Washington State Health Care Authority

Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview: Public Comments and Response

Final evidence report: Peer review, comment and response

October 17, 2024

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Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview: Peer Review and Public Comments and Response

Provided by:

Aggregate Analytics, Inc.

October 17, 2024

Aggregate Analytics Inc. is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during public comment periods are included in this document and attachments. Comments related to program decisions, process or other matters not pertaining to the evidence report, are acknowledged through inclusion only.

Specific responses pertaining to peer reviewer comments are included in **Table 1.** Draft report peer reviewers include:

- Jesse Liu, MD, Assistant Professor Neurological Surgery, School of Medicine, Assistant Professor of Interventional Radiology, School of Medicine, Oregon Health & Science University
- Sohail K. Mirza, MD, MPH, Professor of Engineering, Thayer School of Engineering, Dartmouth College

Responses to public comments from medical and professional organizations on Key Question posting may be found in **Table 2**.

- Ashley Maleki, CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology
- Alda L. Tam, MD, MBA, FSIR, President, Society of Interventional Radiology
- Wendy Chan, MHA, Vice President, Health Economics Policy Reimbursement (HEPR), Neuroscience, Medtronic

Responses to public comments from medical and professional organizations on the Draft Report posting may be found in **Table 3.** These include:

- Ashley Maleki, CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology
- Wendy Chan, MHA, Vice President, Health Economics Policy Reimbursement (HEPR), Neuroscience, Medtronic
- Stan Dietz, Director Reimbursement & Market Access, Stryker
- Robert Poser, DBM, Vice President, Global Spinal Therapies, Merit Medical
- Joshua Rittenberg, MD, President, International Pain and Spine Intervention Society
- Christopher Gharibo, MD, President, American Society of Interventional Pain Physicians
- Laxmaiah Manchikanti, MD, Chairman of the Board and CEO, American Society of Interventional Pain Physicians, Society of Interventional Pain Management Surgery Centers Inc., (ASIPP, SIPMS & KSIPP)
- Amol Soin, MD, Lifetime Director, American Society of Interventional Pain Physicians (ASIPP)
- Washington State Labor & Industries (L&I)
- Joint comments submitted by American Academy of Pain Medicine (AAPM), American Academy of Physical Medicine and Rehabilitation (AAPM&R), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Interventional Pain and Spine Intervention Society (IPSIS), North American Neuromodulation Society (NANS), North American Spine Society (NASS), Society of International Radiology (SIR).

Full texts of peer reviews may be found in the appendix immediately following the list of individuals who provided general public comment.

Table 1 Responses to Clinical and Peer Reviewers

	Comment	Response
Jesse Liu, MD, Assistant Professor Neurological Surgery, School of Medicine, Assistant Professor of Interventional Radiology, School of Medicine, Oregon Health & Science University		
	Specific comments	
Introduction	I think the overview of the topic is adequate. Vertebral and sacral compression fractures can be quite morbid in many populations and these treatments may be able to address them. Public policy should aim to reduce the morbidity and mortality of these pathologies (fractures) to improve the quality and quantity of life for these patients.	Thank you for your comments. The vendor does not suggest or provide positions on policy.
Report Objectives & Key Questions	The Key questions are appropriate and the study design is appropriate. Although given the current research and economic climate, I worry that there may not be further randomized controlled trials to examine the issue and we may be left with cohort studies or non-randomized comparison studies. If that is the case, then we need to somehow adjust the relative weight of the new, current studies in light of the findings from previous RCTs.	Thank you for your comments. All reviews are a snapshot of current evidence. This updated review includes evidence from the most recently reported trials.
Methods	The methods are internally consistent and appropriate. Evaluation of levels of pain, opioid use, functional outcome, and quality of life are all valid. Unfortunately, reliance and influence of past RCTs will confound current practice patterns and trends and will introduce bias in forming new policy.	Thank you for your comments. The vendor does not suggest policy.
Results	I think the results are appropriate and the tables and appendices are easy to read. The major findings are states clearly. But I do think that there should be some weight given to non-randomized cohorts or registries. For example, a 2019 study demonstrated KP was safe, effective, and durable for treating patients with patient VCF due to osteoporosis or cancer. This was not an RCT, but it was a multicenter non-randomized trial. (Beal, 2019) Another study that should be included is a prospective multi-national single-arm study to investigate the safety and effectiveness of radiofrequency ablation for palliation of painful lytic bone metastases. This showed rapid (within 3 days) pain and QoL improvements through the study period of 12 months. (Levy, 2023) The Sacroplasty registry authored by Beall in 2023 is the best data so far to support sacroplasty and the results are extremely promising. According to that study, the sacroplasty	Thank you for the suggestions. We included nonrandomized studies, including those from registries that met the inclusion criteria when higher quality evidence was not available. They were critically appraised and overall strength of evidence was assessed based on the methods described. We recognize that for sacroplasty and malignant fractures nonrandomized studies currently provide the best available evidence. The report focuses on RCTs where available as they have the least potential for bias. Nonrandomized studies are subject to a number of

	Comment	Response
	procedure is safe and efficacious and provides substantial pain relief. Until there is an RCT (and there may never be one), these are the best data we have.	biases. Effects these studies can be misleading due to the subjective nature of pain which may magnify effects such bias and the impact of attentional and other nonspecific effects. There are numerous examples in the pain literature where nonrandomized studies have shown very large responses or estimates for effectiveness in response to treatment which were disproven in subsequent RCTs. All cited publications were reviewed against our final key questions and scope and those meeting inclusion criteria were included in our report. Additionally, the bibliographies of all cited systematic reviews and meta-analyses were hand-searched for publications that may fit our protocol and those publications were then evaluated as well. Please see Appendix Table C1 for a list of studies excluded at full text and rationale for exclusion.
Summary	I think these are well displayed. Facts are laid out well and easy to understand.	Thank you for your comments.
Overall Presentation and Relevancy	This is well structured and well-reviewed. Clinical aspects are discussed as well as socioeconomic and cost aspects. With an aging population and compression fractures more prevalent, these procedures need to be considered for potential treatment.	Thank you for your comments.
Quality Rating	**Quality of Report** Superior Good **X** Fair Poor	Thank you for your comments
Sohail K. Mirza, MD, MPH, Professor of Engineering, Thayer School of Engineering, Dartmouth College		
	Specific comments	

	Comment	Response
Page 1 **Section 1.1**	The introduction adequately defines vertebral compression fractures, vertebroplasty, kyphoplasty, and sacroplasty. However, it does not convey uncertainty about efficacy and safety of these procedures. It does not mention currently available alternative treatments for these fractures. It does not provide justification for needing a repeat assessment since the prior Health Technology Assessment in 2010.	Thank you for the suggestions. The background sections have been edited to include additional information. Justification for the repeat assessment was found with the Policy Context and has been added to the Objective.
Page 1 **Line 1.2**	Policy context is clear. It would be helpful to briefly also mention coverage policies that are discussed in detail in section 2.5.	Thank you for your comments; this statement refers to the HTCC's prior policy decision and context specifically and it not intended to describe other coverage policies.
Page 1 **Line 1.3**	Objectives are clearly stated are directly relevant to clinical and policy concerns.	Thank you for your comments.
Page 2 **Line 1.4**	Key questions are defined clearly and are clinically relevant.	Thank you for your comments
Pages 2 to 4 **Line 1.4**	Scope is presented clearly.	Thank you for your comments.
Pages 5 to 6 **Line 1.5**	Outcomes assessed are explicitly defined. They are clinically relevant. Interpretation and thresholds for significant change are defined clearly.	Thank you for your comments.
Page 6 **Line 1.6**	Washington State utilization data are missing.	These are found under CMS coverage in Table 4 in the final report
Page 7 **Line 2.1**	Background is concise and clinically focused. Relative prevalence in females and the estimated number of fractures are mentioned, but population-based prevalence in females is not listed. It is not clear what fraction of vertebral compression fractures are due to malignancy.	Thank you for the suggestion. These sections have been expanded.
Pages 7 to 9 **Line 2.2**	Technologies and interventions are described clearly and in detail. List of indications and contraindications from published reports is useful. It would be helpful to provide a complete list of FDA approved materials and devices with approval date and FDA-approved label/indications.	These are found in Appendix M.
Pages 9 to 15 **Line 2.3**	Table 1 list of published guidelines is detailed and clear. It would be helpful to summarize the guideline review with a simple list of associations/guidelines that specifically endorse and a list of guidelines/associations that do not endorse vertebroplasty/kyphoplasty/sacroplasty for osteoporotic vertebral compression fractures.	Thank you for the suggestion. An overview of guidelines has been added.

	Comment	Response
Pages 16 to 31 **Line 2.4**	Details of systematic reviews listed in Table 2 are helpful but difficult to understand. It would be more helpful to understand this information if it was summarized in tables according to the specific key questions and specific outcomes specified for this assessment.	We've summarized the primary findings from other SRs with a focus on the outcomes of interest to the re-review that parallel the KQ structure for this update. KQs, scope and focus for the different SRs summarized may differ from those for this review.
Pages 32 to 34 **Line 2.5**	Table 3 summarizing representative insurer coverage policies is useful. It would be helpful to synthesize these policies into a summary table of covered and not covered procedures for each insurer.	As the vendor, we are responsible for summarizing across two bell weather payers and CMS, this is not intended to be a complete listing. We have added information summarizing across policies at a high level in the background.
Pages 35 to 37 **Lines 3.1.1 to 3.1.3**	Objectives, key questions, inclusion/exclusion criteria, and outcomes are clearly defined, appropriate and clinically relevant.	Thank you for your comments.
Pages 37 to 39 **Lines 3.1.4 to 3.1.5**	Data sources are specified and appropriate. Search strategy was thorough. Clinical trials were included in the search. Figure 1 clearly lists the flow for study selection. Data extraction was systematic and objective.	Thank you for your comments.
Pages 39 to 41 **Line 3.1.6**	Risk of bias assessment is described well. Criteria for grading the quality of individual studies (Table 5) are described in detail, appropriate, and justified. Risk of bias was assessed. Strength of Evidence was rated by two researchers and complied with established standards. Reason for not evaluating quality of economic studies is justified.	Thank you for your comments.
Pages 41 to 42 **Lines 3.1.7**	Analyses are explained and well supported by established methods. Risk ratio and confidence intervals were calculated. Meta-analyses were conducted where possible. Statistical heterogeneity was assessed. Effect sizes were estimated consistent with established standards. Interactions were assessed.	Thank you for your comments.
Pages 42 to 45 **Line 4.1**	A detailed description is provided of retained studies. Funding source for each comparison is listed.	Thank you for your comments.
Pages 45 to 206 **Line 4.2.1**	Details are presented for each retained study. Data from each study is tabulated for vertebroplasty, kyphoplasty and sacroplasty by study type, primary and secondary outcomes, and adverse events. However, the results are not summarized across different study types and comparator treatments to explicitly answer the key questions. It is left up	Thank you for your suggestion. We have added an overview of results by KQ to the executive summary.

	Comment	Response
	to the reader to try to synthesize data across studies and various time points of outcome assessment and various different types of outcomes being reported. It would be much more helpful to under, the evidence if it were summarized and presented succinctly to answer each of the key questions: - Efficacy vertebroplasty, kyphoplasty or sacroplasty for short-term and long-term outcomes, function, pain, quality of life, use of pain medications and opioids, return to work - Safety of vertebroplasty, kyphoplasty or sacroplasty in terms of mortality, major morbidity, other, revision/re-operation rates - differential efficacy or safety issues in sub populations: gender, age, Psychological or psychosocial co-morbidities, diagnosis, time elapsed from fracture, other patient characteristics or evidence-based patient selection criteria, provider type, setting or other provider characteristics, payer/beneficiary type: including worker's compensation, Medicaid, state employees - Cost implications (direct and indirect) These data are included for each type of study and comparator, but they are not synthesized to directly answer these key questions in a way that would be easy to interpret.	
Summary	The strength of evidence tables is well organized, and presented in detail. The Executive Summary provides considerable detail and is supported by data. However, high-level syntheses of the analyses are lacking to directly answer the key questions and guide interpretation. Interpretation is difficult because of stratification of the data by study type, different competitors, and different outcomes and adverse events.	Thank you for your suggestion. We have added an overview of results by KQ to the Executive Summary. The Summary Tables in the Executive Summary are intended to provide a complementary high-level overview that includes information on strength of evidence.
Overall Presentation and Relevancy	This assessment is detailed, clear, objective, and presented clearly. The report is well structured and organized. Data are clinically relevant and presented well. Analyses are designed to help with clinical decision making. Summaries will help guide policy to improve public health.	Thank you for your comments.
Quality Rating	**Quality of Report** Superior Good **X** Fair Poor The report is high quality, comprehensive, and objective. Data are presented clearly. Interpretations are well	Thank you for your comments.

	Comment	Response
	supported. However, analyses are not summarized sufficiently to directly answer the key questions.	
Other	The report is unbiased, thorough, clinically relevant, and informative.	Thank you for your comments.

CMS = Centers for Medicare & Medicaid Services; FDA = Food and Drug Administration; HTCC = Health Technology Clinical Committee; KP = kyphoplasty; KQ = key question; RCT = randomized control trial; SR = systematic review.

Responses to Public Comment on Key Question Posting and Draft Report

This second section responds to comments received during the public comment periods from the following:

- Ashley Maleki, CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology
- Alda L. Tam, MD, MBA, FSIR, President, Society of Interventional Radiology
- Wendy Chan, MHA, Vice President, Health Economics Policy Reimbursement (HEPR), Neuroscience, Medtronic
- Ashley Maleki, CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology
- Wendy Chan, MHA, Vice President, Health Economics Policy Reimbursement (HEPR), Neuroscience, Medtronic
- Stan Dietz, Director Reimbursement & Market Access, Stryker
- Robert Poser, DBM, Vice President, Global Spinal Therapies, Merit Medical
- Joshua Rittenberg, MD, President, International Pain and Spine Intervention Society
- Christopher Gharibo, MD, President, American Society of Interventional Pain Physicians
- Laxmaiah Manchikanti, MD, Chairman of the Board and CEO, American Society of Interventional Pain Physicians, Society of Interventional Pain Management Surgery Centers Inc., (ASIPP, SIPMS & KSIPP)
- Amol Soin, MD, Lifetime Director, American Society of Interventional Pain Physicians (ASIPP)
- Washington State Labor & Industries (L&I)
- Joint comments submitted by American Academy of Pain Medicine (AAPM), American Academy of Physical Medicine and Rehabilitation (AAPM&R), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Interventional Pain and Spine Intervention Society (IPSIS), North American Neuromodulation Society (NANS), North American Spine Society (NASS), Society of International Radiology (SIR).

Comments across some sources were duplicative and included similar suggestions for consideration. Similar comments have been grouped together for response. Full text of the comments is appended to the end of the response section.

Table 2 Responses to Public Comments on the Key Question posting

	Comments	Commenter	Response
1	Detailed an overview of the technology, and provided evidence of efficacy, safety, and cost-effectiveness. Cited evidence. Specific recommendations and requests be included in the PICOTs literature search: 1. Evidence related to mortality risk following surgical interventions relative to conservative medical management. 2. Considerations related to oral opioid reduction, as shown in a large retrospective real-world data analysis. 3. Care pathway recommendations developed by a multi-specialty physician panel, developed using the RAND/UCLA Appropriateness Method. 4. Evidence-based national guidelines, with three of the four recommending surgical treatment. 5. Additional cost-effectiveness data that was potentially missed in the last re-review due to exact timing of the publication.	Ashley Maleki Alda L. Tam Wendy Chan	Comments from these sources are duplicative. Thank you for your suggestions. These were reviewed prior to formulation of the final KQ and PICOTS and discussed with the program as needed. Searches for updated evidence focus on evidence published after the 2010 review with some overlap in early search dates. Suggested citations are evaluated in light of the final KQ and PICOTS. The report routinely contains information from evidence-based clinical guidelines.

