

DEPARTME	NT		CRITERIA NUMBER	01-35
	QUALITY RESOURCE MAN	AGEMENT		
SECTION			EFFECTIVE DATE	5/19/05
	<b>REVIEW CRITERIA GEN</b>	NERAL		
TITLE	Vertebroplasty and K	yphoplasty	REVIEW DATES	2/23/2018 2/11/2019 1/27/2020 1/21/2021 1/10/2022 2/21/2023
			REVISION DATE	2/1/2016
POLICY TYP	PE		PAGE NUMBER	
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### Purpose

This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

#### DIAGNOSIS/CONDITION: Vertebroplasty-Vertebral Compression Fracture Kyphoplasty-Acute Vertebral compression fracture treated by Kyphoplasty

### CPT-4/ HCPCS CODE AND DESCRIPTION: S2360-61, 22523-22525

### 1.0 INDICATORS:

- Osteoporotic vertebral compression fracture
  - Subacute compression fracture requiring hospitalization, narcotics administration with decreased ability to perform ADL's or
  - No significant response to conservative measures over 3-6 weeks, such as NSAID's, narcotics, back brace, activity modification and inability to perform ADL's due to the pain.
  - No neurologic compromise
  - MRI confirms continuing edema in the Vertebral body (fracture < 6 months old)
- Malignancy related compression fracture
  - Subacute or acute compression fracture requiring hospitalization, narcotics administration with decreased ability to perform ADL's or
  - No significant response to conservative measures over 3-6 weeks, such as NSAID's, narcotics, back brace, activity modification and inability to perform ADL's due to the pain or
  - Malignant osseous mass comprising a significant portion of the vertebral body
  - No neurologic compromise
- Vertebral hemangioma
  - A lesion comprising 50% or more of the vertebral body with a compression fracture

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- No significant response to conservative measures over 3-6 weeks, such as NSAID's, narcotics, back brace, activity modification and inability to perform ADL's due to the pain.
- No neurologic compromise
- Soft tissue extension or pathologic fracture of vertebrae
- Some hemangiomas can cause pain without compression fracture and can be considered for treatment by PVP.

# 2.0 VIEWS OF THE SOUTHEAST PERMANENTE MEDICAL GROUP:

- <u>Vertebroplasty</u> is an option for selected patients who have back pain refractory to medical therapy over a period of 3-6 weeks. The procedure is FDA and Medicare approved. The procedure is widely used in the Kaiser California regions.
- <u>Kyphoplasty</u> is supported to improve patient care, decrease hospitalization and decrease recurrent vertebral compression fractures in selected patients. This procedure can be scheduled as an outpatient with Interventional Radiology and may require a 23 hour stay. If the patient is admitted for pain control, the procedure can be scheduled as an inpatient with discharge the day after the kyphoplasty.

# 3.0 CLINICAL SUMMARY:

- Most vertebral compression fractures (about two-thirds) are asymptomatic; they are diagnosed as an incidental finding on chest or abdominal x-ray. In some patients, the presence of vertebral fractures may become apparent because of height loss or kyphosis. In patients who have a symptomatic vertebral fracture, there is often no history of preceding trauma. The typical patient presents with acute back pain after sudden bending, coughing, or lifting. Occasionally, minor trauma, such as going over speed bumps, may precipitate a fracture [4]. The pain often radiates bilaterally into the anterior abdomen in the distribution of contiguous nerve routes, a so-called "girdle of pain." By contrast, radiation into the legs, as may be seen with a herniated disc, is rare with compression fractures.
- The pain from a vertebral compression fracture is variable in quality and may be sharp or dull. Sitting and movement often aggravate the discomfort, while muscle spasms may disturb sleep. Acute episodes of pain usually resolve after four to six weeks, but mild pain may persist for up to three months. Severe back pain that persists longer should raise the question of more fractures or another diagnosis.
- Height loss Height loss is typically asymptomatic and gradual.
- <u>Vertebroplasty</u> involves injection of bone cement, polymethylmethacrylate, into the collapsed vertebral body by percutaneous injection by an Interventional Radiologist. CT or fluoroscopic guidance is used to position the needle. The purpose of the procedure is to alleviate pain and strengthen the vertebrae. Studies indicate an 80% improvement rate. Long term studies are not available. Complications include infection, bleeding, and cement leakage, fracture of a rib or vertebrae, allergic reactions to the cement, cement pulmonary embolus, all less than 1%

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and occasional neurologic deficits. Vertebroplasty can also be used in cases of vertebral hemangiomas which extend into soft tissue and/or have caused a pathologic fracture

Kyphoplasty is a procedure performed by an Interventional Radiologist for treatment of acute vertebral compression fracture. It involves the placement of a cannulated obturator over a guidewire into the vertebral body under fluoroscopy. A working cannula is then placed over the obturator and advanced into the posterior portion of the vertebral body. A drill is then used to ream a corridor for passage of the Inflatable Ballon Tamp (IBT). The IBT is placed under the collapsed endplate on a lateral view. The Balloon is inflated under fluoroscopy. Maximum pressure for inflation is 220 psi. The volume of balloon expansion is measured and the IBT is removed. A mixture of bone cement (PMMA) and barium is then injected through cement cannulas that fit into the working cannula. Filling is stopped when the cement reaches 2/3 of the way back to the posterior vertebral body cortex on a lateral view.

