HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: VERTEBROPLASTY, KYPHOPLASTY, SACROPLASTY

Approved 5/9/2013; reaffirmed 1/14/2016

This coverage guidance was created under HERC's 2013 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.

As a part of the coverage guidance monitoring process, the HERC decided on 1/14/2016 (see Appendix A) to reaffirm the existing coverage guidance and reconsider the need to update the topic during the regular two-year review cycle.

HERC COVERAGE GUIDANCE

Vertebroplasty and kyphoplasty should be covered under the following circumstances:

1. The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
2. The severity of the pain prevents unassisted ambulation, and
3. The pain is not adequately controlled with oral or transcutaneous medication.

The patient must have failed an appropriate trial of conservative management.

Vertebroplasty and kyphoplasty should not be covered under other circumstances.

Sacroplasty should not be covered.

Note: This coverage guidance does not address vertebral fractures related to malignancy.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). *Vertebroplasty, kyphoplasty and sacroplasty: Health technology assessment.* Olympia, WA: Health Technology Assessment Program. Retrieved March 20, 2012, from http://www.hta.hca.wa.gov/documents/vks_final_report.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Vertebral compression fractures and sacral insufficiency fractures often result in considerable pain, loss of function, and decreased quality of life. Patients with osteopenic vertebral or sacral fractures are at greater risk of morbidity and mortality, yet operative intervention (e.g., fusion with instrumentation) may be problematic in this elderly population making less invasive methods more attractive.

Vertebroplasty, kyphoplasty and sacroplasty (collectively, percutaneous vertebral and sacral surgery) are surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. These are all cementoplasty techniques that are thought to relieve pain by stabilizing the fractured bone(s), but the mechanism of pain relief is not clear. Osteoporosis, vertebral metastasis and multiple myeloma are the most frequently reported indications for these procedures.

Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body under computed tomography (CT) or fluoroscopic guidance. Kyphoplasty is a modification of vertebroplasty that expands the partially collapsed vertebral body with an inflatable balloon before the injection of bone cement. Sacroplasty is an extension of vertebroplasty, involving the injection of bone cement into the sacrum to repair sacral insufficiency fractures.

These surgical procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy. Although a number of non-randomized studies have reported improvements in pain and functioning following these

procedures, significant questions remain about their safety, efficacy and effectiveness, and cost effectiveness.

Evidence Review

Efficacy/Effectiveness

Vertebroplasty vs. sham surgery or conservative medical therapy

In two RCTs, vertebroplasty was no more effective than sham surgery in reducing pain or improving function or quality of life at one month and three months. In a large RCT comparing vertebroplasty with conservative medical therapy, vertebroplasty was more effective than conservative treatment in reducing self-reported pain intensity for follow-up points of up to one year. In two small RCTs, vertebroplasty and conservative medical therapy patients showed comparable improvement in pain, with inconsistent findings for functional outcomes. In four cohort studies (two prospective and two retrospective), vertebroplasty was more effective than conservative medical therapy in reducing pain up to six months, but pain levels were comparable for the two groups after one year. For a very limited set of functional outcomes, vertebroplasty led to earlier improvements than conservative medical therapy, followed by equivalent levels of functioning after six months to a year.

Kyphoplasty (KP) vs. conservative medical therapy

In one RCT, kyphoplasty was more effective than conservative medical therapy in reducing pain intensity for follow-up points up to one year. Pain was reduced more rapidly in kyphoplasty patients, and although the group differences were diminished by 12 months, they remained statistically significant. Kyphoplasty was also more effective than conservative medical therapy in improving functional outcomes over one year; again, group differences were diminished at 12 months but remained statistically significant. In two cohort studies (one prospective and one retrospective), kyphoplasty reduced pain more than conservative medical therapy for periods up to three years, and kyphoplasty improved a limited set of functional outcomes more than conservative medical therapy.

Vertebroplasty vs. kyphoplasty

One poor-quality RCT found that back pain scores improved equally for vertebroplasty and kyphoplasty patients over six months. Evidence from 12 cohort studies (six prospective and six retrospective) demonstrated that vertebroplasty and kyphoplasty led to comparable pain reduction at follow-up periods up to two years in 8 of 10 studies, and that vertebroplasty and kyphoplasty demonstrated comparable improvements at follow-up times up to two years in four of five studies.

Sacroplasty

No comparative studies were identified; case series suggest improvement in pain following sacroplasty.

Safety

Vertebroplasty and kyphoplasty

New fractures: In comparative studies, the rate of new fractures at any location following vertebroplasty, kyphoplasty, or conservative medical therapy was up to 25% at six months post-surgery, and up to 30% at 12 months, with no consistent pattern across studies in different rates for vertebroplasty, kyphoplasty, and conservative medical therapy. In cohort studies, from 22% to 66% of new fractures occurred in adjacent vertebrae, however, these rates are based on very small numbers. A systematic review concluded that the proportion of new fractures that were adjacent was higher for kyphoplasty (75%) than for vertebroplasty (52%). Systematic reviews of case series report slightly higher rates of new fractures at any location for vertebroplasty (16-21%) than for kyphoplasty (7-17%).

