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1.0 Description of the Procedure, Product, or Service

1.1 Percutaneous Vertebroplasty

Percutaneous vertebroplasty (PVP) is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture, or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty has also been investigated as an adjunct to surgery for aggressive vertebral body hemangiomas, as a technique to limit blood loss related to surgery. The technique has been used in all levels of the vertebrae, i.e., cervical, thoracic, and lumbar.

1.2 Percutaneous Kyphoplasty

Percutaneous kyphoplasty, like vertebroplasty, is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. Kyphoplasty is a variant of vertebroplasty that uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. The technique has been investigated for the same uses as vertebroplasty.

It has been proposed that percutaneous vertebroplasty and kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated including thermal damage to intraosseous nerve fibers, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Vertebroplasty and kyphoplasty are surgical procedures and, as such, are not subject to U.S. Food and Drug Administration (FDA) approval. PMMA bone cement was available as a drug product prior to enactment of the FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. The FDA issued a guidance document on July 17, 2002 that outlines the types of special controls required and describes the recommended labeling information.

Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product prior to 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were issued 510(k) marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. The use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product prior to July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510K marketing clearance by the FDA for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V have been issued 510k marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

The FDA also issued a “Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures,” which is available at www.fda.gov/cdrh/safety/bonecement.html. This notification is intended to inform the public about reports on safety and to encourage hospitals and other user facilities to report adverse events related to bone cement malfunctions either directly to manufacturers or to MedWatch, the FDA’s voluntary reporting program.

1.3 Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are a common problem, and it is estimated that up to one half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or a month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization/bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise.

1.4 Vertebral Body Metastasis

Metastatic malignant disease of the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

1.5 Vertebral Hemangiomas

Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurological compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiation therapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization

techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous vertebroplasty and percutaneous cementoplasty have been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

1.6 Medical Term Definitions

Metastasis: spread of a disease, generally cancer, from the original site to another organ or body part.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Percutaneous Vertebroplasty or Percutaneous Kyphoplasty is covered under the NC Health Choice Program when it is determined to be medically necessary in the following situations:

3.2.1 For vertebral collapse when the following criteria are met:

- a. For osteoporotic vertebral compression fractures with persistent debilitating pain*, which has not responded to standard medical treatment including initial bed rest with progressive activity **AND** narcotic or non-narcotic analgesics.

*Persistent debilitating pain is defined as:

1. Level of pain on a Visual Analog Scale (VAS) greater than four (4) on a daily basis, **OR**
2. Pain on a daily basis that has a documented impact on activities of daily living [at least two (2) ADL's or IADL's]

Up to six (6) weeks of standard medical treatment is required unless the pain is not significantly relieved by rest, narcotic and non-narcotic pain medications (as appropriate), or the recipient is unable to tolerate narcotic and non-narcotic pain medication.

- b. For treatment of severe pain in patients with osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies,

3.3 Policy Guidelines

The decision for treatment should be multidisciplinary and take into consideration the local and general extent of the disease. This includes the spinal level involved, the severity of pain experienced by the recipient, his/her neurologic condition, previous treatments and their outcomes, the general state of health, and life expectancy. The following should be documented prior to performing Percutaneous Vertebroplasty or Percutaneous Kyphoplasty:

- a. There is a high degree of certainty through targeted, documented physical exam and ancillary studies (e.g., x-ray, MRI, CT, fluoroscopy, bone scan), that the pain is caused by a non-healing fracture;
- b. An ancillary study indicates non-healing osteoporotic or pathologic fracture, and does not indicate presence of spinal or disc fragment at the painful vertebral level;
- c. The procedure is not performed on a prophylactic basis, either for osteoporosis of the spine or for chronic back pain of long-standing duration even if associated with old compression fracture(s);
- d. The risks of an open surgical approach are greater than risks associated with a percutaneous approach.

A peer reviewed article published in the January 2006 edition of the American Journal of Neuroradiology indicates that the Mayo Clinic recently conducted a retrospective study on vertebroplasty. They found a potential relationship between vertebroplasty and new fractures in the adjacent vertebrae. It appeared in this study that patients may be at an increased risk of new adjacent-level fractures. These fractures appear to occur sooner than fractures at a nonadjacent level. However, this study was followed by an article in the same journal in August 2006 that notes that there are data that both support and refute such a causal relationship. More study is needed to resolve this question. Meanwhile, it is clear that patients who have endured one vertebral compression fracture are at high risk for another. Therefore, preventive treatment, including a combination of vitamin D and calcium supplementation, micalcin, and bisphosphonates is important for all patients in whom it is not otherwise contraindicated.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;

- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

- a. Percutaneous Vertebroplasty or Percutaneous Kyphoplasty is considered investigational for all indications that do not meet the medical necessity criteria listed in **Subsection 3.2**.
- b. Percutaneous Vertebroplasty or Percutaneous Kyphoplasty is contraindicated in the following conditions:
 - 1. Coagulation disorders
 - 2. Underlying infection (osteomyelitis of the involved vertebra)
 - 3. Very severe cardiopulmonary disease
 - 4. Neurological symptoms related to spinal compression
 - 5. Lack of neurosurgical backup for emergency decompression in the event a neurological deficit develops during the injection of PMMA.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior Approval Prior approval is not required for percutaneous vertebroplasty or for percutaneous kyphoplasty.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
September 30, 2011	Throughout	Policy Date of Termination.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)
22520
22521
22522
22523
22524
22525
72291
72292

HCPCS - Code(s)
S2360
S2361

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges