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Subject: Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDEL, INE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	<u>Reimbursement</u>	Program Exceptions	Definitions	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate into a weakened vertebral body. The technique has been investigated to provide mechanical support and symptomatic relief in those with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty (RFK), and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate into a cavity created in the vertebra I body with a balloon or mechanical device.

Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical, entails guided injection of PMMA through a needle inserted into the fracture zone. It is most often described as a minimally invasive procedure employed as an alternative to conservative management for sacral insufficiency fractures (SIFs).

Summary and Analysis of Evidence: UpToDate review "Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment (Rosen, 2024) states "(p)atients with severe pain from an acute (0 to 4 weeks) vertebral body fracture typically require opioids at the outset. When opioids are required to control pain from vertebral compression fractures, we typically initiate treatment with an immediate-release opioid combined with low-dose acetaminophen. If the pain is

incapacitating, hospital admission and parenteral analgesia for pain management may be necessary. 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 2C). This is typically performed during the initial hospitalization. Vertebroplasty and kyphoplasty appear to perform similarly. Vertebroplasty is performed when there is little to no compression of the vertebral body, but MRI shows bone marrow edema consistent with fracture. It does not rely on the performance of a balloon system ... Kyphoplasty relies on the use of a balloon tamponade system that can have technical difficulties, but it may partially restore vertebral height." UpToDate review "Overview of therapeutic approaches for adult patients with bone metastasis from solid tumors" (Yu, Hoffe; 2024) states "(a)nother option for patients with painful vertebral bone metastases with a compression fracture is percutaneous vertebral augmentation, with (vertebroplasty) or without (kyphoplasty) polymethyl methacrylate. Percutaneous vertebral augmentation has been used to improve the mechanical stability of the vertebrae as well as pain from a vertebral compression fracture. However, only one randomized study has demonstrated improved quality of life and functional outcomes; further research is thus needed. When it is performed, vertebroplasty/kyphoplasty is generally reserved for patients with symptomatic osteolytic spinal metastases, with intact bone cortex and without epidural disease, spinal cord compression, or retropulsion of bone fragments into the spinal cord. For asymptomatic patients with radiographic evidence of significant compromise of mechanical stability due to osteolytic bone metastasis or fracture, vertebral augmentation may be considered by the multidisciplinary team to prevent future symptoms due to further compression of vertebrae." Zhao et al (2017) examined the efficacy and safety of vertebroplasty, kyphoplasty, and conservative treatment for the treatment of osteoporotic vertebral compression fracture. Sixteen RCTs were identified. No significant difference was found between kyphoplasty and vertebroplasty for pain relief, daily function, and quality of life. Network meta-analysis demonstrated that kyphoplasty was superior to conservative therapy as assessed by visual analog scale, European Quality of Life-5 Dimensions, and Roland-Morris Disability Questionnaire. Kyphoplasty was associated with the lowest risk of new fractures. UpToDate review "Minor pelvic fractures (pelvic fragility fractures) in the older adult" (Fitch, 2024) states "(i)nvasive treatment for insufficiency fractures of the pelvis (eg, sacroplasty and ramoplasty) has been described but is not well studied. Indications remain unspecified, but consultation is reasonable when pain control is difficult and mobilization remains limited. These procedures are performed primarily by interventional radiologists. Most authors agree that surgical treatment is needed for fragility fractures of the pelvis (FFP) types III and IV, and for type II fractures that fail to heal with conservative treatment." Frey et al (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty versus nonsurgical management. This prospective, observational cohort study spanned 10 years and comprised 240 patients with sacral insufficiency fractures. Both forms of treatment resulted in significant visual analogue scale improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant visual analogue scale score improvement consistently at many of the follow-up points. Meanwhile, the group with nonsurgical treatment only experienced 1 significant pain improvement score, which was at the 2-week followup post-treatment. One major limitation of this study was that the nonsurgical treatment group was not followed up at the 10-year mark whereas the sacroplasty group did receive follow-up. Due to the limited number of patients and the retrospective nature of the evidence base, harms associated with sacroplasty have not been adequately studied. The

