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MEDICAL POLICY STATEMENT
Michigan Coordinated Health

Policy Name & Number	Date Effective
Intraosseous Basivertebral Nerve Ablation-MI Coordinated Health-MM-1832	11/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

Table of Contents

A. Subject 2
B. Background 2
C. Definitions 2
D. Policy 3
E. Summary of Evidence 4
F. Conditions of Coverage 5
G. Related Policies/Rules 5
H. Review/Revision History 5
I. References 5

A. Subject

Intraosseous Basivertebral Nerve Ablation

B. Background

Interventional procedures for the management of acute and chronic pain are part of a comprehensive pain management care plan that incorporates conservative treatment in a multimodality approach. Multidisciplinary treatments include promoting patient self-management and aim to reduce the impact of pain on a patient's daily life, even if the pain cannot be relieved completely. Interventional procedures for the management of pain unresponsive to conservative treatment should be provided only by providers qualified to deliver these health services.

Chronic low back pain (CLBP) is a common and often debilitating condition, estimated to afflict 80% of adults at some point. Degenerative disc disease (DDD) is an important cause of CLBP. While discs are avascular with limited nerve distribution, vertebral endplates have the potential to trigger a cascade of degenerative events if there is a loss of integrity. Vertebral endplates are a thin interface between bone marrow and discs and contain neural elements. Breakdown of the endplate is believed to cause vertebrogenic chronic low back pain, a type of chronic low back pain. Endplate degeneration can be observed on MRI through Modic changes (MC). Type 1 MC reflect bone marrow edema and inflammation while Type 2 MC represent fatty marrow replacement.

Intraosseous basivertebral nerve ablation (BVNA) is a minimally invasive, image-guided procedure that uses radiofrequency energy to thermally ablate the basivertebral nerve within the vertebral body. The procedure is intended to interrupt nociceptive signaling from the vertebral endplates in individuals with vertebrogenic low back pain.

C. Definitions

- **Chronic Low Back Pain** – Persistent pain in the lumbar region lasting more than 12 weeks.
- **Conservative Therapy** – A multimodality plan of care including both active and inactive conservative therapies.
  - **Active Conservative Therapies** – Actions or activities that strengthen muscle groups and target key spinal structures, including physical therapy, occupational therapy, physician supervised home exercise program (HEP), and/or chiropractic care.
    - **HEP** –A prescribed plan that includes specific goals, frequency, and expected duration, along with a clearly defined timeframe for reassessment (eg, 6 – 12 weeks). Ongoing continuation must be supported by documented clinical progress. Patient inconvenience or noncompliance without explanation does not constitute an inability to complete.
  - **Inactive Conservative Therapies** – Passive activities by the patient that aid in treating symptoms associated with pain, including rest, ice, heat, medical devices, Transcutaneous Electrical Nerve Stimulator (TENS) use, and/or pharmacotherapy (prescription or over the counter [eg, non-steroidal anti-inflammatory drugs, acetaminophen]).

- **Modic Changes** – Vertebral bone marrow signal intensity changes that are observable on MRI and are commonly associated with degenerative disc disease.
  - **Modic Change Type 1** – Characterized by hypo-intense signals on T1-weighted images (T1WI) and hyper-intense signals on T2-weighted images.
  - **Modic Change Type 2** – Characterized by hyper-intense signal intensities on both T1WI and T2WI.
  - **Modic Change Type 3** – Characterized by hypo-intense signal intensities on both T1WI and T2WI.

D. Policy

I. Intraosseous basivertebral nerve ablation (BVNA) is considered medically necessary when **ALL** the following clinical criteria are met:

A. Member has a diagnosis and documentation of low back pain of at least 6 months duration that causes functional deficit measured on a pain or disability scale.

B. Pain is localized primarily to the lumbar spine without predominate radicular symptoms.

C. Failure of conservative therapy, as evidenced by documentation in the medical record of at least 6 weeks of active and inactive conservative therapy (see definition above) within the past 6 months OR inability to complete active conservative therapy due to contraindication, increased pain, or intolerance

D. MRI demonstrates Type 1 or Type 2 Modic changes at one or more vertebral endplates from level L3 to S1, corresponding to the member's pain.

E. Clinical evaluation demonstrates that the member's pain is not primarily attributable to other pain generators, such as symptomatic facet arthropathy, symptomatic lumbar spinal stenosis, or sacroiliac joint dysfunction.

