



MEDICAL COVERAGE POLICY

SERVICE: Vertebroplasty Kyphoplasty Sacroplasty

Policy Number: 084

Effective Date: 11/01/2020

Last Review: 09/24/2020

Next Review Date: 09/24/2021

Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Vertebroplasty, Kyphoplasty and Sacroplasty

PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

- A. Medical necessity determinations for percutaneous vertebroplasty, balloon-assisted percutaneous vertebroplasty, kyphoplasty, and any related procedures will be made by **eviCore®**.
- B. SWHP/FirstCare considers Sacroplasty experimental, investigational and unproven, and therefore NOT considered medically necessary **EXCEPT** for Medicare lines of business where Sacroplasty (0200T, 0201T) may be medically necessary for the following conditions (refer to LCD L35130 for details). InterQual can be used for medical necessity review.

OVERVIEW:

Conservative treatment for painful vertebral compression fractures includes physical therapy, bed rest, bracing, and analgesics. Approximately two-thirds of patients with symptomatic vertebral compression fractures will improve after 4 to 6 weeks. Of note, in 2013, the ACR revised the Appropriateness Criteria for management of vertebral compression fractures. Seven scenarios were presented, percutaneous vertebroplasty was rated as "usually appropriate" in three scenarios, "may be appropriate" in three scenarios, and "usually not appropriate" in one scenario.⁴

Percutaneous vertebroplasty is a minimally invasive procedure which restores bone height lost due to painful vertebral compression fractures. The procedure consists of the injection of a bone-cement (usually polymethylmethacrylate) into a cervical, thoracic or lumbar vertebral body of the affected vertebra for relief of pain and the strengthening of bone.



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Kyphoplasty, also referred to as balloon-assisted vertebroplasty, is an adaptation of vertebroplasty that includes expansion of the collapsed vertebra with an inflatable balloon tamp (thereby restoring the vertebral body height and minimizing the associated kyphotic deformity) prior to the injection of the bone cement.

Complications for percutaneous vertebroplasty and kyphoplasty include cement leakage outside of the vertebral body which has been reported in 30% to 70% of cases (most cases of cement leakage are asymptomatic). Fracture of adjacent vertebral levels following these procedures also occurs. The cause of adjacent fracture is most likely multifactorial and may include the diffuse nature of the disease, and relief of pain with a subsequent return to high levels of physical activity.

There are no proven advantages of kyphoplasty over vertebroplasty with regard to pain relief, vertebral height restoration, or complication rate. It is possible that both vertebroplasty and kyphoplasty are useful in the treatment of vertebral compression fractures and that certain subgroups of patients may derive more benefit from one particular procedure. Features that might affect choice of procedure include degree of compression deformity, age of the fracture, and the presence of neoplastic involvement. However, benefits of kyphoplasty relative to vertebroplasty in such subgroups currently remain undefined.

There are no quality randomized controlled trials for percutaneous sacroplasty. The available literature suggests that this procedure produces rapid and sustained decreases in pain. However, due to the limited studies, harm associated with sacroplasty have not been adequately studied. Therefore, there remains uncertainty regarding the impact of sacroplasty on health outcome.

MANDATES: No applicable mandates.

CMS: LCD L35130 original date 10/1/2015; revision date 04/25/2019.

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.



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CPT Codes:	<p>22510 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance;</p> <p>22511 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance;</p> <p>22512 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional</p> <p>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</p> <p>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;</p> <p>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;</p> <p>22899 Spine surgery procedure</p> <p>For Medicare ONLY:</p> <p>0200T Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device,</p> <p>0201T Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles</p>
CPT Not Covered:	
ICD10 Codes:	<p>M80.88x - OSTEOPOROSIS WITH PATHOLOGIC FRACTURE, VERTEBRAE</p> <p>M48.54X - Collapsed vertebra,</p> <p>M48.55x - Collapsed vertebra,</p> <p>M48.56x</p> <p>S22.000x - thoracic vertebrae wedge fracture</p> <p>S22.010x - thoracic vertebrae wedge fracture</p> <p>S22.020x - thoracic vertebrae wedge fracture</p> <p>S22.030x - thoracic vertebrae wedge fracture</p> <p>S22.040x - thoracic vertebrae wedge fracture</p> <p>S22.050x - thoracic vertebrae wedge fracture</p> <p>S22.060x - thoracic vertebrae wedge fracture</p> <p>S22.070x - thoracic vertebrae wedge fracture</p> <p>S22.080x - thoracic vertebrae wedge fracture</p> <p>S32.000x - lumbar vertebrae wedge fracture</p> <p>S32.010x - lumbar vertebrae wedge fracture</p> <p>S32.020x - lumbar vertebrae wedge fracture</p> <p>S32.030x - lumbar vertebrae wedge fracture</p> <p>S32.040x - lumbar vertebrae wedge fracture</p> <p>S32.050x - lumbar vertebrae wedge fracture</p>

POLICY HISTORY:

Status	Date	Action
New	07/01/2010	New policy
Reviewed	10/18/2011	Reviewed.
Reviewed	03/29/2012	Reviewed..



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Reviewed	03/28/2013	Revised and updated to current LCD
Reviewed	03/27/2014	No changes
Reviewed	04/09/2015	No changes
Reviewed	06/25/2015	Changed coverage to include commercial lines
Reviewed	04/14/2016	CMS coverage updated and reviewed.
Reviewed	03/28/2017	No significant changes.
Reviewed	03/06/2018	Added CMS coverage of sacroplasty
Reviewed	08/07/2018	Updated medical necessity review utilizing eviCore®
Reviewed	10/31/2019	No changes. Confirmed LCD criteria
Reviewed	06/25/2020	Language added for coverage across all LOBs
Reviewed	09/24/2020	Refer Medicare LOBs review to InterQual® for sacroplasty

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. <http://www.nejm.org/doi/full/10.1056/NEJMoa0900429> Buchbinder R, Osborne RH, Ebeling PR, A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med.* 2009 Aug 6;361(6):557-68.
2. Centers for Medicare and Medicaid Services (CMS). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis and malignancy. Draft Technology Assessment. Medicare Coverage Database. Baltimore, MD: CMS; 2005. Available At: <http://cms.hhs.gov/mcd/viewtechassess.asp?shere=inex&tid=25>.
3. Cotten A, Boutry N, Cortet B, Assaker R, Demondion X, Leblond D, Chastanet P, Duquesnoy B, Deramond H. Percutaneous vertebroplasty: state of the art. [Review] [25 refs] *Radiographics.* 18(2):311-20; discussion 320-3, 1998 Mar-Apr.
4. American College of Radiology Guideline for managing vertebral compression fractures. Original review 2010; last update 2013; to be accessed at <https://acsearch.acr.org/docs/70545/Narrative/>
5. Coumans JV, Reinhardt MK, Lieberman IH. Kyphoplasty for vertebral compression fractures: 1-year clinical outcomes from a prospective study. *J Neurosurg.* 2003;99(Suppl 1):44-50.
6. Crandall D, Slaughter D, Hankins PJ, Moore C, Jerman J. Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results. *Spine Journal: Official Journal of the North American Spine Society.* 4(4):418-24, 2004 Jul-Aug.
7. Deen HG, Fenton DS, Lamer TJ. Minimally invasive procedures for disorders of the lumbar spine. *Mayo Clin Proc.* 2003;78(10):1249-56.
8. Deramond H, Depriester C, Galibert P, Le Gars D. Percutaneous vertebroplasty with polymethylmethacrylate. Technique, indications, and results. *Radiologic Clinics of North America.* 36(3):533-46, 1998 May.
9. Diamond TH, Champion B, Clark WA. Management of acute osteoporotic vertebral fractures: a nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. *Am J Med.* 2003;114:257-65.
10. Dudeney S, Lieberman IH, Reinhardt MK, Hussein M. Kyphoplasty in the treatment of osteolytic vertebral compression fractures as a result of multiple myeloma. *J Clin Oncol.* 2002;20(9):2382-2387.
11. Fourney DR, Schomer DF, Nader R, Chlan-Fourney J, Suki D, Ahrar K, Rhines LD, Gokaslan ZL. Percutaneous vertebroplasty and kyphoplasty for painful vertebral body fractures in cancer patients.



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- Journal of Neurosurgery. 98(1 Suppl):21-30, 2003 Jan.
12. Franck H, Boszczyk BM, Bierschneider M, Jaksche H. Interdisciplinary approach to balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures. *Eur Spine J.* 2003;2 Suppl 2:S163-S167.
 13. Fribourg D, Tang C, Sra P, Delamarter R, Bae H. Incidence of subsequent vertebral fracture after kyphoplasty. *Spine.* 29(20):2270-6; discussion 2277, 2004 Oct 15.
 14. Gaitanis IN, Hadjipavlou AG, Katonis PG, Tzermiadianos MN, Pasku DS, Patwardhan AG. Balloon kyphoplasty for the treatment of pathological vertebral compressive fractures. *European Spine Journal.* 14(3):250-60, 2005 Apr.
 15. Garfin SR, Reilley MA. Minimally invasive treatment of osteoporotic vertebral body compression fractures. *Spine J.* 2002;2(1):76-80.
 16. Garfin SR, Yuan HA, Reiley MA. New technologies in spine: kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. *Spine.* 2001;26(14):1511-5
 17. Garfin SR, Yuan HA, Reiley MA. New technologies in spine: kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. *Spine.* 2001;26(14):1511-5.
 18. Heini PF, Orlor R. Kyphoplasty for treatment of osteoporotic vertebral fractures. *Eur Spine J.* 2004;13(3):184-92
 19. Hulme PA, Krebs J, Ferguson SJ. Vertebroplasty and kyphoplasty: a systematic review of 69 clinical studies. *Spine.* 2006;31(17):1983-2001
 20. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009; 361:557
 21. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009; 361:569