Medicare Medical Policy

Percutaneous Vertebroplasty and Sacroplasty

MEDICARE MEDICAL POLICY NUMBER: 342

Effective Date: 2/1/2026

Last Review Date: 1/2026

Next Annual Review: 9/2026

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
Percutaneous Vertebral Augmentation, or PVA (i.e., Vertebroplasty) (CPT 22510-22515)	PVA for ***osteoporotic*** **vertebral compression fracture (VCF):** Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34228) *(**Non-traumatic** fractures [e.g., fractures following a cough, twist, bend, etc.] that led to a VCF would use this LCD. These fractures would likely be reported with an ICD-10 code starting with an "M," as seen in the Noridian LCA A56572.)* PVA for ***malignant*** **VCFs:** PVA for malignant fractures is considered **medically necessary** for Medicare Plan members, based on the Local Coverage Article (LCA): *Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)* (A56572). Specifically, this is based on Group 2 diagnosis codes, which are diagnoses for malignant conditions known to cause or contribute to vertebral fractures. *(See Billing Guidelines below).* **NOTES:** • For ***malignant*** VCFs, the LCA 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. • For PVA for ***traumatic*** VCFs, see the Wisconsin LCD below. • LCD L34228 allows coverage for **acute** and **subacute** ***osteoporotic*** VCF. It reads, "The preponderance of evidence (studies, national and society guidelines, systematic reviews, multispecialty panel clinical care pathway, and Medicare claims data) favors consideration of **early** PVA in select patients

	(moderate to severe and disabling pain due to acute osteoporotic VCF confirmed by physical examination and advanced imaging findings)." At this time, PVA in the treatment of symptomatic older osteoporotic vertebral fractures is the subject of an ongoing clinical trial, VERTOS V (NCT01963039). According to LCAs A58534 and A58535, coverage is not allowed for **chronic** fractures due to a scarcity of evidence showing a benefit of PVA beyond the subacute timeframe. There are no blinded RCTs demonstrating a benefit in chronic VCF, but if new literature emerges to support this indication, it can be submitted to Noridian for further consideration of LCD coverage expansion. • For ***sacral*** *augmentation (sacroplasty)*, see Company criteria below.
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." • **Medicare Coverage Manuals:** Medicare does not have criteria for percutaneous vertebral augmentation (PVA), for any indication, in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for PVA for any indication. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, the Medicare Administrative Contractor (MAC) for the plan service area (Noridian J-F) has an LCD or LCA for PVA; however, the LCD is considered "not fully established," as it is specific to PVA when used for osteoporotic vertebral compression fracture (VCF), while the LCA supports coverage of PVA when used for malignant VCF. For other indications, such as PVA when used for traumatic fractures, the LCD provides no coverage guidance. • In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there are no Medicare coverage criteria available by the plan's service area MAC. ***According to a CMS FAQ dated February 6, 2024, internal coverage criteria used by an MAO may include the use of LCD criteria from a geographic area that is not the MA plan's service area, as long as all requirements of § 422.101(b)(6) are satisfied.*** • For PVA of traumatic fractures, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, **the plan is adopting published LCD criteria from the MAC, Wisconsin Physician Services (WPS). By using the coverage criteria of a Medicare contractor, rather than other sources, the criteria and evidence review are more likely to be focused on individuals generally associated with the Medicare-population.** • See **Policy Guidelines** below for more information about CMS requirements for § 422.101(b)(6).	
*PVA - **Traumatic VCF***	**Wisconsin Physicians Services (WPS) LCD:** Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (L38213) *(**Traumatic** VCF fractures [e.g., fractures following fall or motor vehicle accident] would use this LCD. These fractures would*

	likely be reported with an ICD-10 code starting with an "S," as seen in the WPS LCA A57630.) **NOTES:** See below for the Summary of Evidence and the sources (citations) used in the development of this LCD.
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 LCDs address vertebroplasty for other spinal levels, as of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for percutaneous **sacral augmentation (sacroplasty).** • 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)(C) as the available Medicare coverage policy is silent in regard to sacroplasty. • ***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)].*	
Percutaneous Sacral Augmentation (i.e., Sacroplasty) (CPT 0200T, 0201T)	Company medical policy for Percutaneous Vertebroplasty and Sacroplasty I. This service is considered **not medically necessary** for Medicare based on the Company medical 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

DEFINITIONS

VCF: vertebral compression fracture

Vertebroplasty: an image-guided treatment in which a cement, a fast-setting polymer, is injected into a pathologic vertebral body.

Percutaneous vertebroplasty (PVP): percutaneous injection of polymethyl methacrylate (PMMA) into the vertebral bodies. PMMA is a common bone cement used in spinal procedures.