F. Device is FDA-approved (eg, Intracept System).

G. Member does not have any of the following contraindications:

1. severe cardiac or pulmonary compromise
2. active systemic infection or localized infection in the area to be treated
3. current pregnancy
4. skeletal immaturity
5. implantable electronic devices that cannot be safely managed or deactivated during the procedure (eg, pacemaker, defibrillator)
6. spinal abnormality or anatomic considerations that may preclude safe access to the ablation site (eg, malignancy, sensitive structure not intended to be ablated)

II. Repeat or additional intraosseous BVNA is not considered medically necessary, as it has not been adequately studied in peer-reviewed medical literature.

III. Monitored anesthesia and conscious sedation during intraosseous BVNA are considered not medically necessary and will, therefore, not be reimbursed.

IV. Coverage is limited to the above criteria. Intraosseous BVNA is considered not medically necessary for all other indications.

E. Summary of Evidence

Fischgrund et al (2018) conducted a prospective randomized double-blind sham-controlled Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical trial to evaluate the safety and efficacy of radiofrequency ablation (RFA) of the basivertebral nerve (BVN) for the treatment of chronic low back pain. The trial involved 225 patients diagnosed with chronic low back pain at 18 sites across the United States and Europe. Out of the 147 participants treated with RFA of the BVN, the procedure was deemed successful by imaging in 129 of 145 patients (89%) and in 300 of 317 treated vertebral bodies (94.6%).

Fischgrund et al (2019) reported on the 2-year follow up from the SMART Trial. Following the 1-year mark, participants in the sham arm were allowed to cross over; 57 (73%) chose to receive the Intracept intervention. Intra-patient comparison of patient-reported measures from baseline to each follow-up visit were used to evaluated long-term efficacy and treatment durability in RFA arm participants with 24-month data. 106 patients completed a 24-month follow-up visit. Patients exhibited a durable ODI mean improvement of 23.4 points at 24 months compared to the mean improvements observed during the first year of follow up (20.3, 20.8, and 19.8 points at 3, 6, and 12 months, respectively). Using a 10-point improvement in ODI as a commonly accepted minimum clinically important difference in the treatment of chronic low back pain, 75.6% of treated patients existed a successful response at 3 months, which was sustained at 24 months (76.4% of treated patients). VAS improvement was also maintained at 24 months, starting with a baseline of 6.73 cm and improving by 2.76 and 3.59 cm at 12 and 24-months follow-up, respectively. No device or procedure-related patient deaths, unanticipated adverse device effects, or device related serious adverse events were reported.

Khalil et al (2019) reported on the INTRACEPT Trial, a prospective, randomized, multicenter study at 20 US cites which compared the effectiveness of intraosseous basivertebral nerve ablation to standard of care for the treatment of chronic low back pain. The trial involved 140 patients experiencing chronic low back pain for at least 6 months, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, who had failed to respond to conservative therapy. Similar to the SMART Trial, patients were skeletally mature, with a minimum ODI of 30 points and a minimum VAS of 4cm. Patients had a baseline average ODI of 46.1 and VAS of 6.67. Comparing the RFA arm to the standard of care arm, the mean changes in ODI at 3 months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p<0.001$). 74.5% of RFA patients achieved a ≥10-point improvement in ODI, compared with 32.7% in the standard care arm ($p<0.001$). The study demonstrated that RFA of the BVN led to significant improvement of pain and function at 3 months in patients with chronic vertebrogenic related low back pain.

Fischgrund et al (2020) reported on the 5-year outcome for patients in the SMART Trial. Primary outcome was mean change in ODI. 100 patients of the original 117 US participants were available for review at a minimum of 5-years post BVNA. Mean ODI

score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points. Mean reduction of VAS pain score was 4.38 points. 66% of patients reported more than a 50% reduction in pain, 47% reported more than 75% reduction in pain, and 34% of patients reported complete pain resolution. 5-year results indicate a sustained improvement in patients treated with RFA of the BVN for chronic low back pain.

