



MASSACHUSETTS

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Medical Policy

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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Policy Number: 485

BCBSA Reference Number: 6.01.38

NCD/LCD: Local Coverage Determination (LCD): Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569)

Related Policies

- Percutaneous Vertebroplasty and Sacroplasty, #[484](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Balloon kyphoplasty or mechanical vertebral augmentation using Kiva may be considered **MEDICALLY NECESSARY** for the treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, analgesics, physical therapy, rest) for at least 6 weeks.

Balloon kyphoplasty or mechanical vertebral augmentation using Kiva 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 using Kiva 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**.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code Description
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0PU33JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Approach
0PU34JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0PU43JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Approach
0PU44JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QU03JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Approach
0QU04JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QU13JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Approach

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or ICD Procedure codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C41.2	Malignant neoplasm of vertebral column
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
G89.3	Neoplasm related pain (acute) (chronic)
M48.50xA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M48.50xD	Collapsed vertebra, not elsewhere classified, site unspecified, subsequent encounter for fracture with routine healing
M48.50xG	Collapsed vertebra, not elsewhere classified, site unspecified, subsequent encounter for fracture with delayed healing
M48.50xS	Collapsed vertebra, not elsewhere classified, site unspecified, sequela of fracture
M48.51xA	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, initial encounter for fracture
M48.51xD	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, subsequent encounter for fracture with routine healing
M48.51xG	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, subsequent encounter for fracture with delayed healing
M48.51xS	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, sequela of fracture
M48.52xA	Collapsed vertebra, not elsewhere classified, cervical region, initial encounter for fracture
M48.52xD	Collapsed vertebra, not elsewhere classified, cervical region, subsequent encounter for fracture with routine healing
M48.52xG	Collapsed vertebra, not elsewhere classified, cervical region, subsequent encounter for fracture with delayed healing
M48.52xS	Collapsed vertebra, not elsewhere classified, cervical region, sequela of fracture
M48.53xA	Collapsed vertebra, not elsewhere classified, cervicothoracic region, initial encounter for fracture

M48.53xD	Collapsed vertebra, not elsewhere classified, cervicothoracic region, subsequent encounter for fracture with routine healing
M48.53xG	Collapsed vertebra, not elsewhere classified, cervicothoracic region, subsequent encounter for fracture with delayed healing
M48.53xS	Collapsed vertebra, not elsewhere classified, cervicothoracic region, sequela of fracture
M48.54xA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M48.54xD	Collapsed vertebra, not elsewhere classified, thoracic region, subsequent encounter for fracture with routine healing
M48.54xG	Collapsed vertebra, not elsewhere classified, thoracic region, subsequent encounter for fracture with delayed healing
M48.54xS	Collapsed vertebra, not elsewhere classified, thoracic region, sequela of fracture
M48.55xA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M48.55xD	Collapsed vertebra, not elsewhere classified, thoracolumbar region, subsequent encounter for fracture with routine healing
M48.55xG	Collapsed vertebra, not elsewhere classified, thoracolumbar region, subsequent encounter for fracture with delayed healing
M48.55xS	Collapsed vertebra, not elsewhere classified, thoracolumbar region, sequela of fracture
M48.56xA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M48.56xD	Collapsed vertebra, not elsewhere classified, lumbar region, subsequent encounter for fracture with routine healing
M48.56xG	Collapsed vertebra, not elsewhere classified, lumbar region, subsequent encounter for fracture with delayed healing
M48.56xS	Collapsed vertebra, not elsewhere classified, lumbar region, sequela of fracture
M48.57xA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M48.57xD	Collapsed vertebra, not elsewhere classified, lumbosacral region, subsequent encounter for fracture with routine healing
M48.57xG	Collapsed vertebra, not elsewhere classified, lumbosacral region, subsequent encounter for fracture with delayed healing
M48.57xS	Collapsed vertebra, not elsewhere classified, lumbosacral region, sequela of fracture
M48.58xA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M48.58xD	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, subsequent encounter for fracture with routine healing
M48.58xG	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, subsequent encounter for fracture with delayed healing
M48.58xS	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, sequela of fracture
M80.08xA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.08xD	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.08xG	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.08xK	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.08xP	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.08xS	Age-related osteoporosis with current pathological fracture, vertebra(e), sequela
M80.88xA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture

M80.88xD	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.88xG	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.88xK	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.88xP	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.88xS	Other osteoporosis with current pathological fracture, vertebra(e), sequela
M84.48xA	Pathological fracture, other site, initial encounter for fracture
M84.48xD	Pathological fracture, other site, subsequent encounter for fracture with routine healing
M84.48xG	Pathological fracture, other site, subsequent encounter for fracture with delayed healing
M84.48xK	Pathological fracture, other site, subsequent encounter for fracture with nonunion
M84.48xP	Pathological fracture, other site, subsequent encounter for fracture with malunion
M84.48xS	Pathological fracture, other site, sequela
M84.58xA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture
M84.58xD	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with routine healing
M84.58xG	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with delayed healing
M84.58xK	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with nonunion
M84.58xP	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with malunion
M84.58xS	Pathological fracture in neoplastic disease, other specified site, sequela
M84.68xA	Pathological fracture in other disease, other site, initial encounter for fracture
M84.68xD	Pathological fracture in other disease, other site, subsequent encounter for fracture with routine healing
M84.68xG	Pathological fracture in other disease, other site, subsequent encounter for fracture with delayed healing
M84.68xK	Pathological fracture in other disease, other site, subsequent encounter for fracture with nonunion
M84.68xP	Pathological fracture in other disease, other site, subsequent encounter for fracture with malunion
M84.68xS	Pathological fracture in other disease, other site, sequela

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 1 month. A minority of patients 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.

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.

Kyphoplasty

Balloon kyphoplasty is a variant of vertebroplasty and 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 polymethylmethacrylate (PMMA). Radiofrequency kyphoplasty (also known as radiofrequency targeted vertebral augmentation) is a modification of balloon kyphoplasty. In this procedure, a small diameter articulating osteotome creates paths across the vertebra. An ultra-high viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultra-high viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

It has been proposed that 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, one of which is thermal damage to intraosseous nerve fibers, given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Vertebral Augmentation

Kiva is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body to provide a reservoir for bone cement. The Kiva VCF Treatment System consists of a shaped memory coil and an implant, which is filled with bone cement. The coil is inserted into the vertebral body over a removable guidewire. The coil reconfigures itself into a stack of loops within the vertebral body and can be customized by changing the number of loops of the coil. The implant, made from PEEK-OPTIMA, a biocompatible polymer, is deployed over the coil. The coil is then retracted, and PMMA is injected through the lumen of the implant. The PMMA cement flows through small slots in the center of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

Outcome Measures

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in the ability to function. Kyphoplasty may also restore lost vertebral body height and reduce kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures may be associated with lower health-related quality of life.

Summary

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation with Kiva are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or those with osteolytic lesions of the spine (ie, multiple myeloma, metastatic malignancies).

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other

outcomes. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Two randomized trials that compared mechanical vertebral augmentation (Kiva) with kyphoplasty have reported similar outcomes for both procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral compression fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes RCTs, case series, and a systematic review of these studies. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs have compared balloon kyphoplasty with conservative management, and another has compared Kiva with balloon kyphoplasty. Results of these trials, along with case series, would suggest a reduction in pain, disability, and analgesic use in patients with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, the evidence these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

After consideration of clinical input, we concluded that, although the scientific evidence does not permit conclusions about the impact on health outcomes and that comparative studies with long-term outcomes are lacking, numerous case series, including large prospective reports, have consistently shown that vertebroplasty and percutaneous balloon kyphoplasty may alleviate pain and improve function in patients with osteoporotic vertebral fractures that have failed to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. More recent randomized trials, which have compared percutaneous balloon kyphoplasty with medical management, have also reported benefit. Given the absence of alternative treatment options and the morbidity associated with extended bedrest, percutaneous balloon kyphoplasty and mechanical vertebral augmentation may be considered reasonable treatment options in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy and, therefore, may be considered medically necessary both for this patient population and populations with severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

For individuals who have osteoporotic or osteolytic vertebral compression fractures who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only RCT (N=80) identified showed similar results between radiofrequency kyphoplasty and balloon kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small number of studies as well as possible bias. Corroboration of these results in a larger number of patients would be needed to determine with greater certainty whether radiofrequency kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
6/2018	BCBSA National medical policy review. Policy statements clarified; intent of statements unchanged.
1/2018	BCBSA National medical policy review. New investigational indications described. Radiofrequency kyphoplasty added to title. Clarified coding information. Effective 1/1/2018.
1/2017	BCBSA National medical policy review. Investigational policy statement clarified to delete the wording, "including but not limited to vertebral body stenting." New references added.
9/2015	BCBSA National medical policy review. New medically necessary indications described. Effective 9/1/2015.

1/2015	Clarified coding information.
9/2014	BCBSA National medical policy review. New investigational indications described. Effective 9/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
2/2014	Local Coverage Determination (LCD) for Percutaneous Vertebroplasty/Percutaneous Augmentation (L11417) retired and replaced by LCD L26439 Vertebroplasty and Vertebral Augmentation (Percutaneous). Effective October 25, 2013.
10/2013	BCBSA National medical policy review. New investigational indications described. Effective 10/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2011	BCBSA National medical policy review. Changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/2010	BCBSA National medical policy review. Changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/2009	New policy, effective 6/1/2009, describing covered and non-covered indications.
11/2008	BCBSA National medical policy review. No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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