Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Percutaneous Sacral Augmentation

Description/Background

Approximately one percent to five percent of adults develop fractures due to bone weakness, which are known as insufficiency fractures. In some patients, these fractures occur in the sacrum, the bone in the lowest portion of the spine that connects it to the pelvis. A sacral insufficiency fracture is a type of stress fracture that resulting from normal stress on bone that has been weakened by osteoporosis.

Other causes of sacral insufficiency fractures include steroid therapy, rheumatoid arthritis and radiation treatment of the pelvis or nearby tissues. These fractures occur primarily in women. Common symptoms are groin, lower back and/or buttocks pain that is usually severe enough to prevent or limit walking. For most patients, insufficiency fractures improve substantially or resolve during conservative nonsurgical treatment.

Percutaneous sacral augmentation, also known as percutaneous sacroplasty, evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical, entails guided injection of PMMA through a needle inserted into the fracture zone. While first described in 2001 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive procedure employed as an alternative to conservative management for sacral insufficiency fractures (SIFs). SIFs are the consequence of excessive stress on weakened bone and are often the cause of low back pain among the elderly. Osteoporosis is the most common risk factor for SIF.

Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie in 1982 and presents as lower back and buttock pain with or without referred pain in the legs. Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention. Similar interventions are used for sacral and vertebral fractures including bed rest, bracing, and

analgesics. Initial clinical improvements may occur quickly; however, the resolution of all symptoms may not occur for 9 to 12 months.

Percutaneous sacral augmentation is a minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using polymethylmethacrylate (PMMA) bone cement. For the percutaneous sacral augmentation procedure, two thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from X-rays or computed tomography scans. A needle is advanced through each tube to the site of the sacral fracture and two to five ml of PMMA bone cement are injected, with care taken to avoid allowing cement onto the sacral nerves. Percutaneous sacroplasty is typically performed by a specially trained neurological surgeon or interventional radiologist on an outpatient basis with the patient under conscious sedation.

Metastatic malignant disease involving the spine may involve the sacrum, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain strength in the sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing.

Regulatory Status

The use of PMMA in sacroplasty represents an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V) as the 510(k) marketing clearance was for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included. FDA product code: NDN.

ArthroCare received FDA clearance for the Parallax® Contour® Vertebral Augmentation Device in 2010. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

Vessel-plasty using Vessel-X®, (MAXXSPINE) and a similar procedure from A-Spine, are variations of vertebroplasty that are reported to eliminate leakage of bone cement by containing the filler in an inflatable vessel. These devices do not have clearance for marketing by FDA.

Medical Policy Statement

Percutaneous sacral augmentation (sacroplasty) is experimental/investigational for all indications, including use in sacral insufficiency fractures due to osteoporosis and sacral lesions due to metastatic malignancies or multiple myeloma. It has not been scientifically demonstrated to be safe and effective.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0200T 0201T

Rationale

PERCUTANEOUS SACROPLASTY

Clinical context and Therapy Purpose
The purpose of sacroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, in patients with sacral insufficiency fractures.

The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with sacral insufficiency fractures. Sacral insufficiency fractures are a stress fracture, resulting from a regular stress applied to a bone with reduced elasticity. Often, these fractures are associated with underlying metabolic bone disease condition like osteoporosis. Examples of risk factors include corticosteroid therapy use, female sex, pelvic radiation, rheumatoid arthritis, and hyperparathyroidism.

Interventions
The therapy being considered is sacroplasty, a minimally invasive procedure for treating pathological fractures of the sacral vertebral body. The procedure involves percutaneous insertion of one or more bone needles into the sacrum and injection of bone cement under fluoroscopy and/or computed tomography visual guidance. This intervention is provided by an interventional radiologist typically in an outpatient setting.

Comparators
Comparators of interest include conservative management. Conservative management includes physical therapy, analgesics, narcotics, and hormone treatments. Examples of conservative management for sacral insufficiency fractures are varied and can include bed rest and pain medication to early physical therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, hospitalizations, medication use, and treatment-related morbidity. Possible negative outcomes include complications with sedation, cement leakage into the presacral space, spinal canal, sacral foramen, or sacroiliac joint, and possible spinal compression due to extravasation of cement. At least one year of follow-up is desirable to adequately evaluate outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Sacroplasty is an evolving technique achieved using numerous methods (short-axis, long-axis, balloon-assisted short-axis, iliosacral screws). No randomized trials of sacroplasty were identified. The largest prospective report is an observational cohort study by Frey et al (2008) consisting of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short-axis technique.[10] Patients had a mean age of 75.9 years and a mean duration of symptoms of 34.5 days (range: 4-89 days) and mean VAS score of 8.1 at baseline. Improvement on the VAS scale was measured at 30 minutes and 2, 4, 12, 24, and 52 weeks post procedure. At each interval, statistically significant improvement over baseline was observed and maintained through 52 weeks.

