February 18, 2025

Committee Members
Health Technology Clinical Committee
Washington State Health Care Authority

Re: Washington State Health Technology Clinical Committee (HTCC) review of Vertebroplasty, Kyphoplasty and Sacroplasty.

Members of the Committee:

On behalf of the Society of Interventional Radiology, the American College of Radiology and the Washington State Radiological Society representing nearly 40,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates, we would like to formally request to reopen of the discussion of the Washington State Health Technology Clinical Committee (HTCC) review on Vertebroplasty, Kyphoplasty and Sacroplasty that was conducted virtually on Friday, January 31, 2025. We believe that there was insufficient conversation of the rationale for the committee's coverage determination relative to federal policy and the evidence presented (specifically registry and real-world data), lack of time for public comment and discussion by non-committee members, and incorrect statements made by the HTCC's clinical expert.

Although the committee call lasted five hours and featured ample time for the commentary of the committee members and consultants, there was inadequate time for comments by practicing clinicians. The four clinicians who addressed the committee were given four minutes each and were cut off if they exceeded that time limit. In addition to draconian time limits, the committee did not comment on, consider, or address any of the supplementary information provided by the clinicians well in advance of the committee meeting.

The clinical expert selected by the HTCC did not accurately describe contemporary vertebral augmentation procedures. There were numerous misstatements involving the efficacy of vertebral augmentation, the performance of vertebroplasty and kyphoplasty, and substantial inaccuracies involving the safety of the procedures. For example, there was a statement made about cement "within" the balloon – which is not technically feasible, Balloons are used to inflate the intravertebral space. Once vertebral body height is sufficiently restored, cement is injected through the needle but never into the balloon itself. Because of this, we performed an analysis of Medicare Fee-for-Service,

Medicare Advantage, and subset of Commercial Insurance claims data with the CPT codes for vertebroplasty and kyphoplasty procedures (22510, 22511, 22513, 22514), and found data consistent with the HTCC clinical expert performing no more than 1-2 vertebroplasty or kyphoplasty procedures per year over 2016-2024 . If this claims analysis is correct, we respectfully question the clinical expert's ability to respond to technical questions regarding the procedures reviewed. Because the presenting clinicians could not respond to incorrect information presented during or after committee discussion, the committee did not receive complete, accurate information to make their coverage decisions.

The committee discussed the role of federal coverage decisions (i.e. Medicare) on the committee's review of the literature and ultimate coverage determination. The committee also stated that a Medicare National Coverage Determination (NCD) holds greater importance than Local Coverage Determinations, which vary. This is a misstatement and shows the committee did not review federal coverage information submitted in public comments. For osteoporotic vertebroplasty and kyphoplasty procedures, although there is not an NCD, seven independent LCDs ALL came to identical clinical inclusion and exclusion criteria for coverage. These seven LCDs represent federal Medicare program coverage given CMS budgets cover patients granted treatment under the LCDs. Two of the seven LCDs varied only slightly in defining the diagnosis by providing further detail on what constitutes non-surgical management (NSM). We outline these LCDs again in the **Appendix** to this letter. Regarding the HTCC's bylaws, we see no statement supporting the claim that NCDs hold more importance to the committee than LCDs. Rather, Title 70, Chapter 70.14, Section **70.14.110** of the WA State Legislature states that[i]:

> *"(3) Determinations of the committee under subsection (1) of this section shall be consistent with decisions made under the federal Medicare program and in expert treatment guidelines, including those from specialty physician organizations and patient advocacy organizations, unless the committee concludes, based on its review of the systematic assessment, that substantial evidence regarding the safety, efficacy, and cost-effectiveness of the technology supports a contrary determination."*

The committee did not adequately discuss what "substantial evidence" supported a different coverage determination vs. CMS Medicare Administrative Contractors (MACs). We appreciate the bylaws allow the committee to come to a different conclusion on coverage. However, the committee did not clearly state what evidence led them to come to a conclusion that differs from the LCDs, especially given nearly all RCTs and society guidelines reviewed by the HTCC were also evaluated by Medicare

Administrative Contractor (MAC) medical directors. Considering this unexpected divergence from widely accepted guidelines, we respectfully request an additional public comment meeting with discussion of federal coverage included.

Another consideration is that the discussion was insufficient regarding the literature presented as contained in the Aggregate Analytics final report. The committee members repeatedly stated they were reviewing Randomized Control Trials (RCTs). This evaluation disregards other types of literature, including observational studies, case series, claims-based analyses, and registry data, which is particularly relevant to this patient population. Examining RCTs alone has well known shortcomings including feasibility constraints, short follow-up duration, under-representation of certain complications, patient selection bias, learning curve variability, exclusion of valuable non-RCT evidence, and limited real-world applicability. One example of data that was excluded was several large claims-based analyses that showed significant correlation between percutaneous vertebral augmentation and a mortality reduction of 55% - translating to an additional 2.2 to 7.3 years of life per patient compared to non-surgical management (1, 2) were not included.

