Intraosseous basivertebral nerve ablation for low back pain

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Policy Contains: Low back pain; Intracept; basivertebral nerve ablation

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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 (Relivant Medsystems, 2019).

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 primary procedure.

Findings

Although there are a multitude of guidelines on low back pain treatment from professional medical societies, none have addressed intraosseous basivertebral nerve ablation. No systematic reviews or meta-analyses have been produced. The only evidence of safety and efficacy are included in several recent peer-reviewed publications and clinical trials that are still ongoing.

An early review of the procedure included 17 patients with low back pain for at least six months who were unresponsive to conservative treatment for at least three months. All but one of the subjects were treated successfully. Mean baseline Oswestry Disability Index (self-reported) declined from 52 to 23 ($P < .001$), three months after treatment, an improvement that was maintained through 12 months. In addition, improvements after three months were observed in average visual analogue scale score ($P < .05$), and average baseline physical component summary ($P = .03$) (Becker, 2017).

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 Owestry 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 Owestry 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 Intracept system. Similar results were discovered by another review of 140 of these patients over one year (Khalil, 2019).

A study of 14 Korean patients with chronic low back pain produced similar results to those in the U.S. (Kim, 2018).

A review of 45 patients 12 months after having undergone basivertebral nerve radiofrequency ablation showed Owestry Disability Index improvements of 24.9 for those reporting decreased opioid use versus 7.3 for those reporting increased opioid use, significant at $P < .001$. For the 24 patients receiving sham treatment, disability improvements were almost significantly greater ($P = .053$) for those reporting decreased opioid usage (Markman, 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 basivertebal nerve, showed that after three months the average Owestry Disability Index improved, significant at $P <.0001$ (Truumees, 2019).

References

On August 6, 2019, 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.


Policy updates

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No policy updates.