August 10, 2026

Re: **Request for Reconsideration of Humana and Cohere's Interpretation of Psychological Evaluation Requirements for Basivertebral Nerve Ablation Medicare Advantage Patients**

To whom it may concern:

We are writing to you on behalf of more than 4,000 physicians from the specialties of Anesthesiology, Neurology, Neurosurgery, Orthopedics, Physical Medicine and Rehabilitation and Preventive Medicine & Public Health that form the American Society of Pain and Neuroscience (ASPN). Our membership comprises a significant proportion of physicians who perform neuromodulation procedures like Basivertebral Nerve Ablation (BVNA).

We respectfully request reconsideration of Humana and Cohere's interpretation that Local Coverage Determination language for basivertebral nerve ablation (BVNA) requires every patient to obtain a separate psychological evaluation from an independent mental health provider prior to authorization. We support careful patient selection and appropriate documentation; however, the interpretation currently being applied creates a requirement that is **more restrictive than the applicable LCD** language and not supported by the BVNA evidence base.

Humana Medicare Advantage reviews managed by Cohere have communicated that, in states where Palmetto LCD L39420 and NGS L40302 apply, the psychological evaluation must be completed by an independent provider outside the treating practice, that a treating clinician's documentation is insufficient, and that validated in-office screening tools such as the PHQ-9 do not satisfy the requirement. In Noridian jurisdictions, denials have also referenced multidisciplinary team and mental health professional language even though the Noridian LCD requires only a "physical and psychological assessment of the patient's ability to tolerate and benefit from BVN ablation" and does not specify an external mental health evaluation.

We believe this interpretation should be reconsidered. The LCD language supports careful screening, evaluation, and diagnosis, including assessment of psychological and physical factors that may affect safety, informed consent, or expected outcome. To the extent the LCD references a multidisciplinary team, that language is more appropriately understood to include the clinicians commonly involved in conservative care and patient management, such as physical therapy, primary care, chiropractic care, and other treating providers rather than as a mandate for a separate psychological assessment by an external mental health professional. It does not clearly mandate a universal, stand-alone psychological evaluation by an external mental health professional for every BVNA candidate, regardless of clinical presentation or documented need.

BVNA is a minimally invasive, implant-free procedure for appropriately selected patients with

vertebrogenic chronic low back pain. Unlike spinal cord stimulation or other implantable therapies, BVNA does not require long-term device management, programming, charging, trial participation, or ongoing behavioral adherence that would typically justify a mandatory formal psychological clearance process. The established patient selection framework for BVNA is based on clinical presentation, chronicity of symptoms, failure of conservative care, exclusion of other dominant pain generators, and MRI findings consistent with Modic Type 1 or Type 2 endplate changes.

Importantly, the pivotal BVNA studies excluded patients with significant untreated psychological disease or active substance use concerns when clinically relevant, but they did not establish a requirement that all candidates undergo a separate psychological evaluation by an independent mental health specialist. Treating pain physicians routinely assess depression, substance use, psychosocial factors, functional status, opioid risk, and patient ability to tolerate and benefit from interventional procedures as part of comprehensive evaluation and management. Validated tools such as the PHQ-9, Beck Depression Inventory, opioid risk assessments, and documented clinical history provide clinically meaningful mechanisms to identify patients who may require additional behavioral health evaluation.

**Our perspective is based on the following data:**

***1. The pivotal trials used a validated screening instrument, not a psychiatric clearance requirement***

The clinical evidence base for BVNA consists principally of three prospective trials, the SMART trial (Fischgrund et al.), the INTRACEPT RCT (Khalil et al.), and the Truumees et al. long-term follow-up study, together with the earlier Becker et al. sham-controlled study[1,2,3,4]. In each of these studies, the relevant exclusion criterion was a Beck Depression Inventory (BDI) score greater than 24, indicating moderate-to-severe depression[5]. This was a numeric screening threshold applied at study entry, not a requirement that every patient undergo formal psychiatric evaluation, obtain psychiatric clearance, or be reviewed by a multidisciplinary board prior to treatment. Notably, in the pooled trial population, roughly one-third of enrolled patients had mild-to-moderate depressive or anxiety symptoms and were still eligible for and successfully treated with BVNA[6]. A policy that requires psychiatric clearance for every candidate patient

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[1] Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019;13(2):110-119.

[2] Khalil JG, Smuck M, Koreckij T, et al. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2019;19(10):1620-1632.