Registry data that provides real world treatment effectiveness and crucial evidence for clinical decision making was also not discussed even though the United States Vertebral Augmentation Registry, a registry which includes patients that reside in WA state given its geographic area for enrollment, was submitted to the committee months in advance during open comment periods (3, 4). Results from this registry were presented during public comment, but the committee did not discuss these vital data. The committee also did not consider any data on sacroplasty despite there being many published articles, including retrospective cases series, prospective case series, a prospective cohort study, a 10-year follow-up study, and multiple meta-analyses (5 – 7).

Despite two recent Level 1A meta-analyses published since the last literature update in 2020, the committee appeared to spend disproportionate time reviewing two older sham-controlled trials, which were already reviewed in 2010, 2016, 2017, and 2020 (8, 9). This occurred at the expense of review of published meta-analyses in peer-reviewed journals, including over 30 RCTs from 10 countries, that are more representative of today's outcomes than singular findings from outdated trials. The initial data presentation by Andrea Skelly, PhD highlighted the need for a more comprehensive analysis of the literature, as it showcased a single negative article (10) that compared the difference in the change in mean values of pain scores, a technique that some statisticians consider invalid (11, 12). Two sham trials were also included as Level 1

trials despite being downgraded due to inclusion and exclusion criteria for both articles and cross over in the INVEST trial (13, 14). Finally, a clinical care pathway developed by a multispecialty expert panel using the RAND/UCLA Appropriateness Methodology was also not addressed (15). This care pathway was referenced in all MAC literature reviews in development of their local coverage determinations (LCDs). We respectfully question why a clinician-developed care pathway was deemed relevant for review by MAC administrators and not by the WA Health Technology Committee. This publication, if reviewed, could have answered questions that were raised and then not evaluated on "what the appropriate populations for treatment" are.

In summary, based on the insufficient discussion of the literature , specifically inadequate discussion of justification of a differing coverage conclusion vs. federal policies (LCDs), lack of consideration of real-world registry and claims-based publications, unsatisfactory discussion of level 1A meta-analyses of trial data, insufficient time for practicing clinician input, and the questionable technical expertise with contemporary VCF procedures by the clinical expert, we are formally requesting an immediate reopening of the coverage discussion by the Washington State Health Technology Clinical Committee review of Vertebroplasty, Kyphoplasty and Sacroplasty and not defer until the next timeline for re-review in eighteen months.

Sincerely,

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References

1. Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials? Osteoporos Int. 2018 Feb;29(2):375-383. doi: 10.1007/s00198-017-4281-z. Epub 2017 Oct 24. PMID: 29063215; PMCID: PMC6394540.
2. Edidin AA, Ong KL, Lau E, Kurtz SM. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. J Bone Miner Res. 2011 Jul;26(7):1617-26. doi: 10.1002/jbmr.353. PMID: 21308780.
3. Shonnard NH, Berven S, Anderson PA, Verschuyl E, Norwitz J, Shonnard N, Khor S, Wagoner DD, Yoon ES, Beall DP. Appropriate Management of Vertebral Fragility Fractures: Development of a Pathway Based on a Vertebral Compression Fracture Registry. *Pain Physician*. 2020;23(4):E343-E352.
4. Beall DP, Shonnard NH, Shonnard MC, Yoon ES, Norwitz J, Phillips JE, Phillips TR. An Interim Analysis of the First 102 Patients Treated in the Prospective Vertebral Augmentation Sacroplasty Fracture Registry. *J Vasc Interv Radiol*. 2023 May 18:S1051-0443(23)00356-1. doi: 10.1016/j.jvir.2023.05.024. Epub ahead of print. PMID: 37207812.
5. Chandra V, Wajswol E, Shukla P, Contractor S, Kumar A. Safety andefficacy of sacroplasty for sacral fractures: a systematic review and meta-analysis. J Vasc Interv Radiol 2019; 30:1845–1854.
6. Tarawneh AM, Sabou S, AlKalbani S, Pasku D, Quraishi NA. Clinicaloutcomes of sacroplasty for metastatic sacral tumours: a systematic review and meta-analysis. Eur Spine J 2020; 29:3116–3122.
7. Frey ME, Warner C, Thomas SM, et al. Sacroplasty: a ten-year analysis of prospective patients treated with percutaneous sacroplasty: literature review and technical considerations. Pain Physician 2017; 20:E1063–E1072.
8. Zhang T, Peng Y, Li J. Comparison of clinical and radiological outcomes of vertebral body stenting versus percutaneous kyphoplasty for the treatment of osteoporotic vertebral compression fracture: A systematic review and meta-analysis. Jt Dis Relat Surg 2024;35:218-30.
9. Liu Y, Liu J, Suvithayasiri S, Han I, Kim JS. Comparative Efficacy of Surgical Interventions for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Network Meta-analysis. Neurospine 2023;20:1142-58.
10. Firanescu CE, Vries J,Lodder P, Venmans A, Schoemaker M, Smeet A, Donga E, Juttmann J, Klazen C, Elgersma O, Jansen F, Tielbeek A, Boukrab I, Schonenberg K, van Rooij W, Hirsch JA, Lohle PNM. Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV):
11. Farrar JT, Portenoy RK, Berlin JA, *et al*. Defining the clinically important difference in pain outcome measures. *Pain* 2000;88:287–94.

12. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. *J Orthop Surg Res* 2015;10:24.

13. Kallmes DF, Comstock BA, Heagerty PJ, Turner JA, Wilson DJ, Diamond TH, Edwards R, Gray LA, Stout L, Owen S, Hollingworth W, Ghdoke B, Annesley-Williams DJ, Ralston SH, Jarvik JG. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009; 361:569-579.
14. Buchbinder R, Osborne RH, Ebeling PR, Wark JD, Mitchell P, Wriedt C, Graves S, Staples MP, Murphy B. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009; 361:557-568.
15. Hirsch JA, Beall DP, Chambers MR, Andreshak TG, Brook AL, Bruel BM, Deen HG, Gerszten PC, Kreiner DS, Sansur CA, Tutton SM, van der Meer P, Stoevelaar HJ. Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method. *Spine J*. 2018 Nov;18(11):2152-2161. doi: 10.1016/j.spinee.2018.07.025. Epub 2018 Aug 7. PMID: 30096377.

Appendix A: Summary of Medicare Administrative Contractor (MAC) Local Coverage Determinations (LCDs)

Medicare Administrative Contractor (MAC)	Local Coverage Determination (LCD) Title	LCD ID & Link	Date	Inclusion Criteria: Diagnosis	Inclusion Criteria: Symptoms	Exclusion Criteria: Absolute Contraindications	Exclusion Criteria: Relative Contraindications
CGS Administrators, LLC J-15	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L38201	**10/3/2024**	Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise
First Coast Service Options, Inc. J-N	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L34976	**7/11/2021**	Painful, debilitating, osteoporotic VCFs… not responded to non-surgical management (NSM: medication, physical therapy, rest, bracing) Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise

Medicare Administrative Contractor (MAC)	Local Coverage Determination (LCD) Title	LCD ID & Link	Date	Inclusion Criteria: Diagnosis	Inclusion Criteria: Symptoms	Exclusion Criteria: Absolute Contraindications	Exclusion Criteria: Relative Contraindications
National Government Services, Inc. J-06, J-K	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L33569	**12/1/2020**	Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise
Noridian Healthcare Solutions, LLC J-F	**Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)**	L34106	**1/10/2021**	Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise

Medicare Administrative Contractor (MAC)	Local Coverage Determination (LCD) Title	LCD ID & Link	Date	Inclusion Criteria: Diagnosis	Inclusion Criteria: Symptoms	Exclusion Criteria: Absolute Contraindications	Exclusion Criteria: Relative Contraindications
Noridian Healthcare Solutions, LLC J-E	**Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)**	L34228	**1/10/2021**	Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise
Novitas Solutions, Inc J-H, J-L	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L35130	**7/11/2021**	Painful, debilitating, osteoporotic VCFs… not responded to NSM (medication, physical therapy, rest, bracing) Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise

Medicare Administrative Contractor (MAC)	Local Coverage Determination (LCD) Title	LCD ID & Link	Date	Inclusion Criteria: Diagnosis	Inclusion Criteria: Symptoms	Exclusion Criteria: Absolute Contraindications	Exclusion Criteria: Relative Contraindications
Palmetto GBA J-J, J-M	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L38737	**7/20/2023**	Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17)	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection (c) Pregnancy	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise
Wisconsin Physicians Service Insurance Corporation J-05, J-08	**Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)**	L38213	**8/1/2024**	Painful, debilitating, osteoporotic VCFs… not responded to NSM (medication, physical therapy, rest, bracing) Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5)…documented by imaging	(a) Hospitalized with pain ≥8 OR (b) Non-hospitalized with pain ≥5 AND worsening pain OR Stable pain ≥5 AND 2 or more of: - Progression vertebral height loss - > 25% height reduction - Kyphotic deformity - Severe impact daily functioning (RMDQ > 17) - Steroid-induced fractures - Reinforcement or stabilization of vertebral body prior to surgery	(a) Pain not primarily due to VCF (b) Osteomyelitis, discitis or active infection	(a) >3 fractures per procedure (b) Allergy to bone cement (c) Uncorrected coagulopathy (d) Spinal instability (e) Myelopathy from fracture (f) Neurologic deficit (g) Neural impingement (f) Fracture retropulsion/canal compromise (g) Pregnancy

[i] RCW 70.14.110. Health technology clinical committee determinations.https://app.leg.wa.gov/RCW/default.aspx?cite=70.14.110