The largest series is a retrospective multicenter analysis by Kortman et al (2013) consisting of 204 patients with painful sacral insufficiency fractures and 39 patients with symptomatic sacral lesions treated with either the short-axis or long-axis technique.[18] One hundred and sixty-nine patients had bilateral sacral insufficiency fractures and 65 patients had additional fractures of the axial skeleton. VAS improved from 9.2 before treatment to 1.9 after treatment in patients with sacral insufficiency fractures, and from 9.0 to 2.6 in patients with sacral lesions. There was one case of radicular pain due to extravasation of cement requiring surgical decompression.

More recently, Frey et al (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs. nonsurgical management.[19] This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up ($p<0.001$). However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post [$p<0.001$]; post-treatment through 2 weeks [$p>0.001$]; 12 weeks through 24 weeks [$p=0.014$]; 24 weeks through 1 year [$p=0.002$]).

Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score—at the 2-week follow-up post-treatment (p=0.002). One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

Beall and colleagues (2023) published interim findings on patients who underwent percutaneous sacroplasty.[20] These patients were part of a prospective registry study conducted across multiple centers, which aimed to assess the effectiveness of sacroplasty in treating sacral insufficiency fractures. Pain improvement according to the numeric rating scale (NRS) showed a significant reduction from a mean of 7.8 (standard deviation [SD], 2.4) at baseline to 0.9 (SD, 2.2; p<.001) with 92% showing a clinically meaningful reduction in pain at 6 months follow-up. Rolland-Morris Disability Questionnaire (RMDQ) scores also significantly decreased from baseline levels from a mean of 17.7 (SD 6.4) to 5.2 (SD, 5.2; p<.001) at 6 months follow-up, with 84% achieving a clinically meaningful reduction. One patient had a new neurologic deficit due to cement extravasation, but no other adverse events were reported. A major limitation of this study is an imbalance in baseline characteristic and at the time of publication only 48% of patients have 6 month follow-up data.

Sarigul et al (2023) retrospectively described a single-center's experience with treating sacral insufficiency fractures with sacroplasty (n=83) or conservative treatment (n=102).[21] Participants had a mean age of 69.2 years and required 5 years of follow-up to be included in the study (mean follow-up time was 7.2 years). At baseline, both VAS (8.82 vs. 4.18) and Oswestry Disability Index (ODI) (68.6 vs. 51.8) were significantly higher in the sacroplasty group than those conservatively treated. By 1 year follow-up, mean VAS scores had significantly decreased in the sarcoplasty group to 1.5 and was favored over conservative treatment, which had a reduction to 2.82 (p<.001); a similar trend was observed for ODI, which showed a decrease to 8.4 in the sarcoplasty group compared to 21.2 in the conservative treatment group (p<.001). Cement leaks were identified in 2 patients, but no postoperative radiculopathy or pulmonary embolism were reported. Despite requiring 5-year data for all participants, only one-year outcomes were reported by the authors.

There are several retrospective reviews with about 50 patients each. One of these, Dougherty et al (2014), described a series of 57 patients treated with sacroplasty for sacral insufficiency fractures.[8] The short- or long-axis approach was dictated by the length and type of the fracture and patient anatomy. Follow-up data at 2.5 weeks was available for 45 patients (79%), and the outcome measures were inconsistent. For example, activity pain scores were collected from 13 patients, and rest pain scores were collected from 29 patients. Of the 45 patients with outcome data, 37 (82%) were reported to have experienced either a numerical or descriptive decrease from initial pain of at least 30%.

Additional literature reports are mostly consistent, reporting immediate improvement following the procedure. Due to the small size of the evidence base, harms associated with sacroplasty have not been adequately studied. There are complications of cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of polymethylmethacrylate (PMMA) into the presacral space, spinal canal, sacral foramen, or sacroiliac joint may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction. Performing sacroplasty only on Zone 1 fractures can minimize these risks.[7]

A prospective, uncontrolled study by Frey et al was reported in 2007 and consisted of a prospective observational cohort study of 37 consecutive osteoporotic patients with sacral insufficiency fractures.[11] The patients received sacroplasty after there was no significant improvement in their symptoms with conservative care for a mean of 34.4 days (range 13-82 days). The introduction of PMMA cement across the sacral fracture site may have provided mechanical stabilization, preventing micromotion.

