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:

A. Medical necessity determinations for percutaneous vertebroplasty, balloon-assisted percutaneous vertebroplasty, kyphoplasty, and any related procedures will be made by eviCore®.

B. SWHP considers Sacroplasty experimental, investigational and unproven, and therefore NOT considered medically necessary EXCEPT for Medicare lines of business where Sacroplasty may be medically necessary for the following conditions (refer to LCD L35130 for details):
   - Palliative treatment of an acute or subacute stable fracture of the sacral vertebral body (sacrum) with persistent debilitating pain that has not responded to accepted standard medical treatment appropriate for each patient.
   - Palliative treatment of symptomatic osteolytic sacral metastatic lesions or myeloma associated with severe sacral pain related to a destruction of the sacral vertebral body, not involving the major part of the cortical bone.

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
Vertebroplasty and Kyphoplasty
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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 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.
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:

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MEDICAL COVERAGE POLICY

SERVICE: Vertebroplasty Kyphoplasty Sacroplasty

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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

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.

12. Franck H, Boszczyk BM, Bierschneider M, Jaksche H. Interdisciplinary approach to balloon vertebroplasty and Kyphoplasty
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