KQ = key question; PICOT = population, intervention, comparison, outcome, timing.

Table 3 Responses to Public Comments on the Draft Posting

	Comments	Commenter	Response
1	Request to expand the background and rationale, particularly the natural history of vertebral compression fractures and that of vertebral compression fractures secondary to malignancy	L&I	We have expanded the background to include this information.
2	"Fractures due to high energy trauma" are excluded. Are these procedures contraindicated or ineffective in patients with traumatic vertebral fractures? Please remind us why fractures due to high energy trauma are excluded.	L&I	Vertebral augmentation is contraindicated in people with fractures due to high energy trauma. These types of fractures were excluded in the 2010 HTA and our clinical experts confirmed the appropriateness of this exclusion. Additional context based on clinical expert input has been added to the background.
3	Are you aware of any high-quality studies on vertebroplasty or	L&I	FDA guidance on clinical trial considerations (last reviewed by the FDA in 2018) for

	kyphoplasty for the treatment of fractures due to high energy trauma?		vertebral augmentation recommends exclusion of patients with high energy trauma. We are not aware of high quality RCTs for these, however, we did not investigate this as it was out of scope.
4	Conflicting information on Clark 2016 study in Table 6 and Figure 2. In the table, BME MRI is not required as an inclusion criterion for the subjects in the study, but in figure 2 (page 50), BME MRI is required. Which is correct?	L&I	Thank you for the comment. Table 12 (table 6 in the draft report) has been edited to reflect that MRI evidence of BME was required for inclusion
5	Concerns regarding the use of local anesthetic in the sham-controlled trials (relevant to vertebroplasty and kyphoplasty). - Consider placing more weight on the evidence from VP vs. usual care trials - Ethical concerns regarding the use of sham trials which require placing a patient under sedation to receive an injection versus procedure; particularly in elderly and frail populations. - Concern around potential adverse events related to fractures in sham patients, and ethical concerns around limiting access to vertebral augmentation.	Ashley Maleki (on behalf of SIR and other medical specialty societies) Joshua Rittenberg (IPSIS) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	The report summarizes evidence across studies meeting the inclusion criteria. Additional context related to sham procedures has been added to the executive summary.
6	Agreement regarding quality of studies; suggestions to place emphasis on other specific studies due to low quality in others. - EVOLVE single arm cohort - FREE trial	Ashley Maleki (on behalf of SIR and other medical specialty societies) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for the suggestions. All cited publications were reviewed against our final key questions and scope and those meeting inclusion criteria were included in our report. Additionally, the bibliographies of all cited systematic reviews and meta-analyses were hand-searched for publications that may fit our protocol and those publications were then evaluated as well. Please see Appendix Table C1 for details on why specific studies were excluded at full test. The report summarizes evidence across studies meeting the inclusion criteria. The vendor does not suggest policy or HTCC process.

7	Suggestion that committee leave the decision on choice of operative procedure to the treating physician, given the lower-to-moderate quality evidence	Ashley Maleki (on behalf of SIR and other medical specialty societies) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for the suggestions. The vendor does not suggest policy, HTCC committee process or approach.
8	Recommendations to consider alternative or additional evidence, including: - Administrative claims-based analyses, due to concerns that findings are minimized and limitations overstated - Literature on long-term outcomes due to uncertainty around long-term benefits and limits to short-term outcomes - Literature on mortality, especially from large administrative databases; disagreement with proposed limitations of mortality literature	Ashley Maleki (on behalf of SIR and other medical specialty societies) Joshua Rittenberg (IPSIS) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for the suggestions. The KQ and PICOTS were reviewed by clinical experts prior to finalization. All cited publications were reviewed against our final key questions and scope and those meeting inclusion criteria were included in our report. Additionally, the bibliographies of all cited systematic reviews and meta-analyses were hand-searched for publications that may fit our protocol and those publications were then evaluated as well. Please see Appendix Table C1 the list of excluded studies and rationale for exclusion. When available, longer-term outcomes from studies meeting inclusion criteria were summarized. Administrative data studies were included for harms and mortality and are described in the full report. The review followed accepted methods for critical appraisal of all studies, including nonrandomized studies, and for evaluation of overall strength of evidence. Given risk of bias concerns and, for some outcomes, lack of consistency or imprecision, evidence was considered to be insufficient as described in the full report. Administrative data studies reporting on mortality are summarized in the report, an additional table has been added to the appendices and additional context regarding those reporting mortality is found in the executive summary. In general, there is some lack of consistency across such

			studies with regard to associations seen between augmentation and mortality. Although some suggest an association, others do not. Although studies used various methods to adjust for patient selection and potential confounding, residual confounding and bias are possible. A recent study reported that differences in matching and adjustment methods impacted whether or not an association was seen in administrative data and the direction of the association. Authors suggested caution in interpreting such studies and cite the need for verification from RCTs. Reference: Gold LS, et.al., Mortality among older adults with osteoporotic vertebral fracture. Osteoporos Int 2023;34:1561-75.
9	Comments providing medical insights and advice on the interpretation of outcomes, complications, long-term effects, and cost-effectiveness.	Ashley Maleki (on behalf of SIR and other medical specialty societies) Joshua Rittenberg (IPSIS) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for your comments. The report follows accepted methodological standards for objective systematic review to summarize available evidence based on the scope specified *a priori*. The vendor does not suggest the process or approach for HTCC.
10	Health Technology Assessment Committee should define what economic analysis criteria should be included in a model and what modeling framework/checklists should be followed, with a separately applied framework of Strength of Evidence for models.	Ashley Maleki (on behalf of SIR and other medical specialty societies) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for your comments. The role of the vendor is to summarize and appraise studies meeting the inclusion criteria. It is not the role of the vendor to suggest criteria related to thresholds for economic analyses for the HTAP to consider. There is not a generally accepted approach or consensus for determining strength of evidence across economic studies.

			We have made the program aware of these comments.
11	Suggestions to include additional Medicare Local Coverage determinations.	Ashley Maleki (on behalf of SIR and other medical specialty societies) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical)	The vendor is responsible for summarizing across two bell weather payers and CMS, this is not intended to be a complete listing. If available, the appropriate LCD for this (Washington) region may be included.
12	Suggestion to include the RAND Care Pathway Publication (Hirsch, 2018) in the guidelines section.	Ashley Maleki (on behalf of SIR and other medical specialty societies) Wendy Chan (Medtronic) Stan Dietz (Stryker) Robert Poser (Merit Medical) Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for your comments. This publication has been added to the summary of guidelines in the report.
13	Suggestion to not only stratify results by indication (osteoporotic fracture, tumor) and specific technique (vertebroplasty, kyphoplasty, sacroplasty), but also on the acuity of the fracture (acute <6 weeks, subacute 6-12 weeks, chronic >12 weeks).	Joshua Rittenberg (IPSIS)	There is substantial heterogeneity across trials with regard to fractures acuity and pain duration and enrollment requirements related to these. Information on acuity and duration as provided in the included studies are detailed in the report via text, tables and is identified in the forest plots for primary outcomes. There is insufficient information from RCTs and from stratified analyses across RCTs to effectively evaluate whether facture acuity modifies the treatment response as discussed in Key Question 3. Limitations of these analyses are described. Additional details of the stratified analyses of RCTs reported can be found in: Chou R, et. al., Interventional Treatments for Acute and Chronic Pain: Systematic Review. Comparative Effectiveness Review No. 247. September 2021. DOI: https://doi.org/10.23970/AHRQEPCCER247.

14	Unclear why authors concluded that PMMA volume and marrow edema are not associated with treatment outcomes; multiple studies demonstrate volume/dispersion is an important factor that effects clinical and radiographic outcomes	Joshua Rittenberg (IPSIS)	The results reported and conclusions drawn reflect data available from the highest quality evidence available, i.e., from RCTs and from stratified analyses across RCTS as described in the full report for Key Question 3. The limitations of these analyses are described in multiple places in the report. Additional details of the stratified analyses of RCTs reported can be found in: Chou R, et. al., Interventional Treatments for Acute and Chronic Pain: Systematic Review. Comparative Effectiveness Review No. 247. September 2021. DOI: https://doi.org/10.23970/AHRQEPCCER247
15	Suggestion to use Network Meta-Analysis to incorporate evidence from non-RCTs	Christopher Gharibo Laxmaiah Manchikanti Amol Soin	Thank you for the suggestion. A network meta-analysis is beyond the scope of this HTA. Further, such analyses are considered indirect comparisons.

BME = bone marrow edema; CMS = Centers for Medicare & Medicaid Services; FDA = Food and Drug Administration; HTA = Health Technology Assessment; HTAP = Health Technology Assessment Program; HTCC = Health Technology Clinical Committee; KQ = key question; L&I = Washington State Labor & Industries; LCD = Local Coverage Determinations; MRI = magnetic resonance imaging; PICOT = population, intervention, comparison, PMMA = polymethylmethacrylate; outcome, timing; RCT = randomized control trial; VP = vertebroplasty.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Vertebroplasty, kyphoplasty and sacroplasty Public comment
Date: Wednesday, April 17, 2024 7:40:41 AM
Attachments: WA HTA Vertebroplasty kyphoplasty or sacroplasty final 04172024 001.pdf

External Email

Dear Ms. Birch,

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing the primary specialty of Interventional Radiology. Our 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates are dedicated to improving patient care through image-guided therapy. Interventional radiologists diagnose and treat vertebral compression fractures (VCFs) using Vertebroplasty, kyphoplasty, and sacroplasty procedures. Thank you for allowing us to submit comments during the WA State Health Technology Assessment for Vertebroplasty, kyphoplasty, and sacroplasty 2024 public comment period.

Kind Regards,

Ashley Maleki
Senior Manager, Health Policy and Economics
Society of Interventional Radiology
[redacted]

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Society of Interventional Radiology
The vision to heal

April 17, 2024

Sue Birch
Health Care Authority Director
Cherry Street Plaza
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shtap@hca.wa.gov

RE: Vertebroplasty, kyphoplasty, or sacroplasty 2024 public comment period

Dear Ms. Birch,

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing the primary specialty of Interventional Radiology. Our 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates are dedicated to improving patient care through image-guided therapy. Interventional radiologists diagnose and treat vertebral compression fractures (VCFs) using vertebroplasty, kyphoplasty, and sacroplasty procedures.

Vertebral body and sacral fractures are a common cause of pain and disability, often associated with osteoporosis, cancer, and trauma. Vertebroplasty, kyphoplasty, and sacroplasty (vertebral augmentation) are minimally invasive procedures used to treat these fractures. The information below aims to present a comprehensive review of the most recent literature on their safety and efficacy, emphasizing their effectiveness in alleviating pain, improving functionality, and minimizing complications.

Efficacy of Vertebral augmentation:

a. A systematic review and meta-analysis by Zuo et al. (2018) evaluated 18 studies (n=1993) and reported significant pain reduction and functional improvement in patients undergoing vertebroplasty or kyphoplasty when compared to conservative therapy.[1]
b. A meta-analysis of more than 2 million patients by Hinde et al (2020) showed that those with osteoporotic vertebral compression fractures who underwent vertebral augmentation were 22% less likely to die at up to 10 years after treatment than those who received nonsurgical treatment.[2]
c. A systematic review and meta-analysis by Chandra et al (2019) evaluated 19 studies (n=861) demonstrating significant pain relief from sacroplasty in patients with osteoporotic and malignant sacral fractures.[3]

Safety Profile:

a. A systematic review and meta-analysis by Chandra et al (2019) evaluated 19 studies (n=861) on sacroplasty in patients with osteoporotic and malignant sacral fractures demonstrating a major complication rate of 0.3%.[3]

Cost-Effectiveness:

a. A systematic review by Pron et al (2022) evaluated 10 studies between 2008 and 2020 demonstrating the cost-effectiveness of vertebroplasty and kyphoplasty compared to conservative management with earlier health gains and significantly shorter hospital stays. Both vertebroplasty and kyphoplasty were demonstrated to be cost-effective in multiple healthcare settings.[4]

Access to these therapies today is broad, with WA state as one of the only coverage entities not considering the evidence sufficient for treatment. Medicare Administrative Contractors (MACs) updated their Local Coverage Determinations (LCDs) concerning coverage criteria for the treatment of VCFs in 2021. [4-12] All LCDs cover immediate access to vertebroplasty or kyphoplasty for patients that meet medical necessity criteria.[4-12] In the evidence summaries of these LCDs the MACs reference all prior randomized controlled trials (RCTs) and associated considerations that the WA HTA reviews have previously highlighted; but also review the breadth of evidence available inclusive of recent mortality data, guidelines, and a clinical care pathway created by a multispecialty expert panel.

We support the re-review of vertebroplasty, kyphoplasty, and sacroplasty. We respectfully request that the following bodies of evidence also be included in the next PICOS literature search criteria:

- Evidence related to vertebroplasty, and kyphoplasty on mortality risk following surgical treatment relative to conservative medical management.[13-19]
- Considerations related to oral opioid reduction, as shown in a large retrospective real-world data analysis.[20]
- Care pathway recommendations developed by a multi-specialty physician panel, developed using the RAND/UCLA Appropriateness Method.[21]
- Evidence-based national guidelines, with three of the four recommending surgical treatment.[22-25]
- Additional cost-effectiveness data that was potentially missed in the last re-review due to timing of the publication.[26]

The most recent literature supports the safety and efficacy of vertebral augmentation in managing compression, pathologic, and insufficiency fractures. These procedures effectively alleviate pain and improve functionality, with low rates of major complications and adverse events. Additionally, they have been shown to be cost-effective compared to conservative management. Proper patient selection and procedural expertise remain crucial for optimal outcomes. These procedures are valuable treatment options for individuals suffering from vertebral and sacral fractures, backed by substantial evidence from recent studies.

We appreciate your consideration of our comments. If you have any questions, please contact Ashley Maleki, Senior Manager of Health Policy, and Economics at the Society of Interventional Radiology, at [redacted].

Sincerely,

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

cc:
Keith M. Hume, Executive Director, Society of Interventional Radiology

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References:

1. Zuo XH, Zhu XP, Bao HG, Xu CJ, Chen H, Gao XZ, Zhang QX. Network meta-analysis of percutaneous vertebroplasty, percutaneous kyphoplasty, nerve block, and conservative treatment for nonsurgery options of acute/subacute and chronic osteoporotic vertebral compression fractures (OVCFs) in short-term and long-term effects. Medicine (Baltimore). 2018 Jul;97(29):e11544. doi: 10.1097/MD.0000000000011544. PMID: 30024546; PMCID: PMC6086478.
2. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis Kenji Hinde, Julian Maingard, Joshua A. Hirsch, Kevin Phan, Hamed Asadi, and Ronil V. Chandra Radiology 2020 295:1, 96-103
3. Chandra V, Wajswol E, Shukla P, Contractor S, Kumar A. Safety and Efficacy of Sacroplasty for Sacral Fractures: A Systematic Review and Meta-Analysis. J Vasc Interv Radiol. 2019 Nov;30(11):1845-1854. doi: 10.1016/j.jvir.2019.06.013. Epub 2019 Oct 3. PMID: 31587952.
4. Pron G, Hwang M, Smith R, Cheung A, Murphy K. Cost-effectiveness studies of vertebral augmentation for osteoporotic vertebral fractures: a systematic review. Spine J. 2022 Aug;22(8):1356-1371. doi: 10.1016/j.spinee.2022.02.013. Epub 2022 Mar 5. PMID: 35257838.
5. CMS. L33569. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33569&ver=28&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
6. CMS. L34106. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34106&ver=46&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed Jun 19, 2023.
7. CMS. L34228. Percutaneous Vertebral Augmentation (PVA) for Osteoportotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34228&ver=51&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

8. CMS. L38201. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38201&ver=19&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
9. CMS. L34976. Percutanteous Vertebral Aurgmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34976&ver=34&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
10. CMS. L35130. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35130&ver=66&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
11. CMS. L38737. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38737&ver=11&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
12. CMS. L38213. Percutaneous vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38213&ver=9&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
13. Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the medicare population. *J Bone Joint Surg Am.* 2013;95(19):1729-1736.
14. 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;26(7):1617-1626.
15. Edidin AA, Ong KL, Lau E, Kurtz SM. Morbidity and Mortality After Vertebral Fractures: Comparison of Vertebral Augmentation and Nonoperative Management in the Medicare Population. *Spine (Phila Pa 1976).* 2015;40(15):1228-1241.
16. Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. *AJNR Am J Neuroradiol.* 2020;41(1):178-182.
17. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine (Phila Pa 1976).* 2014;39(4):318-326.
18. McCullough BJ, Comstock BA, Deyo RA, Kreuter W, Jarvik JG. Major medical outcomes with spinal augmentation vs conservative therapy. *JAMA Intern Med.* 2013;173(16):1514-1521.
19. 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;29(2):375-383.
20. Ni W, Ricker C, Quinn M, et al. Trends in opioid use following balloon kyphoplasty or vertebroplasty for the treatment of vertebral compression fractures. *Osteoporos Int.* 2022;33(4):821-837.
21. 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.
22. Esses SI, McGuire R, Jenkins J, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: the treatment of osteoporotic spinal compression fractures. *J Bone Joint Surg Am.* 2011;93(20):1934-1936.

