

Date: May 1, 2023

To: Richard Valdesuso, MD, MBA, MA
National Medical Director Musculoskeletal Solutions
Musculoskeletal AIM Specialty Health
8600 West Bryn Mawr Avenue
South Tower, Suite 800
Chicago, IL 60631

Subject: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture

Dear Dr. Valdesuso,

On behalf of representatives of eleven medical specialty societies, comprised of physicians who utilize and/or perform percutaneous vertebral augmentation procedures, we request an adjustment of the Percutaneous Vertebroplasty or Kyphoplasty medical necessity language contained within the Spine Surgery 2023-01-01 coverage policy, primarily due to concerns surrounding the exclusion of fractures under six weeks old from surgical treatment. In this letter, we would like to take this opportunity to share an overview of the evidence that clearly supports this request.

The proposed revision would mirror the current Medicare Administrative Contractor (MAC) coverage available within all twelve Medicare jurisdictions, which state that PVA is considered medically necessary in patients with the following inclusion and exclusion criteria:

Painful, debilitating, osteoporotic vertebral collapse/compression fractures, that have not responded to non-surgical management (e.g. narcotic and/or non-narcotic medication, physical therapy modalities) with or without methods of immobility (e.g. bed rest, bracing).

Both PVP and PVA will be considered reasonable and necessary for osteoporotic conditions when **ALL** of the following criteria are met [1]:

- Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5) based on symptom onset, and documented by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake) **and**
- The beneficiary is symptomatic and is hospitalized with severe pain (Numeric Rating Scale [NRS] or visual Analog Scale [VAS] pain score ≥ 8) **or** is non-hospitalized with moderate to severe pain (NRS or VAS ≥ 5) despite optimal non-surgical management (NSM) with one of the following:
 - Worsening pain or
 - Stable to improved pain (but NRS or VAS ≥ 5) **when 2 or more of the following are present:**
 - Progression of vertebral body height loss
 - >25% vertebral body height reduction
 - Kyphotic deformity
 - Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire (RDQ) > 17)
 - Steroid-induced fractures
 - Reinforcement or stabilization of vertebral body prior to surgery
- **Continuum of Care**
All patients presenting with vertebral compression fractures (VCF) should be referred for evaluation of

bone mineral density and osteoporosis education for subsequent treatment of osteoporosis as indicated and instructed to take part in an osteoporosis prevention/treatment program.

Malignant Vertebral Fractures

Osteolytic vertebral metastasis or myeloma with severe back pain related to a destruction of the vertebral body, not involving the major part of the cortical bone.

1. Painful osteolytic metastasis
2. Multiple myeloma with painful vertebral body involvement

Limitations

Exclusion criteria for any patient considered for percutaneous vertebroplasty or vertebral augmentation.

1. Absolute contraindication
 - Current back pain is not primarily due to the identified acute VCF(s).
 - Osteomyelitis, discitis, or active systemic infection
2. Relative contraindication
 - Greater than three vertebral fractures per procedure
 - Allergy to bone cement or opacification agents
 - Uncorrected coagulopathy
 - Spinal instability
 - Myelopathy from the fracture
 - Neurologic deficit
 - Neural impingement
 - Fracture retropulsion/canal compromise
 - Pregnancy

To date, there is clear and sufficient evidence that supports vertebral augmentation under our suggested criteria. We believe limiting surgical procedures to fractures over six weeks old should be revised/eliminated as this requirement has the potential to negatively impact patient outcomes and providers' ability to deliver evidence-based, appropriate spinal care to all patients. Notably, recent literature supports this suggestion with positive impacts to patient biomechanical changes, pain scores, quality of life metrics, mortality rates, and long-term economic benefits.

Non-surgical management of fractures may provide pain relief in some patients; however, this conservative approach may not be appropriate for all patients. Many have an insufficient healing response, particularly in patients with spinal deformity, as NSM does not prevent kyphosis or enable orthopedic functional restoration of the damaged vertebra [2]. Thus, delaying surgical treatment in this patient cohort may result in additional negative outcomes. Furthermore, as vertebral fractures are most common in the elderly population, the prolonged bed rest, immobility, and use of narcotics with NSM may lead to decrease in physical condition, poor pulmonary function and increase mortality in this population [3]. According to Medicare Administrative Contractor summary of evidence "there is a recent trend to move toward immediate, focused surgical immobilization and away from prolonged general immobilization (e.g., casting, bracing, bedrest) and prolonged systemic pain management (e.g., opioid analgesics) particularly in the elderly. Medicare also favors early treatment of PVA in appropriate patients"[1].

