Percutaneous Vertebroplasty, Kyphoplasty (Balloon-Assisted Vertebroplasty), Sacroplasty

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L38213 A57630	J5, J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	L33569 A56178	J6, JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L38201 A57282	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	L34228 A56572	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	L34106 A56573	JF – Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L35130 A57752	JH, JL – Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, DC, MD, NJ, PA
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L38737 A58275	JJ, JM – Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	L34976 A57872	JN – First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, US VI

Description

Percutaneous vertebroplasty is a procedure that involves injection of acrylic bone cement (usually a polymethylmethacrylate [PMMA]) into an osteoporotic vertebral body compression fracture or osteolytic lesion of the spine with the goal of relieving pain, improving mobility and preventing further collapse of the

bone. The procedure is performed under fluoroscopic guidance with local anesthesia and moderate sedation.

An alternative to traditional bone cement is **Cortoss Bone Augmentation Material**. Cortoss is an injectable, nonresorbable synthetic material that functions as a strengthening agent for injection into vertebral bodies with compression fractures.

Kyphoplasty (also known as balloon-assisted vertebroplasty) is a modification of the vertebroplasty procedure that involves the use of an inflatable balloon to reduce the fracture prior to the injection of the bone cement. Examples of devices used in kyphoplasty include, but may not be limited to, the **AVAflex Vertebral Balloon System, iVAS Balloon System** (including the **iVAS Elite System**)**, Kyphon Balloon System, Kyphon Express II Inflatable Bone Tamp, Kyphon Xpander II IBT** and **MEDINAUT-X Inflatable Bone Expander System**.

The **Kiva VCF Treatment System** is an implantable device which may be used with either the vertebroplasty or kyphoplasty procedure for reduction and treatment of spinal fractures. PMMA bone cement is used to fill the implant once it is placed. The **SpineJack** device is similar to the Kiva VCF system and has been developed as an additional alternative to the inflatable balloon used in kyphoplasty. SpineJack is an expandable titanium implant designed to restore the height of the vertebral body in osteoporotic vertebral fracture. After implantation, PMMA is injected into the vertebral body to provide additional stabilization.

VCFix was recently granted a breakthrough device designation from the US Food & Drug Administration (FDA) as a proposed treatment for vertebral compression fractures. It utilizes a 3D-printed structure which purportedly stimulates bone ingrowth and provides stability of loads in the spine.

Sacroplasty is a variation of vertebroplasty that has been proposed for the treatment of sacral insufficiency fractures. Under fluoroscopic guidance, PMMA is injected into the sacrum at the fracture site, in an attempt to stabilize the fracture.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Please refer to the above CMS guidance for **percutaneous vertebroplasty/kyphoplasty for osteoporotic vertebral compression fractures**.

Percutaneous vertebroplasty or kyphoplasty (balloon-assisted vertebroplasty) in the cervical, lumbar or thoracic regions of the spine will be considered medically reasonable and necessary when the following requirements are met:

- Imaging studies (x-ray, computed tomography [CT] scan or magnetic resonance imaging [MRI]) eliminates other origins for the pain (eg, herniated intervertebral disc) and confirms the presence of a vertebral compression fracture (VCF) or hemangioma which correlates to the individual's signs and symptoms; **AND**

- In the absence of an osteoporotic vertebral compression fracture;

AND *any* of the following indications:

- Painful and/or aggressive hemangioma; **OR**

- Painful multiple myeloma involving the vertebral body; **OR**

- Painful osteolytic vertebral body metastatic disease; **OR**

- Steroid-induced fracture

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Sacroplasty for any indication including, but not limited to, osteoporotic sacral insufficiency fractures will **not** be considered medically reasonable and necessary. A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Sacroplasty
Hayes evaluated percutaneous sacroplasty for the treatment of sacral insufficiency fractures and reported there is a small, very-low-quality body of evidence that does not allow for conclusions to be drawn.[30]

UpToDate reported that invasive treatments for insufficiency fractures of the pelvis such as sacroplasty have not been well studied.[46]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic	
01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral	
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 cervicothoracic 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 (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)	
CPT® Category III Code(s)	**Description**	**Comments**
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed	
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed	
HCPCS Code(s)	**Description**	**Comments**
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	
C7504	Percutaneous vertebroplasties (bone biopsies included when performed), first cervicothoracic and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance	
C7505	Percutaneous vertebroplasties (bone biopsies included when performed), first lumbosacral and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance	
C7507	Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (eg, kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance	
C7508	Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (eg, kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance	

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Change Summary

- 01/01/2024 New Policy.