Washington State Health Care Authority

March 21, 2025 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

- Meeting minutes: January 31, 2025
- Timeline, overview, and comments – Vertebroplasty, kyphoplasty, sacroplasty
- Draft findings and decision – Vertebroplasty, kyphoplasty, sacroplasty

Washington State Health Care Authority

Health Technology Clinical Committee

Date: January 31, 2025
Time: 8:00 a.m. – 2:30 p.m.
Location: Webinar
Adopted: Pending

Meeting materials and transcripts are available on the **HTA website.**

HTCC Minutes

Members present: John Bramhall, MD, PhD; Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Laurie Mischley, ND, MPH, PhD; Evan Oakes, MD, MPH; Amy Occhino, MD; Jonathan Sham, MD; Jonathan Staloff, MD, MSc; Tony Yen, MD
Clinical expert: Sohail Mirza, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** Dr. Friedly, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, and an overview of the HTA program.
3. **Previous meeting business:**

   September 20, 2024 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Ten committee members approved the September 20, 2024 meeting minutes.

   Vote on treatments for chondral defects of the knee draft findings and decision: Public comments and draft findings reviewed.

   Action: Eight committee members voted to finalize chondral defects draft findings and decision and two members abstained.

   January 10, 2025 retreat meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Ten committee members approved the January 10, 2025 retreat meeting minutes.

   Review and vote on updated bylaw changes: Committee recusal changes were discussed at the January 10, 2025 retreat were reviewed.

   Action: Ten committee members voted to finalize bylaw changes.
4. **Femoroacetabular impingement**

   HTCC reviewed petition and supplemental materials.

Action: Ten committee members voted that the evidence presented would not change the previous determination.

5. Treatments for chondral defects of the knee

HTCC discussion and action:

Discussion

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of vertebroplasty, kyphoplasty, and sacroplasty. The committee decided that the current evidence on vertebroplasty, kyphoplasty, and sacroplasty was sufficient to determine non-coverage. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted not to cover vertebroplasty, kyphoplasty, and sacroplasty.

	Not covered	Covered with conditions	Covered unconditionally
Vertebroplasty	7	3	0
Kyphoplasty	8	2	0
Sacroplasty	10	0	0

Discussion

The committee reviewed and discussed the available studies for use of vertebroplasty, kyphoplasty, and sacroplasty. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. In addition to consideration of the evidence from the report and evidence shared by public commenters, the committee discussed other payer policies and the relationship to Medicare and HTCC decision process. A majority of committee members found the evidence sufficient to determine that use of vertebroplasty, kyphoplasty, or sacroplasty are unproven for being safer, more effective, or more cost-effective than comparators.

Decision

Vertebroplasty is **not a covered benefit**

Kyphoplasty is **not a covered benefit**

Sacroplasty is **not a covered benefit**

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there are no NCD's for vertebroplasty, kyphoplasty, or sacroplasty.

The committee discussed clinical guidelines identified from the following organizations:

- American Academy of Orthopaedic Surgeons (AAOS), 2010 updated 2023
- American College of Radiology (ACR), 2022
- American College of Radiology (ACR), American Society of Neuroradiology (ASNR), Society of Neurointerventional Surgery (SNIS), American Society of Spine Radiology (ASSR), and the Society of Interventional Radiology (SIR), 2017 (updated 2022)
- American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and the American Society of Spine Radiology, 2007
- International Society for the Advancement of Spine Surgery (ISASS), 2019
- North American Spine Society (NASS), 2023
- National Institute for Health and Care Excellence (NICE) (United Kingdom), 2013
- American Academy of Family Physicians (AAFP), 2016
- American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) (Updated 2020)
- Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and Society of NeuroInterventional Surgery (SNIS), 2014
- American Association of Neurological Surgeons (AANS)
- Society of NeuroInterventional Surgery (SNIS), 2014
- German Society for Orthopaedics and Trauma (DGOU), 2018
- WFNS Spine Committee, 2022
- American Society of Anesthesiologist (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA), 2010
- Society of Interventional Radiology (SIR), 2014
- American Society of Pain and Neuroscience (ASPN), 2021
- International Myeloma Working Group (IMWG), 2013
- Cardiovascular and Interventional Radiological Society of Europe (CIRSE), 2017
- RAND/UCLA Appropriateness Method Clinical Care Pathway, multispecialty Expert Panel, 2018

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on vertebroplasty, kyphoplasty, and sacroplasty for public comment to be followed by consideration for final approval at the next committee meeting.

