Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Basivertebral Nerve Ablation

Effective: January 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care Plan – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 888-609-0692

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

The basiverterbal nerve (BVN) is a nerve found within the bones of the spine, the nerve enters the posterior of the vertebrae and sends nerve branches to the vertebral endplates. Pain at the vertebral endplates, transmitted by the BVN, is called vertebrogenic pain, which is a distinct form of chronic low back pain. These endplates serve as a protective layer between the vertebrae and disc and pain can occur at these endplates when the ends of the BVN nerves become damaged or inflamed. Vertebrogenic pain needs to be diagnosed by imaging that show inflammation of the vertebral endplates.

The Intracept procedure is a treatment option to treat vertebrogenic pain. Intracept Intraosseous Nerve Ablation System (Relievant Medsystems Inc.) is used to perform intraosseous basivertebral nerve radiofrequency (RF) neurotomy. This is a minimally invasive approach to access and ablate the basivertebral nerve (BVN) in the outpatient setting. Previously the standard treatment for vertebrogenic pain included conventional non-surgical options.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan Members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For Tuft's Health One Care plan Members, the following criteria is used: LCD - Intraosseous Basivertebral Nerve Ablation (L39642) and Article - Billing and Coding: Intraosseous Basivertebral Nerve Ablation (A59466).

Clinical Guideline Coverage Criteria

The Plan considers basivertebral nerve ablation as reasonable and medically necessary when ALL the following criteria are met:

1. Member is at least 18 years of age with documented skeletal maturity by the treating spine specialist; **and**
2. Member has vertebrogenic lower back pain between L3 to S1 that has lasted for more than 6 months; **and**
3. Member has documentation from the interpreting radiologist and treating spine specialist noted in the MRI report showing Modic type 1 (Modic Type 1 is defined as findings of inflammation and edema while there are no trabecular damage or marrow changes) or Modic Type 2 (Modic Type 2 is defined as changes in bone marrow and that marrow is substituted with fat) changes at one or more of the vertebral endplates at one or more level(s) between L3 to S1; **and**
4. Member has tried and failed at least 6 months of other conventional treatment options to treat their vertebrogenic pain, such as but not limited to, physical therapy, pharmaceuticals, and/or injections.

Note- only 4 levels are covered per lifetime.

Limitations

The Plan will not cover basivertebral nerve ablation in any of the following conditions:

1. Member is pregnant.
2. Unless all other low back/spinal conditions (i.e. symptomatic lumbar stenosis, osteoporosis, spinal infection, active/past spinal tumors, pain arising from lumbar radiculopathy, disc extrusion/ herniation or stenosis) that could impact the vertebrae at the treatment level that is being requested have been ruled out;
3. Member has previously received basivertebral nerve ablation for the spinal level of treatment that is being requested.
4. Member has a BMI>40 unless the member has documentation that their weight is not the main contributing factor for the members chronic low back pain.
5. Member has an active spinal cord stimulator.
6. Member is seeking basivertebral nerve ablation on any level outside of L3 to S1.
7. Member has a severe cardiac or pulmonary compromise.
8. Member has Modic type 3 (sclerotic change and endplate thickening) changes shown on MRI imaging.
9. Member has an active systemic infection or a local infection in the area that is to be treated at the time of the procedure.
10. Member has radiograph evidence of:
    a. Facet arthrosis or facet effusion at any lumbar level that correlates with clinical evidence of facet mediated low back pain
    b. a disc extrusion or disc protrusion more the 5mm at any level
    c. spondylolisthesis 2mm or great at any level
    d. Spondylolysis at any level unless statement by treating physician that this is not a cause of pain
11. Member has had previous lumber spine surgery at the level intended to be treated.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first two vertebral bodies, lumbar or sacral.
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral

References:

1. Basivertebral nerve ablation for the treatment of chronic low back pain in a community practice setting: 6 Months follow-up. Schnapp, William et al. North American Spine Society Journal (NASSJ), Volume 14, 100201

2. 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(8):1925-1934. doi:10.1007/s00586-020-06448-x
3. INTRACEPT: A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain. ClinicalTrials.gov. October 17, 2018. Accessed October 2, 2024. https://clinicaltrials.gov/ Prot_SAP_000.pdf (clinicaltrials.gov).
4. Lorio, M., Clerk-Lamalice, O., Beall, D. P., & Julien, T. (2020). International Society for the Advancement of Spine Surgery Guideline-Intraosseous Ablation of the Basivertebral Nerve for the Relief of Chronic Low Back Pain. *International journal of spine surgery*, *14*(1), 18–25. https://doi.org/10.14444/7002
5. Sayed, D., Naidu, R. K., Patel, K. V., Strand, N. H., Mehta, P., Lam, C. M., Tieppo Francio, V., Sheth, S., Giuffrida, A., Durkin, B., Khatri, N., Vodapally, S., James, C. O., Westerhaus, B. D., Rupp, A., Abdullah, N. M., Amirdelfan, K., Petersen, E. A., Beall, D. P., & Deer, T. R. (2022). Best Practice Guidelines on the Diagnosis and Treatment of Vertebrogenic Pain with Basivertebral Nerve Ablation from the American Society of Pain and Neuroscience. *Journal of pain research*, *15*, 2801–2819. https://doi.org/10.2147/JPR.S378544
6. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results Koreckij, Theodore et al. North American Spine Society Journal (NASSJ), Volume 8, 100089
7. Procedure details - the intracept procedure by relievant. The Intracept Procedure by Relievant - That's Living Proof. January 2, 2024. Accessed August 28, 2024. https://www.relievant.com/intracept/procedure-details/.
8. Wpengine. Relievant Medsystems, Inc. receives FDA 510(k) clearance for INTRACEPT® for the relief of chronic low back pain - the intracept procedure by relievant. The Intracept Procedure by Relievant - That's Living Proof. May 4, 2022. Accessed August 28, 2024. https://www.relievant.com/relievant-medsystems-inc-receives-fda-510k-clearance-for-intracept-for-the-relief-of-chronic-low-back-pain/#:~:text=Relievant%20Medsystems%2C%20Inc.%2C%20a,%C2%AE%20Intraosseous%20Nerve%20Ablation%20System.

Approval And Revision History

October 17, 2024: Reviewed by the Medical Policy Approval Committee (MPAC) effective January 1, 2025

December 13, 2024: Reviewed and Approved by the UM Committee effective January 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.