23. Excellence NNIfHaC. National Institute for Health and Care Excellence. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. https://www.nice.org.uk/guidance/ta279. Published 2013. Accessed June 19, 2023.
24. Lentle B, Cheung AM, Hanley DA, et al. Osteoporosis Canada 2010 guidelines for the assessment of fracture risk. *Can Assoc Radiol J.* 2011;62(4):243-250.
25. McConnell CT, Jr., Wippold FJ, 2nd, Ray CE, Jr., et al. ACR appropriateness criteria management of vertebral compression fractures. *J Am Coll Radiol.* 2014;11(8):757-763.
26. Hopkins TJ, Eggington S, Quinn M, Nichols-Ricker CI. Cost-effectiveness of balloon kyphoplasty and vertebroplasty versus conservative medical management in the USA. *Osteoporos Int.* 2020;31(12):2461-2471.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: WA State HTA Public Comments for Vertebral compression fracture (VCF) procedures
Date: Wednesday, April 17, 2024 2:23:22 PM
Attachments: image001.png
UC202411483 EN MDT WA State HTA VCF Comments April 2024.pdf.pdf

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External Email

To Whom It May Concern,

Medtronic is interested in the WA HTA Review for VCF procedures and have provided our feedback attached in response to the draft key questions for consideration.

Please let me know if you have questions and appreciate the opportunity to respond.

Best, Wendy

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

Medtronic
Neuromodulation, Pelvic Health, & Neurovascular

[redacted]

Medtronic
Engineering the extraordinary

Medtronic

April 8, 2024

Via online submission at: shtap@hca.wa.gov

RE: State of WA Health Care Authority - 2024 HTA Public Comment on Vertebroplasty, Kyphoplasty, Sacroplasty Draft Key Questions

Dear Health Technology Clinical Committee,

We are pleased to see the selection of vertebroplasty, kyphoplasty, and sacroplasty for evidence re-review. This is an important clinical option for patients with vertebral compression fracture or pathological fractures secondary to malignancy, associated with significant effects on pain, functioning, and activities of daily living. In response to public review of the draft key research questions and PICOTS framework for literature selection we respectfully provide our suggestions below.

1) Does the current question set include an intent to review peer-reviewed literature related to excess mortality risk associated with untreated vertebral fracture? It is currently unclear which topic question this would fit within.
2) We suggest adding excess mortality risk associated with non-treated fractures as an additional secondary outcome within the "Outcomes" pillar of the PICOTs. Several peer-reviewed publications are available on this topic.[1-14]
3) Evidence-based national guidelines should be considered as a review question given their importance in clinical-decision making.[15-18] Additionally, care pathway recommendations developed by practicing clinicians should also be evaluated.[19]
4) An additional question specific to national US payer coverage policies (both Commercial and Medicare) should be considered given their widespread impact on patient access to therapy nationally. Medicare Administrative Contractors (MACs) updated their Local Coverage Determinations (LCDs) concerning coverage criteria for the treatment of VCFs in 2021.[20-27] All LCDs cover immediate access to vertebroplasty or kyphoplasty for patients that meet medical necessity criteria.[20-27] In the evidence summaries of these LCDs the MACs reference all prior randomized controlled trials (RCTs) and associated considerations that the WA HTA reviews have previously highlighted; but also included an analysis of mortality publications, guidelines, clinical care pathway established by a multidisciplinary physician panel.

We appreciate your consideration of our comments. If you have questions, feel free to reach out to me at [redacted] or Christine Ricker (Director, HEPR) at [redacted].

Sincerely,

Wendy Chan
Vice President, Health Economics Policy Reimbursement (HEPR), Neurosciences

References

1. Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the medicare population. *J Bone Joint Surg Am.* 2013;95(19):1729-1736.
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;26(7):1617-1626.
3. Edidin AA, Ong KL, Lau E, Kurtz SM. Life expectancy following diagnosis of a vertebral compression fracture. *Osteoporos Int.* 2013;24(2):451-458.
4. Edidin AA, Ong KL, Lau E, Kurtz SM. Morbidity and Mortality After Vertebral Fractures: Comparison of Vertebral Augmentation and Nonoperative Management in the Medicare Population. *Spine (Phila Pa 1976).* 2015;40(15):1228-1241.
5. Hinde K, Maingard J, Hirsch JA, Phan K, Asadi H, Chandra RV. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis. *Radiology.* 2020;295(1):96-103.
6. Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. *AJNR Am J Neuroradiol.* 2020;41(1):178-182.
7. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine (Phila Pa 1976).* 2014;39(4):318-326.
8. Lau E, Ong K, Kurtz S, Schmier J, Edidin A. Mortality following the diagnosis of a vertebral compression fracture in the Medicare population. *J Bone Joint Surg Am.* 2008;90(7):1479-1486.
9. Lavelle WF, Khaleel MA, Cheney R, Demers E, Carl AL. Effect of kyphoplasty on survival after vertebral compression fractures. *Spine J.* 2008;8(5):763-769.
10. Martinez-Gutierrez JC, Leslie-Mazwi T, Chandra RV, et al. Number needed to treat: A primer for neurointerventionalists. *Interv Neuroradiol.* 2019;25(6):613-618.
11. McCullough BJ, Comstock BA, Deyo RA, Kreuter W, Jarvik JG. Major medical outcomes with spinal augmentation vs conservative therapy. *JAMA Intern Med.* 2013;173(16):1514-1521.
12. McDonald RJ, Achenbach SJ, Atkinson EJ, et al. Mortality in the vertebroplasty population. *AJNR Am J Neuroradiol.* 2011;32(10):1818-1823.
13. 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;29(2):375-383.
14. Pascual-Guardia S, Badenes-Bonet D, Martin-Ontiyuelo C, et al. Hospital admissions and mortality in patients with COPD exacerbations and vertebral body compression fractures. *Int J Chron Obstruct Pulmon Dis.* 2017;12:1837-1845.
15. Esses SI, McGuire R, Jenkins J, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: the treatment of osteoporotic spinal compression fractures. *J Bone Joint Surg Am.* 2011;93(20):1934-1936.
16. Excellence NNIfHaC. National Institute for Health and Care Excellence. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. https://www.nice.org.uk/guidance/ta279. Published 2013. Accessed June 19, 2023.
17. Lentle B, Cheung AM, Hanley DA, et al. Osteoporosis Canada 2010 guidelines for the assessment of fracture risk. *Can Assoc Radiol J.* 2011;62(4):243-250.
18. McConnell CT, Jr., Wippold FJ, 2nd, Ray CE, Jr., et al. ACR appropriateness criteria management of vertebral compression fractures. *J Am Coll Radiol.* 2014;11(8):757-763.

19. 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.
20. CMS. L33569. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33569&ver=28&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
21. CMS. L34106. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34106&ver=46&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed Jun 19, 2023.
22. CMS. L34228. Percutaneous Vertebral Augmentation (PVA) for Osteoportotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34228&ver=51&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
23. CMS. L38201. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38201&ver=19&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
24. CMS. L34976. Percutanteous Vertebral Aurgmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34976&ver=34&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
25. CMS. L35130. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35130&ver=66&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
26. CMS. L38737. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38737&ver=11&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.
27. CMS. L38213. Percutaneous vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38213&ver=9&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment Open on Vertebroplasty, Kyphoplasty, Sacroplasty DRAFT KEY QUESTIONS
Date: Wednesday, April 17, 2024 8:20:10 PM
Attachments: washington state comments.docx

External Email

Attached are the comments from ASIPP (The American Society of Interventional Pain Physicians which includes our component society WASIPP = the Washington Society of Interventional Pain Physicians)

Thanks,

--
Amol Soin, MD
Anesthesiology/Pain Management

American Society *of* Interventional Pain Physicians®
"The Voice of Interventional Pain Management"
[redacted]

Re: **WA State Health Care Authority Health Technology Assessment (HTA):**

Public Comment Open on Vertebroplasty, Kyphoplasty, Sacroplasty DRAFT KEY QUESTIONS

Dear Medicare Director:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 48 state societies, thank you for providing an opportunity to comment on our reconsideration request.

Established in 1998, ASIPP is a non-profit professional organization that currently boasts a membership of over 4,500 interventional pain physicians and other practitioners. Its mission is to promote safe, appropriate, fiscally neutral and effective pain management services for patients nationwide who grapple with chronic and acute pain. The United States is home to approximately 8,500 proficient physicians with the requisite training and qualifications in interventional pain management. ASIPP is composed of 48 state societies of Interventional Pain Physicians, encompassing Puerto Rico, and includes the affiliated Texas Pain Society.

In particular, our component society WASIPP = Washington Society of Interventional Pain Physicians has several physicians who service several patients in the state. We have the following comments:

Draft key research questions
The committee outlines 4 key research questions and a draft PICOTS (Population/Participants, Intervention,
Comparators, Outcomes) framework for literature review.
Questions:
1) What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty or sacroplasty, including consideration of short-term and long-term outcomes?

2) What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:
a. Adverse events type and frequency (mortality, major morbidity, other)
b. Revision/re-operation rates

3) What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety issues in sub populations? Including consideration of:
a. Gender

b. Age
c. Psychological or psychosocial co-morbidities
d. Diagnosis or time elapsed from fracture
e. Other patient characteristics or evidence-based patient selection criteria
f. Provider type, setting or other provider characteristics
g. Payer/beneficiary type: including worker's compensation, Medicaid, state employees
4) What is the evidence of cost-effectiveness of vertebroplasty, kyphoplasty and sacroplasty?

Our comments:

• It is unclear whether literature related to excess mortality risk associated with untreated vertebral fracture will be evaluated within this framework of questions. It should be either added as a separate question or specified as a relevant part of Question 1.
• An additional question related to review of national society guidelines for the treatment of vertebral compression fracture (VCF) should be considered.

• An additional question related to a summary of large US commercial payer coverage policies and a review of Medicare Local Coverage Determinations (LCDs) should be considered.

Draft PICOTS:
1) Population: Patients with spinal pain due to vertebral fracture secondary to osteoporosis or malignancy.
2) Intervention: Vertebroplasty, kyphoplasty, sacroplasty
3) Comparators: sham/placebo, conservative/conventional care, other minimally invasive procedures, surgical procedures, vertebroplasty vs. kyphoplasty
4) Outcomes
a. Primary: functional outcomes, pain relief, harms/complications
b. Secondary: quality of life, measures of disability, opioid use, return to work/normal activity

Our comments:

• Excess mortality risk associated with untreated fracture should be considered as an additional important secondary outcome.
Without revision of the proposed questions and PICOTS it is possible the HTA does not evaluate an important
body of mortality risk literature relevant to treatment decision-making

Thanks,

Amol Soin, MD
Lifetime Director, ASIPP
President, SIPMS
CEO, Ohio Society of Interventional Pain Physicians
Medical Director, Ohio Pain Clinic
Clinical Assistant Professor of Surgery, Wright State University
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Re: Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview for August 30, 2024
Date: Thursday, October 3, 2024 1:23:51 PM
Attachments: MPW Comment Letter - WA HCA HTA - VKS_ FINAL 10032024.pdf

External Email

Dear Ms. Birch,

The undersigned medical specialty societies are writing to provide feedback on the Draft HTA Report dated August 30, 2024, concerning vertebroplasty (VP), kyphoplasty (KP), and sacroplasty. This letter aims to inform evidence-based healthcare decision-making for these procedures. If you have any questions or comments about this request, feel free to let me know.

Kind Regards,

Ashley Maleki
Senior Manager, Health Policy and Economics
Society of Interventional Radiology
[redacted]
The vision to heal®

October 3, 2024

Sue Birch, MBA, BSN, RN
Director, Washington State Health Care Authority
Cherry Street Plaza 626 8th Avenue SE
Olympia, Washington 98501
Via e-mail: shtap@hca.wa.gov

Re: Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview for August 30, 2024

Dear Ms. Birch:

The undersigned medical specialty societies are writing to provide feedback on the Draft HTA Report dated August 30, 2024, concerning vertebroplasty (VP), kyphoplasty (KP), and sacroplasty. This report aims to inform evidence-based healthcare decision-making for these procedures.

A previous WA-HCA HTA of the same title was published in November 2010, and based on this, the Committee's Coverage Decision was that VP, KP, and sacroplasty are not covered benefits. We agree that a substantial body of new evidence has been published subsequent to this 2010 review. Longer-term follow-up from previously included trials is now available, as are more recent studies of cost-effectiveness. Given the additional high-quality evidence available, we commend the Committee for reopening this topic and urge reconsidering the non-coverage decision for osteoporotic vertebral compression fractures (VCFs).

After thoroughly reviewing this new draft report, we have several comments and recommendations that we hope the WA-HCA will carefully consider.

1. Concerns Regarding Sham-Controlled Vertebroplasty (VP) Trials

Firstly, we urge the committee to closely evaluate commentary on the use of local anesthetic in the sham-controlled VP trials. Multiple trials have shown that local anesthetic provides short—and intermediate-term pain control among sham patients[1-3]. While the specific forms of sham control used varied, all included some components of analgesia. Given these concerns, we urge the committee to consider placing more weight on the evidence from VP vs. usual care trials.

In addition to the sham-VP trials referenced in the 2010 review, which showed equivocal results[4,5], three sham-VP trials published since then have shown statistically significant improvements in pain and function in acute and subacute fractures[6,7] and chronic fractures[8] for subjects undergoing VP as compared to those subjects randomized to sham treatment.

2. Balloon Kyphoplasty (BKP) Evidence & Ethical Considerations of Sham Trials

Secondly, we acknowledge that this review correctly identified 4 trials of BKP vs. usual care, with no trials of BKP vs. sham currently available. Similar to our comments above on the evidence of VP vs. Sham, the same limitations apply to a BKP vs. sham trial. Furthermore, we cannot ignore ethical concerns surrounding sham trials, specifically placing a patient under sedation to receive simply an injection rather than a BKP procedure, especially as it is an elderly and often frail population suffering from these osteoporotic VCFs. If a sham procedure proves ineffective and the patient opts for a BKP procedure once the blinded follow-up period ends, that patient must then be subjected to a second operative episode.

Other ethical concerns relate to what happens to the subjects that are randomized to sham treatment. In a previous sham versus VP trial, two patients undergoing sham treatment experienced serious adverse events related to the fracture[6]. Both patients developed spinal cord compression due to interval collapse and retropulsion of the fracture several weeks after enrollment. Neither had substantial fracture retropulsion at the time of enrolment. One patient underwent spinal decompressive surgery with subsequent resolution of the neurological deficit. The other patient, not considered a surgical candidate, developed paraplegia.

