### Policy Statement

Percutaneous vertebroplasty may be considered **medically necessary** for the treatment of any of the following indications:

- Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks.
- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.
- Vertebral eosinophilic granuloma with spinal instability
- Vertebral hemangiomas with both of the following:
  - Aggressive signs (e.g., myelopathy, radiculopathy, bone fracture, collapse or destruction)
  - Radiation therapy has failed to relieve symptoms

Percutaneous vertebroplasty may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation.

Percutaneous vertebroplasty is considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous sacroplasty is considered **investigational** for all indications, including use in either of the following:

- Sacral insufficiency fractures due to osteoporosis
- Sacral lesions due to metastatic malignancies or multiple myeloma

### Policy Guidelines

#### Coding

There are CPT codes that describe vertebroplasty:

- **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)

The following are CPT category III codes specific for sacroplasty:

- **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

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a weakened vertebral body. The technique
has been investigated to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fractures or in those with osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies). Percutaneous vertebroplasty has also been investigated as a technique to limit blood loss related to surgery. Injection of PMMA is also being investigated as a treatment for sacral insufficiency fractures.

### Related Policies

- Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

### Regulatory Status

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval.

Polymethylmethacrylate (PMMA) bone cement was available as a drug product before enactment of the FDA’s device regulation and was at first considered what the FDA terms a “transitional device.” It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet “special controls” instead of “general controls” to assure safety and effectiveness. Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were cleared for marketing by the FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

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

In May 2009, Cortoss® Bone Augmentation Material was cleared for marketing by the FDA through the 510(k) process. Cortoss® is a nonresorbable synthetic material that is a composite resin-based, bis-glycidal dimethacrylate. The FDA classifies this product as a PMMA bone cement.

In February 2010, the Parallax® Contour® Vertebral Augmentation Device (ArthroCare) was cleared for marketing by the FDA through the 510(k) process. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.
Rationale

Background
Osteoporotic Fracture

Vertebral Compression Fracture
Osteoporotic compression fractures are common. It is estimated that up to one-half of women and approximately one-quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with ability to ambulate and is not responsive to usual medical management. In addition, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently does not improve with analgesics and may be better addressed through exercise. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Sacral Insufficiency Fractures
Sacral insufficiency fractures (SIFs) are the consequence of stress on weakened bone and often cause low back pain in the elderly population. 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 and include bedrest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.

Vertebral and Sacral Body Metastasis
Metastatic malignant disease of the spine generally involves the vertebrae/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 vertebrae/sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Improvements in pain and function are the primary outcomes of interest for treatment of bone malignancy with percutaneous vertebroplasty or sacroplasty.

Treatment
Percutaneous Vertebroplasty
It has been proposed that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers.

Percutaneous Sacroplasty
Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical to vertebroplasty, entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive alternative to conservative management for SIFs.
Pain and function are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may vary. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of vertebroplasty and sacroplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with alternatives such as continued medical management.

In all clinical situations, adverse effects related to complications from vertebroplasty and sacroplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA. Use of a bis-glycidal dimethacrylate (Bis-GMA) composite material (Cortoss) for vertebroplasty has also been reported.9

**Literature Review**

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition. Following is a summary of key studies to date.

**Percutaneous Vertebroplasty for Vertebral Compression Fractures of Between 6 Weeks and 1 Year Old**

This evidence review was originally informed by a 2000 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment, which was updated periodically through 2010.10-15 Subsequent evidence includes a number of RCTs, 2 of which included a sham control, and numerous RCTs that compared vertebroplasty with conservative management.

**Systematic Reviews**

A 2015 Cochrane review by Buchbinder et al evaluated the evidence on vertebroplasty for the treatment of vertebral compression fractures.16 Eleven RCTs and 1 quasi-RCT were included in the systematic review. Two trials identified compared vertebroplasty with a sham procedure (n=209 patients; Buchbinder et al [2009]17 and Kallmes et al [2009], 18 detailed below), 6 compared vertebroplasty with usual care (n=566), and 4 compared vertebroplasty with kyphoplasty (n=545). The sham-controlled trials were considered to be at low risk of bias. All other trials were judged at high risk of bias due to lack of blinding. Evidence was rated as moderate quality based on the low number of subjects in the sham-controlled trials. Meta-analysis of the 2 sham-controlled trials indicated that vertebroplasty does not result in clinically significant improvements in pain, disability, quality of life, or treatment success. Results did not differ for patients with pain durations of 6 weeks or less compared to pain lasting more than 6 weeks. Sensitivity analysis indicated that studies comparing vertebroplasty to conservative management were likely to have overestimated the treatment effect. The rate of serious adverse events did not differ significantly between the vertebroplasty and control groups, but serious adverse events related specifically to the vertebroplasty procedure included osteomyelitis, cord compression, thecal sac injury, and respiratory failure.

