Percutaneous sacroplasty

Clinical Policy ID: CCP.1247

Recent review date: 7/2021

Next review date: 11/2022

Policy contains: Osteolytic sacral metastatic lesions, osteolytic sacral metastatic myeloma, sacral fracture, sacral augmentation.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's 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 by Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center 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

- Facet joint injection.
- Chiropractic manipulation in the first four weeks if there is no radiculopathy.
- 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).
- Trigger point injections.
- Epidural injections.
- Percutaneous vertebroplasty.
- Percutaneous kyphoplasty.

Background

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).

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 (Hirsch, 2018).

Vertebral compression fracture 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) are treatment options. Sacroplasty is not mentioned in this Medicare Local Coverage Determination (Centers for Medicare & Medicaid Services, L35130, 2019).

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 sacral insufficiency fractures for stabilization using computerized tomography or fluoroscopic guidance. It has been proposed that this procedure may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body (e.g., by sacral metastatic lesions) (Centers for Medicare & Medicaid Services, L35130, 2019).

The treatment goals of this percutaneous, minimally invasive approach are (Guarnieri, 2015):

- Pain relief to facilitate daily activity and improve quality of life.
- Stability to restore biomechanics and alleviate further stress on the spine.

Polymethylmethacrylate bone cement, used in vertebral augmentation, became a class III device requiring 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. Sacroplasty was not included, making it an off-label use for the product (Food and Drug Administration, 2002).

Findings

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, 2017).

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 – 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).

Among studies of small groups of patients, one single-center study of 53 patients documented significant decreases in pain ($P < .001$), functional mobility ($P < .001$), and analgesic scale scores ($P < .01$) after percutaneous sacroplasty. The authors reported no major complications or treatment-related morbidities (Gupta, 2014).

References

On April 1, 2021, 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 "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: Two conditions, percutaneous vertebroplasty and kyphoplasty, were removed from this policy as they are included in InterQual.

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