Additional ethical concerns are associated with limiting access to vertebral augmentation (VA), as seen previously after the equivocal VP versus sham study published in 2009. Following publication, the number of patients being treated decreased substantially, with an estimated 75,452 patients at higher mortality risk. An estimated 6,814 were lost due to a change in treatment patterns, with fewer patients receiving VA[9]. The HTA's draft report [10-18] seems to have inadequately addressed this situation.

Additionally, the report noted that 3 of the 4 trials identified were rated "poor" with unclear/absent blinding, unclear randomization, and between-group heterogeneity. We agree with this assessment and therefore suggest that the committee place more emphasis on the results from the multinational FREE trial, which adequately reports on these items[19, 20]. We suggest the committee also evaluate clinical outcomes from the EVOLVE single-arm clinical follow-up trial of KP[21]. While post-market study is a large multicenter study performed according to Medicare Local Coverage Determination criteria with 354 patients with VCFs across 24 study sites in the US, where back pain, function, and quality of life information were collected at baseline, 7 days, and 1-, 3-, 6-, and 12-months follow-up.

3. Pain Scores and Functioning: Decision-Making for Operative Procedures

The draft report concludes that low-to-moderate quality evidence supports similar improvement in pain and function with KP vs. VP. Given this conclusion, we suggest that the committee leave the decision on the choice of operative procedure to the treating physician, who is best positioned to assess individual patient needs.

4. Retrospective Studies & Mortality Outcomes

SIR and the MPW appreciate the inclusion of retrospective administrative claims studies in this report. While these studies have inherent limitations, they provide valuable long-term insights (up to 10 years) into the efficacy of VA procedures, showing a consistent correlation between surgical treatment and reduced mortality, interestingly in populations studied both within and outside of the US. Of course, it is not possible to conclude that this is a directly causative relationship. There are a variety of factors that may contribute to the decline in physical functioning and increased mortality risk (often referred to as the 'downward spiral') – including decreased lung capacity, prolonged bedrest/periods of inactivity, and neurological complications stemming from untreated VCFs left to heal in a sub-optimal manner [23-25].

Consistently, many manuscripts have shown significantly increased mortality among patients who are treated with non-surgical management (NSM) for their VCF rather than treated with VA[9-18]. Hirsch et al. calculated the number needed to treat to save a life at one year using the Medicare population mortality analysis. They found that it requires surgical treatment of only 15 patients to save one life at one year and even fewer (12 patients) to save a life at five years[26]. Very few procedures or

surgeries save one life for every 12 to 15 patients treated. A meta-analysis of mortality literature that was published this year showed a 10-year mortality rate reduction of 22% for those patients treated with VA versus those patients "treated" with NSM. An earlier meta-analysis showed that the patients' life expectance was increased between 2.2 and 7.3 years after VA compared to their NSM counterparts[27,28]. Additionally, the risk of morbid injury and death from spine fractures is very comparable to that of hip fractures[29]. This high mortality risk is in addition to the fact that vertebral fractures cause tremendous pain and patient disability, thus reducing the quality of life in the remaining years of a patient's life.

The direct causal relationship of vertebral fractures to mortality is addressed in the most extensive analysis of mortality and vertebral compression fractures using propensity score matching that accounted for all listed covariates that could affect those patients receiving the treatment[15]. In the statistical analysis of retrospective data, propensity score matching (PSM) is a statistical matching technique that attempts to estimate the effect of a treatment, policy, or other intervention by retrospectively imitating randomization. By "balancing" an extensive list of sociodemographic and clinical covariates, the "intervention" group, in this case those surgically treated, very closely approximates the NSM group within an extremely small margin of error.

The mortality literature referenced in the draft report is not just based on United States Medicare claims data. The link between non-operative treatment and higher mortality risk using retrospective analyses has been studied extensively by many different research teams globally, including Germany, Taiwan, Sweden, South Korea, and Finland. There are many studies in the United States that document vertebral augmentation decreases morbidity, decreases mortality, and prolongs life[13-18]. If the effect were not true, how could so many research teams draw the same conclusions across disparate populations?

5. Opioid Use Assessment

Next, we would like to comment on the assessment of opioid use across the trials that reported on opioid use. We note that the definition of 'opioid usage' varied widely, ranging from any use, "major" use, and "minor" use. Furthermore, the collection methods for this information varied and were heavily reliant on patient recall. Notably, none provided information on the average daily dose via a morphine milligram equivalent (MME). Given these major limitations with medication use as collected in a trial population, we would suggest that the committee consider retrospective administrative claims-based analysis of opioid use following VA procedures, which is a more objective measure of usage given patient-specific opioid dosages were calculated based on actual medication pharmacy fills billed to the payer. This removes any risk of bias from patient recall. One such study to consider was a retrospective analysis of >8000 patients treated with VP or KP, comparing baseline medication use to that at 7-month follow-up[30].

SIR and the MPW are committed to reducing opioid overuse, especially in the elderly population who disproportionately suffer from VCFs and are at particular risk of the adverse effects of continued reliance on opioids. Our goal aligns with national objectives set forth by the CDC's revised opioid prescribing guidelines and the US Department of Health and Human Services Pain Management Best Practices Task Force Report[31,32]. Any interventions that show a correlation with a reduced need for prolonged opioid use certainly warrant close review.

6. Cement Leakage & Adverse Events

The report identifies cement leakage as a frequent complication. Still, we know that in these studies, the vast majority of these cases are clinically asymptomatic and do not result in significant adverse patient outcomes. Significant complications associated with VA have been previously classified as rare[33]. The adverse events associated with VA are mostly related to the extravasation of bone cement. However, the vast majority of extravasations are clinically unimportant and asymptomatic. They should be separated from symptomatic complications as they don't have any clinical implications regarding patient well-being or need for future treatment. Importantly, this report does not find significant differences in serious adverse events or mortality rates between VP/KP and other interventions. It also should be kept in mind that NSM has significant associated risks and, when employed in an inappropriate situation, can predictably result in more complications for the patient[34]. This increased risk of complications was seen in a 2019 study by Liu et al. that evaluated the clinical effectiveness and complication rates of KP compared to NSM and found that not only was KP statistically significantly better at improving patients' symptoms, but it was also associated with significantly fewer complications at 1.72% as compared to NSM with complications found in 15.52% of the patients ($p < 0.05$). The risk profile for these procedures has been thoroughly investigated, and based on the available evidence, it is comparable to other minimally invasive interventions. Our stance continues to be that the benefits of VA outweigh the low risk of serious complications.

7. Short-Term Benefits & Relevance of Long-Term Outcomes

The draft report consistently recognizes that VP and KP demonstrate moderate to substantial pain reduction and functional improvements in the short term (1–6 months); however, it raises concerns regarding the sustainability of these benefits over the long term. SIR and the MPW want to highlight that early pain relief and functional improvements can mitigate further complications, such as decreased mobility, prolonged opioid use, and increased healthcare costs. Additionally, the relevance of long-term outcomes for an elderly population can be questioned, as factors such as osteoporotic fractures, malignant conditions, and other underlying health issues may limit the practicality of long-term outcome data. Therefore, the primary objective for this population should be short-term symptom relief and the enhancement of immediate quality of life rather than an exclusive emphasis on long-term outcomes.

Despite this, there are multiple examples of literature that investigates and has supported longer-term outcomes, including 5-to-10-year follow-up data in patients undergoing VP and KP[35-38] and a 10-year follow-up of patients undergoing sacroplasty[39]. Thus, long-term data are available and show sustained pain and functional improvement among patients treated with VA.

8. Malignancy-Related VCFs

While only one RCT was identified specific to a population with malignancy-related VCFs, this is an important population we urge the committee to consider. Bone metastases causing fractures can cause significant pain and worsened quality-of-life in a patient population, often at end-of-life care. They are deserving of high-quality, evidence-based treatment options. This procedure is integral in the multi-disciplinary treatment algorithm of spine metastatic disease. It is included in the National Comprehensive Cancer Network (NCCN) guidelines in both Adult Cancer Pain [40] and Metastatic Spine Tumor treatment (v 2.2024)[41] for treating cancer-related fractures.

9. Cost-Effectiveness Analyses

Several cost-effectiveness analyses (and systematic reviews of these studies) were accurately identified in this report. Limitations noted by the authors included the influence of mortality assumptions in the models affecting the final incremental cost-effectiveness ratio. As stated above, retrospective analyses of claims, controlling for confounding variables, are a better model input than carrying forward assumptions on mortality collected at the end of a 2-year randomized trial follow-up, and the more recent retrospective claims-based analyses with propensity score matching have accomplished this. Models cited followed the international HTA standards that model the benefits of an intervention over 10 to 15 years to account for longer-term follow-up related costs of reduced medical resource utilization and, conversely, any adverse events or subsequent surgical interventions required. The aggregate costs are then compared to the aggregate benefits in quality-of-life gains, part of which is patient utility and the other factor being patient longevity (mortality). If the committee is determining coverage based on cost-effectiveness, the HTCC should better define what economic analysis criteria should be included in a model and what modeling frameworks/checklists (e.g., NICE[42], CHEERS[43]) should be followed, with a separately applied framework of Strength of Evidence for models.

10. Medicare Local Coverage Determinations (LCDs) & Guidelines

The review of payer policies identifies one Medicare Local Coverage Determination (LCD) (and does not name the Medicare Administrative Contractor [MAC] of the LCD). It is essential to point out that there are seven separate LCDs, one per MAC, all written in 2019-2021 after extensive CMS review of KP and VP. All seven LCDs cover KP and VP for osteoporotic fracture (with minor nuances in coverage conditions across each). Five of the seven explicitly cover KP and VP for VCFs secondary to osteolytic metastatic disease or myeloma, and two LCDs implicitly cover treatment of malignant VCFs via the clause “coverage will remain available for medically necessary procedures for other conditions not included in this [osteoporotic VCF] LCD.” We suggest the committee closely review these LCDs for the rationale provided for coverage via literature synthesis and a sample framework of coverage criteria applied. Notably, seven separate MAC determinations reached the same coverage conclusions.

11. Management of VCFs: A clinical care pathway developed by a multispecialty panel

Furthermore, we would like to highlight that The RAND Care Pathway publication[44], a multispecialty consensus report on the appropriate patient profile for surgical treatment of VCFs, should have been included in the “guidelines” section of this HTA. This publication was cited in all CMS LCD revisions in 2019-2021 and was an important factor in Medicare coverage determinations on the appropriate population for treatment.

In summary, the evidence base supporting VA procedures has grown significantly since the 2010 HTA review. The safety, efficacy, and potential for cost savings associated with these procedures warrant reconsideration of the non-coverage determination, especially for osteoporotic VCFs. We trust that the committee will carefully review the points raised.

Thank you for your attention to this important matter. We are available for further discussion and look forward to the Committee's final decision. 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 (AAPM)
American Academy of Physical Medicine and Rehabilitation (AAPM&R)
American College of Radiology (ACR)
American Society of Regional Anesthesia and Pain Medicine (ASRA)
American Society of Neuroradiology (ASNR)
American Society of Spine Radiology (ASSR)
Interventional Pain and Spine Intervention Society (IPSIS)
North American Neuromodulation Society (NANS)
North American Spine Society (NASS)
Society of International Radiology (SIR)

References:

1. Wilson D, Owen S, Corkill R. Facet injections as a means of reducing the need for vertebroplasty in insufficiency fractures of the spine. Eur Radiol. 2011 Aug;21(8):1772-8. Epub 2011 Apr 13
2. Wang B, Guo H, Yuan L, Huang D, Zhang H, Hao D. A prospective randomized controlled study comparing the pain relief in patients with osteoporotic vertebral compression fractures with the use of vertebroplasty or facet blocking. Eur Spine J. 2016;25:3486-3494.
3. Im TS, Lee JW, Lee E, Kang Y, Ahn JM, Kang HS. Effects of Facet Joint Injection Reducing the Need for Percutaneous Vertebroplasty in Vertebral Compression Fractures. Cardiovasc Intervent Radiol 2016;39:740-5.
4. Buchbinder R, Osborne RH, Ebeling PR et al. A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures. N Engl J Med 2009;361:557-68.
5. Kallmes DF, Comstock BA, Heagerty PJ et al. A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures. N Engl J Med 2009;361:569-79.
6. Clark W, Bird P, Gonski P et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet. 2016 Oct 1;388(10052):1408-1416. doi: 10.1016/S0140-6736(16)31341-1. Epub 2016 Aug 17.
7. Hansen EJ, Simony A, Rousing R, Carreon LY, Tropp H, Andersen MO. Double blind placebo-controlled trial of percutaneous vertebroplasty (VOPE) Global Spine. 2017;6:1–6.
8. Carli D, Venmans A, Lodder P, Donga E, van Oudheusden T, Boukrab I, Schoemaker K, Smeets A, Schonenberg C, Hirsch J, de Vries J, Lohle P. Vertebroplasty versus Active Control Intervention for Chronic Osteoporotic Vertebral Compression Fractures: The VERTOS V Randomized Controlled Trial. Radiology. 2023 Jul;308(1):e222535. doi: 10.1148/radiol.222535. PMID: 37462495.
9. Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Reply to "At what price decreased mortality risk?". Osteoporos Int. 29(8), 1929-1930. 2018 May 3., doi: 10.1007/s00198-018-4551-4.
10. Edidin A, et al. Mortality Risk for Operated and Non-Operated Vertebral Fracture Patients in the Medicare Population. JBMR, 2011: Feb 9. DOI: 10.1002/jbmr.353
11. Chen AT, Cohen DB, Skolasky RL.Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the Medicare population. J Bone Joint Surg Am. 2013 Oct 2;95(19):1729-36. doi: 10.2106/JBJS.K.01649.
12. Zampini JM, White AP, McGuire KJ. Comparison of 5766 vertebral compression fractures treated with or without kyphoplasty. Clin Orthop Relat Res. 2010 Jul;468(7):1773-80. doi: 10.1007/s11999-010-1279-7.
13. Park J, Park S, Lee HJ, Lee C, Chang B, Kim H. Mortality following benign sacral insufficiency fracture and associated risk factors. Arch Osteoporos (2017) 12: 100. https://doi.org/10.1007/s11657-017-0395-3
14. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and Cost Comparison of Kyphoplasty and Percutaneous Vertebroplasty Using German Claims Data. Spine 2014;39:318–326
15. Edidin AA[1], Ong KL, Lau E, Kurtz SM. Morbidity and Mortality after Vertebral Fractures: Comparison of Vertebral Augmentation and Non-Operative Management in the Medicare Population. Spine (Phila Pa 1976). 2015 May 27.
16. Kanis JA, Oden A, Johnell O, et al. Excess mortality after hospitalisation for vertebral fracture. *Osteoporos Int* 2004;15:108-112
17. Lin JH, Chien LN, Tsai WL, et al. Early vertebroplasty associated with a lower risk of mortality and respiratory failure in aged patients with painful vertebral compression fractures. *Spine J* 2017
18. Niemi-Nikkola, Ville, BM[*,†]; Saijets, Nelli, BM[*,†]; Ylipoussu, Henriikka, BM[*,†]; Kinnunen, Pietari, MD, PhD[‡]; Pesälä, Juha, MD[‡]; Mäkelä, Pirkka, MD[‡]; Alen, Markku, MD, PhD[*,§]; Kallinen, Mauri, MD, PhD[*,§]; Vainionpää, Aki, MD, PhD[*,§,¶] Long-term Posttraumatic Survival of Spinal Fracture Patients in Northern Finland, Spine: December 1, 2018 - Volume 43 - Issue 23 - p 1657-1663. doi: 10.1097/BRS.0000000000002687.
19. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet. 2009 Mar 21;373(9668):1016-24.
20. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J Bone Miner Res. 2011;26(7):1627-1637.