Kyphoplasty is significantly more expensive than vertebroplasty. The choice between kyphoplasty and vertebroplasty is best dictated by the expertise of the practitioner at each institution [15].)

# 4.0 CONTRAINDICATIONS

- Asymptomatic vertebral compression fractures
- Patients improving on medical therapy
- As a prophylaxis in patients with osteoporosis
- Ongoing local or systemic infection including osteomyelitis of involved vertebrae
- Spinal cord or nerve root compression
- Spinal canal compromise secondary to malignancy resulting in myelopathy
- Uncorrectable coagulopathy
- Allergy to bone cement or opacification agent
- Chronic back pain of long standing duration

# 5.0 REFERENCES:

- <u>Aetna-Back Pain Invasive Procedures</u> CPB 1/2022
- 1. Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty

is considered medically necessary for members with persistent, debilitating pain in the cervical, thoracic or lumbar vertebral bodies resulting from *any* of the following:

1. Multiple myeloma; or

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- 2. Painful and/or aggressive hemangiomas; or
- 3. Painful vertebral eosinophilic granuloma; or
- 4. Painful, debilitating osteoporotic collapse/compression fractures (e.g., Kummell's disease); *or*
- 5. Primary malignant neoplasm of bone or bone marrow; or
- 6. Secondary osteolytic metastasis, excluding sacrum and coccyx; or
- 7. Steroid-induced fractures

AND all of the following criteria have been met:

- 8. Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging; *and*
- 9. Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, NSAIDS, narcotic analgesics, braces, physical therapy, etc.); and
- 10. The affected vertebra has not been extensively destroyed and is at least 1/3 of its original height.

# • <u>Up-to-date</u>: June 2020 Osteoporotic Thoracolumbar Vertebral compression fractures: Clinical Manifestations

# • Vertebral augmentation procedures (vertebroplasty and kyphoplasty) —

Vertebroplasty and kyphoplasty involve the percutaneous injection of bone cement under image guidance into a fractured vertebra. Specific to kyphoplasty, inflatable bone tamps are placed into the fractured vertebral body to create a low pressure cavity in which bone cement is placed to reduce the fracture and, in theory, to improve kyphotic deformity [26]. Vertebral augmentation procedures are usually performed in an outpatient setting with sedation or general anesthesia; the optimal timing of the procedure related to fracture acuity is unclear [27, 28]. The potential short-term benefit for both procedures is improvement in pain, whereas potential long-term benefits include prevention of recurrent pain at the treated level(s), limitation or reversal of height loss and spinal deformity, and improved functional capability. However, the evidence supporting the use of these procedures over conservative medical management is of low quality, and therefore the

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indications for and timing of vertebral augmentation procedures for the treatment of osteoporotic compression fractures are controversial.

- Patient selection is a critical factor for both the decision to perform vertebral augmentation and for the selection of the type of procedure. Vertebral augmentation is **not** indicated for patients with mild-to-moderate pain that is responding to medical management. For patients with incapacitating pain from acute and subacute vertebral compression fractures who are unable to taper parenteral or transition to oral opioids within seven days of admission or have intolerable sedation, constipation, or delirium from this therapy, we suggest vertebral augmentation rather than continued medical management (**Grade** <u>2C</u>). This is typically performed during the initial hospitalization. Vertebral augmentation is also an option for those without improvement in pain despite timely (four to six weeks) conservative management with oral opioids and <u>calcitonin</u>, or for those who are intolerant of oral opioids. (See <u>'Candidates for vertebral augmentation'</u> above.)
- •While kyphoplasty is performed more frequently than vertebroplasty, vertebroplasty may be the preferred procedure for a select subset of patients (eg, endplate fractures, wherein the entire vertebral body is not compressed). Vertebroplasty is also technically easier to perform, does not commit to a bipedicular approach, does not rely on the performance of a balloon system, and is less expensive. (See <u>'Vertebral augmentation procedures (vertebroplasty and kyphoplasty)</u>' above and <u>'Selection of procedure'</u> above.)

Арг	proval	
	3/8/06	
Luke Beno M.D Physician Program Director, Quality Resource Management	Date	
	Date	

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**TSPMG Expert Opinion:** Dr. Pamela Vicks-Bope – Pain Management Specialist:- Previously recommended approval from interventional radiology since internal pain does not perform this procedure. 2/18/2020