02-20000-18

Original Effective Date: 02/15/01

Reviewed: 05/28/20

Revised: 06/15/20

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 GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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

DESCRIPTION:

Percutaneous vertebroplasty

Percutaneous vertebroplasty is a surgical procedure that involves the injection of synthetic cement (eg, polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss]) into a fractured vertebra. It has been suggested that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body.

Balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation

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 vertebral body with a balloon or mechanical device.

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 PMMA. Radiofrequency kyphoplasty (RFK; 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.

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 guide wire. 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.

SpineJack is a mechanical vertebral augmentation technique that utilizes bipedicular 4.2 mm to 5.0 mm self-expanding jacks to restore vertebral height. Placement of the titanium devices are verified in AP and lateral view prior to expansion. Once the devices are expanded, the a proprietary bone cement is injected. The proposed benefit is greater control over expansion and greater restoration of vertebral height compared to balloon kyphoplasty.

Percutaneous sacroplasty

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).

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, radiofrequency kyphoplasty, and mechanical vertebral augmentation

Balloon kyphoplasty and or mechanical vertebral augmentation using Kiva® or SpineJack® **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

Mechanical vertebral augmentation using any other device is considered **experimental or investigational**, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

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: Vertebroplasty, Vertebral Augmentation; Percutaneous (L34976) located at fcso.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 05/28/20.

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.
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.