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Medical Policy Manual Surgery, Policy No. 225

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve

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Next Review: November 2025
Last Review: January 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration.

MEDICAL POLICY CRITERIA

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered **investigational.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty. Surgery, Policy No. 118
2. Pulsed Radiofrequency for Chronic Spinal Pain, Surgery, Policy No. 156
3. Ablation of Peripheral Nerves to Treat Pain, Surgery, Policy No. 236

BACKGROUND

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration. The purpose of intraosseous basivertebral nerve ablation in patients who have vertebrogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

REGULATORY STATUS

The Intracept Intraosseous Nerve Ablation System "is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care". FDA reviewed the device and issued a substantially equivalent designation in August 2017 (K170827). FDA product code: GXI.

EVIDENCE SUMMARY

Systematic Reviews

Nwosu (2023) published a systematic review 11 studies of 413 participants who received basivertebral nerve ablation.[1] Included in this review were one systematic review, one meta-analysis, three prospective randomized double-blinded studies, three prospective randomized open-label studies, one prospective single-arm, one randomized single-blinded, and one narrative review. The review concluded that a majority of the participants reported greater than or equal to 10-point improvement in the ODI and greater than or equal to two-point improvement in the VAS at three months post-treatment. It was also reported that some patients receiving ablation reported complete pain resolution demonstrating therapy success and the superiority of basivertebral nerve ablation over sham and standard treatment.

Mekhail (2023) published a systematic review of 27 studies of pain management interventions for the treatment of low back pain, including basivertebral nerve ablation.[2] Other interventions included in the review were disc annulus and facet nerve structures, steroid injection of the disc, facet joint, and medial branch, biological therapies, and multifidus muscle stimulation. Reported outcomes were ODI, VAS, adverse events, and quality of life measures. The review concluded that basivertebral nerve ablation was effective in improving VAS and ODI for up to 24 months follow-up. It was also reported that biological therapy and multifidus stimulation were equally effective in improving VAS and ODI compared to ablation.

Conger (2021) published a systematic review of seven studies including 321 participants who received basivertebral nerve ablation.[3] The reported three-month success rate for ≥50% pain reduction ranged from 45% to 63%. Rates of functional improvement (≥10-point Oswestry Disability Index improvement threshold) ranged from 75% to 93%. For comparison to sham treatment, the relative risk of treatment success defined by ≥50% pain reduction and ≥10-point Oswestry Disability Index improvement was 1.25 (95% CI 0.88 to 1.77) and 1.38 (95% CI: 1.10 to 1.73), respectively. For comparison to continued standard care treatment, the relative risk of treatment success defined by ≥50% pain reduction and ≥10-point Oswestry Disability Index improvement was 4.16 (95% CI 2.12 to 8.14) and 2.32 (95% CI 1.52 to 3.55), respectively.

Conger (2022) published an updated review which included several more studies and came to the same general conclusions as the primary review. No additional high-quality studies were included in the updated review.

The currently published systematic reviews conclude there is evidence suggesting the procedure may be effective in reducing pain and disability in certain patients. However, there is a need for non-industry funded, high-quality, large prospective studies to confirm the findings as the included studies on basivertebral nerve ablation suffer from significant methodological limitations and lack long-term comparative outcomes between basivertebral nerve ablation and sham or standard of care treatments

Randomized Controlled Trials

Fischgrund conducted a randomized, double-blind, sham controlled study (SMART trial) of basivertebral nerve ablation using the Intracept system in 225 participants from the U.S. and Europe.[4] Patients had chronic isolated lumbar pain that had not responded to at least 6 months of nonoperative management. Additional study inclusion criteria were a minimum Oswestry Disability Index of 30 points (on a 100 point scale), a minimum visual analog scale of 4, and Modic type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. Treatment was limited to a minimum of 2 and a maximum of 3 consecutive vertebral levels from L3 to S1. The active treatment group (n=147) received radiofrequency and the sham group (n=78) underwent the same protocol for the same overall duration as the treatment group; however, the radiofrequency treatment was simulated. Patients were blinded to the group assignment for 1 year, at which time those in the sham arm were allowed to cross over, 57 (73%) of whom elected to do so, and receive the Intracept treatment. The primary endpoint of the original study was comparative change in Oswestry Disability Index from baseline to 3 months, and in the intent-to-treat analysis there was no statistically significant difference in this outcome between groups at this time point. There was a difference between groups in the 3-month per protocol analysis (mean Oswestry Disability Index improved 20.5 and 15.2 points in the treatment and sham arms, respectively; p=.019). However, at the 12 month per protocol analysis, the difference in mean Oswestry Disability Index between groups was no longer statistically significant. Pain severity, measured by visual analog scale, was not significantly different between groups at 3 months (p=.083) but there was significantly greater improvement in the treatment group at 6 and 12 months.

The 24 month follow-up results were reported for the active treatment group from the SMART trial.[5] Of the per protocol population treated with ablation (treatment arm), 106 (83%) completed a 24-month follow-up visit. A durable Oswestry Disability Index mean improvement was observed (23.4 points). Data for Oswestry Disability Index outcomes were not available for the sham group because of the high crossover rate. Therefore, long-term comparative outcomes are not available.

Five year results were reported for the 100 U.S. patients from the treatment arm from the original SMART trial who were available for follow-up.[6] Mean Oswestry Disability Index scores improved from 42.8 to 16.9 at 5 years, a reduction of 25.9 points. Mean reduction in visual analog scale score was 4.4 points (baseline 6.7, p<.001).

