Health Technology Clinical Committee
Findings and Coverage Decision
Topic: **Vertebroplasty, Kyphoplasty and Sacroplasty**
Meeting Date: **December 10th, 2010**
Final Adoption: **March 18th, 2011**

Number and Coverage Topic

20101210A – Vertebroplasty, Kyphoplasty and Sacroplasty

HTCC Coverage Determination

Vertebroplasty, Kyphoplasty and Sacroplasty are **not a covered benefit**.

HTCC Reimbursement Determination

- **Limitations of Coverage**
  - N/A
- **Non-Covered Indicators**
  - Vertebroplasty, Kyphoplasty and Sacroplasty are not covered benefits
- **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The Vertebroplasty, Kyphoplasty and Sacroplasty topic was selected and published in December 2009 to undergo an evidence review process. The evidence based technology assessment report indicates that vertebroplasty, kyphoplasty and sacroplasty are surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. There 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. 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.

Fractures secondary to osteoporosis, vertebral metastasis and multiple myeloma are an important source of acute and chronic back pain as well as spinal deformity, reduced pulmonary function, decreased mobility and increased mortality. The majority of patients with osteoporotic fractures are older women. Patients with osteoporotic fracture are on average older than those with malignant fractures. Osteoporosis, vertebral metastasis and multiple myeloma are the most frequently reported indications for vertebroplasty and kyphoplasty. Sacroplasty is most frequently used to treat sacral insufficiency fractures (SIF), the majority of which are due to osteoporosis.

Patients with vertebral compression fracture (VCF) may or may not be symptomatic. Treatment of pain in VCF in the acute phase is not standardized. Chronic pain may be secondary to multiple fractures but the mechanism may be related more to muscle and ligament strain secondary to kyphosis. Such pain does not generally improve with analgesic use but may be addressed through exercise. While most patients are successfully treated with conservative therapy and pain relief occurs within a few weeks, persistent pain in a small percentage of patients leads to the consideration of operative treatment in this subset of patients. Vertebroplasty, kyphoplasty and sacroplasty are typically indicated for patients with painful insufficiency fracture due to osteoporosis or malignancy that is not responding to conservative treatment such as rest and analgesic use.

Vertebroplasty, kyphoplasty and sacroplasty are minimally invasive procedures which have purported benefits of relieving pain due to osteoporotic stress-related and tumor-related fractures and restoring function in patients whose bone maybe poor and/or who are poor candidates for more invasive surgical intervention. All involve the percutaneous injection of cement into the bone. These surgical procedures are less invasive than other spinal surgical procedures (e.g. fixation using screws), but more invasive than conservative medical therapy. Vertebroplasty, kyphoplasty and sacroplasty may relieve pain due to osteoporotic or malignant fracture by stabilizing the fracture and reducing pain from bone rubbing against bone.

In October 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Vertebroplasty, Kyphoplasty and Sacroplasty report is 126 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on December 10th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Vertebroplasty, Kyphoplasty and Sacroplasty have been collected and summarized. The evidence is presented below:

- The evidence based technology assessment report indicates that vertebral compression fractures and sacral insufficiency fractures occur, commonly as part of the natural disease progression of osteoporosis or osteopenia. Some patients with fractures are asymptomatic but others experience acute pain, loss of function, and decreased quality of life thought to be caused by the fracture.
- Vertebroplasty (PV), kyphoplasty (KP) and sacroplasty are all cementoplasty techniques that aim to relieve pain thought to be caused by the fracture by stabilizing the fractured bone(s). Vertebroplasty and sacroplasty are considered minimally invasive procedures and are usually performed using only local anesthesia or with conscious sedation. General anesthesia may be used. Kyphoplasty almost always requires general anesthesia and at least one overnight stay in the hospital. The patient must lie prone during all three procedures. Multiple levels can be treated during the same session. Patients are usually selected based on failure of conservative treatment or incapacitating pain. Alternatives include conservative management and surgical fixation, though invasive surgery may be problematic due to common comorbidities in the elderly and female population most often considered for this treatment.
- Despite increasing use of these procedures (rates of kyphoplasty doubled between 2001 and 205), the evidence for the procedure remains low and the efficacy, safety and economic impact are not well understood. Patients are generally elderly women with osteopenic fractures and most included studies focused on this population.
- The timing of intervention is an important consideration. Most patients are successfully treated with conservative care which resolves pain in 4 to 6 weeks and is generally recommended first. However, patients with acute fractures (less than six weeks) may be more likely to experience pain relief and the rapid recovery from debilitating pain is a primary treatment aim. Fracture age is difficult to determine as patients may have difficulty pinpointing the onset of pain and whether a certain event may be associated with the onset.
- In addition to typical complications from invasive procedures, cementoplasty techniques include risk of possible increase of subsequent compression fractures near a cemented vertebra due to increased rigidity of the treated vertebrae and risk of cement leakage.
- Evidence included in the technology assessment review was obtained through systematic searches of the medical literature for systematic reviews including meta-analyses, randomized controlled trials, observational studies, and economic studies. 11 RCTs, 23 Observational studies, and 3 economic studies met inclusion criteria and were included in the review. Overall strength of evidence from these studies was low to very low or inconclusive. Two RCTs compared vertebroplasty with sham procedure; three RCTs compared vertebroplasty to conservative care; one RCT compared kyphoplasty to conservative care; and one RCT compared kyphoplasty and vertebroplasty.
    - The evidence based technology assessment report identified 4 clinical guidelines; there is no National Coverage decision on vertebroplasty, kyphoplasty or sacroplasty.
    - The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, agency medical directors and the public.

