MEDICAL COVERAGE POLICY	
SERVICE:	**Vertebroplasty Kyphoplasty Sacroplasty**
Policy Number:	**084**
Effective Date:	**04/01/2024**
Last Review:	**03/11/2024**
Next Review:	**03/11/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

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) L35130 Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

For ALL PLANS, except Medicaid and select Self-funded plans, medical necessity determinations for percutaneous vertebroplasty, balloon-assisted percutaneous vertebroplasty, kyphoplasty, and any related procedures will be made by **eviCore®**.

BSWHP 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 criteria may be used when available.

BACKGROUND:

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.

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 multifactoral 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: None

CODES:

Important note: *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.*

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

POLICY HISTORY:

Status	Date	Action
New	07/01/2010	New policy

Reviewed	10/18/2011	Reviewed.
Reviewed	03/29/2012	Reviewed..
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
Reviewed	09/23/2021	No changes
Reviewed	09/22/2022	No changes
Reviewed	11/29/2023	Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes
Reviewed	03/11/2024	Corrected the “For Medicaid Plans” section to utilize this Medical Policy if TMPPM does not have medical necessity guidance.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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 CoverageDatabase. 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):23822387.
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. 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, Orler 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

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.