# Basivertebral Nerve Ablation

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## DEFINING APPROPRIATE COVERAGE POSITIONS

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COVERAGE COMMITTEE

# NASS Coverage Recommendations

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## Introduction

North American Spine Society (NASS) coverage recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may benefit both payers and members in helping achieve consensus on coverage, avoiding unnecessary controversies.

This coverage recommendation reflects the best available data as of 7/2/2021; information and data published after 7/2/2021 is thus not reflected in this recommendation and could warrant deviations from this recommendation, if appropriate.

## Methodology

The coverage recommendations put forth by NASS use an evidence-based approach to spinal care. When the available data does not meet strict evidence-based criteria, the recommendations reflect the multidisciplinary expertise of the authors in order to reflect reasonable, standard practice indications in the United States.

*NASS Coverage Recommendation Methodology*

## Scope and Clinical Indications

Low back pain is a major contributor to patient disability and affects a significant portion of patients worldwide. Persistent lower back pain lasting longer than 12 weeks, known as chronic low back pain (CLBP), is often presumed to follow the discogenic model, which suggests that there are sensitized nociceptors in the annulus fibrosus of degenerating discs leading to pain. However, there is some evidence that elevated intraosseous pressure can also cause back pain.[1-3] The idea that the degenerative process in the spine could result in an intraosseous source of pain becomes very plausible given the observations made using peri-endplate magnetic resonance imaging (MRI) signal changes, which were indicative of intraosseous edema or inflammation, and correlated with clinical low back pain.[2-5] There is a growing body of evidence that damage to the innervated vertebral endplates can result in vertebrogenic back pain (VBP) transmitted through branches of the basivertebral nerve (BVN).[2-3,6-8]

Radiofrequency ablation of the BVN via a percutaneous interosseous approach has emerged as a possible interventional therapy for this condition. Current BVN ablation evidence demonstrates consistent short- to intermediate-term improvements in function and pain.[7-16] In addition to two prospective single-arm studies reporting clinically significant improvements in Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) from baseline, two Level 1 randomized controlled trials (RCTs) have demonstrated superiority over standard care at 3 months and 12 months and over sham control at 12 months.[17-22]

BVN ablation is indicated when:

- Patients are skeletally mature and have CLBP for at least 6 months, and lower back pain is their main symptom
- Patients have failed to adequately improve despite attempts at nonsurgical management
- Patients have Type 1 or Type 2 Modic changes on MRI — endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving in the endplates between L3 and S1

BVN ablation is **NOT** indicated in ANY of the following scenarios:

- Evidence on imaging (MRI, flexion/extension radiographs, etc.) suggests another obvious etiology for the patient's LBP symptoms, including but not limited to lumbar stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis or facet arthropathy or effusion with clinically suspected facet joint pain
- Metabolic bone disease (eg, osteoporosis), treatment of spine fragility fracture, trauma/compression fracture or spinal cancer
- Spine infection or active systemic infection

- Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression (eg, HNP, stenosis), as primary symptoms
- Patients with severe cardiac or pulmonary compromise
- Patients with implantable pulse generators (eg, pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety

## Rationale for Coverage Recommendations

The most recent randomized clinical trial published by Khalil et al, compared the effectiveness of intraosseous radiofrequency (RF) ablation of the BVN to standard care for the treatment of CLBP in a specific subgroup of patients suspected to have vertebrogenic-related symptomatology.[19] A total of 140 patients with CLBP of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized 1:1 to undergo either RF ablation of the BVN or continue standard care. ODI was collected at baseline, 3, 6, 9 and 12-months post-procedure. Other outcome measures included a 10-point VAS for LBP, ODI and VAS responder rates, SF-36 and EQ-5D-5L. The primary endpoint was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. The authors concluded that minimally invasive RF ablation of the BVN leads to significant improvement of pain and function at 3 months in patients with chronic vertebrogenic related LBP. It should be noted that there was a high rate of cross-over after the 3-month follow-up in this trial, which followed an interim analysis that showed superiority of the intervention arm.

Fischgrund et al performed a randomized double-blind sham-controlled trial to compare the efficacy of RF ablation of the BVN in 225 patients with CLBP.[20-22] Patients who demonstrated Modic Type 1 or 2 vertebral endplate changes in one or more L3 to S1 segments and were nonresponsive to a minimum of 6 months of nonsurgical treatment were included in the study. The patients were randomized using 2:1 block randomization to either treatment or sham group and evaluated at multiple intervals until their final follow-up at five years. The per-protocol population analysis of the study reported the intervention to have superiority in terms of ODI scores at 3 months, and VAS scores at 6 and 12 months of follow-up. Most enrolled patients crossed over after 12 months in the study and continued to be followed. At the five-year follow-up, the study reported continued superiority of the intervention in terms of ODI and VAS scores compared to baseline.

A prospective, single-arm study performed by Truumees et al, evaluated the effectiveness of intraosseous RF ablation of the BVN for the treatment of vertebrogenic-related CLBP.[18] Patients with CLBP of at least 6 months duration and with Modic Type 1 or 2 vertebral endplate changes between L3 and S1 were treated with RF ablation of the BVN in up to four vertebral bodies. Ninety-three percent (93%) of patients achieved a ≥10-point improvement in ODI, and 75% reported ≥20-point improvement. They concluded that minimally invasive RF ablation of the BVN results in a significant improvement in pain and function in this population of real-world patients with chronic vertebrogenic-related LBP.

Markman et al evaluated the hypothesis that CLBP patients reporting reduced opioid use have superior functional outcomes following BVN radiofrequency ablation.[23] Data were obtained from 225 patients enrolled in a 2:1, randomized, sham-controlled, double-blind trial examining the effects of BVN ablation on CLBP. Patients who demonstrated Modic Type 1 or 2 vertebral endplate changes in one or more L3 to S1 segments and were nonresponsive to a minimum of 6 months of nonsurgical treatment were included in the study. The authors concluded that subjects undergoing BVN ablation reported lower opioid use and had greater improvement in ODI and VAS scores.

Macadaeg et al conducted a prospective, single arm trial including 48 patients with more than 6 months of CLBP and Type 1 or 2 Modic changes on MRI.[24] Patients were followed post-procedure for 12 months using ODI, VAS, EQ-5D-5L and SF-36 patient-reported outcome metrics. The authors concluded that BVN ablation results in improvements in ODI and VAS scores out to 12 months.

Transforaminal epiduroscopic basivertebral nerve laser ablation was studied by Kim et al, who presented a cohort of 14 patients with CLBP greater than 6 months which is unresponsive to at least 4 months of conservative care.[4] This cohort included patients with MRI findings of Modic Type 1 or 2 changes and positive confirmatory provocation dis-

cography to determine the affected levels. The results of this single-arm case series were promising, yet the role of the transforaminal epiduroscopic ablation remains to be further investigated. Therefore, the present recommendation is limited to percutaneous interosseous ablation of the BVN.

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## Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.