small numbers of treated patients leave uncertainty regarding the impact of sacroplasty on health outcomes. The authors stated "Although the clinical outcomes in our study are encouraging, this study has several limitations. First, only 18 patients were enrolled in our study; the sample size is too small to prove the feasibility and efficacy of this technique. Second, the retrospective nature of the study design lacked randomization of patients. Therefore, enrolling patients to undergo different treatment methods to compare clinical outcomes was impossible. Third, some patients had comorbidities, such as hypertension and diabetes mellitus. We did not take these comorbidities into consideration because they have no direct correlation with pedicle screws loosening. However, these comorbidities may have influenced the treatment results."

POSITION STATEMENT:

Percutaneous vertebroplasty

Percutaneous vertebroplasty **meets the definition of medical necessity** for the following indications:

- Treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, analgesics, physical therapy, rest) for at least 6 weeks, **OR**
- Treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation, **OR**
- Treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies, **OR**
- Treatment of acute vertebral fractures due to trauma, when at least 2 weeks of conservative treatment (eg, analgesics, physical therapy, rest) has failed

Balloon kyphoplasty and mechanical vertebral augmentation

Balloon kyphoplasty or mechanical vertebral augmentation using an FDA cleared device **meets the definition of medical necessity** for the following indications:

- Treatment of symptomatic osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (eg, analgesics, physical therapy, rest) for at least 6 weeks, **OR**
- Treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies, **OR**
- Treatment of acute vertebral fractures due to trauma, when at least 2 weeks of conservative treatment (eg, analgesics, physical therapy, rest) has failed

Radiofrequency kyphoplasty

Radiofrequency kyphoplasty is considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

Percutaneous sacroplasty

Percutaneous sacroplasty is considered **experimental or investigational** for all indications, including sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies, or multiple myeloma. The available published clinical literature does not support clinical value.

BILLING/CODING INFORMATION:

CPT Coding:

0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s),
	including the use of a balloon or mechanical device, when used, one or
	more needles, includes imaging guidance and bone biopsy, when
	performed (investigational)
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections,
	including the use of a balloon or mechanical device, when used, two or
	more needles, includes imaging guidance and bone biopsy, when
	performed (investigational)
22510	Percutaneous vertebroplasty (bone biopsy included when performed) 1
	vertebral body, unilateral or bilateral injection, inclusive of all imaging
	guidance, cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed) 1
	vertebral body, unilateral or bilateral injection, inclusive of all imaging
	guidance, lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed) 1
	vertebral body, unilateral or bilateral injection, inclusive of all imaging
	guidance, each additional cervicothroacic or lumbosacral, vertebral body
	(List separately in addition to code for primary procedure)
22513	Percutaneous vertebral augmentation, including cavity creation (fracture
	reduction and bone biopsy included when performed) using mechanical
	device (e.g., 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 (e.g., 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 (e.g., 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 Diagnosis Codes That Support Medical Necessity:

C41.2	Malignant neoplasm of vertebral column
C79.51 – C79.52	Secondary malignant neoplasm of bone and bone marrow
C90.00 – C90.02	Multiple myeloma
D18.09	Hemangioma of other sites
D47.Z9	Other unspecified neoplasms of uncertain behavior of lymphoid,
	hematopoietic and related tissue
M48.50XA – M48.58XS	Collapsed vertebra, not elsewhere classified

M80.08XA – M80.08XS	Age-related osteoporosis with current pathological fracture, vertebra(e)
M84.48XA – M84.48XS	Pathological fracture, other site
M84.58XA – M84.58XS	Pathological fracture in neoplastic disease, vertebrae
M84.68XA – M84.68XS	Pathological fracture in other disease, other site

