Date: November 25, 2019

To: Palmetto GBA Part B – MAC, AG-655
P.O. Box 100190
Columbia, SC 29202-3190

Subject: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A57436)
POLICY EFFECTIVE DATE: November 18, 2019

Dear Palmetto,

On behalf of representatives of ten medical specialty societies, comprising of physicians who utilize and/or perform percutaneous vertebral augmentation procedures, the North American Spine Society (NASS) would like to take this opportunity to share comments regarding Palmetto's recently published Future Local Coverage Determinations for Percutaneous Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (A57436). As you are aware, NASS was a signatory to a letter produced by the Multi-society Pain Workgroup (MPW) dated February 19, 2019 that expressed in detail the concerns with both the methodology used and conclusions reached by the American Society for Bone and Mineral Research (ASBMR) Task Force. NASS, along with representatives of ten other societies, continue to have significant concerns with the way the current LCD is written primarily with regards to the exclusion from treatment for all fractures over six weeks old and the requirement that a multidisciplinary team be involved, and have provided the following recommended changes to the policy that will address our primary concerns.

- Suggested revision: PVA (percutaneous vertebroplasty (PVP) or kyphoplasty (PKP) is covered in patients who have been clinically evaluated by a physician with expertise managing spine disorders (Orthopaedic Surgeon, Physiatrist, Neurosurgeon, Pain management specialist, etc.) with the following:
  1. Inclusion criteria **(a and b, omit c)**
     a. Acute to subacute osteoporotic VCF (T5 – L5) by recent (within 30 days) confirmed by advanced imaging performed within 30 days of proposed procedure (confirmed by bone marrow edema on MRI **or** bone-scan uptake/SPECT uptake/CT findings of fracture)
     b. Symptomatic:
        i. Hospitalized with severe pain [Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8] **OR**
        ii. Non-hospitalized moderate to severe pain (NRS or VAS still ≥5) despite optimal non-surgical management (NSM) (10) **(with one of the following):**
            1. Worsening or persistent pain **or**
            2. Stable to improved pain (but NRS or VAS ≥5) **(with ≥2 of the following):**

A. Progression of vertebral body height loss
B. > 25% vertebral body height reduction
C. Kyphotic deformity
D. Severe impact of VCF on daily functioning

2. Exclusion criteria:
    a. Absolute:
        i. Active infection at surgical site
        ii. Untreated blood borne infection
    b. Strong contraindication:
        i. Osteomyelitis
    c. Usually contraindicated:
        i. Pregnancy
    d. Relative Contraindications to perform vertebral augmentation alone:
        i. Allergy to fill material
        ii. Coagulopathy
        iii. Spinal instability
        iv. Myelopathy from the fracture
        v. Neurologic deficit
        vi. Neural impingement
        vii. Fracture retropulsion with neurologic compromise

As indicated in the attached letter signed by many organizations and also mentioned at the March 2019 Multijurisdictional Contractor Advisory Committee (CAC) meeting by various groups and stakeholders, there is sufficient literature available to support vertebral augmentation for the patient population identified above in our suggested criteria. Limiting this procedure to fractures <6 weeks old should be revised/eliminated as this requirement will have a negative impact on patient outcomes and providers' ability to provide evidence-based and appropriate spine care to our patients. Additionally, MPW disagrees with requiring a consensus from a multidisciplinary team including four physicians. MPW believes that this requirement is not established in the literature and will lead to increased costs and delays in patient care. For example, why does a neurologically intact patient with an acute painful osteoporotic vertebral compression fracture require consultation from a neurologist? Some data/info on the source of this restriction would be helpful.

We recommend removing the reference to the Roland Morris Disability Questionnaire as there are multiple valid tools to demonstrate functional disability. Our subject matter experts have also recommended some changes to the exclusion criteria that further stratify the degree of contraindication to allow for a more individualized approach to treatment in unusual circumstances. The relative contraindication regarding fracture retropulsion needs to be modified to include "with neurologic compromise" as vertebral augmentation can be carefully performed in patients with limited degrees of posterior vertebral wall involvement.

While periosteal infiltration remains a treatment option as part of nonoperative care, we do not believe the literature supports this as a required treatment prior to vertebral augmentation. Finally, based on our review it seems that the coverage benefits for this

procedure seem to vary by each region. We are hopeful that an appropriate coverage decision can be crafted that allows for patients to have access to appropriate treatment regardless of their region/location across the country.

After reviewing the above comments, it is hoped that Palmetto will consider our comments and revise this Local Coverage Determination to reflect all new evidence and provide coverage accordingly. We welcome the opportunity to further elaborate on the comments provided herein and look forward to working with Palmetto to improve patient access to care and outcomes.

Please contact Shweta Trivedi, RHIA, NASS Associate Executive Director of Health Policy at strivedi@spine.org if you have any questions or comments.

Sincerely,

American Academy of Pain Medicine (AAPM)

American Academy of Physical Medicine and Rehabilitation (AAPMR)

American Association of Neurological Surgeons (AANS)

American College of Radiology (ACR)

American Society of Neuroradiology (ASNR)

American Society of Spine Radiology (ASSR)

North American Neuromodulation Society (NANS)

Congress of Neurological Surgeons (CNS)

North American Spine Society (NASS)

Society of Interventional Radiology (SIR)

Spine Intervention Society (SIS)