Cement leakage: Rates of asymptomatic cement leakage are up to 80% for vertebroplasty and 50% for kyphoplasty. Comparative studies and systematic reviews (consisting largely of case series) suggest that cement leakage is greater in vertebroplasty than in kyphoplasty; however, symptomatic leaks are rare.

Pulmonary cement embolism (PCE): One RCT reported a PCE rate for vertebroplasty of 26%, with all cases asymptomatic. Systematic reviews of case series report pooled PCE rates from 0.1% to 1.7%, with insufficient information to compare rates for vertebroplasty and kyphoplasty.

Mortality (data from systematic reviews primarily of case series): Rates in prospective studies of 2.1% for vertebroplasty and 0.6% for retrospective studies. Overall mortality for kyphoplasty ranged from 2.3% to 3.2% in 2 different reviews. Perioperative mortality was 0.01%.

Sacroplasty

Across four case series, rate of cement leakage was 20.5%.

[Evidence Source]

Overall Summary

Vertebroplasty is no more effective than sham surgery, and comparisons to conservative medical therapy are inconsistent. Vertebroplasty appears to have similar efficacy as kyphoplasty. No trials of kyphoplasty to sham surgery have been conducted, but kyphoplasty may be more effective than conservative medical therapy early on, although differences diminish by 12 months. There are no RCTs of sacroplasty. Mortality rates for vertebroplasty and kyphoplasty range from 0.6% to 3.2%, and both are associated with high rates of cement leakage.

PROCEDURE

Vertebroplasty
Kyphoplasty
Sacroplasty

DIAGNOSES

Vertebral compression fracture
Sacral insufficiency fracture

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
733.13	Pathologic fracture of vertebrae
805.00	Closed fracture of cervical vertebra, unspecified level
805.01	Closed fracture of first cervical vertebra
805.02	Closed fracture of second cervical vertebra
805.03	Closed fracture of third cervical vertebra
805.04	Closed fracture of fourth cervical vertebra
805.05	Closed fracture of fifth cervical vertebra
805.06	Closed fracture of sixth cervical vertebra
805.07	Closed fracture of seventh cervical vertebra
805.08	Closed fracture of multiple cervical vertebrae
805.2	Closed fracture of dorsal [thoracic] vertebra without mention of spinal cord injury
805.4	Closed fracture of lumbar vertebra without mention of spinal cord injury
805.6	Closed fracture of sacrum and coccyx without mention of spinal cord injury
805.8	Closed fracture of unspecified vertebral column without mention of spinal cord injury
ICD-9 Volume 3 (Procedure Codes)	
81.65	Percutaneous Vertebroplasty
81.66	Percutaneous Vertebral Augmentation
CPT Codes	
22520	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic
22521	lumbar
+22522	each additional thoracic or lumbar vertebral body
22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
22524	lumbar
+22525	each additional thoracic or lumbar vertebral body
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles

CODES	DESCRIPTION
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles
HCPCS Codes	
S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
S2361	Each additional cervical vertebral body

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Appendix A: 2015 Rescanning Summary

HERC Decision (1/14/2016): Reaffirm the existing coverage guidance and reconsider the need to update the topic during the regular two-year review cycle.

Bottom Line: Additional evidence supports that vertebroplasty and kyphoplasty may offer improved pain relief at up to 1 year following acute osteoporotic compression fractures when compared with optimal medical treatment. However, in studies that compare these percutaneous procedures with sham procedures that include local anesthesia, the benefits are not apparent. Clinical guidelines generally support the use kyphoplasty and vertebroplasty for intractable pain from osteoporotic compression fractures despite optimal medical treatment. There is limited additional evidence regarding sacroplasty for sacral insufficiency fractures.

Scope Statement

Population description	Adults with acute or chronic vertebral compression or sacral insufficiency fractures *Population scoping notes: None*
Intervention(s)	Percutaneous vertebral and sacral procedures *Intervention exclusions: None*
Comparator(s)	Open spinal surgical procedures, sham/placebo surgery, medical therapy (including non-pharmacologic interventions like physical therapy or acupuncture)
Outcome(s) (up to five)	Critical: All-cause mortality, short- and long-term improvement in function Important: Short- and long-term improvements in pain or quality of life, recurrent fracture, clinically significant embolization *Considered but not selected for GRADE table: Length of stay*
Key questions	1. What is the comparative effectiveness of percutaneous interventions for vertebral compression or sacral insufficiency fractures? 2. What are the harms of percutaneous interventions for vertebral compression or sacral insufficiency fractures?