6. Meeting adjourned

Washington State Health Care Authority

Vertebroplasty, kyphoplasty, sacroplasty

Draft findings and decision

Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Selected technologies published	July 7, 2023	
Public comments	July 7 to August 7, 2023	**31**
Draft key questions published	April 4, 2024	
Public comments	April 4 to April 17, 2024	**14**
Final key questions published	May 15, 2024	
Draft report published	September 4, 2024	
Public comments	September 4 to October 3, 2024	**30**
Final report published	October 18, 2024	
Public meeting	January 31, 2025	
Draft findings & decision published	February 6, 2025	
Public comments	February 6 to 20, 2025	**15**

Overview

Category	Comment Period *February 6 to 20, 2025*	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	1	Yes
Professional society & advocacy organization	2	Yes
Total	**3**	

Comments

	Respondents	Representing	Cited Evidence
1.	Douglas Beall, MD	Comprehensive Specialty Care	Yes
2.	Joshua Rittenberg, MD	International Pain and Spine Intervention Society	Yes
3.	Wendy Chan	Medtronic	Yes

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: AA State Health Tech Clinical Committee review of VP, KP and SP
Date: Wednesday, February 19, 2025 6:37:25 AM
Attachments: Outlook-drqgbnpk.png
WA State HCA_HTCC Coverage VCF - Letter.pdf

External Email

Committee Members-

Please see the attached letter objecting to the seriously flawed review of the literature, inadequate discussion of coverage justification, insufficient consideration of literature, lack of adequate expert representation, etc. that formally requests an immediate reopening of the coverage discussion by the Washington State Health Technology Clinical Committee for its review of Vertebroplasty, Kyphoplasty and Sacroplasty. Note the signatories on this letter include an experts in the field of Vertebral Augmentation including the PIs of the worlds largest VA registry and representative of the American College of Radiology, the Society of Interventional Radiology and the Washington State Radiological Society.

Sincerely,

Douglas P. Beall, M.D.
Fellow of Interventional Pain Practice (FIPP)
Fellow of the Society of Interventional Radiology (FSIR)
Diplomate of the Academy of Integrative Pain Management (DAIPM)
Chief of Services, Comprehensive Specialty Care; Director of Research Clinical Investigations LLC.
Specializing in Musculoskeletal Intervention
[redacted]

COMPREHENSIVE
SPECIALTY CARE

February 12, 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,

Douglas P. Beall, MD, FSIR
Chief of Radiology Services, Clinical Radiology of Oklahoma

Neal Shonnard, MD
Rainier Orthopedic Institute

Jack Jennings, MD PhD
Mallinckrodt Institute of Radiology, Washington University

Robert J. Lewandowski, MD, FSIR
President, Society of Interventional Radiology

Edward Kim MD
President, Washington State Radiological Society (WSRS)

References

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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

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: IPSIS Comments on VKS
Date: Thursday, February 20, 2025 6:13:30 AM
Attachments: IPSIS to WA State - VKS 2025.pdf

External Email

Good morning,

On behalf of the International Pain and Spine Intervention Society (IPSIS), I am submitting the attached letter regarding the draft findings and decision concerning vertebroplasty, kyphoplasty, and sacroplasty (VKS). IPSIS sincerely appreciates the opportunity to provide input on this matter and remains committed to ensuring that patients have access to appropriate, evidence-based interventional pain treatments.

If you have any questions, please do not hesitate to reach out.

Thank you,
-Sarah

Sarah Cartagena, MS
Director of Health Policy
International Pain and Spine Intervention Society (IPSIS)
[redacted]

February 20, 2025

Josh Morse, MPH
Health Technology Assessment Program Director
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PO Box 42712
Olympia, WA 98504-2712

On behalf of the International Pain and Spine Intervention Society (IPSIS), we sincerely appreciate the opportunity to comment on the draft findings and decision regarding vertebroplasty, kyphoplasty, and sacroplasty (VKS). IPSIS is a multi-specialty association consisting of nearly 3,500 physicians dedicated to developing and promoting the highest standards for the practice of interventional procedures in the diagnosis and treatment of pain. The Society's membership includes leading clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care, as well as interventional pain management for musculoskeletal care, is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

We must express our strong objection to the draft findings and decision concerning vertebroplasty and kyphoplasty. It is profoundly concerning that most committee members concluded that current evidence is insufficient to demonstrate that these procedures are safer, more effective, or more cost-effective than alternative treatments. Additionally, the committee did not acknowledge or consider the supplementary information that stakeholders provided in response to the draft health technology assessment in advance of the January 31st open meeting, which outlined a significant body of evidence related to the safety and effectiveness of these procedures.