Staples et al (2011) conducted a patient-level meta-analysis of the 2 sham-controlled trials (described below) to determine whether vertebroplasty is more effective than sham in specific subsets of patients.19 This subset analysis focused on duration of pain (≤6 weeks vs >6 weeks) and severity of pain (score <8 or ≥8 on an 11-point numeric rating scale [NRS]). Included in the analysis were 209 participants (78 from the Australian trial, 131 from the U.S. trial); 27% had pain of recent onset and 47% had severe pain at baseline. The primary outcome measures (pain scores and function on the Roland-Morris Disability Questionnaire [RMDQ] at 1 month) did not differ significantly between groups. Responders’ analyses were also conducted based on a 3-unit improvement in pain scores, a 3-unit improvement on RMDQ scores, and a 30%
improvement in each of the pain and disability outcomes. The only difference observed between groups was a trend for a higher proportion of the vertebroplasty group to achieve at least 30% improvement in pain scores (relative risk, 1.32; 95% CI, 0.98 to 1.76; p = 0.07), a result that may have been confounded by the greater use of opioid medications in that group.

**Randomized Controlled Trials**

**Vertebroplasty vs Medical Management with Sham Controls**

Two sham-controlled trials were published in 2009 and were included in the systematic reviews described above. The 2 RCTs compared vertebroplasty to medical management using a sham control (that included local anesthetic), which mimicked the vertebroplasty procedure up to the point of cement injection. Buchbinder et al reported results of a 4-center, randomized, double-blind, sham-controlled trial with 78 patients with 1 or 2 painful osteoporotic vertebral fractures with a duration of less than 1 year. Patients were assigned to vertebroplasty or to sham procedure (i.e., injection of local anesthetic into the facet capsule and/or periosteum). Ninety-one percent of participants completed 6 months of follow-up. The participants, investigators (other than the radiologists performing the procedure), and outcome assessors were blinded to the treatment assignment. Blinding was maintained through 24-month follow-up of this trial.

The primary outcome was overall pain (over the course of the previous week) measured on a visual analog scale (VAS) from 0 to 10, with 1.5 representing the minimal clinically important difference. A sample size of 24 per group was calculated to provide sufficient power to show a 2.5-point postprocedure difference assuming a 3-point standard deviation. All analyses were performed using intention-to-treat (ITT) principles. For the primary outcome of overall pain, reviewers reported no significant differences in VAS pain score at 3, 12, or 24 months. With reductions in pain and improvements in quality of life observed in both groups, the authors concluded vertebroplasty provided no benefit.

Kallmes et al conducted a multicenter, randomized, double-blind, sham-controlled trial (INVEST) in which 131 participants with 1 to 3 painful osteoporotic vertebral fractures were assigned to vertebroplasty or to sham procedure (injection of local anesthetic into the facet capsule and/or periosteum). Participants had back pain for no more than 12 months and had a current pain rating of at least 3 on VAS at baseline. Participants were evaluated at baseline, and at various time points to 1 year postprocedure. Ninety-seven percent completed a 1-month follow-up, and 95% completed 3 months. The primary outcomes were scores on the RMDQ and average back pain intensity during the preceding 24 hours at 1 month, with a reduction of 30% in RMDQ and VAS pain scores considered a clinically meaningful difference. The trial initially had 80% power to detect differences in both primary and secondary outcomes with 250 patients, with a 2-sided \( \alpha \) of 0.05 on the basis of a 2.5-unit advantage for vertebroplasty over placebo on the RMDQ and 1.0-point difference on the VAS. After recruitment difficulty and interim analysis on the first 90 participants, target sample size was decreased to 130 participants with 80% power for primary aims maintained. All primary analyses were performed using ITT principles and results presented as mean scores for the RMDQ and pain intensity.

