

March 21, 2024

Charles Harrison, MD, Senior Medical Director  
Barbara Muller, MD, Medical Director  
United Healthcare  
9700 Health Care Lane  
Minnetonka, MN 55343

Re: United Healthcare Ablative Treatment for Spinal Pain  
Policy Number 2024T0107DD  
Effective Date: January 1, 2024

Dear Dr. Harrison and Dr. Muller,

We are writing for the more than 47,000 members our undersigned societies represent to express our concern with United Healthcare's para policy around basivertebral nerve ablation (BVNA). Our members include anesthesiologists, neurologists, neurosurgeons, orthopedic surgeons, physiatrists, psychologists, engineers, scientists, and health care professionals. We are all dedicated to improving the care patients receive when dealing with chronic neurologic disorders, including severe debilitating pain.

Our primary concern is around United Healthcare's outlier position holding that:

*"There is insufficient evidence to establish the safety and efficacy of intraosseous RFA of the basivertebral nerve for treating low back pain ..."*

Position: Well-established science supports BVNA as a safe and effective procedure.

**Rationale:** Basivertebral nerve ablation (BVNA) is a technology in use for approximately 9 years. Its use in a specific subgroup of patients with a vertebrogenic source of chronic low back pain is supported by extensive, prospective, clinical research. Specifically, the efficacy of BVNA was proven in SMART (Surgical Multi-center Assessment of RF Ablation for the Treatment of Vertebrogenic Back Pain, NCT01446419), a sham-controlled, multicenter, randomized trial<sup>1</sup>.

Additionally, the robust clinical effectiveness of BVNA over standard care was demonstrated in a second, multicenter, randomized controlled trial, INTRACEPT (NCT03246061)<sup>2</sup>. Results of both randomized, controlled trials reveal statistically significant and highly clinically relevant improvements following BVNA in patients with a vertebrogenic source of chronic low back pain, including reduced low back pain and associated improvements in disability and health-related quality of life. Furthermore, these improvements after BVNA were shown to be durable in long-term follow-up of the original BVNA treatment arms of each RCT at 3 and 5 years<sup>3,4</sup>, and result in reduced low back pain-related healthcare utilization<sup>5</sup>. A systematic review and a level-one meta-analysis of BVNA outcomes each confirmed positive results from BVNA<sup>6,7</sup>.

BVNA is not a treatment for all patients with chronic low back pain. Rather, it is a targeted treatment for a specific subgroup of patients with a vertebrogenic source of low back pain. When the inclusion and exclusion criteria of the two BVNA RCTs are applied to all patients presenting with chronic low back pain to a specialty clinic, the BVNA treatable subgroup accounts for approximately 3% of this population<sup>8</sup>. Importantly, the NASS coverage recommendations for BVNA conform to these inclusion and exclusion criteria, and multiple commercial insurance carriers and all of the Medicare MACs have adopted coverage policies that generally follow the NASS coverage recommendations<sup>9</sup>. Thus, United Healthcare's perspective on BVNA is a substantial outlier.

**Rebuttal:** Unfortunately, United Healthcare continues to rely on a "*Hayes report*" from an infamous third party review by Hayes Inc. The North American Spine Society contends the aforementioned "*Hayes report*" takes an unusual set of circumstances to volitionally mischaracterize the current state of the literature.

- **Background:** During the 140-patient comparative effectiveness, randomized controlled trial of BVNA compared to standard, at the predetermined interim analysis the Data Management Committee witnessed a marked statistically significant difference in the primary outcome and all secondary outcomes in favor of BVNA. Enjoining the *ethical duty of care exemption*, they recommended halting enrollment and offering immediate cross-over to all participants in the standard care arm. This result 'opened' the study and allowed members of the 'control group' to 'cross over' and receive treatment due to the ethical duty of care that is part of every study's ethical conduct review requirement.
- **Results:** NASS is aware that several "for-profit scientific-review companies" (Hayes, Simplr, Milliman, OneDigital) have used this unusual circumstance to 'downgrade' the level of evidence from the two RCT publications (1-year data, 3-year data, 5-year data). We believe this constitutes a misapplication of the RAND-GRADE criteria for evaluating evidence.

In summary, the North American Spine Society stands by its coverage recommendations; supplied below are additional supporting studies not included in the NASS BVN Coverage Recommendations.

The undersigned societies have a long track record of working collaboratively with United Healthcare to act in the best interest of their patients to achieve the highest outcome, at the least risk and cost for their patients. BVNA has shown secondary outcomes of decreasing opioid narcotic usage and decrease in subsequent health visits.

