

February 27, 2026

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To Whom It May Concern:

The International Pain and Spine Intervention Society (IPSIS), along with the undersigned medical specialty societies comprising physicians who utilize and/or perform interventional pain and spine procedures to accurately diagnose and treat patients, would like to take this opportunity to provide comments on the proposed Local Coverage Determination titled “Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Low Back Pain.” We appreciate NGS’s efforts to establish coverage for basivertebral nerve ablation (BVNA) and respectfully submit recommendations to refine the policy and better align it with current evidence, clinical practice, and patient access considerations.

Psychological Evaluation and Multidisciplinary Screening

The current language requires that patients undergo evaluation by a “multidisciplinary team,” including psychological assessment. While psychosocial factors are important in chronic pain management, this requirement lacks sufficient clarity and may be interpreted in a manner that imposes unnecessary access barriers.

Psychological screening is not routinely mandated for comparable spine procedures such as lumbar radiofrequency ablation or kyphoplasty. Psychological evaluations are required for interventional pain procedures that require an implanted device. BVNA is a one-time procedure without any implantable device and no maintenance. Requiring formal psychological evaluations by specialists (i.e., psychiatrists or psychologists) could create an undue burden, particularly in geographic areas with limited behavioral health resources. While psychological evaluation is commonly required for spinal cord stimulation, this reflects the unique considerations associated with an implanted, programmable device that requires ongoing patient engagement, maintenance, and long-term follow-up. Clarification that documentation by the treating physician or primary care physician is sufficient would reduce unnecessary administrative burden while preserving appropriate patient screening.

Recommendations:

- Clarify that psychological screening may be performed by the treating pain physician or the patient’s primary care physician, and a statement confirming no active untreated psychological disorder is sufficient, rather than necessitating referral to a mental health specialist.
- More precisely define what constitutes a “multidisciplinary team” for this LCD to promote consistent interpretation and implementation.

Modic Changes as a Selection Criterion

We agree that Modic Type 1 and Type 2 changes currently represent the best available imaging biomarker for vertebrogenic pain and are a reasonable consideration in identifying candidates for BVNA. However, we encourage consideration of reasonable flexibility for patients who cannot safely undergo MRI. In such cases, alternative imaging modalities demonstrating endplate changes (e.g., CT or SPECT, when clinically appropriate) may be considered. Additionally, radiology reports may not consistently use the specific terminology “Modic changes” despite clear endplate signal alterations. Allowing physician interpretation would reduce unnecessary report addenda and administrative burden while maintaining appropriate diagnostic standards.

Recommendations:

- Consider allowing alternative imaging modality options (e.g., CT/SPECT) with evidence of endplate changes as an alternate biomarker when MRI cannot be safely performed.
- Clarify that the treating physician’s interpretation of the MRI, supplemented by the radiology report, is sufficient to document presence of Modic Type 1 or Type 2 changes.

Imaging-Based Exclusion Criteria

We are concerned about the exclusion criteria related to radiographic findings, such as:

- Disc extrusion or protrusion >5 mm,
- Spondylolisthesis >2 mm,
- Spondylolysis,
- Facet arthrosis/effusion, where imaging correlates with “predominant physical complaints.”

While similar imaging exclusion criteria were used in the major clinical trials^{1,2,3} supporting BVNA, rigid application of quantitative thresholds in the LCD may lead to unintended denials in patients whose overall clinical presentation remains consistent with vertebrogenic pain. Degenerative imaging findings are common in older adults and often do not, by themselves, explain a patient’s pain. Importantly, patients may have multiple coexisting pain generators, and the presence of one or more of these imaging findings should not automatically preclude consideration of otherwise appropriate treatment options. The current language found in this section may inadvertently serve as a mechanism for inappropriate denials rather than a true clinical safeguard.

Recommendation:

- Revise to clarify that image findings should be interpreted in conjunction with the overall clinical presentation, and that radiographic findings alone, without clinical concordance, should not preclude coverage when vertebrogenic pain remains the primary diagnosis.

Osteoporosis as an Exclusion

The LCD excludes patients with diagnosed osteoporosis (T-score $\leq$ -2.5). While osteoporosis was an exclusion criterion in earlier BVNA clinical trials, emerging evidence suggests that outcomes may differ between treated and untreated osteoporosis. Specifically, a large national

retrospective study found that patients with osteoporosis or osteopenia experienced a higher relative risk of vertebral compression fracture following BVNA; however, the absolute fracture rate remained low.⁴

Recommendations:

- Modify the exclusion to specify “untreated or unstable osteoporosis.”
- Allow coverage for appropriately selected patients with treated osteoporosis, supported by documented risk-benefit counseling and shared decision-making.

Clarification of Radicular Pain Exclusion

We recommend adding “predominant radicular pain” to the exclusion criteria to reinforce appropriate patient selection and align with established clinical practice and analogous coverage policies.

We strongly support coverage of BVNA and commend NGS for advancing access to this therapy. The proposed LCD can be further strengthened through targeted refinements to psychological screening, imaging-based exclusions, osteoporosis criteria, and the evidence narrative on Modic changes. These modifications would better align the policy with current evidence, preserve appropriate utilization, and minimize unintended barriers to care for Medicare beneficiaries.

We greatly appreciate your consideration. If you require any additional information or would like to discuss this request further, please do not hesitate to contact Sarah Cartagena, Director of Health Policy, at scartagena@ipsismed.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American College of Radiology
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology

References:

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