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| MEDICAL POLICY | Back: Percutaneous Vertebral Augmentation |
| Effective Date: 1/1/2022  1/1/2022 | Medical Policy Number: 196 Medical Policy Committee Approved Date: 12/17; 12/18; 8/19; 3/2020; 8/2020; 12/2020; 8/2021; 11/2021 |
| Medical Officer | Date |

See Policy CPT CODE section below for any prior authorization requirements

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”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

For all lines of business, the following Centers for Medicare & Medicaid Services (CMS) guidelines should be utilized for medical necessity coverage determinations. This CMS guidance was identified as of the last policy review date on 7/21/2021.

| Service | Medicare Guidelines |
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| <i>Percutaneous vertebral augmentation</i> | <ul style="list-style-type: none"> 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 |

Per the [Medicare Policy Manual](#), commercial evidence-based reviews may be applied to Medicare coverage determinations in the absence of an appropriate NCD, LCD, LCA, or CMS Coverage Manual. Therefore the commercial evidence-based review applies to the following services:

- Sacroplasty

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

BILLING GUIDELINES

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.

CPT CODES

| All Lines of Business | |
|---------------------------------|---|
| No Prior Authorization Required | |
| 01937 | Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic |
| 01938 | Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral |

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| 01939 | Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic |
| 01940 | Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral |
| 01941 | Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic |
| 01942 | Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral |
| 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) |
| C1062 | Intravertebral body fracture augmentation with implant (e.g., metal, polymer) |
| Not Covered | |
| 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 |

DESCRIPTION

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.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of sacroplasty as a treatment for sacral insufficiency fractures. Below is a summary of the available evidence identified through July of 2021.

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 effected 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 7/21/2021, no clinical practice guidelines were identified on sacroplasty for treating sacral insufficiency fractures.

POLICY 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.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106). Effective 1/10/2021. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34106>. Accessed 7/21/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573). Effective 1/10/2021. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56573>. Accessed 7/21/2021.
3. Hayes. Percutaneous Sacroplasty For Treatment Of Sacral Insufficiency Fractures. Published 11/12/2018. Reviewed 1/27/2021. <https://evidence.hayesinc.com/report/htb.1099percutaneous>. Accessed 7/21/2021.
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.