Percutaneous Vertebroplasty and Sacroplasty

MEDICAL POLICY NUMBER: 196

Effective Date: 12/1/2024

Last Review Date: 9/2024

Next Annual Review: 8/2024

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners, as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Percutaneous Vertebroplasty and Sacroplasty : Guideline Note 109

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Percutaneous Vertebral Augmentation (i.e. Vertebroplasty)

I. Percutaneous vertebral augmentation vertebroplasty (PVP) or kyphoplasty may be considered **medically necessary** when one of the following conditions is met:

   A. For Osteoporotic vertebral compression fracture (VCF) (T1-L5):
      1. Acute (<6 weeks) or subacute (6-12 weeks) osteoporotic vertebral compression fracture (VCF) (T1-L5) based on symptom onset, and documented by advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake); **AND**
      2. Either hospitalized with severe pain or non-hospitalized with moderate to severe pain despite optimal non-surgical management; or
   B. Multiple myeloma; or
   C. Painful and/or aggressive hemangiomas; or
   D. Painful vertebral eosinophilic granuloma; or
   E. Primary malignant neoplasm of bone or bone marrow; or
   F. Secondary osteolytic metastasis, excluding sacrum and coccyx, but including cervical; or
   G. Steroid-induced fractures

II. Percutaneous vertebroplasty or kyphoplasty is considered **not medically necessary** when criteria above are not met or when member has any of the following conditions:

   A. Current back pain is not primarily due to the identified acute or subacute VCF

B. Osteomyelitis, discitis, or active systemic or surgical site infection is present
C. Pregnancy
D. Greater than 3 vertebral fractures are treated per procedure
E. Allergy to bone cement or opacification agents
F. Uncorrected coagulopathy
G. Spinal instability
H. Myelopathy from fracture
I. Neurologic deficit
J. Neural impingement
K. Fracture retropulsion/canal compromise

Percutaneous Sacral Augmentation (i.e. Sacroplasty)

III. Percutaneous sacral augmentation (i.e. sacroplasty) is considered **not medically necessary** for all indications, including the treatment of sacral insufficiency fractures.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)(L34106)[1]
- Local Coverage Article (LCA): Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)(A56573)[2]

BACKGROUND

Vertebral Fractures

In the US, more than one quarter of the population age 50 years or older experiences one vertebral fracture in the later years of life. Fractured vertebral bodies may produce intractable pain. Vertebral augmentation procedures are some of the invasive treatments that may be employed to address pain refractory to non-invasive therapeutic modalities. The percutaneous injection of medical cement or polymethylmethacrylate (PMM) or other material FDA-approved for this purpose into the vertebral body may reduce pain and improve function. One type of vertebral augmentation procedure, e.g. Kyphoplasty, also includes fracture reduction by expanding the intrabody space with a device such as a balloon. Following reduction, the bone cement is injected.

Percutaneous Vertebroplasty

Percutaneous Vertebroplasty is a minimally invasive, percutaneous, interventional radiological procedure designed to stabilize vertebral compression factors. During the procedure, bone cement is injected percutaneously into a partially collapsed vertebrae under image guidance. Once in place, the cement hardens and stabilizes the fractured vertebra. The most commonly used cement is polymethyl methacrylate (PMMA), which has inherent shortcomings, including inflammation-causing exothermic polymerization, and the potential for poor integration between the cement and bone.

Percutaneous Sacroplasty

Percutaneous sacroplasty involves the injection of bone cement into the sacral insufficiency fractures to restore the mechanical integrity and stability of the sacrum. The goal of the treatment is to relieve pain and restore mobility.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

Systematic Reviews

- Hayes conducted a health technology assessment in 2018, reviewed in 2021, on percutaneous sacroplasty for the treatment of sacral insufficiency fractures (SIF).[3] A literature found 4 studies that met Hayes inclusion criteria and investigated sacroplasty for SIF. All 4 studies assessed pain on a visual analog scale and reported statistically and clinically significant improvements in pain after the procedure. Only one of these studies had a comparator group, a prospective observational study by Frey et al (2017).[4] The study compared sacroplasty to non-surgical management and found that both treatment options reduced pain at 2- year follow up. Sacroplasty had significant reduction in pain at each time interval from baseline to 2 years, while conversive management only have significant reduction from baseline to 2 weeks. The study had many limitations. Participants were placed into the control group if they were not eligible for sacroplasty, and the two groups were not directly compared in the analysis.

  Two retrospective studies measured disability and found that sacroplasty improved functionality, but there were no comparator groups and results can be affected by bias and placebo effect. Similarly, two studies found that sacroplasty reduced analgesic use in patients, but neither compared reduction to a control group.

Hayes concluded that there was an overall very-low-quality body of evidence and therefore they cannot draw conclusions regarding the efficacy and safety of percutaneous sacroplasty for SIF. More prospective comparative studies are needed with long term follow up and large sample sizes.

- In 2023, Hayes conducted another evidence review on percutaneous sacroplasty, focusing on sacral insufficiency fractures due to causes other than malignancy.[5] The updated review found minimal support from clinical studies and systematic reviews and no support from clinical guidelines. Two poor-quality studies and 1 very-poor quality study found sacroplasty to be reasonably safe and found that it may result in decreased pain and improved function from baseline. The benefit of sacroplasty compared with conservative treatment remains unclear due to poor study quality and a paucity of comparative studies with between-group statistical analyses.