The INTRACEPT trial was an open-label RCT conducted at 20 U.S. sites.[7] A total of 140 patients with lower back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized to undergo radiofrequency ablation of the basivertebral nerve or continue standard care. Standard care consisted of pain

medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections; the specific treatment(s) administered were determined by the treating investigator in conjunction with the patient. Treatment of up to four vertebrae in non-consecutive levels from L3 to S1 was allowed. The primary study endpoint was change in Oswestry Disability Index at three months. A pre-planned interim analysis was undertaken when 60% of participants reached the three month follow-up (n=51 in the treatment group and n=53 in the standard care group), and reported statistically significant differences between groups on all patient-reported outcome measures, favoring the treatment group. The study was halted and the individuals were allowed to cross over to the treatment arm. Study limitations include short term follow-up, lack of a sham group, and allowance of crossover at three months.

Twelve month follow-up results were reported from the INTRACEPT trial; after a median of 175 days postrandomization, 92% of patients initially randomized to the standard care arm elected to receive early treatment with basivertebral nerve ablation.[8] Six month results for the Oswestry Disability Index were significantly improved with basivertebral nerve ablation (n=66) compared to standard care (n=74) (least squares mean difference between groups, -24.5; 95% CI, -29.4 to -19.6; p=.0001). Improvements in the Oswestry Disability index and mean visual analog scale that were reported among patients initially treated with basivertebral nerve ablation were maintained throughout the 12-month study period, with reported reductions of -25.7±18.5 points, and -3.8±2.6 cm, respectively (p<.001 for both comparisons to baseline). However, comparative data were not available beyond six months due to the high rate of crossover. Twenty-four month follow up data from the treatment arm of the INTRACEPT trial is also available that demonstrated positive outcomes in patients who received basivertebral nerve ablation.[9] These results and conclusions about the comparative effectiveness of the treatment and conservative therapy are significantly limited due to the inability to compare groups beyond six months due to crossover. It is unclear from the data if comparative differences in treatment versus conservative therapy are durable.

Section Summary

Two RCTs have been conducted to assess the efficacy of basivertebral nerve ablation for treatment of vertebrogenic back pain. One RCT did not find a difference in the Oswestry Disability Index between patients treated with basivertebral nerve ablation or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. A second RCT found a significant difference in the Oswestry Disability Index and other pain scores between patients treated with basivertebral nerve ablation and standard care at 3 months. Comparative data at 6 months postrandomization showed similar results. However, 92% of patients initially assigned to standard care elected to cross over to receive early basivertebral nerve ablation, thus, long-term comparative data beyond 6 months are not available which are necessary to understand the durability of this treatment in this patient population suffering from chronic low back pain. Additional limitations to this RCT include lack of a sham control. Long-term, comparative outcomes are necessary to determine the effectiveness of this procedure.

Nonrandomized Studies

Khalil (2024) published a five year pooled analysis of three trials including the SMART, INTRACEPT, and an additional single-arm study.[10] A total of 249 of the 320 participants

across the three studies completed a five year follow-up visit. The authors report improvement in pain and functional outcomes in addition to 32% of participants reporting being pain free and 73% reporting that their condition improved. This aggregate analysis of five year follow up data is limited by the key features noted above in the summaries of the included clinical trials including but not limited to a lack of comparative data between treatment arms.

Additional nonrandomized studies including but not limited to narrative reviews and case studies or series have been published. These are generally considered to be low quality evidence and suffer from several limitations such as small sample sizes, noncomparative outcomes, and/or nonrandomized designs.[11-15] Conclusions must be drawn cautiously from these studies and this topic requires additional high quality, comparative studies to be published.

PRACTICE GUIDELINE SUMMARY

International Society for the Advancement of Spine Surgery

In 2020, the International Society for the Advancement of Spine Surgery published guidelines on intraosseous ablation of the basivertebral nerve for relief of chronic low back pain.[16] The guidelines suggest that basivertebral nerve ablation is an appropriate treatment for chronic low back pain in select patients who meet the following additional criteria:

- "CLBP (chronic low back pain) of at least 6 months duration,
- Failure to respond to at least 6 months of nonsurgical management, and
- MRI (magnetic resonance imaging)-demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1."

This guideline does not have detailed methodology on searching for and evaluating the evidence-base and its quality. There are limitations to the quality of evidence which are not addressed in this guideline. Additionally, there are potential conflicts of interest with authors that are not addressed.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published best practice guidelines on intraosseous ablation of the basivertebral nerve for relief of chronic low back pain, giving a Grade A recommendation.[17] This guideline does not have detailed methodology on searching for and evaluating the evidence-base and its quality. There are limitations to the quality of evidence which are not addressed in this guideline.

International Society for the Advancement of Spine Surgery

The International Society for the Advancement of Spine Surgery (ISASS) published a policy statement in 2022 that recommended that vertebrogenic low back pain is most successfully addressed by intraosseous ablation of the basivertebral nerve.[18] This policy statement does not have detailed methodology on searching for and evaluating the evidence-base and its quality. There are limitations to the quality of evidence and potential conflicts of interest that are unmitigated.

North American Spine Society

In 2023, the NASS published a policy recommendation, Defining Appropriate Coverage Positions, that recommends basivertebral nerve ablation for a certain population of individuals experiencing chronic low back pain.[19] This policy statement does not have detailed methodology on searching for and evaluating the evidence-base and its quality. There are limitations to the quality of evidence and potential conflicts of interest included in the society recommendation as noted above in the evidence section.

SUMMARY

There is not enough research to show that intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) improves net health outcomes in patients with vertebrogenic back pain. Therefore, the use of intraosseous radiofrequency ablation of the basivertebral nerve for the treatment of vertebrogenic back pain is considered investigational.

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CODES

Codes	Number	Description
CPT	64628	Thermal destruction of intraosseous basivertebral nerve, first 2 vertebral bodies
	64629	Thermal destruction of intraosseous basivertebral nerve, each additional vertebral body
HCPCS	None	

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