Frey stated that he would like to see controlled trials to compare sacroplasty to a sham procedure. It is conceivable, he said, that sacroplasty is no better than placebo. In his study, none of the patients who declined sacroplasty was pain free at 12 weeks, though at six months and one year their pain had subsided to a level comparable to that of patients who received sacroplasty. The limitations of this study include its small size, limited duration of follow-up and lack of control group.[10]

In two small-uncontrolled studies, Strub et al (2007) and Jayaraman et al (2009) evaluated percutaneous sacroplasty for SIFs in 26 patients. These studies did not indicate whether patients underwent a trial of conservative therapy before sacroplasty. Jayaraman reported that all 13 patients had pain relief but did not provide any details concerning the extent of relief. Strub et al surveyed 11 patients an average of 12 days after treatment and reported that pain relief was moderate or complete in seven (64 percent) patients, slight in two (18 percent) patients, and absent or uncertain in two (18 percent) patients. At 15 months follow-up of six patients, five (83 percent) reported complete pain relief and one (16 percent) had persistent pain on a single side.[15,26]

The largest experience is a prospective observational cohort study of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short axis technique.[23] Patients had a mean age of 75.9 years and a mean duration of symptoms of 34.5 days (range: 4-89 days) and mean VAS score of 8.1 at baseline. Improvement on the VAS scale was measured at 30 minutes and 2, 4, 12, 24, and 52 weeks post procedure. At each interval, statistically significant improvement over baseline was observed and maintained through 52 weeks. Additional literature reports are mostly consistent reporting immediate improvement following the procedure. Due to the small size of the evidence base, harms associated with sacroplasty have not been adequately studied.

Adverse Events

There are complications of cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of PMMA into the presacral space, spinal canal, sacral foramen or sacroiliac joint may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction.[28,29]

Further controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures. The treatment of sacral insufficiency fractures by sacroplasty remains an evolving field.

SUMMARY OF EVIDENCE

No RCTs evaluating percutaneous sacroplasty for sacral insufficiency were identified. The available evidence includes 2 prospective cohort studies and several retrospective series. These studies have reported rapid and sustained decreases in pain following percutaneous

sacroplasty. Additional reports are mostly consistent in reporting immediate improvement following the procedure. Due to the limited number of patients and the retrospective nature of the evidence base, harms associated with sacroplasty have not been adequately studied. The small numbers of treated patients leave uncertainty regarding the impact of sacroplasty on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
There are no current practice guidelines or position statements for sacral augmentation.

Ongoing and Unpublished Clinical Trials
No ongoing trials were identified that might influence this policy.

Government Regulations
National / Local:

There is no national determination for percutaneous sacral augmentation (sacroplasty).

Local Coverage Determination L35490. Category III CPT Codes. Effective on or after 03/28/2024.
Codes 0200T and 0201T are listed under the Group I Category III CPT codes that are considered not medically necessary.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Percutaneous Vertebroplasty and Kyphoplasty (Retired)
- Sacroiliac Joint Fusion for the Treatment of Low Back Pain

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/10	10/29/09	10/13/09	Joint policy established
9/1/10	6/15/10	6/15/10	Codes added to policy, 72291 and 72292, considered to be experimental/investigational for the diagnosis 805.6, fracture of vertebral column without mention of spinal cord injury, sacrum and coccyx, closed.
9/1/12	6/12/12	6/19/12	Routine maintenance; updated references; policy reformatted on new template. No change in policy status
9/1/14	6/20/14	6/23/14	Updated references, no change in policy status.
1/1/16	10/13/15	10/27/15	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine policy maintenance. Deleted codes 72291 & 72292
1/1/18	10/19/17	10/19/17	Routine policy maintenance, no change in policy status.
1/1/19	10/16/18	10/16/18	Routine policy maintenance. No change in policy status.
1/1/20	10/15/19		Routine policy maintenance, no change in policy status.
1/1/21	10/20/20		Routine policy maintenance, no change in policy status.
1/1/22	10/19/21		Routine policy maintenance. MPS “spinal” changed to “sacral”. No change in policy status.
1/1/23	10/18/22		Routine policy maintenance, no change in policy status.
1/1/24	10/17/23		Routine policy maintenance, no changes in policy status. Vendor managed: N/A (ds)
1/1/25	10/15/24		Updated rationale, added references 20 & 21. No change in status. Vendor managed: N/A (ds)

Next Review Date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PERCUTANEOUS SACRAL AUGMENTATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	0200T and 0201T are not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.