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following Local Coverage Determinations (LCD) was reviewed on the last guideline revised date: Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (L34976), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

Joline Kyphoplasty System Allevo TRACKER Kyphoplasty System TRACKER Plus Kyphoplasty System Stryker iVAS Elite Inflatable Vertebral AugmentationSystem (Stryker iVAS Elite Balloon Catheter) SpineKure Kyphoplasty System Modified Winch Kyphoplasty (15 and 20 mm) 11 GaugeBalloon Catheters 13G InterV Kyphoplasty Catheter (Micro) and 11GInterV Kyphoplasty Catheter (Mini-Flex) MEDINAUT Kyphoplasty System AVAflex Vertebral Balloon System

Osseoflex SB Straight Balloon 10g/4ml Osseoflex SBStraight Balloon 10g/2ml

InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (BalloonLength: 10 15 and 20mm)

GUARDIAN-SG Inflatable Bone Expander System

ZVPLASTY

Kiva VCF Treatment System

SpineJack Expansion Kit

V-Strut Vertebral Implant

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/23/25.

GUIDELINE UPDATE INFORMATION:

01/25/01	Medical Coverage Guideline developed.
07/15/02	Revised coverage criteria for vertebroplasty and added investigational statement for
	kyphoplasty.
07/15/03	Reviewed; added coverage criteria for kyphoplasty.
01/01/04	HCPCS coding update.
06/15/04	Review and revision of guideline; consisting of updated references.
04/15/05	Review and revision of guideline; consisting of updated references.
01/01/06	Annual HCPCS coding update consisting of the addition of 22523 – 22525.
04/01/06	2nd qtr HCPCS coding update consisting of the deletion of S2362 – S2363.
01/01/07	Annual HCPCS coding update consisting of the deletion of 76012 – 76013 and the
	addition of 72291 – 72292.
09/15/07	Review and revision of guideline consisting of updated references and reformatted
	guideline.
04/15/09	Scheduled review; no change in position statement. Update references.
07/15/09	HCPCS coding revision; add 0200T & 0201T. Add investigational statement for
	sacroplasty. Update description section. Update guideline title. Update references.
01/01/10	Annual HCPCS coding update: revised descriptors for CPT codes 22520, 22521, 22523,
	72291, and 72292.
10/15/10	Revision; related ICD-10 codes added.
01/01/11	Annual HCPCS coding update. Revised descriptors for codes 0200T, and 0201T.
06/15/11	Scheduled review; position statements maintained and references updated.
01/01/12	Annual HCPCS coding update. Revised 22520, 22521 and 22522 descriptors.
05/11/14	Revision: Program Exceptions section updated.

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01/01/15	Annual CPT/HCPCS update. Added 22510, 22511, 22512, 22513, 22514, 22515. Revised
	0200T, 0201T descriptors. Deleted 22520, 22521, 22522, 22523, 22524, 22525, 72291,
	72292.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/16	Annual CPT/HCPCS coding update. Deleted codes S2360, S2361. Revised Program
	Exceptions section.
03/15/16	Scheduled review. Revised description section and position statement. Updated
	references.
10/15/17	Revision: revised description section. Added coverage statement for percutaneous
	radiofrequency kyphoplasty. Updated references.
06/15/18	Unscheduled review. Revised criteria for percutaneous vertebroplasty, balloon
	kyphoplasty, and vertebral augmentation with KIVA. Updated references.
10/01/18	Revision: updated ICD10 coding section.
06/15/20	Scheduled review. Revised description. Revised position statement (added coverage
	statements for acute fracture due to trauma). Updated references.
03/15/22	Scheduled review. Revised description and index terms. Maintained position statement.
	Updated references.
05/23/23	Update to Program Exceptions section.
02/15/24	Scheduled review. Revised description, maintained position statements, and updated
	references.
02/15/25	Scheduled review. Revised description. Maintained position statement and updated
	references.