ND

Medical Policies

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Policy Number:	X-5038		
Policy Name:	Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation		
Policy Type:	Medical	**Policy Subtype:**	Radiology
Effective Date:	09-15-2025	**End Date:**	11-02-2025

Description

Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to 50% of women and 25% of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. A minority of individuals will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest , immobilization or 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. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures.

Osteolytic Vertebral Body Fractures

Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint.

Treatment

While radiotherapy 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.

Regulatory Status

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the United States Food and Drug Administration (U.S. FDA). Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX ® inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Other devices with the FDA 510(k) marketing clearance include the AVA *max*® Vertebral Balloon system (CareFusion), NeuroTherm Parallax ® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS ® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes [West Chester, PA]). StabiliT ® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009. FDA product code NDN.

In 2014, the Kiva ® VCF Treatment System (Benvenue Medical) was cleared for marketing by the FDA through the 510(k) process. FDA product code NDN.

Polymethylmethacrylate bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the FDA termed a 'transitional device.' It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet 'special controls' instead of 'general controls' to assure safety and effectiveness. In July 2004, KyphX ® HV-RTM bone cement was cleared for marketing by the FDA through the 510(k) process for the treatment of pathologic 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, KYPHON ® HV-R ® Bone Cement, and Osteopal ® V (Heraeus) have received issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN .

Policy Application

All claims submitted under this policy's section will be processed according to the policy effective date and associated revision effective dates in effect on the date of service.

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Balloon kyphoplasty may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least six (6) weeks.

Mechanical vertebral augmentation with an FDA cleared device may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least six (6) weeks.

Balloon kyphoplasty may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Mechanical vertebral augmentation with an FDA cleared device may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Balloon kyphoplasty or mechanical vertebral augmentation with an FDA cleared device are considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Radiofrequency kyphoplasty is considered **investigational** .

Mechanical vertebral augmentation using any other device is considered **investigational**

Procedure Codes

22513	22514	22515

Professional Statements and Societal Positions Guidelines

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology et al

The American College of Radiology (2014) and seven (7) other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation. [30,] This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate individuals with symptomatic osteoporotic and neoplastic fractures. The statement also indicated that these procedures be offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering the individual's quality of life.

A joint practice parameter for the performance of vertebral augmentation was updated in 2017. [31,]

Society of Interventional Radiology

In a quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology (2014) vertebral augmentation was recommended for compression fractures refractory to medical therapy. [30,] Failure of medical therapy includes the following situations:

1. Individuals who are 'rendered non-ambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy';
2. Individuals with 'sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy'; or
3. Individuals with 'a weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.'

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (2010) approved clinical guidelines on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering kyphoplasty to individuals who 'present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms...and who are neurologically intact.' [32,] The American Academy of Orthopaedic Surgeons indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on the literature reviewed through September 2009.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2013) issued a guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for treating osteoporotic vertebral compression fractures in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging at the level of the fracture. [33,] This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.

The Institute (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2014, and placed on the static list (no major ongoing studies identified, with the next review in five (5) years). [34,] The guidance stated that vertebroplasty or kyphoplasty should be considered for individuals who have vertebral metastases, and no evidence of spinal cord compression or spinal instability if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists, agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of individuals, that early surgery may be more effective at maintaining mobility than radiotherapy.

Diagnosis Codes

C41.2	C79.51	C79.52	C90.00	C90.01	C90.02	D18.09
D47.Z9	M48.50XA	M48.50XD	M48.50XG	M48.50XS	M48.51XA	M48.51XD
M48.51XG	M48.51XS	M48.52XA	M48.52XD	M48.52XG	M48.52XS	M48.53XA
M48.53XD	M48.53XG	M48.53XS	M48.54XA	M48.54XD	M48.54XG	M48.54XS
M48.55XA	M48.55XD	M48.55XG	M48.55XS	M48.56XA	M48.56XD	M48.56XG
M48.56XS	M48.57XA	M48.57XD	M48.57XG	M48.57XS	M48.58XA	M48.58XD
M48.58XG	M48.58XS	M54.6	M80.08XA	M80.08XD	M80.08XG	M80.08XK
M80.08XP	M80.08XS	M84.48XA	M84.48XD	M84.48XG	M84.48XK	M84.48XP

M84.48XS	M84.58XA	M84.58XD	M84.58XG	M84.58XK	M84.58XP	M84.58XS
M84.68XA	M84.68XD	M84.68XG	M84.68XK	M84.68XP	M84.68XS	

CURRENT CODING

CPT:

22513	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULATION	Commercial
22514	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULJ LMBR	Commercial
22515	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULJ EACH	Commercial
22513	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULATION	Medicaid Expansion
22514	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULJ LMBR	Medicaid Expansion
22515	PERQ VERT AGMNTJ CAVITY CRTJ UNI/BI CANNULJ EACH	Medicaid Expansion

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ND Committee Review

Internal Medical Policy Committee 9-26-2019 New policy

Internal Medical Policy Committee 9-21-2020 Annual Review, no changes

Internal Medical Policy Committee 9-21-2021 Revision of clarifying statements

Internal Medical Policy Committee 9-28-2022 Annual Review, no changes in criteria

Internal Medical Policy Committee 9-12-2023 Annual Review, no changes in criteria

Internal Medical Policy Committee 1-14-2025 Coding update - *Effective March 03, 2025*

- *Added* diagnosis code M54.6

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.