Percutaneous sacroplasty

Clinical Policy ID: CCP.1247

Recent review date: 7/2024

Next review date: 11/2025

Policy contains: Percutaneous sacroplasty; sacral augmentation; sacral fracture; sacral insufficiency fracture.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Percutaneous sacral augmentation (sacroplasty) is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

None.

Alternative covered services

- Physical therapy/exercise programs.
- Heat and cold modalities for home use.
- Low-impact exercise as tolerated (e.g., stationary bike, swimming, walking).
- Pharmacotherapy (e.g., nonnarcotic analgesics, nonsteroidal anti-inflammatory drugs).
- Injection therapy.
- Surgical fixation.

Background

Intractable low back pain is a frequent condition associated with significant healthcare costs and disability. Vertebral osteoporotic fractures and sacral insufficiency fractures are common causes (Urits, 2020).

Osteoporosis is common in Americans over age 50. Osteoporosis presents a strong risk factor for low-trauma

fractures from normal activity, which eventually occur in 50% of women and 20% of men. Vertebral compression fractures constitute one-quarter of osteoporotic fractures, often at the mid-thoracic (T7-T8) and thoracolumbar junction (T12-L1) (Chandra, 2018).

With sacral insufficiency fractures, the sacroiliac joint may be compromised and the sacrum weakened, resulting in a destabilized pelvis. Risk factors include osteoporosis, steroid-induced osteopenia, post-menopause, pelvic radiation, and rheumatoid arthritis. Symptoms are often nonspecific with variable radiographic findings. The incidence of sacral insufficiency fractures from 1.0% to as high as 5% has been reported. Treatment for sacral insufficiency fractures consist of physical therapy, modified bed rest, injection therapy, traditional analgesics, and, in some cases, surgical fixation (Urits, 2020).

Vertebral compression fractures may cause acute and chronic pain, leading to impaired mobility and complications such as pneumonia, loss of bone and muscle mass, incidental falls, deep venous thrombosis, depression, and isolation. Underdiagnosis and undertreatment of the condition are common. Treatments immobilize the fracture, reduce pain, and improve alignment. Nonsurgical options include anti-osteoporosis therapy, analgesics, limited activity/bed rest, back brace, and physical therapy. In some cases, percutaneous vertebroplasty (nonsurgical) or percutaneous vertebral augmentation (kyphoplasty, a minimally invasive surgery) may be performed (Hirsch, 2018).

Sacroplasty, also known as percutaneous sacral augmentation, is a minimally invasive technique to stabilize the sacral area. Percutaneous sacroplasty is a variation of the percutaneous vertebroplasty technique. It involves the injection of polymethylmethacrylate into bone using computerized tomography or fluoroscopic guidance. The goals of the procedure are to provide structural stability and alleviate symptoms, and, thereby, improve mobility and quality of life (Urits, 2020).

Polymethylmethacrylate bone cement, used in vertebral augmentation, became a class III device requiring U.S. Food and Drug Administration premarketing approval in 1976, and was changed to class II in 1999, requiring a stricter set of controls for safety and effectiveness. Polymethylmethacrylate is intended for use in arthroplasty procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone. Sacroplasty was not included, making it an off-label use for the product (U.S. Food and Drug Administration, 2018).

Findings

Guidelines

A position statement on percutaneous vertebral augmentation from eight professional medical associations did not mention percutaneous sacroplasty (Barr, 2014).

A practice parameter on vertebral augmentation issued by five professional medical organizations, headed by the American College of Radiology, did not mention percutaneous sacroplasty (American College of Radiology, 2022).

Evidence reviews

The evidence described below consists of case series and small, uncontrolled cohort studies of highly selected patients with sacral insufficiency fractures, other fractures, and malignancy. Sacroplasty using varying approaches was mostly performed under intravenous sedation or general anesthesia with the use of intraoperative fluoroscopy or computed tomography. The most commonly reported outcomes were subjective and objective measures of pain relief, and follow up ranged from one month to one year after the procedure.

The evidence suggests sacroplasty offers short-term pain relief according to visual analog scales and patient self-reports. Complications were minimal, the most common being cement extravasation, which resulted in no

clinically significant effects. Changes in oral analgesic use and early return to function were reported inconsistently and rarely documented systematically, as many studies were retrospective. Future prospective studies are needed comparing sacroplasty to conservative treatment (e.g., physical therapy and analgesics) measuring changes in mobility, analgesic use, and quality of life to inform determinations of relative effectiveness and optimal patient selection.

A systematic review/meta-analysis of 19 studies (n = 861) of sacroplasty for sacral insufficiency fractures secondary to osteoporosis (n = 664), malignancy (n = 167), and other nonspecific fractures (n = 30) included 18 case series and one cohort study. Technical and clinical success rates were 98.9% and 95.7%, with a major complication rate of 0.3%. Compared with an average visual analog scale score of 8.32 before the procedure, averages 24 to 48 hours, six months, and 12 months later were 3.55, 1.48, and 0.923 (Chandra, 2019).

A systematic review (Mahmood, 2019) included 31 prospective cohort studies, retrospective cohort studies, or case series (n = 1,155). Follow-up periods ranged from one month to one year. Mean reduction in visual analog pain scale at latest follow-up was 5.8 points. Two studies had participants with persistent pain that required reoperation. The authors concluded that sacroplasty is both safe and effective for treatment of sacral insufficiency fractures.

A review of 243 people undergoing sacroplasty studied visual analog scores before and after the procedure. The average score for those with painful sacral insufficiency fractures (n = 204) decreased from 9.2 to 1.9 ($P < .001$), indicating pain improvement. For those with sacral lesions (n = 39) the average score decreased from 9.0 to 2.6 ($P < .001$). No patient had a major complication or procedure-related death. The authors stated that the procedure was safe and effective (Kortman, 2013).

A study of 244 people who underwent sacroplasty (n = 210) or nonsurgical treatment (n = 34) found statistically significant reductions in pain levels up to two years ($P < .0001$). The surgical group was monitored for up to 10 years; improvements were upheld, and opioid and nonopioid analgesic use was reduced (Frey, 2017).

A systematic review of seven trials (n = 107) of patients with secondary metastatic lesions to the sacrum followed patients for up to 30.5 months after treatment. The mean visual analog scale score improved from 8.38 to 3.01 ($P < .001$). The most frequent complication was cement leakage (25.4%) (Tarawneh, 2020).

In 2022, we identified no new relevant information to add to the policy. No policy changes are warranted.

In 2023, we identified no new relevant information to add to the policy. No policy changes are warranted.

In 2024, we identified no new relevant information to add to the policy. No policy changes are warranted.

References

On June 3, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were ”vertebroplasty” (MeSH), “spinal fractures” (MeSH), “sacrum” (MeSH), “percutaneous sacral augmentation,” and “percutaneous sacroplasty." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2016: initial review date and clinical policy effective date: 8/2016

7/2017: Policy references updated.

7/2018: Policy references updated.

7/2019: Policy references updated. Policy number changed to CCP.1247.

4/2020: Policy references updated. Percutaneous vertebroplasty and kyphoplasty removed from coverage.

7/2021: Policy references updated. Policy changed from medically necessary to investigational.

7/2022: Policy references updated.

7/2023: Policy references updated.

7/2024: Policy references updated.