Scanning Results

1. McConnell, C. T. Jr., Wippold, F. J. II, Ray, C. E. Jr., Weissman, B. N., Angevine, P. D., Fries, I. B., … Rubin, D. A., Expert Panels on Neurologic Imaging, Interventional Radiology and Musculoskeletal Imaging. (2013). *ACR Appropriateness Criteria® management of vertebral compression fractures*. Reston (VA): American College of Radiology. Retrieved from https://acsearch.acr.org/docs/70545/Narrative/

Citation 1 is an American College of Radiology Appropriateness Criteria guideline. Depending on the clinical scenario, the recommendations for vertebroplasty, kyphoplasty, and sacroplasty vary from “usually not appropriate” to “usually appropriate.”

2. Baerlochr, M. O., Saad, W. E., Dariushnia, S., Barr, J. D., McGraw, J. K., Nikolic, B., & Society of Interventional Radiology Standards of Practice Committee. (2014). Quality improvement guidelines for percutaneous vertebroplasty. *Journal of Vascular and Interventional Radiology, 25*(2), 165-70.

Citation 2 is a quality improvement guideline from the Society of Interventional Radiology. It offers indications and contraindications for vertebroplasty, but the degree to which these recommendations are evidence-based in unclear.

3. Barr, J. D., Jensen, M. E., Hirsch, J. A., McGraw, J. K., Barr, R. M., Brook, A. L., … Cardella, J. F. (2014). Position statement on percutaneous vertebral augmentation: A consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). *Journal of Vascular and Interventional Radiology, 25*(1), 171-81.

Citation 3 is a multi-society clinical practice guideline pertaining to vertebroplasty. It recommends vertebroplasty as an “appropriate therapy for treatment of painful VCFs refractory to nonoperative medical therapy and for vertebrae weakened by neoplasia…”

4. Bouza, C., Lopez-Cuadrado, T., Almendro, N., & Amate, J. M. (2015). Safety of balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures in Europe: a meta-analysis of randomized controlled trials. *European Spine Journal,* 24(4), 715-23.

Citation 4 is a systematic review and meta-analysis of RCTs examining the safety of balloon kyphoplasty. Serious complications are common, occurring in 10-20% of cases. Overall, the authors estimate 17 severe complications per 100 balloon kyphoplasties.

5. Buchbinder, R., Golmohammadi, K., Johnston, R. V., Owen, R. J., Homik, J., Jones, A., … Lambert, R. G. W. (2015). Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. *Cochrane Database of Systematic Reviews,* Issue 4. Art. No.: CD006349. DOI: 10.1002/14651858.CD006349.pub2.

Citation 5 is Cochrane Review of 11 RCTs and 1 quasi-randomized trial of vertebroplasty for osteoporotic compression fractures. The review concludes that "[b]ased upon moderate quality evidence, our review does not support a role for vertebroplasty for treating osteoporotic vertebral fractures in routine practice. We found no demonstrable clinically important benefits compared with a sham procedure and subgroup analyses indicated that results did not differ according to duration of pain ≤ 6 weeks versus > 6 weeks."

6. Chang, X., Lv, Y. F., Chen, B., Li, H. Y., Han, X. B., Yang, K., … Li, C. Q. (2015). Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. *International Orthopaedics*, *39*(3), 491-500.

Citation 6 is a systematic review and meta-analysis of prospective studies comparing vertebroplasty and kyphoplasty for osteoporotic compression fractures. Most outcomes were similar between the two procedures, including measures of pain relief, though it appears that cement leakage was slightly more common in vertebroplasty procedures.

7. HAYES, Inc. (2012). *Percutaneous kyphoplasty*. Lansdale, PA: HAYES, Inc.

Citation 7 is a Hayes review of kyphoplasty. They offer D2 ratings (insufficient evidence) of kyphoplasty for patients with medically refractory pain after osteoporotic or malignant vertebral compression fractures. This reflects the absence of high quality evidence of benefit and the possibility of serious harms.

8. HAYES, Inc. (2014). *Percutaneous sacroplasty for treatment of sacral insufficiency fractures*. Lansdale, PA: HAYES, Inc.

Citation 8 is Hayes review of sacroplasty. They offer a D2 rating (insufficient evidence) of sacroplasty for sacral insufficiency fractures. This is based on low-quality evidence from studies with serious methodologic flaws.

9. HAYES, Inc. (2012). *Percutaneous vertebroplasty*. Lansdale, PA: HAYES, Inc.

Citation 9 is a Hayes review of vertebroplasty. They offer a C rating (potential but unproven benefit) of vertebroplasty for osteoporotic compression fractures and a D2 rating (insufficient evidence) of vertebroplasty for malignant compression fractures.

10. Khan, O. A., Brinjikji, W., & Kallmes, D. F. (2014). Vertebral augmentation in patients with multiple myeloma: a pooled analysis of published case series. *American Journal of Neuroradiology, 35*(1), 207-10. DOI: 10.3174/ajnr.A3622.

Citation 10 is a pooled analysis of published case series of vertebral augmentation (vertebroplasty and kyphoplasty) in patients with fractures related to multiple myeloma. It appears that both procedures are effective at reducing pain at up to 1 year of follow-up.

11. Lange, A., Kasperk, C., Alvares, L., Sauermann, S., & Braun, S. (2014). Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine, 39*(4), 318-326. DOI: 10.1097/BRS.0000000000000135.

Citation 11 is an observational study based on claims data from a single German health insurance fund. It concludes that in patients with osteoporotic vertebral compression fractures, kyphoplasty and vertebroplasty are associated with reduced risk of mortality over 5 years. This is a methodologically limited study that was funded by Medtronic.

12. NICE. (2013). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. London: NICE. Retrieved from http://www.nice.org.uk/guidance/ta279/resources/guidance-percutaneous-vertebroplasty-and-percutaneous-balloon-kyphoplasty-for-treating-osteoporotic-vertebral-compression-fractures-pdf

Citation 12 is a NICE technology appraisal guidance on vertebroplasty and kyphoplasty for osteoporotic compression fractures. They recommend that “[p]ercutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people: who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.”

13. Song, D., Meng, B., Gan, M., Niu, J., Li, S., Chen, H., & Yang, H. (2015). The incidence of secondary vertebral fracture of vertebral augmentation techniques versus conservative treatment for painful osteoporotic vertebral fractures: a systematic review and meta-analysis. *Acta Radiologica*, *59*, 970-979.

Citation 13 is a systematic review and meta-analysis examining whether kyphoplasty or vertebroplasty for osteoporotic fractures is associated with secondary fractures. The percutaneous procedures appear not to be associated with a greater risk of secondary fracture compared to conservative management.

14. Stevenson, M., Gomersall, T., Lloyd Jones, M., Rawdin, A., Hernández, M., Dias, S., … Rees, A. (2014). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis. *Health Technology Assessment, 18*(17), 1-289. Retrieved from http://www.journalslibrary.nihr.ac.uk/__data/assets/pdf_file/0017/114317/FullReport-hta18170.pdf

Citation 14 is an evidence review conducted by the National Health Service. The NHS concludes that "[f[or people with painful osteoporotic VCFs refractory to analgesic treatment, PVP and BKP perform significantly better in unblinded trials than OPM in terms of improving quality of life and reducing pain and disability. However, there is as yet no convincing evidence that either procedure performs better than OPLA [operative placebo with local anesthesia] with data from two high-quality trials…"

15. Tian, J., Xiang, L., Zhou, D., Fan, Q., & Ma, B. (2014). The clinical efficacy of vertebroplasty on osteoporotic vertebral compression fracture: a meta-analysis. *International Journal of Surgery, 12*(12), 1249-1253. DOI: 10.1016/j.ijsu.2014.10.027.

Citation 15 is a systematic review and meta-analysis of 5 RCTs of vertebroplasty for osteoporotic compression fractures. Compared with patients receiving optimal medical treatment, those who underwent vertebroplasty had significant improvements in pain score at up to 48 weeks of follow-up. There was no difference the occurrence of secondary fractures at adjacent vertebrae.

16. Xiao, H., Yang, J., Feng, X., Chen, P., Li, Y., Huang, C., … Chen, H. (2014). Comparing complications of vertebroplasty and kyphoplasty for treating osteoporotic vertebral compression fractures: a meta-analysis of the randomized and non-randomized controlled studies. *European Journal of Orthopaedic Surgery and Traumatology, 25*(Suppl 1), 77-85.

Citation 16 is a systematic review and meta-analysis of randomized and non-randomized trials comparing the complications of vertebroplasty vs kyphoplasty for osteoporotic compression fractures. Complication rates appear to be similar between procedures with the exception of cement leakage which is more common with vertebroplasty.

17. Zhang, Y. Z., Kong, L. D., Cao, J. M., Ding, W. Y., & Shen, Y. (2014). Incidence of subsequent vertebral body fractures after vertebroplasty. *Journal of Clinical Neuroscience*, *21*(8), 1292-1297.

Citation 17 is a systematic review and meta-analysis of four studies examining the risk of subsequent fractures after vertebroplasty. In the pooled analysis, vertebroplasty was not associated with an increased risk of new or adjacent vertebral fractures.

Methods

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms "vertebroplasty," "kyphoplasty," and "sacroplasty." Searches of core sources were limited to citations published after 2009 for kyphoplasty and Sacroplasty, and after 2013 for vertebroplasty.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® (Ovid) search was conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of original evidence sources. The search was limited to publications in English published after 2009.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse

New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessment, or clinical practice guidelines.