21. Beall DP, Chambers MR, Thomas S, et al. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. Neurosurgery. 2019;84(1):169-178.
22. Brunton S, Carmichael B, Gold D, et al. Vertebral compression fractures in primary care: recommendations from a consensus panel. *J Fam Pract.* 2005;54(9):781-788.
23. Schlaich C, Minne HW, Bruckner T, et al. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int.* 1998;8(3):261-267.
24. R V. Management of osteoporotic vertebral compression fractures: a review. *Am J Clin Med.*6(4):14-18.
25. Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. *Bone.* 1996;18(3 Suppl):185s-189s.
26. Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. AJNR Am J Neuroradiol. 2020 Jan;41(1):178-182. doi: 10.3174/ajnr.A6367. Epub 2019 Dec 19
27. Hinde K, Maingard J, Hirsch JA, Phan K, Asadi H, Chandra RV. MortalityOutcomes of VertebralAugmentation (Vertebroplasty and/or BalloonKyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis. Radiology. 2020 Apr;295(1):96-103. doi: 10.1148/radiol.2020191294. Epub 2020 Feb 18.
28. Edidin A, et al. Mortality Risk for Operated and Non-Operated Vertebral Fracture Patients in the Medicare Population. JBMR, 2011: Feb 9. DOI: 10.1002/jbmr.353
29. Cauley JA, Thompson DE, Ensrud KC, et al. Risk of mortality following clinical fractures. Osteoporos Int. 2000;11(7):556-61.
30. Ni W, Ricker C, Quinn M, et al. Trends in opioid use following balloon kyphoplasty or vertebroplasty for the treatment of vertebral compression fractures. *Osteoporos Int.* 2022;33(4):821-837.
31. Services USDoHaH. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Published 2019. Accessed 09/24/2024.
32. D D. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w. Published 2022. Accessed 09/24/2024.
33. National Institute for Health and Clinical Excellence Draft scope for the proposed appraisal of vertebroplasty and kyphoplasty for the treatment of osteoporotic vertebral fractures. http://guidance.nice.org.uk/TA/Wave22/18
34. Liu Q, Cao J Kong JJ. Clinical effect of balloon kyphoplasty in elderly patients with multiple osteoporotic vertebral fracture. Niger J Clin Pract 2019; 22:289-92.
35. Aregger FC, Gerber F, Albers C, Oswald K, Knoll C, Benneker L, Heini P, Berlemann U, Hoppe S. Long-term follow-up after vertebroplasty - A mean 10-years follow-up control study. Brain Spine. 2024 Apr 3;4:102783. doi: 10.1016/j.bas.2024.102783. PMID: 38618227; PMCID: PMC11015514.
36. Kim JH, Yoo SH, Kim JH. Long-term Follow-up of Percutaneous Vertebroplasty in Osteoporotic Compression Fracture: Minimum of 5 Years Follow-up. Asian Spine J. 2012 Mar;6(1):6-14. doi: 10.4184/asj.2012.6.1.6. Epub 2012 Mar 9. PMID: 22439082; PMCID: PMC3302917.
37. Zhan, Z., Li, R., Fu, D. *et al.* Clinical efficacy and influencing factors of percutaneous kyphoplasty for osteoporotic vertebral compression fractures: a 10-year follow-up study. *BMC Surg* **24**, 29 (2024). https://doi.org/10.1186/s12893-024-02322-5
38. Yavuz AY, Aydın MV. Long-term Clinical and Radiological Results of Vertebral Augmentation Techniques in Osteoporotic Lumbar Compression Fractures: Vertebroplasty or Kyphoplasty?. J Turk Spinal Surg. 2023 Oct;34(4):180-188. doi:10.4274/jtss.galenos.2023.30502.
39. Frey ME, Warner C, Thomas SM, Johar K, Singh H, Mohammad MS, Beall DP. Sacroplasty: A Ten-Year Analysis of Prospective Patients Treated with Percutaneous Sacroplasty: Literature Review and Technical Considerations. Pain Physician. 2017 Nov;20(7):E1063-E1072. PMID: 29149151.
40. National Comprehensive Cancer Network. Adult Cancer Pain (Version 2.2024). Accessed September 30, 2024. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf
41. National Comprehensive Cancer Network. Central Nervous System Cancers (Version 2.2024). Accessed September 30, 2024. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
42. (NICE) NIoHaCE. https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness Published 2012. Accessed 09/24/2024.
43. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. Value Health. 2013;16(2):e1-5.
44. 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.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Public Comment- Vertebroplasty, Kyphoplasty, Sacroplasty - Draft Evidence Report Review
Date: Wednesday, October 2, 2024 11:16:50 AM
Attachments: image001.png
Industry Letter WA HTA Draft Report_Final Oct 2 2024.pdf
Importance: High

External Email

Dear WA State Health Technology Assessment Committee,

We appreciate the opportunity to submit comments on behalf of Industry partners who represent the global medical device companies that support these technologies.

We are encouraged to see the re-review of the evidence supporting vertebral compression fracture procedures and look forward to participating in the public meeting in November.

Feel free to reach out to us if you have questions.

Kind regards,

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

Stan Dietz
Director Reimbursement & Market Access, Stryker
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RE: Vertebroplasty, Kyphoplasty, Sacroplasty – Rereview – Draft Evidence Report

October 2, 2024

To Members of the Health Technology Assessment Program Committee,

We appreciate the opportunity to submit comments to the Washington State Health Care Authority's (HCA) Draft Evidence Report on Vertebroplasty, Kyphoplasty, and Sacroplasty. Given the marked increase in available literature since the initial 2020 review of this topic, and broad coverage of vertebroplasty procedures by both national Commercial payers and all Medicare Administrative Contractors (MACs), we hope that this updated review will highlight to the committee the breadth of evidence in support of these therapies. Any positive changes in coverage policy resulting from this report would increase access to therapies that substantially improve pain control and quality of life in an overwhelmingly elderly and fragile patient population.

The signatories of this letter represent global medical device companies (Medtronic, Merit Medical, and Stryker) involved in the delivery of high quality and clinically appropriate treatment to patients suffering from vertebral compression fractures (VCFs). These products, approved by the FDA, are indicated for patients suffering from a range of conditions including but not limited to VCFs caused by pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions.

After reviewing the draft report, we commend the Committee and Aggregate Analytics on a thorough review of the evidence. Below we outline areas for consideration in the final report.

Randomized Controlled Trials (RCTs)

As was correctly noted in the draft report, there are inherent limitations with historic VP vs. Sham designed randomized clinical trials (RCTs). Most notably the sham arm of all trials included an analgesic component. This raises significant questions if a "Sham" that

provided even short-term pain control was truly a Sham procedure. Given these concerns we urge the committee to place more emphasis in their decision-making on evidence from VP vs. Usual Care trial designs.

Concerning RCT-level evidence of Kyphoplasty (KP) reviewed, the report identified four trials comparing KP vs. Usual care.[1-5] Authors noted that three of the four trials identified were rated "poor" with unclear/absent blinding, unclear randomization, and between-group heterogeneity.[2,5,6] Given the "poor" ratings we urge the committee place more emphasis on results from the multinational FREE trial which was of higher quality.[1,3,4] In addition to the FREE trial, and given the potential design flaws of other KP trials identified, we point the committee to the large EVOVLE single-arm prospective clinical study for inclusion in the final report to include a more representative set of KP literature used in Commercial and Medicare coverage policy analyses. While not randomized, the EVOLVE study was large (N = 354), spanned numerous study sites (24 in US), and collected both pain and functioning through 12-months of follow-up.[7]

Opioid Use

With the unabating national opioid crisis, any procedure which has the potential to impact a reduction in opioid prescribing should be given careful consideration. This is consistent with CDC's Clinical Practice Guideline for Prescribing Opioids for Pain, HHS' Pain Management Best Practices Task Force Report, and NCCN's Guidelines for Adult Cancer.[8-10] In addition to trial-reported opioid use endpoints, we suggest the final report broaden the study inclusion criteria to include retrospective studies, particularly retrospective administrative claims analyses. These study designs are more appropriate for measuring a medication endpoint given it removes the factor of patient recall, and instead analyzes the objective measure of prescription fills at a pharmacy. This allows researchers to calculate the average daily dosage in morphine milligram equivalents (MMEs) that patients are prescribed. One such study analyzed over 8,000 patients treated with KP or VP comparing baseline to follow-up opioid utilization.[11]

Mortality

We respectfully disagree with the stated limitations of mortality literature made in the draft report Executive Summary and Cost-Effectiveness sections regarding the validity of literature consistently pointing to lower long-term mortality among surgically treated patients with VCF versus those treated with CMM / non-surgical intervention. Operationally, and ethically, it would be prohibitive to perform a randomized study with mortality as an endpoint over 5-to-10-year follow-up. An opinion piece published in NEJM in 2010 provided an excellent summary of the ethics of running placebo or non-treated

randomized studies in an osteoporotic population, stating "many believe that it is ethical to withhold an effective treatment when adverse consequences are minor or rare. However, osteoporotic hip and vertebral fractures have serious consequences, including increased risk of death…".[12] Authors further go on to state that as effective treatments are identified and the consequence of untreated disease is better defined, the questions on ethics of a placebo or non-treated study design only increase. This is exactly the scenario that researchers face today given the breadth of retrospective mortality studies linking non-treatment to increased risk of mortality.

Not only have retrospective claims analysis of the full Medicare population (appropriately cited in the draft report) concluded a reduction in mortality for patients with VCF receiving surgical treatment, but several other retrospective analyses globally have also come to the same conclusion (Germany, Sweden, and Taiwan).[13-16] We call to the committee's attention one additional retrospective study in Sweden that was not captured in the draft report.[14] Additionally, while limited to two studies, prospective studies (one registry and one trial with long term follow-up) have confirmed the same reductions in mortality among patients with VCF treated surgically, citations which we also recommend for inclusion in the final report.[17,18]

Concerns over limitations of administrative claims databases are pervasive in HTA assessments and not unique to this review. However, as noted above, there is no immediate perfect alternative short of running a long-term follow-up registry tracking mortality among patients, which would be subject to its own set of biases in terms of patients ultimately enrolled in such a registry (particularly those for whom surgical treatment was not provided).

The propensity-score matching (PSM) approach used in all retrospective claims-based analyses cited is a well-validated and standard statistical approach to minimizing bias in retrospective analyses of healthcare interventions.[19] While complete balance between unmeasured or unmeasurable factors cannot be assumed in PSM studies, several techniques are applied to minimize such potential for bias. For example, the use of "calipers", i.e. the degree of difference that may be tolerated between a treatment and control matched group, allows researchers to define the degree of tolerance on the precision of a match. The typically applied caliper is 0.2 times the standard deviation of a propensity score. Secondly, variable selection for matching should consider all potential factors related to the propensity/odds of receiving treatment and/or association with the outcome of interest. All retrospective PSM literature cited used a robust set of covariates in matching models, including age, sex, race, census region, socioeconomic status, comorbidities diagnosed prior to treatment, type of fracture, year of fracture, among others. Thus, the major factors assumed to be correlated with both odds of receiving

treatment and mortality risk were well-accounted for in the PSM models identified in literature; thus, reducing concerns of "unmeasured confounding" bias.

We strongly urge the committee to consider this body of evidence, despite the absence of randomized information confirming the implications of surgical VCF treatment on future mortality given the ethical concerns over collecting this data prospectively. Subsequently, the base case analyses of all cost-effectiveness models cited should be given appropriate consideration, where a mortality "benefit" is built into the core model structure.

Medicare and Private Insurer Coverage Policies

The draft report lists just one Medicare Local Coverage Determination (LCD), effective 01/10/2015. There are not one, but seven LCDs, one per Medicare Administrative Contractor (MAC).[20-26] All seven LCDs cover KP and VP. We suggest the committee closely review each of these LCDs given substantial review was recently completed between 2019-2021, with all providing good examples of how evidence was assessed and thus applied to coverage criteria. One such critical publication cited in all LCDs was a multispecialty consensus panel on the patient population most appropriate for VP or KP treatment of a VCF, following the RAND/UCLA Appropriateness Method.[27]

In conclusion, we thank the HTA Program Committee for their close review of the evidence in support of surgical treatment of VCFs. We strongly urge the WA State HTA to reconsider their long-standing non-coverage of VCF based on the latest body of evidence supporting approved indications for use for pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions. Should you have any questions, please do not hesitate to contact signatories of this letter at the email addresses noted below.

Sincerely,

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

Stan Dietz
Director Reimbursement & Market Access, Stryker
[redacted]

Robert Poser
Vice President, Global Spinal Therapies, Merit Medical
[redacted]

1. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res*. 2011;26(7):1627-1637.

2. Liu Q, Cao J, Kong JJ. Clinical effect of balloon kyphoplasty in elderly patients with multiple osteoporotic vertebral fracture. *Niger J Clin Pract*. 2019;22(3):289-292.

3. Van Meirhaeghe J, Bastian L, Boonen S, Ranstam J, Tillman JB, Wardlaw D. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. *Spine (Phila Pa 1976)*. 2013;38(12):971-983.

4. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. 2009;373(9668):1016-1024.

5. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. *Arch Orthop Trauma Surg*. 2014;134(1):21-30.

6. Y L. comparative study of percutanous kyphoplasty and conservative therapy on vertebral osteoporotic compression fractures in elderly patients. *Int J Clin Exp Med*. 2017;10:8139-8145.

7. Beall DP, Chambers MR, Thomas S, et al. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. *Neurosurgery*. 2019;84(1):169-178.

8. (NCCN) NCCN. NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Published 2024. Updated 03/11/2024. Accessed 10/2/2024.

9. D D. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w. Published 2022. Accessed 09/13/2024.

10. Services USDoHaH. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Published 2019. Accessed 09/13/2024.

11. Ni W, Ricker C, Quinn M, et al. Trends in opioid use following balloon kyphoplasty or vertebroplasty for the treatment of vertebral compression fractures. *Osteoporos Int*. 2022;33(4):821-837.

12. Stein CM, Ray WA. The ethics of placebo in studies with fracture end points in osteoporosis. *N Engl J Med*. 2010;363(14):1367-1370; discussion e1321.

13. Huang KY, Lee SC, Liu WL, Wang JD. Long Term Survival of Pathological Thoracolumbar Fractures Treated with Vertebroplasty: Analysis Using a Nationwide Insurance Claim Database. *J Clin Med*. 2019;9(1).

14. Kanis JA, Oden A, Johnell O, De Laet C, Jonsson B. Excess mortality after hospitalisation for vertebral fracture. *Osteoporos Int*. 2004;15(2):108-112.

15. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine (Phila Pa 1976)*. 2014;39(4):318-326.

16. Lin JH, Chien LN, Tsai WL, Chen LY, Chiang YH, Hsieh YC. Early vertebroplasty associated with a lower risk of mortality and respiratory failure in aged patients with painful vertebral compression fractures: a population-based cohort study in Taiwan. *Spine J*. 2017;17(9):1310-1318.

17. Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black D. Risk of mortality following clinical fractures. *Osteoporos Int.* 2000;11(7):556-561.

18. Kado DM, Duong T, Stone KL, et al. Incident vertebral fractures and mortality in older women: a prospective study. *Osteoporos Int.* 2003;14(7):589-594.

19. Johnson ML, Crown W, Martin BC, Dormuth CR, Siebert U. Good research practices for comparative effectiveness research: analytic methods to improve causal inference from nonrandomized studies of treatment effects using secondary data sources: the ISPOR Good Research Practices for Retrospective Database Analysis Task Force Report--Part III. *Value Health.* 2009;12(8):1062-1073.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Comments on Vertebroplasty, Kyphoplasty, and Sacroplasty Technology Assessment
Date: Tuesday, October 1, 2024 11:31:50 AM
Attachments: IPSIS_WA HTA VKS 10-1-2024.pdf

External Email

Good afternoon,

On behalf of Dr. Joshua Rittenberg, President of the International Pain and Spine Intervention Society, please find attached a comment letter on the draft technology assessment of Vertebroplasty, Kyphoplasty, and Sacroplasty. We hope that our feedback is helpful and taken into consideration as you work to finalize the technology assessment.

Confirmation of receipt would be greatly appreciated.

Please do not hesitate to reach out if you have any questions or wish to discuss any of our comments.