2. Is the technology safe?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- The evidence based technology assessment report concluded that the overall strength of evidence for safety is low for vertebroplasty and kyphoplasty and very low for sacroplasty and evidence based estimate of effect are uncertain. While it appears that rates of serious complications are low for vertebroplasty and kyphoplasty, studies with long-term (> 5 year) follow-up are few and comparative studies, especially RCTs, may have too few patients to detect more rare but serious outcomes. Primary safety outcomes reported include rates of new fracture, cement leakage, pulmonary cement embolism, and mortality related to vertebroplasty and kyphoplasty.
- *New fractures (adjacent or non-adjacent)* – in comparative studies, rates of new fractures were up to 30% at 12 months, with no consistent pattern across studies of increased fracture rates for any one treatment (vertebroplasty, kyphoplasty, or conservative treatment). One RCT reported that the distribution of fracture location (adjacent or non-adjacent) was similar for vertebroplasty and non-surgical patients. Systematic reviews, incorporating information on longer-term follow-up with a large (pooled) number of patients in case series, suggest that rates of new fracture may be slightly higher in vertebroplasty (18-19% of patients, 16-21% of vertebral levels) than kyphoplasty (7-17% of patients, 11-13% of levels). One systematic review concluded that the proportion of new fractures that were in adjacent vertebrae was higher for kyphoplasty (75%) than for vertebroplasty (52%).
- C*ement leakage* – in comparative studies, rates of cement leakage (largely asymptomatic) approached 80% for vertebroplasty and 50% for kyphoplasty, with some evidence that leakage is more common with vertebroplasty than with kyphoplasty. Systematic reviews also suggest that leakage is more common in vertebroplasty (19.7% - 79.0% of levels treated) than in kyphoplasty (0.51% - 11.2%), and that rates of symptomatic leakage are quite low (0.5%-1.6%of levels treated for vertebroplasty and 0% - 0.3% for kyphoplasty).
- *Pulmonary cement embolism* – as a result of differential surveillance in RCTs, non-randomized studies, and case series, rates vary widely across studies. One RCT using computed tomography to detect emboli reported that 26% (15/54) of vertebroplasty patients had a cement embolism, all of which were asymptomatic. No incidents of symptomatic embolism were reported in comparative studies. A systematic review of cement embolism reported rates of 1.6% for asymptomatic PCE and 1.1% for symptomatic PCE (all but one of the case series included in the review were of vertebroplasty patients).
- *Mortality* – systematic reviews (based on case series) estimate mortality rates at 2.1% for vertebroplasty and 2.3%-3.2% for kyphoplasty; the timing of mortality was not reported. Peri-operative mortality rate for kyphoplasty was .01% across 11 case series. Since the majority of patients receiving these procedures are elderly and/or have malignant disease, the extent to which mortality can be attributed to the procedures is unclear.
- *Sacroplasty* – the evidence based technology assessment report indicates that the overall strength of evidence about safety of sacroplasty is very low, and all data are from case series. Cement leakage was the only reported complication and occurred in 7 of 34 (20.6%) patients across four case series.

3. Is the technology effective?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- Vertebroplasty:

- *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to reduce/relieve pain is *low*; any effect estimate is uncertain and may change with additional research. The low strength of evidence and lack of ability to estimate effect based on evidence is due to the limitations of the studies and that the studies reported differing outcomes (some studies showed benefit others did not). The RCTs were limited to patients with osteoporotic fractures and evaluated short-term effects (≤12 months). Two sham-controlled RCTs demonstrated no difference in pain relief (up to 1month in one study and 6 months in the other), though both studies were limited in power to detect differences in the proportion of patients with clinically meaningful improvement. Another RCT demonstrated statistically significant improvement in pain scores sustained to the 12-month follow-up compared to conservative care and included more patients but was not blinded and did not include a placebo comparison. Two small RCTs reported no advantage for vertebroplasty over 2 weeks or 12 months. Four nonrandomized studies with follow-up up to one year found that vertebroplasty was more effective in reducing pain than conservative medical treatment at up to approximately six months, but no difference at one year.
- *Function and quality of life* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to improve patient function or quality of life is *low*; any effect estimate is uncertain and may change with additional research. One larger RCT demonstrated that PV was more effective than conservative treatment in improving functioning as measured by the QualEffo and RDQ, although it is possible that early differences in improvement diminish over time. Two small RCTs found comparable improvements in function over 2 weeks and 12 months for vertebroplasty and non-surgical patients. In 4 non-randomized studies, vertebroplasty showed superior effectiveness in improvements in functioning and quality of life in the first 3-6 months was followed by equivalence at one year.