[3] Truumees E, Macadaeg K, Pena E, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Eur Spine J. 2019;28(7):1594-1602.

[4] Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a prospective randomized double-blind sham-controlled multi-center study. Spine J. 2017;17(2):218-232.

[5] Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019;13(2):110-119 (Table 1, inclusion/exclusion criteria).

[6] Sperry BP, McCormick ZL, Bendorf J, et al. Low back pain-related healthcare utilization following intraosseous basivertebral nerve radiofrequency ablation: a pooled analysis from three prospective clinical trials. Pain Med. 2024;25(1):20-29.

goes materially beyond what the underlying trials actually required and imposes a barrier to care that has no counterpart in the evidence the LCD itself relies upon.

### *2. Peer-reviewed pooled analyses show depression score is, at most, a weak predictor of outcome, not a diagnostic gate*

A pooled cohort analysis of 296 patients across the three prospective BVNA trials examined which baseline demographic and clinical characteristics predicted treatment success [7]. While higher baseline BDI scores were associated with modestly reduced odds of an optimal outcome, the authors' regression models demonstrated that this variable had limited discriminative value, and BDI score was not identified as a criterion that should be used to exclude patients from treatment altogether [8]. This finding has since been confirmed in subsequent long-term pooled analyses: both the 3-year and 5-year aggregate outcome studies from the INTRACEPT and SMART trial cohorts explicitly note that baseline BDI differences between cohorts "have limited predictive value of treatment outcome," and no statistical adjustment for BDI was needed in reporting long-term results [9,10]. A pooled analysis of post-procedure healthcare utilization reached the same conclusion, describing BDI as a "weak predictor of treatment failure" [11]. In short, the best available published evidence does not support treating a depression or anxiety history as a contraindication requiring specialist clearance; it supports continuing to identify and manage more severe, unaddressed psychiatric illness through routine screening, which any treating physician is equipped to perform.

### *3. Vertebrogenic pain already has an objective, reproducible diagnostic biomarker that does the diagnostic work a psychiatric evaluation is meant to do*

Unlike many chronic low back pain presentations historically treated based on nonspecific clinical impressions, vertebrogenic pain is defined by an objective radiographic biomarker — Type 1 and/or Type 2 Modic changes on MRI at the treatment level, correlating with a clinical

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[7] Boody BS, Sperry BP, Harper K, Macadaeg K, McCormick ZL. The relationship between patient demographic and clinical characteristics and successful treatment outcomes after basivertebral nerve radiofrequency ablation: a pooled cohort study of three prospective clinical trials. Pain Med. 2022;23(Suppl 2):S2-S13.

[8] Boody BS, Sperry BP, Harper K, Macadaeg K, McCormick ZL. The relationship between patient demographic and clinical characteristics and successful treatment outcomes after basivertebral nerve radiofrequency ablation: a pooled cohort study of three prospective clinical trials. Pain Med. 2022;23(Suppl 2):S2-S13.

[9] Kim C, et al. Intraosseous basivertebral nerve ablation: pooled long-term outcomes from two prospective clinical trials. N Am Spine Soc J. 2023 (3-year pooled analysis).

[10] McCormick ZL, et al. Intraosseous basivertebral nerve ablation: a 5-year pooled analysis from three prospective clinical trials. N Am Spine Soc J. 2024.

[11] Sperry BP, McCormick ZL, Bendorf J, et al. Low back pain-related healthcare utilization following intraosseous basivertebral nerve radiofrequency ablation: a pooled analysis from three prospective clinical trials. Pain Med. 2024;25(1):20-29.

presentation of midline pain aggravated by flexion, sitting, and driving [12,13,14]. Published predictive-analysis work has shown that treatment outcome after BVNA is driven by this correlation between clinical presentation and Modic changes, not by volume or location of the changes, degree of disc degeneration, or the presence of endplate defects alone [15,16]. Both the International Society for the Advancement of Spine Surgery (ISASS) and the American Society of Pain and Neuroscience (ASPN) have issued guidance recognizing BVNA as a safe, durable, Level I evidence-supported treatment for appropriately selected patients using these established clinical and imaging criteria, without conditioning that recognition on a separate mental health clearance pathway [17,18]. Requiring an additional, resource-intensive psychiatric clearance step does not improve diagnostic accuracy for a condition whose diagnostic criteria are already objective and imaging-based. In fact, it adds a barrier without a corresponding evidentiary benefit.