Best wishes,
Belinda

IPSISmed.org

Belinda Duszynski
Senior Director of Policy and Practice
International Pain and Spine Intervention Society (IPSIS)
[redacted]

IPSIS 2025 Winter Seminar

October 1, 2024

Josh Morse, MPH
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Washington State Health Care Authority
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Submitted via e-mail: shtap@hca.wa.gov

Re: Draft Technology Assessment on Vertebroplasty, Kyphoplasty, and Sacroplasty

Dear Mr. Morse:

The International Pain and Spine Intervention Society (IPSIS), a multi-specialty association of nearly 3,500 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of pain, would like to take this opportunity to thank you for inviting comments on the draft report. The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional pain management 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 promoting access to appropriate, effective, and responsible treatments to improve quality of life.

The Washington State Health Technology Assessment Program has commissioned the development of this technology assessment to inform the Washington State Health Care Authority's decisions related to coverage of vertebroplasty, kyphoplasty, and sacroplasty. It is paramount that the technology assessment presents an unbiased assessment of the evidence regarding the safety and effectiveness of these procedures to ensure that the Washington State Health Care Authority can make an appropriate determination about whether these procedures should be covered for appropriate patients. The authors of the technology assessment have generated an expansive report of more than 250 pages that merits careful review. Unfortunately, a four-week comment period has proven insufficient to allow for that level of review by busy physician volunteers within our organization. However, we have attempted to identify some areas of concern and suggest issues that merit further consideration and revision.

Methodology

While the methodology appears reasonable, it is critical that the assessment not only stratify results by indications (e.g., osteoporotic fracture vs. tumor/malignancy fracture) and specific technique (e.g., vertebroplasty vs. kyphoplasty) but also on the acuity of the fracture – specifically assessing effectiveness for acute (<6 weeks), subacute (6-12 weeks), and chronic (>12 weeks) fractures.

Accuracy of Evidence Assessment
Based on a cursory assessment of the narrative review of individual studies, the summaries appear reasonable. More time to review the report would have allowed for careful evaluation of the original studies and the report's summaries, which was not feasible with the 4-week deadline.

Discussion/Conclusions

Effectiveness of Vertebroplasty vs. Sham -- Osteoporosis
In the studies of vertebroplasty versus sham, there is a tendency towards improvement in vertebroplasty over sham procedures. The benefit of vertebroplasty over sham is supported by the observation that when allowed to cross over, "substantially more" patients crossed over to the vertebroplasty group compared with the sham group at 3 months (51% vs. 13%) [1].

Effectiveness of Vertebroplasty vs. Kyphoplasty -- Osteoporosis
While pain relief and functional improvement were similar between vertebroplasty and kyphoplasty, it is essential to note that the two procedures are significantly different. The kyphoplasty procedure produces improved vertebral height restoration and spinal architecture, which minimizes subsequent spinal deformity and angulation above the site of the vertebral compression fracture. A multicenter retrospective review by the French Society for Spine Surgery (SFCR) found that kyphoplasty significantly improved the wedge angle by +6° compared to +2° with vertebroplasty (P=0.002) [2]. A biomechanical and radiographic study demonstrated that kyphoplasty restored 97% of the anterior vertebral body height immediately after the procedure, which reduced to 79% after consolidation, whereas vertebroplasty restored 59% and 47%, respectively (P<.001) [3]. Additionally, a cadaveric study showed that kyphoplasty increased vertebral height by 5.1 mm compared to 2.3 mm with vertebroplasty (P<.05) [4]. Furthermore, a meta-analysis indicated that kyphoplasty was associated with significant improvements in vertebral body height and kyphosis angle compared to vertebroplasty [5].

PMMA Volume
It is unclear why the authors concluded that PMMA volume and marrow edema are not associated with treatment outcomes. A number of studies demonstrate that volume/dispersion is an important factor that affects multiple clinical and radiographic outcomes [6-10].

Ethical Issues – Sham-Controlled Studies
While there have been sham-controlled studies performed in the past, an expectation of conducting additional sham-controlled trials poses ethical concerns. The current evidence base supports the efficacy of the procedures, as reported in multiple RCTs and high-quality comparative studies. Because the procedure requires access via the pedicle and vertebral body, the procedure alters anatomy and can be considered "surgical" based on the AMA definition of surgery [11]. Given this fact, a sham study would be unethical in line with the opinion of ethicists and surgeon-scientists [12-14]. Downgrading or discounting the existing high-quality evidence is unwarranted.

Cost Effectiveness and Mortality Benefit
The discussion cites a body of evidence uniformly supporting the cost-effectiveness and mortality benefit of vertebral augmentation over usual care but then minimizes the findings of this large body of research because some of the evidence is derived from database studies. While we acknowledge the limitations of database research, the cost-effectiveness and mortality benefit should not be discounted.

- The finding of a mortality rate 8.6 times higher than age-matched controls and a 40% higher mortality rate after 8 years is quite convincing [15,16].
- Although not supportive of a causal effect, the longitudinal, population-based study using Medicare data from 2005 to 2008, which included 858,978 patients with vertebral compression fractures, was significant given the size of the population being studied [17]. This dataset comprised 119,253 patients who underwent balloon kyphoplasty, 63,693 patients who received vertebroplasty, and the remaining patients who received nonsurgical management. At the 4-year follow-up, patients who received vertebral augmentation had a 37% lower mortality rate than those who received nonsurgical management, and their adjusted life expectancy was 85% higher. Among the treated groups, those who underwent balloon kyphoplasty had a life expectancy 115% greater than those who received vertebroplasty and significantly better than the nonsurgical management group. Overall, median life expectancy across all treated groups was extended by 2.2 to 7.3 years compared to nonsurgical management.
- Additionally, a retrospective review found a significant survival benefit for vertebroplasty over usual care, regardless of comorbidities, age, or the number of fractures present at the start [18].

We encourage you to consider our feedback and revise the technology assessment to properly characterize the evidence and clinical importance of these procedures for patients suffering from vertebral fractures. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide assistance, please contact Belinda Duszynski, Senior Director of Policy and Practice, at [redacted]

Best wishes,

Joshua Rittenberg, MD
President
International Pain and Spine Intervention Society

References:

1. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures [published correction appears in N Engl J Med. 2012 Mar 8;366(10):970]. *N Engl J Med*. 2009;361(6):569-579. doi:10.1056/NEJMoa0900563
2. Garnier L, Tonetti J, Bodin A, et al. Kyphoplasty versus vertebroplasty in osteoporotic thoracolumbar spine fractures. Short-term retrospective review of a multicentre cohort of 127 consecutive patients. *Orthop Traumatol Surg Res*. 2012;98(6 Suppl):S112-S119. doi:10.1016/j.otsr.2012.03.018
3. Landham PR, Baker-Rand HL, Gilbert SJ, et al. Is kyphoplasty better than vertebroplasty at restoring form and function after severe vertebral wedge fractures?. *Spine J*. 2015;15(4):721-732. doi:10.1016/j.spinee.2014.11.017
4. Hiwatashi A, Sidhu R, Lee RK, deGuzman RR, Piekut DT, Westesson PL. Kyphoplasty versus vertebroplasty to increase vertebral body height: a cadaveric study. *Radiology*. 2005;237(3):1115-1119. doi:10.1148/radiol.2373041654
5. Zhao G, Liu X, Li F. Balloon kyphoplasty versus percutaneous vertebroplasty for treatment of osteoporotic vertebral compression fractures (OVCFs). *Osteoporos Int*. 2016;27(9):2823-2834. doi:10.1007/s00198-016-3610-y
6. Röder C, Boszczyk B, Perler G, Aghayev E, Külling F, Maestretti G. Cement volume is the most important modifiable predictor for pain relief in BKP: results from SWISSspine, a nationwide registry. *Eur Spine J*. 2013;22(10):2241-2248. doi:10.1007/s00586-013-2869-3
7. He X, Li H, Meng Y, et al. Percutaneous kyphoplasty evaluated by cement volume and distribution: an analysis of clinical data. *Pain Physician*. 2016;19(7):495-506.
8. Lin D, Hao J, Li L, et al. Effect of bone cement volume fraction on adjacent vertebral fractures after unilateral percutaneous kyphoplasty. *Clin Spine Surg*. 2017;30(3):E270-E275. doi:10.1097/BSD.0000000000000204
9. Khalilollah S, Abdolhoseinpour H, Rezaei E, Fakhr MS. The relationship between pain relief and the amount and distribution of injected cement in kyphoplasty for osteoporotic vertebral fractures. *Eur Rev Med Pharmacol Sci*. 2023;27(18):8540-8549. doi:10.26355/eurrev_202309_33779
10. Krüger A, Baroud G, Noriega D, et al. Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used. *Clin Biomech (Bristol, Avon)*. 2013;28(7):725-730. doi:10.1016/j.clinbiomech.2013.06.007
11. AMA. Definition of Surgery H-475.983. https://policysearch.ama-assn.org/policyfinder/detail/surgery?uri=%2FAMADoc%2FHOD.xml-0-4317.xml (Accessed 9/27/2024)
12. Polgar S, Mohamed S. Evidence-Based Evaluation of the Ethics of Sham Surgery for Parkinson's Disease. *J Parkinsons Dis*. 2019;9(3):565-574. doi:10.3233/JPD-191577
13. Miller FG, Kaptchuk TJ. Sham procedures and the ethics of clinical trials. *J R Soc Med*. 2004;97(12):576-578. doi:10.1177/014107680409701205
14. Miller, Frankling G., 'Sham surgery: An ethical analysis', *The Ethical Challenges of Human Research: Selected Essays* (New York, 2012; online edn, Oxford Academic, 27 May 2015), https://doi.org/10.1093/acprof:osobl/9780199896202.003.0009 (Accessed 9/27/2024)
15. Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black D. Risk of mortality following clinical fractures. *Osteoporos Int*. 2000;11(7):556-561. doi:10.1007/s001980070075

16. Lau E, Ong K, Kurtz S, Schmier J, Edidin A. Mortality following the diagnosis of a vertebral compression fracture in the Medicare population. *J Bone Joint Surg Am*. 2008;90(7):1479-1486. doi:10.2106/JBJS.G.00675
17. 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;26(7):1617-1626. doi:10.1002/jbmr.353
18. Gerling MC, Eubanks JD, Patel R, Whang PG, Bohlman HH, Ahn NU. Cement augmentation of refractory osteoporotic vertebral compression fractures: survivorship analysis. *Spine (Phila Pa 1976)*. 2011;36(19):E1266-E1269. doi:10.1097/BRS.0b013e31820a0b3f

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: ASIPP Comments on VCF in WA state
Date: Friday, October 4, 2024 4:05:15 PM
Attachments: ASIPP Comments on VCFs FINAL.pdf

External Email

ASIPP Comments on VCF in WA state are attached.

Thank you.

Best regards,
Christopher Gharibo, M.D.
Professor of Anesthesiology, Peri-Operative Care & Pain Medicine
Professor of Orthopedics

Medical Director of Pain Medicine
NYU Langone Health

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Past President, NYSIPP, EPA

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Letter of Strong Support for the Consideration and Implementation of VCF as a Viable and Cost-Effective Treatment Option within Washington State.

On behalf of the American Society of Interventional Pain Physicians (ASIPP) members, its state societies, Board of Directors and the Society of Interventional Pain Management Surgery Centers we would like to express our gratitude for the opportunity to comment on the draft report on VCF treatments in WA state.

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 48 state societies (including Washington via our Washington Society of Interventional Pain Physicians) of Interventional Pain Physicians, including Puerto Rico and the affiliated Texas Pain Society.

Interventional pain management is defined as, “the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment”

Interventional pain management techniques are defined as, “minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain”.

We are writing to express our strong support for the consideration and implementation of VCF as a viable and cost-effective treatment option for patients suffering from chronic

pain within the state of Washington. The evidence behind the efficacy and cost savings associated with VCF is compelling and warrants careful attention.

Level of Evidence for VCF and Sacroplasty

We agree with the draft evidence report's conclusion that there is *substantially* more RCT-level evidence since the last 2010 review (32 RCTs reviewed versus 7). Therefore, we are pleased that the topic has been re-opened and hope that the additional evidence provides sufficient assurance of safety and efficacy to consider removing the prior non-covered determination specific to osteoporotic VCFs. While only 1 RCT was identified specific to a population with malignancy-related VCFs, this is an important population to consider as bone metastases causing fracture can cause significant pain and worsened quality-of-life in a patient population often at end-of-life care. We agree there is currently insufficient Level 1 evidence specific to sacroplasty.

VP vs. Sham and VP vs. Usual Care

Pg 28: *"In trials of VP versus sham, effects for pain improvement with VP were smaller compared with sham at some time frames when an association was seen, and improvement was similar between VP and sham at other times. In contrast, VP was associated with large or moderate improvements in pain compared with usual care, at all but one time. The reason for this is not clear. This observation may be in part due to placebo and nonspecific effects not related to treatment, given the inability to blind patients receiving usual care leading to a potential overestimate of effect."….."The use of local anesthetic might be considered a more "active" control and partially explain the smaller or no effect seen between VP and sham control."*

We urge the committee to closely evaluate the commentary on the use of local anesthetic in the "sham" controlled VP trials; which was very likely providing short-term pain control among sham patients. As further noted in the summary on Pg 81, there was variability on the specific form of sham control used (4 trials used the same periosteal infiltration of local anesthetic as patients in the treatment arm, one injected a local anesthetic into the vertebral body, and another trial included subcutaneous lidocaine), however all included some component of analgesia.

Given these concerns over effects of an "active" sham we urge the committee to place more weight on the evidence from VP vs. Usual Care trials designs.

KP vs. Usual Care (Pg 110)

The review correctly identified four trials of BKP vs. usual care and no trials of BKP vs. Sham.

Similar to our comments above on the existing evidence base of VP vs. Sham, the same limitations would apply if a BKP vs. Sham trial were available. Furthermore, this trial design introduces ethical concerns over placing a patient under sedation to receive simply an injection rather than a BKP procedure; especially given the elderly population suffering from osteoporotic VCFs. If the sham procedure proves ineffective, that patient is then subject to two operative episodes if opting for the BKP procedure once the blinded follow-up period ends.

Authors noted that three of the four trials identified were rated “poor” with unclear/absent blinding, unclear randomization, and between-group heterogeneity. We agree with this assessment and therefore suggest that the committee place more emphasis on the results from the multinational FREE trial which adequately reports on these items.

Given this leaves just one RCT with a higher level of evidence, we would suggest the committee also evaluate clinical outcomes from the EVOLVE single-arm trial of kyphoplasty. While we acknowledge this is not a fully randomized study, it is a large study of 354 patients with VCFs across 24 study sites in the US, where back pain, functioning (ODI, SF-36 PCS), and quality of life (EQ-5D) information were collected at baseline, 7 days, and 1-, 3-, 6-, and 12-months follow-up. There are statistical techniques via Network Meta-Analysis available in which the committee may incorporate this evidence with that from the active treatment arm of the FREE trial.

KP vs. VP

Authors conclude with low-to-moderate quality (SoE) that there is similar improvement in pain scores and functioning with KP vs VP (Table 5.1.5). Given this conclusion we would suggest that the committee leave the decision on operative procedure to the treating physician.

Mortality

Pg 29: *"While the RCTs are less biased and allow for causal inference, some may have been underpowered to detect differences in mortality and had shorter follow-up. Causal inference, however, is not possible from such [administrative database] studies, and their results should be considered within the context of the general limitations of administrative database studies (claims data).*

We acknowledge the committee's concern over risk of bias in retrospective administrative claims database studies evaluating mortality; but appreciate that in response to public comments on the draft key questions that this set of literature was included in the report. Given the inability of randomized evidence to look over long-term follow-up (5 to 10 years) this set of retrospective literature is important to consider in the wider context of efficacy of VCF procedures. While studies may have varied in the rigorous application of control for confounding, all provided similar conclusions suggesting a correlation between active treatment of a VCF and reduced risk of mortality, interestingly in both populations studied within the US and OUS. This is not a causative conclusion, merely correlation, and there are a variety of factors that may contribute to this decline in physical functioning and thus mortality risk – including decreased lung capacity, prolonged inactivity, and neurological complications stemming from untreated VCFs left to heal in a sub-optimal manner.