The International Society for the Advancement of Spine Surgery (ISASS) released a guideline in 2020 and subsequently updated its policy statement in 2022 supporting intraosseous BVNA to treat patients with chronic vertebrogenic low back pain. ISASS states that BVNA from L3 through S1 vertebrae may be medically necessary for individuals with low back pain when pain lasted for at least 6 months duration, the individual failed to respond to at least 6 months of nonsurgical management, and MRI demonstrated Type 1 MC or Type 2 MC in at least 1 vertebral endplate at 1 or more levels from L3 to S1.

F. Conditions of Coverage

NA

G. Related Policies/Rules

NA

H. Review/Revision History

	DATE	ACTION
Date Issued	06/18/2025	New market. Approved at Committee.
Date Revised	12/17/2025 08/12/2026	Review: updated references. Approved at Committee. Review: updated HEP and Modic definitions; clarified pain criteria in section D.I.D & E; updated contraindications and background. Approved at Committee.
Date Effective	11/01/2026	
Date Archived		

I. References

1. *Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain*. North American Spine Society; 2020. Accessed June 24, 2026. www.spine.org
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. *Euro Spine J.* 2018;27:1146-1156. doi:10.1007/s00586-018-5496-1
3. 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;13(2):110-119. doi:10.14444/6015
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;29:1925-1934. doi:10.1007/s00586-020-06448-x
5. Health Technology Assessment: Intracept Intraosseous Nerve Ablation System (Relievant Medsystems Inc.) for Treatment of Adults with Low Back Pain. Hayes; 2025. Reviewed November 20, 2025. Accessed June 24, 2026. www.evidence.hayesinc.com
6. Khalil JG, Smuck M, Koreckij T, et al. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. *Spine J*. 2019;19(10):1620-1632. doi:10.1016/j.spinee.2019.05.598
7. Lorio M, Clerk-Lamalice O, Beall DP, Julien T. ISASS guideline: intraosseous ablation of the basivertebral nerve for the relief of chronic low back pain. *Int J Spine Surg*. 2020;14(1):18-25. doi:10.14444/7002
8. Lorio M, Clerk-Lamalice O, Rivera M, Lewandrowski K. ISASS policy statement 2022: literature review of intraosseous basivertebral nerve ablation. *Int J Spine Surg*. 2022;16(6):1084-1094. doi:10.14444/8362
9. McCormick ZL, Curtis T, Cooper A, Wheatley M, Smuck M. Low back pain-related healthcare utilization following intrasosseous basivertebral nerve radiofrequency ablation: a pooled analysis from three prospective clinical trials. *Pain Med*. 2024;25:20-32. doi:10.1093/pm/pnad114
10. Nwosu M, Agyeman WY, Bisht A, et al. The effectiveness of intraosseous basivertebral nerve ablation in the treatment of nonradiating vertebrogenic pain: a systematic review. *Cureus*. 2023;15(4):e37114. doi:7759/cureus.37114
11. Sayed D, Grider J, Strand N, et al. The American Society of Pain and Neuroscience (ASPN) evidence-based clinical guidelines of interventional treatments for low back pain. *J Pain Res*. 2022;15:3728-3832. doi:10.2147/JPR.S386879
12. Sayed D, Naidu RK, Patel KV, et al. Best practice guidelines on the diagnosis and treatment of vertebrogenic pain and basivertebral nerve ablation from the American Society of Pain and Neuroscience. *J Pain Res*. 2022;15:2801-2819. doi:10.2147/JPR.S378544
13. Smuck M, Khalil J, Barrette K, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month result. *Reg Anesth Pain Med*. 2021;46:683-693. doi:10.1136/rapm-2020-102259
14. Smuck M, McCormick ZL, Gilligan C, et al. A cost-effectiveness analysis of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. *Spine J*. 2025;25(2):201-210. doi:10.1016/j.spinee.2024.09.016
15. U.S. Food and Drug Administration. 510(k) Premarket Notification: Intracept Intraosseous Nerve Ablation System, 510(k) approval K222281; 2022. Accessed June 24, 2026. www.accessdata.fda.gov
16. U.S. Food and Drug Administration. 510(k) Premarket Notification: Relievant Medsystems RF Generator, 510(k) number: K171143; 2017. Accessed June 24, 2026. www.accessdata.fda.gov
17. Viswanathan VK, Shetty AP, Rajasekaran S. Modic changes: an evidence-based, narrative review on its pathophysiology, clinical significance and role in chronic low back pain. *J Clin Orthop Trauma*. 2020;11(5):761-769. doi:10.1016/j.jcot.2020.06.025