Several key studies support the use of VA for the treatment of OVCFs with the key clinical benefits outlined below:

- FREE trial (2009)

- Improvement in patient QoL, function, mobility, and pain over nonsurgical management at 1 month post intervention [4]
- VAPOUR trial (2016)[5]
 - QoL outcomes improved at 6 months compared to control group when surgical intervention was performed within 3 weeks of fracture [4, 5]
 - Analysis of early surgical intervention (<3 weeks) shows clinically significant benefits exist, with reductions in pain scores[6]. This has been further supported by more recent studies that show early intervention (under 6 weeks) resulted in greater pain relief compared with conservative treatment or delayed treatment (greater than 12 weeks) [7, 8]
- VERTOS II trial (2012) [9]
 - Fractures (mean onset 5.6 weeks) treated with surgical intervention had a significantly decreased VAS score when compared to NSM as early as 1 day post procedure and the result was sustained at 1 year [9]
 - QoL questionnaires showed improved outcomes after VA compared to conservative treatment [9]

In addition to these key studies, the clinical benefits of vertebroplasty treatment in less than 6 weeks as opposed to treatment beyond that period is supported by biomechanical changes [10]. Furthermore, the ability to restore vertebral body height to correct segmental kyphosis has been shown to decrease with time, highlighting that there may be a key tradeoff between delaying treatment with prolonged NSM and the need to treat early to correct this condition [11]. Early PVA has been shown to not only increase vertebral height restoration, but also support a reduction in the rate of further collapse and refracture, further supporting our proposal for earlier intervention [12, 13].

Established patient care guidelines recommend early treatment of VCF. The National Institute for Health and Care Excellence (NICE) recommends VA in patients “who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging”[14]. In a 2014 consensus statement, the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spin Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS) considered PVA a proven medically appropriate therapy for treatment of painful VCFs refractory to brief (24 hrs.) nonoperative medical therapy[15].

Finally, the first step in the downward spiral that occurs for elderly patients with VCF may begin due to delayed VA which can have negative outcomes for patient’s psychological state and social interactions [16]. A meta-analysis recently performed demonstrated that VA performed prior to 6 weeks post fracture resulted in significantly better QoL in both the medium and long term compared to the control group [17]. There was also an increase in patient satisfaction and fewer complications when patients were treated in 2-21 days as compared to those that received NSM [7]. Moreover, it has been shown that patients who were treated with VA within 2 weeks of onset, took significantly fewer painkillers such as opiates compared to those with older fracture onset, despite decreased pain score at 6 weeks [18]. This suggests prolonged painkiller use may result in a challenge for patients to stop consumption despite decreased pain. This is key when considering the long-term effects of delayed interventional treatment. Most importantly, a recent analysis of 2,000,000 patients with vertebral compression fractures concluded that there is a significant mortality benefit for VA over NSM with a low number needed to treat of 15, in order to save a life at one year [19], and an economic benefit as shown by overall and quality-adjusted survival [20].

Overall, while NSM remains a first line treatment option for VCF, our group does not believe the literature supports delay of surgical interventions to patients who will benefit from earlier interventional treatment. Based on our review of the current body of literature, we ask that the Carelon Medical Benefits Management Musculoskeletal medical necessity criteria for PVA allow for appropriate treatment of patients that meet the criteria consistent with the Local Coverage Determinations from Medicare Administrative Contractors in all 12 jurisdictions [1, 21-27].

If you have any questions or comments related to this request. Please contact Ashley Maleki, Senior Manager of Health Policy and Economics at the Society of Interventional Radiology, at amaleki@sirweb.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
American Society of Spine Radiology
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology
Spine Intervention Society

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27. *NGS LCD L33569: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)*. 12/01/2020.