A universal requirement for an independent psychological evaluation in all BVNA patients is therefore duplicative when the treating clinician has already documented appropriate screening and there is no evidence of severe untreated psychological disease, active untreated substance use disorder, or another clinically significant concern. Such a requirement may delay medically necessary care, increase patient cost-sharing, create avoidable administrative burden, and disproportionately affect patients in rural or underserved areas where behavioral health resources are limited.

**Requested revision:**

We respectfully request that Humana and Cohere revise their interpretation and authorization guidance to recognize that the psychological assessment requirement may be satisfied by the treating pain physician's documented clinical evaluation and routine screening when no additional behavioral health concern is identified. Referral for separate psychological or psychiatric evaluation should be required only when clinically indicated by severe or untreated psychological disease, active untreated substance use disorder, impaired informed consent

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[12] Lotz JC, Fields AJ, Liebenberg EC. The role of the vertebral end plate in low back pain. Global Spine J. 2013;3(3):153-164.

[13] McCormick ZL, Sperry BP, Boody BS, et al. Pain location and exacerbating activities associated with treatment success following basivertebral nerve ablation: an aggregated cohort study of multicenter prospective clinical trial data. Pain Med. 2022;23(Suppl 2):S14-S33.

[14] McCormick ZL, Conger A, Smuck M, et al. Magnetic resonance imaging characteristics associated with treatment success from basivertebral nerve ablation: an aggregated cohort study of multicenter prospective clinical trials data. Pain Med. 2022;23(Suppl 2):S34-S49.

[15] McCormick ZL, Sperry BP, Boody BS, et al. Pain location and exacerbating activities associated with treatment success following basivertebral nerve ablation: an aggregated cohort study of multicenter prospective clinical trial data. Pain Med. 2022;23(Suppl 2):S14-S33.

[16] McCormick ZL, Conger A, Smuck M, et al. Magnetic resonance imaging characteristics associated with treatment success from basivertebral nerve ablation: an aggregated cohort study of multicenter prospective clinical trials data. Pain Med. 2022;23(Suppl 2):S34-S49.

[17] Lorio M, Clerk-Lamalice O, Rivera M, Lewandrowski KU. ISASS policy statement 2022: literature review of intraosseous basivertebral nerve ablation. Int J Spine Surg. 2022;16(4):8362.

[18] Sayed D, Naidu RK, Patel KV, et al. Best practice guidelines on the diagnosis and treatment of vertebrogenic pain with basivertebral nerve ablation from the American Society of Pain and Neuroscience. J Pain Res. 2022;15:2801-2819.

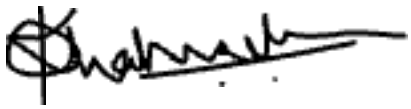
capacity, or another documented concern that could reasonably affect patient safety or expected outcome.

**Conclusion:**

We recommend the following clarifying language for Humana and Cohere authorization guidance: ***"Patients must have undergone careful screening, evaluation, and diagnosis prior to BVNA. Such screening may be performed and documented by the treating pain physician or other qualified treating clinician and should include assessment for clinically significant untreated psychological disease, active untreated substance use disorder, and other factors that may affect patient safety, informed consent, or expected outcome. A separate psychological or psychiatric evaluation is not required unless clinically indicated. Validated screening tools, such as the PHQ-9 or Beck Depression Inventory, may be used when appropriate."***

This clarification would preserve appropriate LCD requirements for patient screening and safety while avoiding unnecessary referrals, inconsistent denials, and access barriers that are not aligned with the clinical nature of BVNA. We appreciate your review of this issue and welcome the opportunity to discuss the evidence, clinical workflow, and LCD interpretation with Humana and Cohere medical leadership.

Sincerely,



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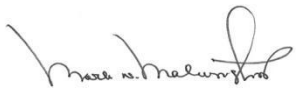

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Additional Supporting References

1. Centers for Medicare & Medicaid Services / Noridian Healthcare Solutions. Response to Comments: Intraosseous Basivertebral Nerve Ablation. Article A59598 (Comment/Response #1). Available at: cms.gov/medicare-coverage-database.

2. Centers for Medicare & Medicaid Services / Noridian Healthcare Solutions. Response to Comments: Intraosseous Basivertebral Nerve Ablation. Article A59598 (Comment/Response #9). Available at: cms.gov/medicare-coverage-database.

3. Centers for Medicare & Medicaid Services / National Government Services. Response to *Comments: Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain. Article A60430 (Comment/Response #2). Available at: cms.gov/medicare-coverage-database.*