During the open meeting, the committee failed to define what constituted substantial evidence to justify a coverage decision that differs from the Medicare Administrative Contractors (MACs) multiple Local Coverage Determinations (LCDs) on VKS. While there is no National Coverage Determination (NCD) for vertebroplasty and kyphoplasty, seven LCDs have established consistent clinical criteria for coverage, including both inclusion and exclusion criteria, and provide coverage for appropriately selected patients.

We are profoundly concerned that the Health Technology Clinical Committee's decision to deny coverage for vertebroplasty and kyphoplasty poses a significant threat to patient care, which will result in reduced quality of life and increased mortality. This decision unjustly restricts access to vital, evidence-based procedures that offer hope and healing to patients who have exhausted other treatment options. We implore you to urgently reconsider both the

[redacted]

evidence and your decision to ensure that patients in Washington receive the critical care they deserve.

We offer our ongoing input and expertise in this matter. Should you require additional information or wish to discuss this further, please do not hesitate to contact Sarah Cartagena, Director of Health Policy, at scartagena@ipsismed.org.

Sincerely,

Joshua Rittenberg, MD
President
International Pain and Spine Intervention Society

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Medtronic comments for WA HTA Draft Decision on VCF Procedures
Date: Monday, February 17, 2025 3:52:13 PM
Attachments: image001.png
Medtronic Letter WA HTA VCF Draft Decision Feb 2025.pdf

External Email

To Whom It May Concern,

Please see attached comments for the WA State HCA's request on vertebral compression fracture procedures.

We appreciate the opportunity to comment. We strongly hope that the WA State HCA will take these comments into consideration prior to implementing their non-coverage policy.

If you have questions, please contact me or Christine Ricker.

Kind regards,

Wendy Chan

Wendy Chan, MHA
Vice President, Health Economics, Policy and Reimbursement

Medtronic
Neuromodulation, Pelvic Health, Neurovascular & ENT

[redacted]

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Engineering the extraordinary

Medtronic

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712

Via email: shtap@hca.wa.gov

RE: Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview – Draft Decision

February 17, 2025

To Members of the Health Technology Clinical Committee,

In response to public comment on the Health Technology Clinical Committee's (HTCC)'s public meeting held January 31st, we are writing to express grave concern with the draft non-coverage decision for vertebroplasty, kyphoplasty, and sacroplasty. We appreciate the opportunity for public comment throughout the process but are deeply concerned with several aspects of the public meeting. There was inadequate review of technical aspects of these procedures and misstatements made by the clinical expert, insufficient time for practicing clinicians to present their experiences with patient outcomes and safety, and most importantly continued misalignment of the HTCC's interpretation of the literature with federal coverage policy.

As noted in our comment letter on the draft report, there are seven active Medicare Local Coverage Determination (LCD), one per Medicare Administrative Contractor (MAC).[1-7] All seven LCDs cover KP and VP, representing national coverage among patients with Medicare. Each LCD included a review of clinical evidence and concluded that vertebroplasty and kyphoplasty met the "reasonable and necessary" standard for treatment. The public meeting did not sufficiently review each of these LCDs prior to opening the committee to voting. There was dialogue by the HTCC that there is no National Coverage Determination (NCD) for vertebral compression fracture treatments, however in absence of an NCD, LCDs are considered federal coverage policy. We appreciate the committee may come to a different determination than federal policy, however the WA HTA program's bylaws indicate that …"determinations of the committee…shall be consistent with the federal Medicare program….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 decision".[8] The rationale for the

HTCC's differing interpretation of safety and efficacy vs. federal coverage was not discussed prior to opening for voting. It remains unclear why the HTCC feels their review of clinical literature supports a different conclusion on safety and efficacy relative to identical reviews by seven independent MACs.

Finally, we again point to relevant literature that the HTCC did not discuss prior to opening the committee to vote. We previously submitted the care pathway publication in 2018 by Hirsch et al.[9] which employed a rigorous RAND-UCLA appropriateness method to proper patient identification for treatment which was cited in all LCDs. This provides detailed information on potential coverage criteria for discussion and was omitted from the final report – despite our bringing it to the committee's attention during comment on the draft evidence report. Additionally, during the Jan 31st live meeting, Dr. Shonnard presented real-world outcomes from over 700 patients enrolled in a registry created to support the Noridian MAC's "coverage with evidence development" decision.[10] This is inclusive of patients that reside in WA, therefore it is a disservice to not evaluate findings from this registry further.

We are concerned this decision continues to limit patient access to a treatment for a debilitating fracture – a restriction that unduly places patients at risk of opioid dependency or worse.