Kyphoplasty or percutaneous kyphoplasty (PKP): frequently mentioned in connection with vertebroplasty, but the procedures differ in that kyphoplasty adds an extra step: insertion and inflation of a balloon before cement delivery, which also serves to restore vertebral body height and spine alignment.

Percutaneous vertebral augmentation (PVA): encompasses both PVP and PKP

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."[1] Risk of fragility fractures rises with age and vertebral compression fractures (VCFs) are the most common osteoporotic fractures.[1]

Vertebral fractures can be caused by either a high-energy impact (e.g., car accident, a sports injury, a major fall, etc.) or a low-energy trauma. Osteoporotic fractures (aka, fragility fractures or low-trauma fractures) are commonly defined as those occurring from a fall from a standing height or less, without major trauma such as a motor vehicle accident.[2] Osteporotic fractures can also be caused by everyday actions, such as reaching, twisting, coughing or sneezing.[3]

There are three main types of compression fractures:

- wedge fracture - the front of the vertebra collapses, while the back remains intact, giving the bone the appearance of a "wedge."
- crush fracture – the entire vertebral body collapses and flattens.
- burst fracture - more severe type of fracture, where the vertebral body shatters, with potential for fragments to spread towards the spinal cord.

"Treatment options for symptomatic osteoporotic VCF range from NSM (anti-osteoporosis therapy, analgesics, limited activity/bed rest, back brace, physical therapy) to PVA (PVP and PKP). PVP involves the percutaneous injection of bone cement under image guidance into the VCF. PKP adds balloon tamponade within the fractured vertebral body to create a low pressure cavity prior to cement injection. Both treatments aimed to immobilize the fracture, reduce pain, and improve alignment." *(LCD L34228)*

In patients with good bone quality, implant anchorage is easy to achieve. In contrast, osteoporotic fractures present additional and unique challenges. Therefore, differentiation between traumatic osteoporotic and non-osteoporotic vertebral fractures is crucial for optimal therapy planning.[4]

For some types of fractures, stabilization using pedicle screws is indicated, but can pose difficulties due to the need to reach a sufficient implant anchorage. The most common method to enhance pedicle screw anchorage is screw augmentation. Polymethylmethacrylate-based (PMMA) bone cement is used to increase the bone-screw interface and thus increase the stability of the entire instrumentation. Several studies showed a higher static (pull-out force) and dynamic (cycles to failure) strength, and additional clinical studies pointed out a reduced frequency in the risks of implant loosening and a significant reduction of the correction loss. However, pedicle screw augmentation is connected to relevant risks and complications (e.g., prolonged operation time with increased blood loss and risk of infection, cement leakage, cement embolism), making it imperative to identify the patients who will best benefit from this procedure.[4]

PVA may be ill-suited for fractures with significant collapse (over 65–75% height reduction), unstable fractures like those with posterior wall dehiscence or pedicle fractures, and traumatic fractures with extensive endplate fracturing. This is because some fractures may be too severe for effective treatment with PVA alone (e.g., severe vertebral collapse), while others pose an increased risk of cement leakage (e.g., unstable fractures or traumatic fractures with extensive endplate fracturing).[5] PVA systems (e.g., SpineJack by Stryker) are intended to be used in combination with validated bone cement. Therefore, contraindications for both the system and the bone cement that will be used must be considered when determining surgical candidacy.

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 Plan's Medicare 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.

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.

SUMMARY AND SOURCES OF EVIDENCE

This LCD is based on current evidence in widely used treatment guidelines or clinical literature, and it includes a systemic review of evidence-based guidelines and published literature, which were considered in the development of the LCD criteria. In addition, the summary of evidence, as well as the list of citations (bibliography list), that were used in the development of the LCD coverage criteria, are provided within the LCD, and are also publicly available. *[CFR § 422.101(b)(6)(ii)(A) and (B)]* As of the date of the most recent policy review, the summary of evidence and the sources of information used in the development of the WPS LCD L38213 are as follows:

SUMMARY OF EVIDENCE

Analysis of Evidence (Rationale for Determination)

Traumatic Compression Fractures
WPS received multiple comments primarily concerning the denial of claims when PVA is performed for conditions related to trauma and malignancy. Our data supported the findings stated by the commenters. Since WPS had previously covered PVA for these conditions, we are reinstating coverage in this revision of the LCD.

SOURCES OF EVIDENCE

Sources of Information

N/A

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Details regarding the review of this literature can be found in the LCD directly.

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:

- Noridian LCA: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56572)
- WPS LCA: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (A57630)

CODES*		
CPT	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)
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 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.

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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
10/2025	Annual review; no criteria changes (11/11/2025: Replaced L34106 with L34228 and updated companion LCA due to Noridian JF consolidation with JE LCD policies)
2/2026	Interim update; revise criteria source for traumatic vertebral compression fractures, update references