Washington State Health Care Authority, HTA Program
Final Key Questions
Vertebroplasty, Kyphoplasty and Sacroplasty
(Percutaneous vertebral and sacral surgery)

Introduction

HTA has selected Vertebroplasty, Kyphoplasty and Sacroplasty to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

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.

Key Questions

When used in patients with spinal pain due to vertebral fracture:

1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:
    a. Short-term and long-term outcomes
    b. Impact on Function, Pain, quality of life
    c. Other reported measures including: use of pain medications and opiods, return to work

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, cement leakage, dural tears, adjacent vertebral fracture, other)
    b. Revision/re-operation rates (if not addressed in efficacy)

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. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees

4. What evidence of cost implications and cost-effectiveness of vertebroplasty, kyphoplasty and sacroplasty? Including consideration of:
    a. Costs (direct and indirect) in short term and over expected duration of use
    b. Replacement

Policy Context:

Technology Description: Percutaneous vertebral and sacral surgeries are minimally invasive procedures proposed to relieve back pain thought to be caused by fracture. Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body, while Kyphoplasty involves expansion of the partially collapsed vertebral body with an inflatable bone tamp, in an effort to relieve pain and provide stability. Sacroplasty involves surgical treatment that attempts to repair sacral insufficiency fractures using bone cement.

Issues: These surgical procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy. Significant questions remain about the safety, efficacy and effectiveness (particularly long term and appropriate selection and therapy phase), and the cost effectiveness of vertebroplasty, kyphoplasty and sacroplasty.

Public Comment and Response

HTA received one timely public comment and input from the technology assessment center. HTA reviewed the public comments, consulted technology assessment centers, and gathered follow up information from the nominating agencies. A summary of the input and modification to key questions is below.

Overall topic: One commenter felt that the key questions should be separated by each surgical type (e.g. separate key questions for vetebroplasty, kyphoplasty, and sacroplasty).

The related procedures are commonly grouped together, percutaneous injections of bone bonding cement to treat bone fractures thought to cause back pain. It is unnecessary to separate key questions, though descriptions will include key differentiators, evidence based findings that distinguish surgical types will be reported, and functionally, evidence is gathered on each surgical type. Report structure (e.g. separate or combined findings) will be determined by the vendor after reviewing the identified literature base and its similarities or differences.

Introduction: One commenter felt that "due to vertebral fracture" should be added to the introductory clause.

The introductory clause is modified.