KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Basivertebral Nerve Ablation

- Intracept® Intraosseous Nerve Ablation System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Intraosseous Basivertebral Nerve Ablation (L39644)
Local Coverage Article (LCA)	Billing and Coding: Intraosseous Basivertebral Nerve Ablation (A59468)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Basivertebral nerve ablation (BVN), such as with the Intracept System (Relievant Medsystems Inc.), is intended to relieve chronic low back pain (CLBP) thought to be due to vertebrogenic causes by inhibiting the transmission of pain signals (Freburger et al., 2009).

The Intracept Procedure is a treatment option for patients who have not had adequate pain relief with conservative therapy. The minimally invasive procedure can be performed in the outpatient setting. Treatment-refractory CLBP and magnetic resonance imaging–detected Modic 1 or Modic 2 changes are listed as key indications by the manufacturer and were inclusion criteria in the identified studies. In the reviewed clinical studies, patients with symptomatic spinal stenosis, radiculopathy, disk protrusion, or spondylolisthesis were excluded.

The Intracept System consists of the Intracept Introducer Cannula, the Intracept Curved Cannula, the Intracept Radiofrequency Probe, and the Intracept Radiofrequency Generator. According to Relievant Medsystems Inc., the cannula is inserted via minimally invasive procedure under fluoroscopic guidance through the pedicle using a transpedicular approach. The Curved Cannula is then passed through the Introducer to create a channel to the trunk of the BVN. Next, the Radiofrequency Probe is inserted via the Curved Cannula and placed at the BVN.

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Bipolar radiofrequency (RF) energy is provided using the Radiofrequency Generator to accomplish the thermal ablation of the BVN. The RF destruction of the BVN is intended to stop the transmission of pain.

Insights

Clinical studies consistently indicate benefits in patient-oriented outcomes after the Intracept System was used to treat chronic low back pain (CLBP) believed to be due to vertebrogenic origin; however, a randomized controlled trial (RCT) did not convincingly indicate advantages over sham. A second RCT did find short-term treatment advantages over continued standard care; however, given the placebo response observed in the sham-controlled RCT, the findings of this open-label study should be interpreted carefully. Although 1 spine specialty society noted Intracept may be considered, no other guidance documents were identified and payer policies are generally unfavorable, possibly due to the lack of comparative research convincingly demonstrating advantages over treatment alternatives.

Reference

Hayes. Hayes Evolving Evidence Review. Intracept Intraosseous Nerve Ablation System (Relievant Medsystems) for Treatment of Adults with Low Back Pain. Dallas, TX: Hayes; July 9, 2020. Retrieved April 20, 2021 from https://evidence.hayesinc.com/report/eer.intraceptlbp4481.

Medical Technology Assessment Committee (MTAC)

Intraosseous Radiofrequency Basivertebral Nerve Ablation for the Treatment of Adults with Chronic Vertebrogenic Low Back Pain

06/24/2022: INTC Review

Evidence Conclusion: Low-certainty evidence from two RCTs, two open-label extensions, two prospective case series, and one post-hoc RCT analysis (Total N = 429 patients; 330 patients received Intracept and had data analyzed) demonstrate that the Intracept procedure improved function, pain, and QOL in adults with CLBP (≥6 months) with some patients showing durable and sustained improvements up to 5 years post-procedure. However, these improvements were not significantly different (either statistically or clinically) when compared to sham procedure at 3 months and up to 12 months. Statistically and clinically important differences in these outcomes favoring Intracept were found in one open-label RCT comparing Intracept June 24, 2022 | SCPMG Evidence-Based Medicine Services Page 3 of 35 KAISER PERMANENTE CONFIDENTIAL INFORMATION – internal use only, do not distribute outside of KP to standard care up to 3 months but given the context of no significant differences between Intracept and sham procedure at this timepoint, the results of this RCT must be interpreted with caution. Intracept appears to be relatively safe as no serious adverse events occurred during these clinical trials, but adverse events were not uncommon, with complication rates ranging from 2.7% to 25% among Intracepttreated patients across studies. Complications rates were similar between treatment and control arms in comparative RCTs. One of the most common AEs was postoperative leg pain due to a pedicle breach, often at levels L5 or S1. As with all interventional procedures, the experience of the operator and accurate patient selection will correlate with the safety of the procedure. More rigorous RCTs not funded and/or affiliated with the manufacturer and with longer-term comparative data are needed to validate any findings of benefit of the Intracept procedure over sham or standard care. Additionally, trials evaluating the comparative effectiveness of Intracept compared to other minimally invasive procedures are needed to determine its role among several available interventions for CLBP.

Articles: The Medical Technology Assessment Team (MTAT) reviewed the evidence on intraosseous radiofrequency basivertebral nerve ablation (i.e., Intracept®) for the treatment of chronic low back pain on June 24, 2022. Based on 2 RCTs of two different comparisons, 2 follow-up open-label extensions of these RCTs, 2 prospective case series, and 1 post-hoc RCT analysis, conclusions are limited by the overall low quantity and quality of the body of evidence.

Applicable Codes

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare: Considered Not Medically Necessary

CPT® or HCPC Codes	Description

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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)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/21/2021	05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC], 09/03/2024[MPC]	01/16/2024

[MPC] Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved adoption of non-coverage policy for Basivertebral nerve ablation. Requires 60-day notice, effective October 1, 2021.
01/16/2024	Updated Medicare LCD and Billing coding article for NEW coverage policies for Basivertebral Nerve Ablation Effective 1/28/2024.

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