

Back: Percutaneous Vertebroplasty and Sacroplasty

MEDICAL POLICY NUMBER: 196

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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, Providence Plan Partners, and Ayin Health Solutions 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.

**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 (i.e. vertebroplasty) may be considered **medically necessary** when criteria in the following Medicare guidance documents are met (A.-B):
 - A. Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)([L34106](#))¹; **and**
 - B. Local Coverage Article (LCA): Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)([A56573](#))²
- II. Percutaneous vertebral augmentation (i.e. vertebroplasty) is considered **not medically necessary and not covered** when criterion I. above is not met.

Percutaneous Sacral Augmentation (i.e. Sacroplasty)

- III. Percutaneous sacral augmentation (i.e. sacroplasty) is considered **not medically necessary and not covered** 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

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 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 conservative 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.

CLINICAL PRACTICE GUIDELINES

As of July 1, 2022, no clinical practice guidelines were identified on sacroplasty for treating sacral insufficiency fractures.

EVIDENCE SUMMARY

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

Percutaneous vertebral augmentation may be considered medically necessary when the criteria above are met and when billed with the medically necessary diagnosis codes included in the LCA.² These diagnosis codes are as follows:

- M80.08XA: Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
- M80.08XS: Age-related osteoporosis with current pathological fracture, vertebra(e), sequela
- M80.88XA: Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
- M80.88XS: Other osteoporosis with current pathological fracture, vertebra(e), sequela
- C41.2*: Malignant neoplasm of vertebral column
- C79.51*: Secondary malignant neoplasm of bone
- C79.52*: Secondary malignant neoplasm of bone marrow
- C90.00*: Multiple myeloma not having achieved remission
- C90.01*: Multiple myeloma in remission
- C90.02*: Multiple myeloma in relapse
- M84.58XA: Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture

- M84.58XS: Pathological fracture in neoplastic disease, other specified site, sequela

* Must be reported with either M84.58XA or M84.58XS.

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

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34106>. Published 2015. Accessed 7/1/2022.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56573>. Published 2019. Accessed 1/23/2022.
3. Hayes Inc. Percutaneous Sacroplasty For Treatment Of Sacral Insufficiency Fractures. <https://evidence.hayesinc.com/report/htb.1099percutaneous>. Published 2021. Accessed 7/1/2022.
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

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.

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