For the primary end points at 1 month, there were no significant between-group differences. There was a trend toward a higher clinically meaningful improvement in pain at 1 month (30% reduction from baseline) in the vertebroplasty group (64% vs 48%, respectively; \( p = 0.06 \)). At 3 months, 51% from the control group and 13% in the vertebroplasty group crossed over (\( p < 0.001 \)). The crossovers did not affect study outcomes, because they occurred after the primary outcome assessment. By 1 year, 16% of patients who underwent vertebroplasty and 60% of control subjects had crossed over to the alternative procedure (\( p < 0.001 \)). As-treated analysis found no significant difference in RMDQ or pain scores between the 2 groups. ITT analysis found a modest 1-point difference in pain rating, but no significant difference in RMDQ score. There was a significant difference in the percentage of patients showing a 30% or greater improvement in pain (70% of patients randomized to vertebroplasty vs 45% of patients randomized to the control group).
Vertebroplasty vs Medical Management without Sham Controls
Chen et al reported on a nonblinded RCT comparing vertebroplasty with conservative management in 2014. The trial included 89 patients with chronic compression fractures confirmed by magnetic resonance imaging (MRI) and persistent severe pain for 3 months or longer. Evaluation was performed at 1 week and at 1, 3, 6, and 12 months. Over the course of 1 year, pain scores decreased from 6.5 to 2.5 in the vertebroplasty group and from 6.4 to 4.1 in the control group (p<0.001). Complete pain relief was reported by 84.8% of patients in the vertebroplasty group compared with 34.9% of controls. The final Oswestry Disability Index (ODI) score was 15.0 in the vertebroplasty group and 32.1 in the conservative management group (p<0.001), and the final RMDQ score was 8.1 for vertebroplasty and 10.7 for controls (p<0.001).

In 2011, Farrokhi et al reported blinded RCT that compared vertebroplasty with optimal medical management in 82 patients. Patients had painful osteoporotic vertebral compression fractures that were refractory to analgesic therapy for at least 4 weeks and less than 1 year. The patients and the physicians involved in the treatment were not aware of the treatment that the other group was receiving. Control of pain and improvement in quality of life were measured by independent raters before treatment and at 1 week and 2, 6, 12, 24, and 36 months after treatment began. Radiologic evaluation to measure vertebral body height and correction of deformity was performed before and after treatment and after 36 months of follow-up. At 1 week, the mean VAS score decreased from 8.4 to 3.3 in the vertebroplasty group and from 7.2 to 6.4 in the conservative management group, with between-group differences that remained significant through 6 months of follow-up. Group differences on the ODI lower back pain score were significantly lower in the vertebroplasty group throughout the 36 months of the study. New symptomatic adjacent fractures developed in 1 (2.6%) patient in the vertebroplasty group and 6 (15.4%) patients in the conservative management group. In 1 patient, epidural cement leakage caused severe lower-extremity pain and weakness that was treated with bilateral laminectomy and evacuation of bone cement.

Nonrandomized Comparative Studies
In 2011 and 2015, Edidin et al reported mortality risk rates in Medicare patients who had vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty or nonoperatively. These studies were industry-funded. In the 2015 report, they identified 1,038,956 patients who had vertebral compression fractures between 2005 and 2009. The data set included 141,343 kyphoplasty patients and 75,364 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to 4 years). Propensity matching was used to control for multiple covariates, which included age, sex, race, census region, socioeconomic status, comorbidities in 12 months prior to diagnosis, type of fracture, and year of fracture. The matched cohort included 100,649 nonoperated patients, 36,657 kyphoplasty patients, and 24,313 vertebroplasty patients. Analysis of the whole data set before matching indicated that patients in the nonoperated cohort had a 55% (95% CI, 53% to 56% p<0.001) higher risk of mortality than the kyphoplasty cohort and a 25% (95% CI, 23% to 26% p<0.001) higher mortality risk than the vertebroplasty cohort. After propensity matching, the risk of mortality at 4 years was 47.2% in the nonoperated group compared to 42.3% in the kyphoplasty group (p<0.001) and 46.2% in the vertebroplasty group (p<0.001).

Section Summary: Percutaneous Vertebroplasty for Vertebral Compression Fractures of Between 6 Weeks and 1 Year Old
Despite evidence from numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures of less than 1 year remains uncertain. A 2016 meta-analysis, which included the 2 randomized, sham-controlled trials from 2009, concluded that vertebroplasty showed no significant benefit above sham for painful osteoporotic fractures. However, some uncertainty remains around the interpretation of these conclusions. While the use of a sham procedure is a major methodologic strength to control for nonspecific (placebo) effects, the sham used in the trial was not without controversy, given that the effect of injecting local anesthetic in the facet capsule and/or periosteum is unknown. Also, the appropriateness of outcome measures used to detect clinically meaningful differences in
pain may not have been optimal, as the studies were underpowered to detect differences in clinical response rates. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate (PMMA) injected, and the inclusion of patients with chronic pain.