We believe that the volitional mischaracterization of straightforward data by '*science-harvesting mercenaries*' has led to inappropriate denial of care to United Healthcare's members. The likely outcome will be higher costs and risks for the subset of treatable patients. Those risks have been somewhat quantified and captured in the recent OIG (office of inspector general) report on spinal cord stimulation and increasing lumbar fusions with decreasing mean age.

In summary, we urge United Healthcare to join the undersigned societies, all of the Medicare MACs, and more than 20 other insurance carriers and approve the appropriate use of BVNA.

After reviewing the above comments, it is hoped that United Healthcare will consider revising these policy changes to reflect the new evidence and provide coverage accordingly. NASS and the undersigned societies welcome the opportunity to further elaborate on the comments provided herein and willing to facilitate a conference call with UHC Medical Directors to discuss the coverage issue further if that would be of assistance. We look forward to working with United Healthcare to improve patient access to care and outcomes.

Please contact Karen James, Senior Manager of Health Policy, NASS at [kjames@spine.org](mailto:kjames@spine.org) if you have any questions or comments.

Sincerely,

American Academy of Physical Medicine & Rehabilitation  
American College of Radiology  
American Society of Neuroradiology  
American Society of Regional Anesthesia & Pain Medicine  
American Society of Spine Radiology  
North American Spine Society  
Society of Interventional Radiology

#### References

1. Fischgrund JS, Rhyne A, Franke J, Sasso R, Kitchel S, Bae H, Yeung C, Truumees E, Schaufele M, Yuan P, Vajkoczy P, DePalma M, Anderson DG, Thibodeau L, Meyer B. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J.* 2018 May;27(5):1146-1156. doi: 10.1007/s00586-018-5496-1. PMID: 29423885
2. Smuck M, Khalil J, Barrette K, Hirsch JA, Kreiner S, Koreckij T, Garfin S, Mekhail N; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *Reg Anesth Pain Med.* 2021 Aug;46(8):683-693. doi: 10.1136/rapm-2020-102259. PMID: 34031220
3. Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, Truumees E, Schaufele M, Yuan P, DePalma M, Anderson DG, Buxton D, Reynolds J, Sikorsky M. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J.* 2020 Aug;29(8):1925-1934. doi: 10.1007/s00586-020-06448-x. PMID: 32451777

4. Smuck M, Truumees E, Macadaeg K, Jaini AM, Chatterjee S, Levin J. Intraosseous basivertebral nerve ablation: Pooled long-term outcomes from two prospective clinical trials. *Interventional Pain Medicine*. June 2023, Volume 2, Issue 2, 100256, ISSN 2772-5944, <https://doi.org/10.1016/j.inpm.2023.100256>.
5. McCormick ZL, Curtis T, Cooper A, Wheatley M, Smuck M. Low back pain-related healthcare utilization following intraosseous basivertebral nerve radiofrequency ablation: a pooled analysis from three prospective clinical trials. *Pain Med*. 2024 Jan 4;25(1):20-32. doi: 10.1093/pm/pnad114. PMID: 37643639
6. Conger A, Burnham TR, Clark T, Teramoto M, McCormick ZL. The Effectiveness of Intraosseous Basivertebral Nerve Radiofrequency Ablation for the Treatment of Vertebrogenic Low Back Pain: An Updated Systematic Review with Single-Arm Meta-analysis. *Pain Med*. 2022 Jul 20;23(Suppl 2):S50-S62. PMID: 35856331
7. Nwosu M, Agyeman WY, Bisht A, Gopinath A, Cheema AH, Chaludiya K, Khalid M, Yu AK. The Effectiveness of Intraosseous Basivertebral Nerve Ablation in the Treatment of Nonradiating Vertebrogenic Pain: A Systematic Review. *Cureus*. 2023 Apr 4;15(4):e37114. PMID: 37034146
8. Sherwood D, Miller S, Epps A, Gill B, Zhivotenko O, Khan S, Swenson T, Gardner J, Roehmer C, Martin D, Kennedy DDJ, Modic M, Schneider BJ. A First Estimate of the Annual Prevalence of Basivertebral Nerve Ablation Candidates in a Spine Clinic. *Pain Med*. 2022 Oct 29;23(11):1858-1862. PMID: 35652735
9. NASS Coverage Committee. *NASS Coverage Recommendations on Basivertebral Nerve Ablation*. North American Spine Society, Burr Ridge, IL; February 2023. Retrieved from: <https://www.spine.org/Product-Details?productid=%7B0113E751-F070-ED11-9562-00224820E810%7D>.