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July 25, 2019

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Submitted electronically via cmd.inquiry@cgsadmin.com

SUBJECT: Comments on Proposed LCD DL 38201 for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

Dear Dr. Berman:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), we appreciate the opportunity to provide our comments on the Celerian Group Company (CGS) Administrators, LLC, Local Coverage Determination (LCD) DL38201 for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). In our comments below, we reference the published LCD as well as the March 20, 2019, Multi-jurisdictional Medicare Administrative Contractor (MAC) Carrier Advisor Committee (CAC) conference call on PVA for Osteoporotic Vertebral Compression Fracture and other scientific evidence where noted.

PVA has emerged as a minimally invasive surgical treatment option to expedite pain control, improve quality of life, and reduce morbidity and mortality after osteoporotic compression fracture. Although some of the early trials of PVA failed to demonstrate clinical benefit over nonoperative management,[1,2] a multitude of subsequent studies have demonstrated that PVA is safe, effective and durable.[3-5]

In response to questions about the clinical literature, a consensus position statement was published in 2014 representing many of the leading professional organizations relevant to PVA.[6] The position statement supported PVA for the treatment of osteoporotic compression fractures and offered evidence-based guidelines on its proper utilization. The statement represented the views of the Society of Interventional Radiology (SIR), the American Association of Neurological Surgeons (AANS), the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the American Society of Spine Radiology (ASSR), the Canadian Interventional Radiology Association (CIRA), the Congress of Neurological Surgeons (CNS) and the Society of NeuroInterventional Surgery (SNIS). Furthermore, in 2018, Hirsch et al. introduced a clinical care pathway to facilitate decision-making for best practices on PVA based on the existing literature.

While portions of the proposed LCD are consistent with these published guidelines, several deviations lack evidence-based support and warrant revision. Our specific concerns and recommendations are as follows:

- Concern about statement 1a: “Acute (< 6 weeks).” The 6-week cut-off is inappropriate. While some of the clinical trials elected to choose six weeks as an arbitrary cut-off point for enrollment, there is no evidence that benefit is lost beyond six weeks. On the contrary, there is high-quality

evidence demonstrating benefit beyond this window. For example, the randomized controlled FREE trial[4] (referenced by the LCD) included patients with fracture age up to 3 months and demonstrated the superiority of PVA over nonoperative management. We recommend that the 6-week limitation be removed from this statement.

- Recommend dropping the statement, "**consider including pedicle periosteal infiltration" on Page 4, 1b, ii "Non-hospitalized moderate to severe pain (NRS or VAS still ≥5) despite optimal non-surgical management." This should be removed from the LCD as this is not part of routine clinical practice. Pedicle periosteal infiltration is not considered the standard of care, and despite it being used as a sham active control in the VERTOS IV study,[12] the significance of findings in this study cohort is controversial. The significance of this controversy was evident during the March 20, 2019, Multi-jurisdictional Medicare Administrative Contractor (MAC) Carrier Advisor Committee (CAC) conference call on Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture. We recommend removal of this condition.

- Concern about statement 1c on page 3: "Multidisciplinary team consensus (referring physician (e.g., rheumatologist, endocrinologist), treating physician (i.e., performing the PVA), radiologist, neurologist)." There is currently no evidence to support that multidisciplinary consensus is needed for appropriate decision-making or treatment. The treating physician, whether a neurosurgeon, interventional radiologist, or other specialist, should have the freedom to make independent decisions based on the clinical scenario.

- Concern regarding the list of exclusion criteria on page 3: We do not agree with the present wording stating that candidates for vertebral augmentation, "can have NONE of the following." As published in the RAND/UCLA Appropriateness study,[7] there are only two absolute contra-indications to vertebral augmentation, specifically: 1) active infection at the surgical site — discitis and osteomyelitis; and 2) untreated blood-borne infection. The exclusion criteria in the draft LCD are overly restrictive and do not account for the heterogeneous presentation and conditions of patients with osteoporotic vertebral fractures. Below are specific examples:

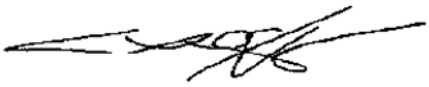
  - Page 3, 2a. "Other cause of back pain." Back pain is the leading cause of disability in the United States[8] and is particularly prevalent in the elderly population. Patients with osteoporotic fractures are very likely to also have back pain from other conditions, such as degenerative disease. These patients are no less likely to benefit from cement augmentation. Patients with "other causes of back pain" should not be excluded from PVA: this restriction has the potential to eliminate a high percentage of patients who may benefit from the procedure.
  - Page 3, 2b. "Osteomyelitis, discitis or active systemic infection." The wording here should be changed to reflect "*Active* osteomyelitis, discitis or systemic infection." PVA may still be appropriate in a treated infection.[7]
  - Page 3, 2c. "Neurological complications." As written, this is too vague, and the exact meaning is unclear. It is assumed that this implies deficit due to the fracture. Vertebral body fracture in the presence of neurologic deficit may mean that additional surgery is required such as decompression and/or stabilization. However, PVA may also be appropriate as part of the surgical treatment plan and should be left to the discretion of the treating physician and should not be an exclusion criterion.[9,10]
  - Page 3, 2d. "Significant spinal stenosis or compressive myelopathy resulting from retropulsion of fractured fragment." Again, the same rationale applies as described in our "Neurological complications" comment above. This should be left to the discretion of the treating physician.

PVA may be included in a more complex surgical treatment paradigm and should not be an exclusion criterion.[9,10]

- Page 3, 2e. "Unstable spinal fracture." In the presence of instability, surgical stabilization may also be required, but PVA may still be appropriate to include in the treatment plan.[9.10] Surgery may be required but not necessarily at the same time as augmentation. Many factors determine the stability of a fracture, and this should be left to the discretion of the treating physician and should not be an exclusion criterion. Different specialists may vary in their definition of an unstable fracture, and as written, this policy recommendation is far too restrictive.
- Page 3, 2g. "Allergy to bone cement or opacification agents." This is not an absolute contraindication. If for example, the allergy is mild, pretreatment may be all that is required, and the procedure could still be safely performed. This should be left to the discretion of the treating physician. Alternatively, a different fill material can be used.
- Page 3, 2h. "Fracture of the posterior column." The same reasoning applies here as is described our comment on 2e, "Unstable spinal fracture." Surgical stabilization may also be required, but PVA may still be appropriate to include in the treatment plan. This should be left to the discretion of the treating physician and should not be an exclusion criterion. Clinical correlation is essential, and radiographic description alone is not grounds for exclusion. Simply having a fracture of the posterior column is not a contra-indication.
- Page 3, 2i. "Greater than three vertebral fractures." Up to 20% of patients presenting with osteoporotic compression fractures have fractures at multiple levels.[11] These fractures are often of various ages (acute, subacute, chronic, etc.). Determining the actual age of a fracture is extremely difficult, and excluding patients based on the number of fractured vertebrae may limit the benefit of intervention to many patients. Any patient with a vertebral body fracture has the potential to benefit from PVA, and the number of fractures in any given patient should not be used to exclude patients.
- Page 3, 2j. "Pregnancy." Although generally contra-indicated, there may be situations where surgical or medical treatment (use of opioids, for example) is prohibitive, and PVA may be considered. Acknowledgment of the application of this intervention in such circumstances should remove it from exclusion.

Thank you for considering our recommendations on the proposed LCD for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). If you have any questions, or need additional information, please contact us.

Sincerely,



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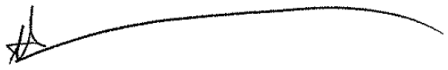

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