

# Medicare Medical Policy

## Percutaneous Vertebroplasty and Sacroplasty

MEDICARE MEDICAL POLICY NUMBER: 342

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**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

## PRODUCT AND BENEFIT APPLICATION

Medicare Only

### MEDICARE COVERAGE CRITERIA

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<p><i>Percutaneous Vertebral Augmentation (i.e., Vertebroplasty) (CPT 22510-22515)</i></p>	<p>For <b>osteoporotic vertebral compression fracture (VCF):</b></p> <ul style="list-style-type: none"> <li>Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (<a href="#">L34106</a>)</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>The LCD is specific to <b>osteoporotic</b> VCF. See the next rows for the use of VCF for other indications.</li> <li><b>Sacral augmentation</b> is excluded from this LCD entirely. See Company criteria below.</li> </ul> <p>For <b>malignant fractures:</b></p> <ul style="list-style-type: none"> <li>VCF for malignant fractures is considered <b>medically necessary</b> for Medicare Plan members.</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>Medicare coverage of PVA for <b>malignant</b> fractures is based on the Local Coverage Article (LCA): <u><i>Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573)</i></u>. Specifically see Group 2 diagnosis codes, which are diagnoses for malignant conditions known to cause or contribute to vertebral fractures. (See Billing Guidelines below).</li> <li>The LCA A56573 states “Exclusion for total number of levels involved will not apply for a diagnosis of multiple myeloma.” Therefore, LCD contraindications which limit the number of vertebral fractures per procedure would not apply to this indication.</li> </ul> <p>For <b>other VCFs:</b></p>

	<ul style="list-style-type: none"> <li>For <b>other non-osteoporotic</b> VCFs (e.g., fractures caused by endocrine disease, drug inducement, injury or external causes, vertebral hemangioma, etc.), see Company criteria below.</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>The above LCD states, “Provisions in this LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF). Coverage will remain available for medically necessary procedures for other conditions not included in this LCD.” Therefore, while PVA for some other conditions may be eligible for coverage, they are not within scope of this LCD, nor are coverage criteria provided to advise which specific conditions this coverage may apply to.</li> </ul>
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**Medicare Coverage Criteria:** “MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs.” (§ 422.101(b)(6) – see [Policy Guidelines](#) below)

- Medicare Coverage Manuals:** Medicare does not have criteria for percutaneous sacral augmentation (sacroplasty) in a coverage manual.
- National Coverage Determination (NCD):** There is no NCD which addresses percutaneous sacral augmentation (sacroplasty).
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** While the above LCD addresses vertebroplasty for other levels, as of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for percutaneous sacral augmentation (sacroplasty). In addition, the LCD above states, “Provisions in this LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF).” This LCD is considered “not fully established” under CFR § 422.101(6)(i)(B) as it provides explicit flexibility for coverage decisions beyond the scope of the LCD.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan’s service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policy provides flexibility for coverage decisions beyond the LCD.
- NOTE:** *The summary of evidence, as well as the list of citations/references used in the development of the Company’s internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

<p><i>Percutaneous Vertebral Augmentation (i.e., Vertebroplasty) for Indications Not Otherwise Addressed (CPT 22510-22515)</i></p> <p><i>Percutaneous Sacral Augmentation (i.e.,</i></p>	<p>Company medical policy for <a href="#">Percutaneous Vertebroplasty and Sacroplasty</a></p> <ol style="list-style-type: none"> <li>I. These services may be considered <b>medically necessary</b> for Medicare when the Company medical policy criteria are met.</li> <li>II. These services are considered <b>not medically necessary</b> for Medicare either when the Company medical policy criteria are <b>not met</b> <u>or</u> when a service is deemed “not medically</li> </ol>
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Sacroplasty) (CPT 0200T, 0201T)

necessary” by the Company policy . [See Policy Guidelines below.](#)

**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

## POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### BACKGROUND

“Osteoporosis is a prevalent disease characterized by reduced bone mass and architectural deterioration, which leads to structurally weakened bone and an increased risk of fragility fractures. A fragility fracture is defined as a fracture occurring with minimal trauma, such as falling from standing height.” Risk of fragility fractures rises with age and vertebral compression fractures (VCFs) are the most common osteoporotic fractures.<sup>1</sup> “A vertebral compression fracture occurs when too much pressure is placed on a weakened vertebra, and the front of it cracks and loses height. Vertebral compression fractures are often the result of a fall, but people with osteoporosis can suffer a fracture even when doing everyday things, such as reaching, twisting, coughing, and sneezing.”<sup>2</sup>

### MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member’s unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (*§ 422.101(c)(1)*)

In addition:

“MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or

conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.” (§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for percutaneous sacral augmentation (sacroplasty) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for percutaneous sacral augmentation (sacroplasty) will be applied.

Since the LCD is not considered “fully established coverage criteria” for PVA used for indications **other than** osteoporotic vertebral compression fractures, then Company medical policy criteria will be applied for additional indications as well.

See the [Medicare Coverage Criteria](#) table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

## REGULATORY STATUS

### U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

## BILLING GUIDELINES AND CODING

### GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- LCA: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) ([A56573](#))

### CODES\*

<b>CPT</b>	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
	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)
<b>HCPCS</b>	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 code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database

(MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)

- 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. Chou S, Grover A, LeBoff MS. New Osteoporotic/Vertebral Compression Fractures. [Updated 2022 Mar 9]. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK279035/>. Last Cited 8/19/2024.
2. American Academy of Orthopaedic Surgeons (AAOS). Osteoporosis and Spinal Fractures. Last Reviewed November 2021. Available from: <https://orthoinfo.aaos.org/en/diseases--conditions/osteoporosis-and-spinal-fractures/#:~:text=>. Last Cited 8/19/2024.

## POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
9/2023	Annual review; no criteria changes but language revision due to previous Company policy change from “investigational” to “not medically necessary”
7/2024	Interim update; no criteria change, update to configuration to align with LCA
12/2024	Annual review; update criteria to expand beyond the scope of the LCD and provide additional medically necessary indications