

**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
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Plan: Keystone First Community HealthChoices	Submission Date: December 27, 2021
Policy Number: CCP.1431	Effective Date: 10/2015 Revision Date: December 7, 2021
Policy Name: Intraosseous basivertebral nerve ablation for low back pain	
Type of Submission – Check all that apply: <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: Please see revisions below using tracked changes.	
Name of Authorized Individual (Please type or print): Akintayo Akinlawon, MD	Signature of Authorized Individual: 



Intraosseous basivertebral nerve ablation for low back pain

Clinical Policy ID: CCP.1431

Recent review date: 12/2021

Next review date: 4/2023

Policy contains: Low back pain, intracept, basivertebral nerve ablation.

AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices and Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Intraosseous basivertebral nerve ablation for low back pain is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Various conservative treatments, medications, and surgical procedures for low back pain.

Background

Low back pain is a very common disorder, affecting 80% of Americans at some point in their lifetime. At any one time, one-quarter of U.S. adults report having the condition. Most cases are acute and do not last more than days or weeks; others are subacute (4 - 12 weeks) or chronic (> 12 weeks). Mechanical causes of low back pain include sprains, strains, intervertebral disc degeneration, herniated discs, ruptured discs, radiculopathy, sciatica, spondylolisthesis, traumatic injury, spinal stenosis, and skeletal irregularities.

The variety of treatments for low back pain include conservative measures (hot/cold packs, activity, strengthening exercises, and physical therapy). Medicinal therapy can be used, including analgesics, non-steroidal anti-inflammatory drugs, anti-convulsants, anti-depressants, and counter-irritants. A variety of surgical interventions are used, with fusion probably the most common method (National Institute of Neurological Disorders and Stroke, 2019).

Up to 15% of patients with low back pain do not respond to treatment and chronically suffer from the condition (Baker, 2015). Moreover, fusion and other surgeries have raised concerns after reports showed elevated rates of complications and re-operations, long periods of rehabilitation, and high costs. Alternative procedures have been developed, one of which is intraosseous basivertebral nerve ablation. The procedure was based on the belief that the origin of low back pain is the vertebral endplate, with pain transmitted via the basivertebral nerves. These nerves are denser in the nociceptors of the endplate region, resulting in greater inflammation transmitted to the central nervous system, resulting in pain (Fischgrund, 2019; Lotz, 2013).

On September 14, 2018, the Food and Drug Administration notified Relievant Medsystems it could market the Intracept Intraosseous Nerve Ablation System. The product is used with radiofrequency generators to ablate basivertebral nerves of the L3 through S1 vertebrae. Approval is for use on persons with low back pain lasting at least six months and unresponsive to at least six months of conservative care (Kreuger, 2018).

The Intracept procedure first places Access Instruments (introducers, cannulas, stylets) into the vertebral body to create a path or channel to the terminus of the basivertebral foramen. It then places the radiofrequency probe into this channel at the terminus of the basivertebral foramen and controlled radiofrequency energy is delivered to ablate the basivertebral nerve (Kreuger, 2018).

The manufacturer asserts that Intracept provides an option for patients with low back pain who are unresponsive to conservative therapy that is minimally invasive (performed outpatient), is implant-free, and preserves the structure of the spine (Relievant Medsystems, 2021).

Two HCPCS codes describing the procedure were added on January 1, 2019. One is destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (C9752). The other, C9753, is to be listed separately in addition to the C9752 code for each additional vertebral body.

Findings

Until 2020, no professional guideline addressed intraosseous basivertebral nerve ablation. The International Society for the Advancement of Spine Surgery's February 2020 guideline recommended the procedure from the L3 through S1 vertebrae be considered for individuals with chronic low back pain if all the following criteria are met:

- Chronic axial low back pain of at least six months duration
- Failure to respond to at least six months of non-surgical treatment
- Magnetic resonance imaging demonstrated Modic Type 1 or 2 changes in at least one vertebral endplate, at one or more levels from L3 to S1 (Lorio, 2020).

The Society based its recommendation on recent literature (Becker, 2017; Fischgrund, 2018; Fischgrund, 2019; Khalil, 2019; Truumees, 2019).

A systematic review of seven studies (n = 321) found that intraosseous basivertebral neurotomy had a three month success rate for > 50% pain reduction from 45% to 63%. Authors consider the evidence on effectiveness to be moderate-quality, and suggested that non-industry sources should conduct trials (Conger, 2021).

A study of 225 persons with low back pain (Type I or II Modic changes of the treated vertebral bodies, diagnosed through magnetic resonance imaging) were randomized to intraosseous basivertebral nerve ablation (n = 147) or sham controls (n = 78). After three months the Oswestry Disability Index improvement was significantly greater ($P = .019$) for the intervention group (Fischgrund, 2018).

A follow up of the treatment group two years after treatment (106 of the original 147 subjects) confirmed the initial improvements continued for the treatment group; the Oswestry Disability Index and Visual Analog Scale declined (improved) 53.7% and 52.9%, both significant at $P < .001$ (Fischgrund, 2019). These data were cited by the U.S. Food and Drug Administration in its approval of the Intrasept system.

A follow up of this study of 100 patients, with a mean of 6.4 years after treatment revealed mean Oswestry Disability Index score improved from 42.81 to 16.86 after five years, significant at $P < .001$. Mean Visual Analog Scale pain score improved from 6.74 to 2.36, significant at $P < .001$. These findings indicate that intraosseous basivertebral nerve ablation may have long-lasting positive effects (Fischgrund, 2020).

Similar results were discovered by another review of 104 of these patients randomized to treatment and standard care groups for three months. . Mean changes in the Oswestry Disability Index at 3 months were -25.3 points (treated group) versus -4.4 points (standard care group), respectively, significant at $P < .001$). Mean changes in the Visual Analog Scale were -3.46 versus -1.02, respectively, also significant at $P < .001$) (Khalil, 2019).

A review of patients with low back pain, 75% of whom had symptoms for at least five years, and received intraosseous radio frequency ablation of the basivertebral nerve, showed that after three months the average Oswestry Disability Index improved, significant at $P < .0001$ (Truumees, 2019).

A study of low back pain (n = 140) randomized subjects into those who underwent basivertebral nerve ablation and those given standard care. The treatment group had superior pain improvement and quality of life outcomes, and the proportion of opioid use did not change in either group (Smuck, 2021).

In mid-2021, two literature reviews addressed current progress in intraosseous basivertebral nerve ablation for low back pain. One concluded that the procedure was safe and effective (Francio, 2021). The other expressed optimism based on current success, but noted that all trials to date were industry sponsored, and that trials independent of industry were needed (Michalik, 2021).

References

On September 23, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “basivertebral nerve ablation,” “intraosseous,” and “low back pain.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

12/2019: initial review date and clinical policy effective date: 1/2020

12/2020: Policy references updated.

12/2021: Policy references updated.