

Geisinger Health Plan Policies and Procedure Manual

Policy: MP371

Section: Medical Policy

Subject: Intraosseous Basivertebral Nerve Ablation

Applicable Lines of Business

Commercial	x	CHIP	X
Medicare	х	ACA	Х
Medicaid	х		

I. Policy: Intraosseous Basivertebral Nerve Ablation

II. Purpose/Objective: To provide a policy of coverage regarding Intraosseous Basivertebral Nerve Ablation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
into account both the functional capacity of the Member and those functional capacities that are appropriate for
Members of the same age.

DESCRIPTION:

Intraosseous radiofrequency ablation of the basivertebral nerve is a minimally invasive procedure for members with chronic vertebrogenic pain. Also known as the Intracept Intraosseous Nerve Ablation System, the procedure is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae.

CRITERIA FOR COVERAGE: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR or Designee

Intraosseous radiofrequency ablation of the basivertebral nerve may be considered for coverage when **ALL** of the following criteria are met:

- Member is skeletally mature (age >18 years old), AND
- Chronic low back pain for at least 6 months, AND
- Failure to respond to at least 6 months of conservative therapy (NSAIDS and/or acetaminophen; AND physical therapy) with documentation of the types of treatments, **AND**
- MRI demonstrates Type 1 or Type 2 Modic changes* in at least one vertebral endplate at one or more vertebrae from L3 to S1, AND
- Activities of daily living limited due to persistent low back pain

Type 1 – Vascular development in the vertebral body, inflammation and edema, vertebral endplate changes, vascularized fibrous tissues within the adjacent marrow, hypointensive signals.

Type 2 – Changes in the vertebral body's bone marrow including replacement of normal bone marrow by fat, and hyperintensive signals.

LIMITATIONS:

Repeat procedures will be considered at a frequency no sooner than 12 months.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

^{*} There are 2 types of Modic changes found on Magnetic Resonance Imaging (MRI):

REFERENCES:

Khalil, JG, Smuck, M, Koreckij, T, Keel, J, Beall, D, Goodman, B, Kalapos, P, Nguyen, D, 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.

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Fischgrund, JS, Rhyne, A, Franke, J, Sasso, R, Kitchel, S, Bae, H, Yeung, C, Truumees, E, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. European Spine Journal. 2018;27(5):1146-1156.

Fischgrund, JS, Rhyne, A, Franke, J, Sasso, R, Kitchel, S, Bae, H, Yeung, C, Truumees, E, 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.

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Truumees, E, Macadaeg, K, Pena, E, Arbuckle, J, Gentile, J, Funk, R, Singh, D, and Vinayek, S. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. European Spine Journal. 2019;28(7):1594-1602.

Macadaeg, K, Truumees, E, Boody, B, Pena, E, Arbuckle, J, 2nd, Gentile, J, Funk, R, Singh, D, et al. A prospective, single arm study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. N Am Spine Soc J. 2020;3:100030.

Becker, S, Hadjipavlou, A, and Heggeness, MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. Spine J. 2017;17(2):218-223.

International Society for the Advancement of Spine Surgery Guideline. Lorio M, Clerk-Lamalice O, Beall DP, Julien T. 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. 2020 Feb 29;14(1):18-25.

Lorio M, Clerk-Lamalice O, Beall DP, Julien T. 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. 2020 Feb 29;14(1):18-25.

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Medical Device Reports for FDA MAUDE online database.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/23

Revised:

Reviewed:

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.