- A 2018 systematic review and meta-analysis published by Zuo et al. lends additional support to percutaneous vertebral augmentation (vertebroplasty/kyphoplasty) for treatment of osteoporotic vertebral compression fractures.[6] This group of authors concluded after reviewing 18 RCTS involving 1994 subjects that percutaneous kyphoplasty was considered a first option in relieving pain in the case of "acute/subacute" compression fractures for long term and "chronic" compression fractures for both short and long term. Percutaneous vertebroplasty had the most superiority in the case of the acute/subacute compression fractures for short term. Overall, the authors concluded percutaneous vertebral augmentation had better performance compared with conservative therapy for alleviating acute/subacute and chronic pain for both the short and long term.

- In 2022, Shamhoot and colleagues performed a retrospective clinical case series study to evaluate the outcome of percutaneous vertebroplasty of more than two multi-level osteoporotic and malignant fractures.[7] This study was conducted on 30 patients. Visual analogue scale (VAS) was used to evaluate the functional outcome. All patients were treated using percutaneous vertebroplasty. They were followed for 6 months postoperatively. The functional state of all patients improved after percutaneous vertebroplasty. According to the visual analogue scale (VAS), the preoperative VAS score was (8.43 ±1.19). Immediate postoperative VAS was (3.07 ±1.20) and after six months it dropped to (1.13 ±0.67). There was noted improvement of pain ($p < 0.001$). Asymptomatic leakage in the disc space was reported in two patients. A single case of pulmonary embolism was reported who complained of dyspnea. This patient was admitted to ICU and managed with proper medications with satisfactory results. The authors concluded that multilevel PV is proved to be a safe, cost effective and successful procedure that could reduce pain and improve patient's mobility.

CLINICAL PRACTICE GUIDELINES

North American Spine Society (NASS)

The North American Spine Society (NASS) published coverage recommendations in March 2023 regarding the use of vertebral augmentation (VA) for the treatment of painful vertebral body fractures

due to osteoporosis or neoplasm. The authors stated, "Evidence supports VA for the treatment of painful vertebral body fractures in those with persistent moderate to severe pain, intolerance of analgesics, and physical limitations."[8] This coverage recommendation does not address vertebral augmentation for traumatic fractures, primary vertebral body tumors, or pedicle screw augmentation in patients with poor bone quality. NASS recommends coverage for vertebral augmentation when the following criteria are met:

- Vertebral body fracture secondary to osteoporosis, avascular necrosis or neoplasm
- Moderate to severe fracture-related pain that is not responding to conservative treatment or pain that interferes with mobilizing the patient despite the use of analgesic medications
- Activities of daily living are impaired secondary to fracture-related pain
- Index fracture is acute/active as indicated by increased signal on STIR or fat suppressed T2 MRI images, bone scan, SPECT or comparative films within the last 8 weeks; or demonstrates nonunion in the form of a fracture cleft visible on CT

As of August 2024, no clinical practice guidelines were identified on sacroplasty for treating sacral insufficiency fractures.

EVIDENCE SUMMARY

There is enough evidence to support the treatment of vertebral fractures with percutaneous vertebroplasty or kyphoplasty. Current literature shows improvement in pain levels and activities of daily life for osteoporotic compression fractures, pain due to hemangiomas, multiple myeloma, and osteolytic metastatic disease. Clinical guidelines also recommend vertebroplasty for these indications. Therefore, percutaneous vertebroplasty or kyphoplasty may be considered medically necessary for certain indications.

The available evidence investigating sacroplasty is insufficient to determine efficacy and has conflicting outcomes. A majority of the studies lack comparator groups, randomization, large sample sizes, long term follow up, and have a high risk of bias. Furthermore, no clinical guidelines were identified in support of sacroplasty for sacral insufficiency fractures or any indication. Therefore, sacroplasty is considered not medically necessary for any indication.

BILLING GUIDELINES AND CODING

CODES*		
CPT	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)
	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	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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573). Revised 1/10/2021. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56573. Accessed 7/18/2024.
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4. Frey ME, Warner C, Thomas SM, et al. Sacroplasty: A Ten-Year Analysis of Prospective Patients Treated with Percutaneous Sacroplasty: Literature Review and Technical Considerations. *Pain Physician.* 2017;20(7):E1063-e1072.
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7. Shamhoot E, Balaha A, Elkholy A. Evaluation and outcome of percutaneous vertebroplasty for multilevel osteoporotic and malignant vertebral fractures (more than two). *Interdisciplinary Neurosurgery.* 2022;28:101473.
8. NASS. NASS covereage policy recommendation. Vertebral Augmentation. 2023. https://www.spine.org/Portals/0/assets/downloads/PolicyPractice/CoverageRecommendations/Vertebral-Augmentation-DRAFT.pdf. Accessed 8/22/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
9/2023	Annual Review. No changes.
12/2024	Annual update. Updated criteria to include new medically necessary indications. Coding configuration changes.