

October 3, 2024

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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 patients¹⁻³. 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 fractures⁸ 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 fracture⁶. 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 VA⁹. The HTA's draft report¹⁰⁻¹⁸ 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 KP²¹. 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 manner²³⁻²⁵.

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 VA⁹⁻¹⁸. 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 years²⁶. 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 expectancy 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 fractures²⁹. 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 treatment¹⁵. 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 life¹³⁻¹⁸. 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-up³⁰.

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 rare³³. 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 patient³⁴. 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 KP³⁵⁻³⁸ and a 10-year follow-up of patients undergoing sacroplasty³⁹. 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 Pain⁴⁰ 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., NICE⁴², CHEERS⁴³) 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 publication⁴⁴, 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)

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