August 31, 2023

Noridian Healthcare Solutions, LLC JF Part B Contractor Medical Director(s) Attention: LCD Comments PO Box 6781 Fargo, ND 58108-6781 via email: policydraft@noridian.com

Re: Proposed LCD - Intraosseous Basivertebral Nerve Ablation (DL39644)

To Whom It May Concern:

On behalf of representatives of ten medical specialty societies comprising physicians who utilize and/or perform intraosseous basivertebral nerve ablation, we would like to take this opportunity to share comments regarding Noridian's Proposed Local Coverage Determination for Intraosseous Basivertebral Nerve Ablation (DL39644). We have two significant concerns with the proposed LCD's covered indication: 1) the exclusion of patients with <u>any</u> non-vertebral pathology that *could* contribute to symptoms, and 2) the requirement that patients undergo screening, evaluation, and diagnosis by a multidisciplinary team to include psychological and physical assessment.

Neither of these requirements is rational or evidence-based. The studies, appropriately cited by the LCD, that have demonstrated the procedure's effectiveness did not preclude the treatment of patients with non-vertebral pathology that *could* contribute to symptoms or complaints, nor did they require extensive screening, evaluation, and diagnosis by a multidisciplinary team and implementation of a psychological assessment.

Many patients have multiple, potential pain generators and achieve significant improvement in their *vertebrogenic pain* following basivertebral nerve ablation. There are almost always physical, historical, radiological, or clinical assessment findings that *could* contribute to symptoms for which basivertebral nerve ablation is indicated and appropriate. To ensure that appropriate patients have access to this treatment, we strongly suggest you omit this bullet point ("Absence of non-vertebral pathology by physical, history, radiologic or clinical assessment including, but not limited to, fracture, tumor, infection, deformity, trauma, or post-surgical change which could explain or contribute to symptoms or complaints") from the Covered Indications section and replace the language of the second bullet point in the Limitations section to be consistent with the NASS Coverage Policy recommendations used extensively within and cited by the LCD:

• Evidence on imaging (MRI, flexion/extension radiographs, CT) suggesting alternative **another obvious** etiology for the patient's LBP symptoms...

The intent is to ensure that the patient's pain is most likely vertebrogenic in nature, so if findings on an MRI or other imaging modality suggest an alternate etiology that is **highly**

likely to be causing the symptoms, other more appropriate treatments should be considered.

Requiring screening, evaluation, and diagnosis by a multidisciplinary team is not reasonable and serves only as a barrier to treatment. A psychological assessment in these patients is unnecessary as these patients have chronic pain (≥ 6 months); have already undergone extensive conservative, non-surgical management; and have Type 1 or Type 2 Modic changes on MRI. For this patient population, the treatment is highly effective. There simply is no basis for a psychological assessment in these patients.

We hope that Noridian will consider our comments and revise this Local Coverage Determination to ensure that appropriate patients have access to this procedure. We welcome the opportunity to further elaborate on the comments provided herein and look forward to working with you to improve patient access to care and outcomes.

If you have any questions or wish to discuss our comments, please contact Sarah Cartagena, Director of Health Policy at the Spine Intervention Society, at scartagena@spineintervention.org.

Sincerely,

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 American Society of Spine Radiology North American Neuromodulation Society North American Spine Society Society of Interventional Radiology Spine Intervention Society