- Kyphoplasty:
  - *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of kyphoplasty to relieve/reduce pain is very *low*; any effect estimate is uncertain and may change with additional research.
  - Only one RCT compared kyphoplasty with conservative treatment, reporting that while pain was reduced more rapidly in kyphoplasty patients, this advantage over conservative treatment was diminished by the one-year follow-up. Because of the paucity of RCTs comparing kyphoplasty to conservative treatment, the overall strength of evidence is low and effect estimates may change with additional research. In two non-randomized studies, kyphoplasty reduced pain more than conservative medical treatment for periods up to 3 years.
  - *Function and quality of life* – the evidence based technology assessment report indicated that it is uncertain whether kyphoplasty improves patient functioning and quality of life. In these two studies, kyphoplasty improved a limited set of functional outcomes more than conservative medical treatment.
- Sacroplasty: There is no evidence of efficacy for sacroplasty. Very limited data from 9 case series (N = 141 total patients) is available, the case series showed pain relief with sacroplasty; but the absence of comparative studies, small patient size do not permit an evidence based conclusion.

4. Special Populations?

- The evidence based technology report concluded that there is insufficient evidence for any conclusion of differential effect.

- Fracture age was one key potential differentiator; however no studies were designed to directly compare efficacy or safety outcomes between patients with acute, sub-acute, and/or chronic fractures. Two RCTs reported that improvements in pain and functional outcomes were not significantly different for patients with acute and chronic fractures; however, the studies may not have had adequate power for these post-hoc analyses. One RCT of PV vs. CMT in patients with acute fractures reported greater improvement in pain and function for PV patients, but evidence for differential efficacy cannot be derived since there was no direct comparison with more chronic fractures in the same underlying population
- The evidence based technology assessment report indicates that no studies were found that addressed differential efficacy or safety issues for subpopulations defined by gender, age, psychological or psychosocial co-morbidities, provider characteristics, or payer type.
- Diagnosis (osteoporosis or tumor-related fractures) – the evidence based technology assessment report indicates that there are no studies that assessed differential outcomes of vertebroplasty or kyphoplasty by fracture etiology. The majority of studies were limited to patients with osteoporotic fractures. Only two retrospective cohort studies (both comparing vertebroplasty with kyphoplasty) studied patients with fractures due to malignancy, with one study reporting comparable outcomes both procedures and the other reporting that kyphoplasty led to more improvement in pain than vertebroplasty over one year.

5. Is the technology cost-effective?

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- The evidence based technology report summarized three economic studies, however, because the evidence about efficacy, effectiveness, and safety is low to very low and evidence based estimates of effect are uncertain; conclusions about cost effectiveness are premature. No cost studies were conducted with U.S. data, the cost effectiveness of vertebroplasty, kyphoplasty or sacroplasty in a US setting is unknown.
- The economic impact of complications, reoperation, or revision following vertebroplasty, kyphoplasty, or sacroplasty is unknown.
- Washington state agency utilization and cost information indicates that the single agency that reimburses (UMP) for these procedures expended $868,543 in the last four years, with an average cost of $10,837; and both procedure volume and costs are rising annually.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report. Overall, the clinical guidelines and Medicare coverage decisions included in the evidence report and the AAOS guideline published subsequent either do not cite evidence or rely on evidence assess as low or very low quality or consensus statements.

- Centers for Medicare and Medicaid Services (CMS) have no published National or Local coverage determinations for vertebroplasty, kyphoplasty or sacroplasty.
- The evidence based technology assessment report identified three guidelines on vertebroplasty, kyphoplasty and/or sacroplasty, although no guideline specifically addressed the procedures for osteoporosis or malignancy – the studied indications.
    - Two guidelines mentioned vertebroplasty and kyphoplasty as part of the assessment and management of spinal cord compression and chronic pain and indicate they may be considered.
        - Institute for Clinical Systems Improvement (ICSI), 2008

- National Collaborating Centre for Cancer, National Institute for Health and Clinical Excellence (NICE), 2008

- *American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons / Congress of Neurological Surgeons, and American Society of Spine Radiology* -- A consensus statement on percutaneous vertebral augmentation was developed: "It is the position of the Societies that vertebral augmentation with vertebroplasty or kyphoplasty is a medically appropriate therapy for the treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards[1-3]."
- *American Association of Orthopaedic Surgeons (AAOS)* -- recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Strong.* Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Weak*.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence indicated there is insufficient evidence to cover Vertebroplasty, Kyphoplasty and Sacroplasty; therefore, the committee unanimously agreed to not cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted 10 to 0 to not cover Vertebroplasty. Based on these findings, the committee voted 10 to 0 to not cover Kyphoplasty. Based on these findings, the committee voted 10 to 0 to not cover Sacroplasty.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.