Opioid Use

Opioid overutilization has ravaged communities across the United States and has affected the young and old disproportionately. ASIPP has released multiple Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain on responsible opioid prescribing, latest in 2023.

Across the trials which reported on opioid use, the definition / data collection of usage varied widely (any use, "major" opioids, "minor" opioids) and were heavily reliant on patient recall and accurate reporting of use. None provided information on average daily dose via a morphine milligram equivalent (MME).

Given these major limitations with medication use as collected in a trial population, we would suggest that the committee consider retrospective administrative claims-based analysis of opioid use following VCF procedures, which is a more objective measure of usage given patient-specific opioid dosages were calculated based on actual

medication pharmacy fills billed to the payer. This removes any risk of bias from patient recall. One such study to consider including was a retrospective analysis of over 8,000 patients treated with VP or KP which compared baseline medication use to that at 7-month follow-up (including a 1-month postoperative washout).

Reducing opioid use, particularly in the elderly population who disproportionately suffers from VCFs, aligns with national objectives set forth by the CDC's revised opioid prescribing guidelines and the US Department of Health and Human Services Pain Management Best Practices Task Force Report. Any intervention which shows correlation with reduced need for prolonged opioid use warrants close review by the HTCC.

Cost-Effectiveness

Several cost-effectiveness analyses (and systematic reviews of these studies) were accurately identified in the study report. Limitations noted by authors included the influence of mortality assumptions in the models affecting the final incremental cost-effectiveness ratio. As noted above, retrospective analyses of claims, controlling for confounding, are a better model input than carrying forward assumptions on mortality collected at the end of two-year randomized trial follow-up. Models cited followed the international HTA standards that model the benefits of an intervention over 10 to 15 years to account for longer term follow-up related costs of reduced medical resource utilization and conversely any adverse events or subsequent surgical interventions required. The aggregate costs are then compared to the aggregate benefits in quality-of-life gains, part of which is patient utility and the other factor being patient longevity (mortality).

If the committee is determining coverage based on cost-effectiveness, the HTCC should be better define what economic analysis criteria should be included in a model and what modeling frameworks/checklists (e.g. NICE, CHEERS etc) should be followed, with a separately applied framework of Strength of Evidence for models.

Review of Medicare and Representative Private Insurer Coverage Policies (Pg 67)

The review of payer policies identifies one Medicare Local Coverage Determination (LCD), effective 01/10/2015 (and does not name the Medicare Administrative Contractor [MAC] of the LCD). It is important to point out that there are seven separate LCDs, one per MAC, all of which were written in 2019-2021 after extensive CMS review of KP and

VP. All seven LCDs cover KP and VP for osteoporotic fracture (with minor nuances in coverage conditions across each). Five of the seven explicitly cover KP and VP for VCFs “secondary to osteolytic vertebral metastatic disease or myeloma involving a vertebral body” and two LCDs implicitly cover treatment of malignant VCFs via the clause “coverage will remain available for medically necessary procedures for other conditions not included in this [osteoporotic VCF] LCD”.

We suggest the committee closely review each of these LCDs for the rationale provided for coverage via literature synthesis, as well as a sample framework of coverage criteria applied. It is notable that seven separate MAC determinations all reached the same coverage conclusions, including representatives from ASIPP.

Missing from the review:

The RAND care pathway publication, which was a multispecialty consensus on the appropriate patient profile for surgical treatment of VCF should be included in the “guidelines” section of this HTA. This study was cited in all CMS LCD revisions in 2019-2021 and was an important factor in Medicare coverage determinations on the appropriate population for treatment.

References

1. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res.* 2011;26(7):1627-1637.
2. Liu Q, Cao J, Kong JJ. Clinical effect of balloon kyphoplasty in elderly patients with multiple osteoporotic vertebral fracture. *Niger J Clin Pract.* 2019;22(3):289-292.
3. Van Meirhaeghe J, Bastian L, Boonen S, Ranstam J, Tillman JB, Wardlaw D. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. *Spine (Phila Pa 1976).* 2013;38(12):971-983.
4. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet.* 2009;373(9668):1016-1024.
5. Manchikanti L, Sanapati J, Pampati V, Kaye A, Hirch J, Utilization of Vertebral Augmentation Procedures in the USA: a Comparative Analysis in Medicare Fee-

for-Service Population Pre- and Post-2009 Trials, Current Pain and Headache Reports (2020) 24: 22 https://doi.org/10.1007/s11916-020-00850-2.

6. Hirsch J, Chandra R, Pampati, V, Barr J, Brook A, Manchikanti L, Analysis of vertebral augmentation practice patterns: a 2016 update, J NeuroIntervent Surg 2016;8:1299–1304.
7. Manchikanti L, et al, Utilization and Expenditures of Vertebral Augmentation Continue to Decline: An Analysis in Fee-For-Service (FFS) Recipients from 2009 to 2018, Pain Physician 2021; 24:401-415
8. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. *Arch Orthop Trauma Surg.* 2014;134(1):21-30.
9. Y L. comparative study of percutanous kyphoplasty and conservative therapy on vertebral osteoporotic compression fractures in elderly patients. *Int J Clin Exp Med.* 2017;10:8139-8145.
10. Beall DP, Chambers MR, Thomas S, et al. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. *Neurosurgery.* 2019;84(1):169-178.
11. Brunton S, Carmichael B, Gold D, et al. Vertebral compression fractures in primary care: recommendations from a consensus panel. *J Fam Pract.* 2005;54(9):781-788.
12. Schlaich C, Minne HW, Bruckner T, et al. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int.* 1998;8(3):261-267.
13. R V. Management of osteoporotic vertebral compression fractures: a review. *Am J Clin Med.*6(4):14-18.
14. Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. *Bone.* 1996;18(3 Suppl):185s-189s.
15. Ni W, Ricker C, Quinn M, et al. Trends in opioid use following balloon kyphoplasty or vertebroplasty for the treatment of vertebral compression fractures. *Osteoporos Int.* 2022;33(4):821-837.
16. Services USDoHaH. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Published 2019. Accessed 09/13/2024.
17. D D. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w. Published 2022. Accessed 09/13/2024.

18. (NICE) NIoHaCE. https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness. Published 2012. Accessed 09/13/2024.
19. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *Value Health.* 2013;16(2):e1-5.
20. 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.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: RE: ASIPP Comments on VCF in WA state
Date: Monday, October 7, 2024 5:10:13 PM
Attachments: LETTER TO WASHINGTON STATE AUTHORITY Re Letter of Support for theConsideration and Approval of Vertebral Augmentation Procedures for theManagement of Vertebral Compression Fractures.pdf

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External Email

Hello Ms. Hamann,

Thank you for the accommodation. Dr. Manchikanti sent me attached today and I am truly thankful for its consideration.

CG

------ Original Message ------
Received: Mon, 07 Oct 2024 05:34:47 PM EDT
From: HCA ST Health Tech Assessment Prog <SHTAP@HCA.WA.GOV>
To: Christopher Gharibo [redacted]
Subject: RE: ASIPP Comments on VCF in WA state

> Hi Dr. Gharibo,
>
> Thank you for submitting your comments outside the VKS draft report comment period. These were received and will be taken under consideration.
>
> Thanks again,
>
> Val Hamann
> Program Specialist 3
> Health Services/Health Technology Assessment
> Clinical Quality and Care Transformation
> valerie.hamann@hca.wa.gov
> Pronouns: she/her
>
>
> hca.wa.gov |
> Connect with us
>
>
>
>
> -----Original Message-----
> From: Christopher Gharibo [redacted]
> Sent: Friday, October 4, 2024 4:05 PM
> To: HCA ST Health Tech Assessment Prog <SHTAP@HCA.WA.GOV>
> Subject: ASIPP Comments on VCF in WA state
>
> External Email
>
> ASIPP Comments on VCF in WA state are attached.
>
> Thank you.
>
>

> Best regards,
> Christopher Gharibo, M.D.
> Professor of Anesthesiology, Peri-Operative Care & Pain Medicine Professor of Orthopedics
>
> Medical Director of Pain Medicine
> NYU Langone Health
>
> President, ASIPP
> Past President, NYSIPP, EPA
>
[redacted]
>
[redacted]
> ASIPP
>
>

American Society *of* Interventional Pain Physicians®
Society *of* Interventional Pain Management Surgery Centers Inc.
"The Voice of Interventional Pain Management"
[redacted]

Re: Letter of Support for the Consideration and Approval of Vertebral Augmentation Procedures for the Management of Vertebral Compression Fractures

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 48 state societies, the Board of Directors, and the Society of Interventional Pain Management Surgery Centers (SIPMS), we would like to express our support for the consideration and implementation of vertebral augmentation for management of vertebral compression fractures for patients suffering with chronic pain within the state of Washington. The evidence behind the effectiveness and cost savings associated with vertebral augmentation procedures have been described extensively.

Established in 1998, ASIPP is a non-profit professional organization that currently boasts a membership of over 4,500 interventional pain physicians and other practitioners. Its mission is to promote SAFE (Safe, Appropriate, Fiscally Neutral and Effective) pain management services for patients nationwide who grapple with chronic and acute pain. The United States is home to approximately 8,500 proficient physicians with the requisite training and qualifications in interventional pain management. ASIPP is composed of 48 state societies of Interventional Pain Physicians, encompassing Puerto Rico, and includes the affiliated Texas Pain Society.

Established in 2005, SIPMS is a non-profit professional organization comprising surgical centers specializing in interventional pain management. The organization is committed to guaranteeing safe, appropriate, and equitable access to essential pain management services for patients nationwide experiencing chronic pain. The nation hosts around 500 Medicare-approved surgery centers that predominantly provide interventional pain management services or exclusively focus on them.

Interventional pain management is defined as, “the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment”.

Interventional pain management techniques are defined as, “minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain”.

Level of Evidence for Vertebral Compression Fracture and Sacroplasty

We agree with the draft evidence report's conclusion that there is *substantially* more RCT-level evidence since the last 2010 review (32 RCTs reviewed versus 7). Therefore, we are pleased that the topic has been re-opened and hope that the additional evidence provides sufficient assurance of safety and efficacy to consider removing the prior non-covered determination specific to osteoporotic vertebral compression fractures. While only 1 RCT was identified specific to a population with malignancy-related vertebral compression fractures, this is an important population to consider as bone metastases causing fracture can cause significant pain and worsened quality-of-life in a patient population often at end-of-life care. We agree there is currently insufficient Level 1 evidence specific to sacroplasty.

Vertebroplasty vs. Sham and Vertebroplasty vs. Usual Care

Pg 28: *"In trials of VP versus sham, effects for pain improvement with VP were smaller compared with sham at some time frames when an association was seen, and improvement was similar between VP and sham at other times. In contrast, VP was associated with large or moderate improvements in pain compared with usual care, at all but one time. The reason for this is not clear. This observation may be in part due to placebo and nonspecific effects not related to treatment, given the inability to blind patients receiving usual care leading to a potential overestimate of effect."….."The use of local anesthetic might be considered a more "active" control and partially explain the smaller or no effect seen between VP and sham control."*

We urge the committee to closely evaluate the commentary on the use of local anesthetic in the "sham" controlled vertebroplasty trials; which was very likely providing short-term pain control among sham patients. As further noted in the summary on Pg 81, there was variability on the specific form of sham control used (4 trials used the same periosteal infiltration of local anesthetic as patients in the treatment arm, one injected a local anesthetic into the vertebral body, and another trial included subcutaneous lidocaine), however all included some component of analgesia.

Given these concerns over effects of an "active" sham we urge the committee to place more weight on the evidence from vertebroplasty vs. Usual Care trials designs.

Kyphoplasty vs. Usual Care (Pg 110)

The review correctly identified four trials of balloon kyphoplasty vs. usual care and no trials of balloon kyphoplasty vs. Sham.

Similar to our comments above on the existing evidence base of vertebroplasty vs. Sham, the same limitations would apply if a balloon kyphoplasty vs. Sham trial were available. Furthermore, this trial design introduces ethical concerns over placing a patient under sedation to receive simply an injection rather than a balloon kyphoplasty procedure; especially given the elderly population suffering from osteoporotic vertebral compression fractures. If the sham procedure proves ineffective, that patient is then subject to two operative episodes if opting for the balloon kyphoplasty procedure once the blinded follow-up period ends.

Authors noted that three of the four trials identified were rated "poor" with unclear/absent blinding, unclear randomization, and between-group heterogeneity. We agree with this assessment and therefore suggest that the committee place more emphasis on the results from the multinational FREE trial which adequately reports on these items.

Given this leaves just one RCT with a higher level of evidence, we would suggest the committee also evaluate clinical outcomes from the EVOLVE single-arm trial of kyphoplasty. While we acknowledge this is not a fully randomized study, it is a large study of 354 patients with vertebral compression fractures across 24 study sites in the US, where back pain, functioning (ODI, SF-36 PCS), and quality of life (EQ-5D) information were collected at baseline, 7 days, and 1-, 3-, 6-, and 12-months follow-up. There are statistical techniques via Network Meta-Analysis available in which the committee may incorporate this evidence with that from the active treatment arm of the FREE trial.

Kyphoplasty vs. Vertebroplasty

Authors conclude with low-to-moderate quality (SoE) that there is similar improvement in pain scores and functioning with kyphoplasty vs vertebroplasty (Table 5.1.5). Given this conclusion we would suggest that the committee leave the decision on operative procedure to the treating physician.

Mortality

Pg 29: *"While the RCTs are less biased and allow for causal inference, some may have been underpowered to detect differences in mortality and had shorter follow-up. Causal inference, however, is not possible from such [administrative database] studies, and their results should be considered within the context of the general limitations of administrative database studies (claims data).*

We acknowledge the committee's concern over risk of bias in retrospective administrative claims database studies evaluating mortality; but appreciate that in response to public comments on the draft key questions that this set of literature was included in the report. Given the inability of randomized evidence to look over long-term follow-up (5 to 10 years) this set of retrospective literature is important to consider in the wider context of efficacy of vertebral compression fracture procedures. While studies may have varied in the rigorous application of control for confounding, all provided similar conclusions suggesting a correlation between active treatment of a vertebral compression fracture and reduced risk of mortality, interestingly in both populations studied within the US and OUS. This is not a causative conclusion, merely correlation, and there are a variety of factors that may contribute to this decline in physical functioning and thus mortality risk – including decreased lung capacity, prolonged inactivity, and neurological complications stemming from untreated vertebral compression fractures left to heal in a sub-optimal manner.

Opioid Use

Opioid overutilization has ravaged communities across the United States and has affected the young and old disproportionately. ASIPP has released multiple Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain on responsible opioid prescribing, latest in 2023.

Across the trials which reported on opioid use, the definition / data collection of usage varied widely (any use, "major" opioids, "minor" opioids) and were heavily reliant on patient recall and accurate reporting of use. None provided information on average daily dose via a morphine milligram equivalent (MME).

Given these major limitations with medication use as collected in a trial population, we would suggest that the committee consider retrospective administrative claims-based analysis of opioid use following vertebral compression fracture procedures, which is a more objective measure of usage given patient-specific opioid dosages were calculated based on actual medication pharmacy fills billed to the payer. This

removes any risk of bias from patient recall. One such study to consider including was a retrospective analysis of over 8,000 patients treated with vertebroplasty or kyphoplasty which compared baseline medication use to that at 7-month follow-up (including a 1-month postoperative washout).

Reducing opioid use, particularly in the elderly population who disproportionately suffers from vertebral compression fractures, aligns with national objectives set forth by the CDC's revised opioid prescribing guidelines and the US Department of Health and Human Services Pain Management Best Practices Task Force Report. Any intervention which shows correlation with reduced need for prolonged opioid use warrants close review by the HTCC.

