

MEDICAL POLICY

POLICY TITLE	INTRAOSSIOUS BASIVERTEBRAL NERVE ABLATION
POLICY NUMBER	MP 1.124
CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	6/1/2026

POLICY

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered **investigational**.

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

Discogenic Low Back Pain

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures. Pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

MEDICAL POLICY

POLICY TITLE	INTRAOSSIOUS BASIVERTEBRAL NERVE ABLATION
POLICY NUMBER	MP 1.124

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.

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 (Relieva 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).” FDA product code: GXI.

RATIONALE

Summary of Evidence

For individuals who have vertebrogenic back pain who receive intraosseous ablation of basivertebral nerves, the evidence includes 2 RCTs (the SMART and INTRACEPT trials). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The SMART trial 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 is not available. The INTRACEPT trial 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

MEDICAL POLICY

POLICY TITLE	INTRAOSSIOUS BASIVERTEBRAL NERVE ABLATION
POLICY NUMBER	MP 1.124

DEFINITIONS

ANNULAR LAMELLAE are circular plates of collagen fibers found in secondary (mature, adult) bone.

INTERVERTEBRAL DISC is the fibrocartilaginous tissue between the vertebral bodies. The outer portion is the annulus fibrosus; the inner portion is the nucleus pulposus. The disc is the shock absorber, or cushion, and permits movement.

NOCICEPTORS are free nerve endings that are receptors for painful stimuli.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational and therefore not covered:

Procedure Codes							
64628	64629						

REFERENCES

1. U.S. Food & Drug Administration. K213836 Intracept Intraosseous Nerve Ablation System 510k Summary. 2022
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
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

MEDICAL POLICY

POLICY TITLE	INTRAOSSIOUS BASIVERTEBRAL NERVE ABLATION
POLICY NUMBER	MP 1.124

- Double-Blind Sham-Controlled Multicenter Study. Int J Spine Surg. Apr 2019; 13(2): 110-119. PMID 31131209*
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. Aug 2020; 29(8): 1925-1934. PMID 32451777*
 5. *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. Oct 2019; 19(10): 1620-1632. PMID 31229663*
 6. *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 results. Reg Anesth Pain Med. Aug 2021; 46(8): 683-693. PMID 34031220*
 7. *Koreckij T, Kreiner S, Khalil JG, et al. 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. Dec 2021; 8: 100089. PMID 35141653*
 8. *Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. Pain Physician. Apr 2013;16(2 Suppl):S49-S283. PMID 23615883*
 9. *Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. Jan 2007;10(1):7-111. PMID 17256025*
 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; 15: 3729-3832. PMID 36510616*
 11. *Lorio M, Clerk-Lamallice O, Beall DP, et al. International Society for the Advancement of Spine Surgery Guideline-Intraosseous Ablation of the Basivertebral Nerve for the Relief of Chronic Low Back Pain. Int J Spine Surg. Feb 2020; 14(1): 18-25. PMID 32128298*
 12. *Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11)*

POLICY HISTORY

MP 1.124	05/12/2020 Consensus Review. No change to policy statements. References and Summary of Evidence section updated. Language under Disclaimer, Product Variations and Benefit Variations sections revised. Coding reviewed.
	03/18/2021 Consensus Review. No change to policy statement. References updated.
	12/01/2021 Administrative Update. New codes 64628 and 64629 added to policy. Effective 01/01/2022.
	05/26/2022 Minor Review. Policy title changed to include Intraosseous Basivertebral Nerve Ablation. Policy statement updated to include “Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered investigational”. FEP language updated. Background, Rationale and References revised.

MEDICAL POLICY

POLICY TITLE	INTRAOSSIOUS BASIVERTEBRAL NERVE ABLATION
POLICY NUMBER	MP 1.124

	05/30/2023 Consensus Review. No change to policy statement. Background, Rationale and References updated.
	05/31/2024 Consensus Review. No change to policy statement. References updated.
	05/13/2025 Consensus Review. No change to policy statement. Benefit Variation and Disclaimer updated. Reference added.
	07/23/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	01/07/2026 Minor Review. Policy title changed to Intraosseous Basivertebral Nerve Ablation. Indications for Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty were removed, along with CPT codes 22526 and 22527. Background, Rationale and References updated.

Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company[®], Capital Advantage Assurance Company[®] and Keystone Health Plan[®] Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies