, and 2.08 cm at 6, and 12 months, respectively in the sham group ($p = 0.083$, 0.008, and 0.038). The safety profile revealed no device- or procedure-related patient deaths, unanticipated adverse device effects, nor device-related serious adverse events. Eight procedure-related events were reported in six patients, two of which were in the sham group, for a complication rate of 2.7%. The authors concluded that using a 10-point ODI improvement as a threshold, 75.6% of treatment arm patients as opposed to 55.3% of sham arm patients were characterized as responders. The publication highlighted placebo affect research and emphasized that comparison of the difference in outcome score between the sham and treatment groups does not represent the clinical utility of BVNA because a sham treatment is not a clinically acceptable treatment for CLBP, nor is a sham response likely to occur in an open label setting. The authors urged that the overall therapeutic value of the procedure should be viewed through its safety profile and observed improvements from patient baseline, to which the results of the study supported BVNA as a minimally invasive treatment for CLBP.

The 2 year follow up results of the SMART trial were published by Fischgrund et al. (2019) to include follow up on the 57 (73% of the original 78) sham group participants that elected to cross over into the treatment arm after one year, for a total of 117 participants successfully treated with BVNA. The primary outcomes evaluated were ODI and VAS scores. The mean percent improvements in ODI and 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 patients showing clinically meaningful improvements in both: ODI ≥ 10-point improvement in 76.4% of patients and ODI ≥ 20-point improvement in 57.5%; VAS ≥ 1.5 cm improvement in 70.2% of patients.

The 5 year follow up results of the SMART trial were published by Fischgrund et al. (2020) to reveal that 100 of the 117 treated participants (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. Overall responder rate at 5 years was 75% using thresholds of ≥ 15-point ODI and ≥ 2-point VAS for function and pain.

National/Specialty Organizations

The **International Society for the Advancement of Spine Surgery (ISASS)** issued a policy statement supporting intraosseous BVNA. Lorio et al. (2022) highlighted the growing evidence for vertebrogenic origins of CLBP, and the addition of medical codes for BVNA, as well as designated vertebrogenic codes in the *International Classification of Diseases, 10th revision, Clinical Modification.* The guideline went on to summarize the current evidence supporting BVNA, and stated "Collectively, the studies reviewed demonstrate that BVNA provides clinically meaningful improvements in pain and function at 5+ years with an excellent safety profile. This evidence supports BVNA as a treatment option for a well-defined subpopulation of CLBP patients." The policy statement ended with indications and contraindications for the BVNA procedure.

The **American Society of Pain and Neuroscience (ASPN)** published an evidence based clinical guideline of interventional treatment for low back pain. Sayed et al. (2022) summarized the various current treatment modalities for CLBP, their indications, and safety profiles. The clinical guideline supported the use of intraosseous BVNA at the

L3 through S1 vertebrae for the treatment of vertebrogenic CLBP in patients with pain refractory to conservative treatment for at least 6 months, and with evidence of vertebral endplate change on MRI. The guideline reported the adverse event rate is quite low for BVNA, with the most commonly reported adverse event being minor and self-limiting issues, such as incisional pain and transient worsening of back pain. The guideline assigned a Grade A recommendation (The ASPN Back Group recommends the service. There is high certainty that the net benefit is substantial.) with Level 1a Certainty (At least one controlled and randomized clinical trial, properly designed).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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)

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/10/2024 New policy. IRO Peer Review on March 31, 2024, by a practicing physician board-certified in Orthopedic Surgery and Spine Surgery.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed March 22, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx.
2. Conger A, Burnham TR, Clark T, Teramoto M, McCormick ZL. The Effectiveness of Intraosseous Basivertebral Nerve Radiofrequency Ablation for the Treatment of Vertebrogenic Low Back Pain: An Updated Systematic Review with Single-Arm Meta-analysis. Pain Med. 2022 Jul 20;23(Suppl 2): S50-S62. doi: 10.1093/pm/pnac070. PMID: 35856331; PMCID: PMC9297160.
3. De Vivo AE, D'Agostino G, D'Anna G, Al Qatami H, Gil I, Ventura F, Manfrè L. Intra-osseous basivertebral nerve radiofrequency ablation (BVA) for the treatment of vertebrogenic chronic low back pain. Neuroradiology. 2021 May;63(5):809-815. doi: 10.1007/s00234-020-02577-8. PMID: 33051706.
4. Fischgrund JS, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020 Aug;29(8):1925-1934. doi: 10.1007/s00586-020-06448-x. PMID: 32451777.
5. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: 2-Year Results From a Prospective Randomized Double-Blind Sham-Controlled Multicenter Study. Int J Spine Surg. 2019 Apr 30;13(2):110-119. doi: 10.14444/6015. PMID: 31131209; PMCID: PMC6510180.
6. 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. 2018 May;27(5):1146-1156. doi: 10.1007/s00586-018-5496-1. PMID: 29423885.
7. Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results. N Am Spine Soc J. 2021 Oct 26; 8:100089. doi: 10.1016/j.xnsj.2021.100089. PMID: 35141653; PMCID: PMC8820067.
8. Lorio M, Clerk-Lamalice O, Rivera M, Lewandrowski KU. ISASS Policy Statement 2022: Literature Review of Intraosseous Basivertebral Nerve Ablation. Int J Spine Surg. 2022 Dec;16(6):1084-1094. doi: 10.14444/8362. PMID: 36266051; PMCID: PMC9807041.
9. Nwosu M, Agyeman WY, Bisht A, et al. Effectiveness of Intraosseous Basivertebral Nerve Ablation in the Treatment of Nonradiating Vertebrogenic Pain: A Systematic Review. Cureus. 2023 Apr 4;15(4): e37114. doi: 10.7759/cureus.37114. PMID: 37034146; PMCID: PMC10075185.
10. 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 Dec 6; 15:3729-3832. doi: 10.2147/JPR.S386879. Erratum in: J Pain Res. 2022 Dec 24; 15:4075-4076. PMID: 36510616; PMCID: PMC9739111.
11. Tieppo Francio V, Sayed D. Basivertebral Nerve Ablation. StatPearls [Internet]. Treasure Island, FL. Updated May 22, 2023. Accessed March 22, 2024. https://www.ncbi.nlm.nih.gov/books/NBK572127/
12. United States Food and Drug Administration (FDA). 510(k) Premarket Approval: Intracept Intraosseous Nerve Ablation System. Product code

GXI. 510(k) number: K153272. Accessed March 22, 2024. https://www.accessdata.fda.gov.