Cost-Effectiveness

Several cost-effectiveness analyses (and systematic reviews of these studies) were accurately identified in the study report. Limitations noted by authors included the influence of mortality assumptions in the models affecting the final incremental cost-effectiveness ratio. As noted above, retrospective analyses of claims, controlling for confounding, are a better model input than carrying forward assumptions on mortality collected at the end of two-year randomized trial follow-up. Models cited followed the international HTA standards that model the benefits of an intervention over 10 to 15 years to account for longer term follow-up related costs of reduced medical resource utilization and conversely any adverse events or subsequent surgical interventions required. The aggregate costs are then compared to the aggregate benefits in quality-of-life gains, part of which is patient utility and the other factor being patient longevity (mortality).

If the committee is determining coverage based on cost-effectiveness, the HTCC should be better define what economic analysis criteria should be included in a model and what modeling frameworks/checklists (e.g. NICE, CHEERS etc) should be followed, with a separately applied framework of Strength of Evidence for models.

Review of Medicare and Representative Private Insurer Coverage Policies (Pg 67)

The review of payer policies identifies one Medicare Local Coverage Determination (LCD), effective 01/10/2015 (and does not name the Medicare Administrative Contractor [MAC] of the LCD). It is important to point out that there are seven separate LCDs, one per MAC, all of which were written in 2019-2021 after extensive CMS review of kyphoplasty and medication pharmacy fills billed to the payer. This removes any risk of bias from patient recall. One such study to consider including was a retrospective analysis of over 8,000 patients treated with vertebroplasty or kyphoplasty which compared baseline medication use to that at 7-month follow-up (including a 1-month postoperative washout).

Reducing opioid use, particularly in the elderly population who disproportionately suffers from vertebral compression fractures, aligns with national objectives set forth by the CDC's revised opioid prescribing guidelines and the US Department of Health and Human Services Pain Management Best Practices Task Force Report. Any intervention which shows correlation with reduced need for prolonged opioid use warrants close review by the HTCC.

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Review of Medicare and Representative Private Insurer Coverage Policies (Pg 67)
The review of payer policies identifies one Medicare Local Coverage Determination (LCD), effective 01/10/2015 (and does not name the Medicare Administrative Contractor [MAC] of the LCD). It is important to point out that there are seven separate LCDs, one per MAC, all of which were written in 2019-2021 after extensive CMS review of kyphoplasty and vertebroplasty. All seven LCDs cover kyphoplasty and vertebroplasty for osteoporotic fracture (with minor nuances in coverage conditions across each). Five of the seven explicitly cover kyphoplasty and vertebroplasty for vertebral compression fractures "secondary to osteolytic vertebral metastatic disease or myeloma involving a vertebral body" and two LCDs implicitly cover treatment of malignant vertebral compression fractures via the clause "coverage will remain available for medically necessary procedures for other conditions not included in this [osteoporotic VCF] LCD".

We suggest the committee closely review each of these LCDs for the rationale provided for coverage via literature synthesis, as well as a sample framework of coverage criteria applied. It is notable that seven separate MAC determinations all reached the same coverage conclusions, including representatives from ASIPP.

Missing from the review:
The RAND care pathway publication, which was a multispecialty consensus on the appropriate patient profile for surgical treatment of vertebral compression fracture should be included in the "guidelines" section of this HTA. This study was cited in all CMS LCD revisions in 2019-2021 and was an important factor in Medicare coverage determinations on the appropriate population for treatment.

Once again, thank you for your consideration of our comments on this important issue. Please feel free to contact any of us by contacting Melinda Martin, Director of Operations, ASIPP at mmartin@asipp.org or any of us at the email addresses listed below.

Laxmaiah Manchikanti, MD

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[redacted]

REFERENCES

1. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res.* 2011;26(7):1627-1637.
2. Liu Q, Cao J, Kong JJ. Clinical effect of balloon kyphoplasty in elderly patients with multiple osteoporotic vertebral fracture. *Niger J Clin Pract.* 2019;22(3):289-292.
3. Van Meirhaeghe J, Bastian L, Boonen S, Ranstam J, Tillman JB, Wardlaw D. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. *Spine (Phila Pa 1976).* 2013;38(12):971-983.
4. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet.* 2009;373(9668):1016-1024.
5. 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.
6. Manchikanti L**,** Kaye AM, Knezevic NN, et al. Comprehensive, evidence-based, consensus guidelines for prescription of opioids for chronic non-cancer pain from the American Society of Interventional Pain Physicians (ASIPP). *Pain Physician.* 2023; 26(7S):S7-S126.
7. Manchikanti L, Sanapati J, Pampati V, Kaye A, Hirsch J. Utilization of Vertebral Augmentation Procedures in the USA: A Comparative Analysis in Medicare Fee-for-Service Population Pre- and Post-2009 Trials. *Curr Pain Headache Rep.* 2020; 24:22 https://doi.org/10.1007/s11916-020-00850-2.
8. Hirsch J, Chandra R, Pampati, V, Barr J, Brook A, Manchikanti L, Analysis of vertebral augmentation practice patterns: a 2016 update. *J NeuroIntervent Surg.* 2016;8:1299–1304.
9. Manchikanti L, et al. Utilization and Expenditures of Vertebral Augmentation Continue to Decline: An Analysis in Fee-For-Service (FFS) Recipients from 2009 to 2018. *Pain Physician.* 2021; 24:401-415.
9. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. *Arch Orthop Trauma Surg.* 2014;134(1):21-30.
10. YL. comparative study of percutanous kyphoplasty and conservative therapy on vertebral osteoporotic compression fractures in elderly patients. *Int J Clin Exp Med.* 2017;10:8139-8145.
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13. Schlaich C, Minne HW, Bruckner T, et al. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int.* 1998;8(3):261-267.
14. Vedantam R. Management of osteoporotic vertebral compression fractures: a review. *Am J Clin Med.* 2009; 6(4):14-18.
15. Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. *Bone.* 1996;18(3 Suppl):185s-189s.

16. Ni W, Ricker C, Quinn M, et al. Trends in opioid use following balloon kyphoplasty or vertebroplasty for the treatment of vertebral compression fractures. *Osteoporos Int.* 2022;33(4):821-837.
17. U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force. Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019. Accessed 10/7/2024. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
18. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC clinical practice guideline for prescribing opioids for pain - United States, 2022. *MMWR Recomm Rep* 2022; 71:1-95. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w. Accessed 10/7/2024.
19. National Institute for Health and Care Excellent (NICE). The guidelines manual. https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness. Published 2012. Accessed 09/13/2024.
20. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *Value Health.* 2013;16(2):e1-5.

APPENDIX: Clinical/peer reviews and public comments received

Peer Reviewer #1: Jesse Liu, MD, Assistant Professor Neurological Surgery, School of Medicine, Assistant Professor of Interventional Radiology, School of Medicine, Oregon Health & Science University

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Vertebroplasty, Kyphoplasty and Sacroplasty (VKS)** HTA update. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/vertebroplasty-kyphoplasty-and-sacroplasty

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form.

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: [redacted] please cc: [redacted]

We will need your review by October 1, 2024, at the latest.

If you have questions or concerns, please contact [redacted] Many thanks!

Reviewer Identification Information

Reviewer Name	**Jesse Liu**
Address	[redacted]
Phone	
Fax	
E-mail	[redacted]

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

I think the overview of the topic is adequate. Vertebral and sacral compression fractures can be quite morbid in many populations and these treatments may be able to address them.

Public policy should aim to reduce the morbidity and mortality of these pathologies (fractures) to improve the quality and quantity of life for these patients.

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BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

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REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

The Key questions are appropriate and the study design is appropriate. Although given the current research and economic climate, I worry that there may not be further randomized controlled trials to examine the issue and we may be left with cohort studies or non-randomized comparison studies. If that is the case, then we need to somehow adjust the relative weight of the new, current studies in light of the findings from previous RCTs.

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METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

The methods are internally consistent and appropriate. Evaluation of levels of pain, opioid use, functional outcome, and quality of life are all valid. Unfortunately, reliance and influence of past RCTs will confound current practice patterns and trends and will introduce bias in forming new policy.

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RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Are the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?

I think the results are appropriate and the tables and appendices are easy to read. The major findings are stated clearly. But, I do think that there should be some weight given to non-randomized cohorts or registries.

For example, a 2019 study demonstrated KP was safe, effective, and durable for treating patients with patient VCF due to osteoporosis or cancer. This was not an RCT, but it was a multicenter non-randomized trial.

> Beall DP, Chambers MR, Thomas S, Amburgy J, Webb JR Jr, Goodman BS, Datta DK, Easton RW, Linville D 2nd, Talati S, Tillman JB. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. Neurosurgery. 2019 Jan 1;84(1):169-178. doi: 10.1093/neuros/nyy017. PMID: 29547939; PMCID: PMC6354561.

Another study that should be included is a prospective multi-national single-arm study to investigate the safety and effectiveness of radiofrequency ablation for palliation of painful lytic bone metastases. This showed rapid (within 3 days) pain and QoL improvements through the study period of 12 months.

> Levy J, David E, Hopkins T, Morris J, Tran ND, Farid H, Massari F, O'Connell WG, Vogel A, Gangi A, Sunenshine P, Dixon R, Von der Höh N, Bagla S. Radiofrequency Ablation Provides Rapid and Durable Pain Relief for the Palliative Treatment of Lytic Bone Metastases Independent of Radiation Therapy: Final Results from the OsteoCool Tumor Ablation Post-Market Study. Cardiovasc Intervent Radiol. 2023 May;46(5):600-609. doi: 10.1007/s00270-023-03417-x. Epub 2023 Apr 3. PMID: 37012392; PMCID: PMC10156864.

The Sacroplasty registry authored by Beall in 2023 is the best data so far to support sacroplasty and the results are extremely promising. According to that study, the sacroplasty procedure is safe and

efficacious and provides substantial pain relief. Until there is an RCT (and there may never be one), these are the best data we have.

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Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy).

I think these are well displayed. Facts are laid out well and easy to understand.

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

This is well structured and well reviewed. Clinical aspects are discussed as well as socioeconomic and cost aspects. With an aging population and compression fractures more prevalent, these procedures need to be considered for potential treatment.

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QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior ☐

Good ☑ ☐

Fair ☐

Poor ☐

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We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

Enter Form Comments Here

Peer Reviewer #2: Sohail K. Mirza, MD, MPH, Professor of Engineering, Thayer School of Engineering, Dartmouth College

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Vertebroplasty, Kyphoplasty and Sacroplasty (VKS)** HTA update. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/vertebroplasty-kyphoplasty-and-sacroplasty

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to [redacted] please cc: [redacted]

We will need your review by October 1, 2024, at the latest.

If you have questions or concerns, please contact [redacted]. Many thanks!

Reviewer Identification Information

Reviewer Name	**Sohail K. Mirza MD MPH**
Address	[redacted]
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INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

Page 1 Section 1.1

The introduction adequately defines vertebral compression fractures, vertebroplasty, kyphoplasty, and sacroplasty. However, it does not convey uncertainty about efficacy and safety of these procedures. It does not mention currently available alternative treatments for these fractures. It does not provide justification for needing a repeat assessment since the prior Health Technology Assessment in 2010.

Page 1 Line 1.2

Policy context is clear. It would be helpful to briefly also mention coverage policies that are discussed in detail in section 2.5

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page 1 Line 1.3

Objectives are clearly stated are directly relevant to clinical and policy concerns.

Page 2 Line 1.4

Key questions are defined clearly and are clinically relevant.

Page 2-4 Line 1.4

Scope is presented clearly.

Page 5-6 Line 1.5

Outcomes assessed are explicitly defined. They are clinically relevant. Interpretation and thresholds for significant change are defined clearly.

Page 6 Line 1.6

Washington state utilization data are missing.

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Page 7 Line 2.1

Background is concise and clinically focused.

Relative prevalence in females and the estimated number of fractures are mentioned, but population-based prevalence in females is not listed.

It is not clear what fraction of vertebral compression fractures are due to malignancy.

Page 7-9 Line 2.2

Technologies and interventions are described clearly and in detail. List of indications and contraindications from published reports is useful. It would be helpful to provide a complete list of FDA approved materials and devices with approval date and FDA-approved label/indications.

Page 9-15 Line 2.3

Table 1 list of published guidelines is detailed and clear. It would be helpful to summarize the guideline review with a simple list of associations/guidelines that specifically endorse and a list of guidelines/associations that do not endorse vertebroplasty/kyphoplasty/sacroplasty for osteoporotic vertebral compression fractures.

Page 16-31 Line 2.4

Details of systematic reviews listed in Table 2 are helpful but difficult to understand. It would be more helpful to understand this information if it was summarized in tables according to the specific key questions and specific outcomes specified for this assessment.

Page 32-34 Line 2.5

Table 3 summarizing representative insurer coverage policies is useful. It would be helpful to synthesize these policies into a summary table of covered and not covered procedures for each insurer.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

Page 35-37	Line 3.1.1 to 3.1.3

Objectives, key questions, inclusion/exclusion criteria, and outcomes are clearly defined, appropriate and clinically relevant.

Page 37-39	Line 3.1.4 to 3.1.5

Data sources are specified and appropriate. Search strategy was thorough. Clinical trials were included in the search. Figure 1 clearly lists the flow for study selection. Data extraction was systematic and objective.

Page 39-41	Line 3.1.6

Risk of bias assessment is described well. Criteria for grading the quality of individual studies (Table 5) are described in detail, appropriate, and justified. Risk of bias was assessed. Strength of Evidence was rated by two researchers and complied with established standards. Reason for not evaluating quality of economic studies is justified.

Page 41-42	Line 3.1.7

Analyses are explained and well supported by established methods. Risk ratio and confidence intervals were calculated. Meta-analyses were conducted where possible. Statistical heterogeneity was assessed. Effect sizes were estimated consistent with established standards. Interactions were assessed.

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Are the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?

Page 42-45 Line 4.1

A detailed description is provided of retained studies. Funding source for each comparison is listed.

Page 45-206 Line 4.2.1

Details are presented for each retained study. Data from each study is tabulated for vertebroplasty, kyphoplasty and sacroplasty by study type, primary and secondary outcomes, and adverse events. However, the results are not summarized across different study types and comparator treatments to explicitly answer the key questions. It is left up to the reader to try to synthesize data across studies and various time points of outcome assessment and various different types of outcomes being reported. It would be much more helpful to under, the evidence if it were summarized and presented succinctly to answer each of the key questions:

- efficacy vertebroplasty, kyphoplasty or sacroplasty for short-term and long-term outcomes, function, pain, quality of life, use of pain medications and opioids, return to work
- safety of vertebroplasty, kyphoplasty or sacroplasty in terms of mortality, major morbidity, other, revision/re-operation rates
- differential efficacy or safety issues in sub populations: gender, age, Psychological or psychosocial co-morbidities, diagnosis, time elapsed from fracture, other patient characteristics or evidence-based patient selection criteria, provider type, setting or other provider characteristics, payer/beneficiary type: including worker's compensation, Medicaid, state employees
- cost implications (direct and indirect)

These data are included for each type of study and comparator, but they are not synthesized to directly answer these key questions in a way that would be easy to interpret.

Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy)

The strength of evidence tables are well organized, and presented in detail. The Executive Summary provides considerable detail and is supported by data. However, high-level syntheses of the analyses are lacking to directly answer the key questions and guide interpretation. Interpretation is difficult because of stratification of the data by study type, different competitors, and different outcomes and adverse events.

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

This assessment is detailed, clear, objective, and presented clearly. The report is well structured and organized. Data are clinically relevant and presented well. Analyses are designed to help with clinical decision making. Summaries will help guide policy to improve public health.

QUALITY OF REPORT

Quality Of the Report (Click in the gray box to make your selection)
Superior
Good X
Fair
Poor

The report is high quality, comprehensive, and objective. Data are presented clearly. Interpretations are well supported. However, analyses are not summarized sufficiently to directly answer the key questions.

We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

The report is unbiased, thorough, clinically relevant, and informative.