Sincerely,

Wendy Chan
Vice President Health Economics & Reimbursement, Medtronic
[redacted]

1. CGS. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). L38201. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38201. Published 2023. Accessed 09/27/2024.
2. FCSO. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). L34976. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34976. Published 2021. Accessed 09/27/2024.
3. NGS. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). L33569. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33569. Published 2020. Accessed 09/27/2024.

4. Noridian. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). L34228 and L34106. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34228. Published 2021. Accessed 09/27/2024.
5. Novitas. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). L35130. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35130. Published 2021. Accessed 09/27/2024.
6. Palmetto. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). L38737. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38737. Published 2023. Accessed 09/27/2024.
7. WPS. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). L38213. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38213. Published 2024. Accessed 09/27/2024.
8. Legislature WS. Health technology clinical committee determinations. RCW 70.14.110. https://app.leg.wa.gov/RCW/default.aspx?cite=70.14.110. Published 2006. Accessed Feb 14, 2025.
9. Hirsch JA, Beall DP, Chambers MR, et al. Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method. *Spine J.* 2018;18(11):2152-2161.
10. Shonnard NH, Berven S, Anderson PA, et al. Appropriate Management of Vertebral Fragility Fractures: Development of a Pathway Based on a Vertebral Compression Fracture Registry. *Pain Physician*. 2020;23(4):E343-e352.

Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision
Topic: Vertebroplasty, kyphoplasty, and sacroplasty
Meeting date: January 31, 2025
Final adoption: Pending

Number and coverage topic:
20250131A – Vertebroplasty, kyphoplasty, and sacroplasty

HTCC coverage determination:
Vertebroplasty is **not a covered benefit**

Kyphoplasty is **not a covered benefit**

Sacroplasty is **not a covered benefit**

HTCC reimbursement determination:
Limitations of coverage: N/A

Non-covered indicators: N/A

Related documents:
- Final key questions
- Final evidence report
- Meeting materials and transcript

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of vertebroplasty, kyphoplasty, and sacroplasty. The committee decided that the current evidence on vertebroplasty, kyphoplasty, and sacroplasty was sufficient to determine non-coverage. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted not to cover vertebroplasty, kyphoplasty, and sacroplasty.

	Not covered	Covered under certain conditions	Covered unconditionally
Vertebroplasty	7	3	0
Kyphoplasty	8	2	0
Sacroplasty	10	0	0

Discussion

The committee reviewed and discussed the available studies for use of vertebroplasty, kyphoplasty, and sacroplasty. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. In addition to consideration of the evidence from the report and evidence shared by public commenters, the committee discussed other payer policies and the relationship to Medicare and HTCC decision process. A majority of committee members found the evidence sufficient to determine that use of vertebroplasty, kyphoplasty, or sacroplasty are unproven for being safer, more effective, or more cost-effective than comparators.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there are no NCD's for vertebroplasty, kyphoplasty, or sacroplasty.

The committee discussed clinical guidelines identified from the following organizations:

- American Academy of Orthopaedic Surgeons (AAOS), 2010 updated 2023
- American College of Radiology (ACR), 2022
- American College of Radiology (ACR), American Society of Neuroradiology (ASNR), Society of Neurointerventional Surgery (SNIS), American Society of Spine Radiology (ASSR), and the Society of Interventional Radiology (SIR), 2017 (updated 2022)
- American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and the American Society of Spine Radiology, 2007
- International Society for the Advancement of Spine Surgery (ISASS), 2019
- North American Spine Society (NASS), 2023

- National Institute for Health and Care Excellence (NICE) (United Kingdom), 2013
- American Academy of Family Physicians (AAFP), 2016
- American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) (Updated 2020)
- Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and Society of NeuroInterventional Surgery (SNIS), 2014
- American Association of Neurological Surgeons (AANS)
- Society of NeuroInterventional Surgery (SNIS), 2014
- German Society for Orthopaedics and Trauma (DGOU), 2018
- WFNS Spine Committee, 2022
- American Society of Anesthesiologist (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA), 2010
- Society of Interventional Radiology (SIR), 2014
- American Society of Pain and Neuroscience (ASPN), 2021
- International Myeloma Working Group (IMWG), 2013
- Cardiovascular and Interventional Radiological Society of Europe (CIRSE), 2017
- RAND/UCLA Appropriateness Method Clinical Care Pathway, multispecialty Expert Panel, 2018

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on vertebroplasty, kyphoplasty, and sacroplasty for public comment to be followed by consideration for final approval at the next committee meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company that takes public input at all stages.

Pursuant to RCW 70.14.110, a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.