Percutaneous Vertebroplasty for Vertebral Compression Fractures of less than 6 Weeks Old Randomized Controlled Trials

Vertebroplasty vs Medical Management with Sham Controls

In 2016, Clark et al reported on results from the VAPOUR trial (see Table 1).27 VAPOUR was a multicenter double-blind trial of vertebroplasty in 120 patients with vertebral fractures of less than 6 weeks in duration and back pain of at least 7 out of 10 on an NRS. Two authors had participated in the 2009 study published by Kallmes et al and the trial followed a similar protocol. Both outcomes assessors and patients were masked to treatment allocation, and independent statisticians unmasked the data and prepared the trial report. The sham-vertebroplasty procedure included subcutaneous lidocaine but no periosteal numbing. Manual skin pressure and tapping on the needle was performed to simulate the needle advance, and the investigators discussed PMMA mixing and injection during the procedure. The primary outcome (the percentage of patients with an NRS score <4 out of 10 at 14 days postprocedure) was met in a greater percentage of patients in the vertebroplasty group (44%) than in the sham control group (21%). This between-group difference was maintained through 6 months.

Table 1. Results From the Sham-Controlled Trial of Vertebroplasty by Clark et al (2016)27

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Vertebroplasty</th>
<th>Sham</th>
<th>Difference (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n (%) or Mean (SD)</td>
<td>N</td>
<td>n (%) or Mean (SD)</td>
</tr>
<tr>
<td>Proportion of patients with NRS score &lt;4</td>
<td>14 days</td>
<td>55</td>
<td>24 (44%)</td>
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<td></td>
<td>6 months</td>
<td>51</td>
<td>35 (69%)</td>
<td>51</td>
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<td>Reduction in NRS pain score</td>
<td>14 days</td>
<td>55</td>
<td>4.2 (2.7)</td>
<td>57</td>
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<tr>
<td></td>
<td>6 months</td>
<td>51</td>
<td>6.1 (3.3)</td>
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<td>Reduction in RMDQ scores</td>
<td>14 days</td>
<td>53</td>
<td>5.9 (5.8)</td>
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<td></td>
<td>6 months</td>
<td>49</td>
<td>11.7 (6.5)</td>
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<tr>
<td>VAS pain score (patient-reported)</td>
<td>14 days</td>
<td>41</td>
<td>39 (28)</td>
<td>47</td>
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<tr>
<td></td>
<td>6 months</td>
<td>42</td>
<td>23 (26)</td>
<td>46</td>
</tr>
<tr>
<td>VAS pain score (physician-observed)</td>
<td>14 days</td>
<td>41</td>
<td>25 (23)</td>
<td>48</td>
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<td></td>
<td>6 months</td>
<td>39</td>
<td>14 (21)</td>
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<tr>
<td>QUALEFFO score</td>
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<td>49 (13)</td>
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<tr>
<td></td>
<td>6 months</td>
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<tr>
<td></td>
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<td>56</td>
<td>49 (88%)</td>
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<tr>
<td></td>
<td>6 months</td>
<td>50</td>
<td>29 (58%)</td>
<td>51</td>
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</table>

CI: confidence interval; EQ-5D: EuroQol 5 dimensions questionnaire; NRS: Numeric Rating Scale Pain; RMDQ: Roland-Morris Disability Questionnaire; QUALEFFO: Quality Of Life Questionnaire of the European Foundation for Osteoporosis; VAS: Visual Analog Scale.

<sup>a</sup> Primary end point.

<sup>b</sup> Proportion of patients using analgesic medication within the previous 24 hours.
Other outcome measures were significantly improved in the vertebroplasty group at 1 or both of the time points (see Table 1). The benefit of vertebroplasty was found predominantly in the thoracolumbar subgroup, with 48% (95% CI, 27% to 68%) more patients meeting the primary end point (61% in the vertebroplasty group vs 13% in the control group). The investigators commented that the thoracolumbar junction is subject to increased dynamic load, and fractures at this junction have the highest incidence of mobility. No benefit from vertebroplasty was found in the nonthoracolumbar subgroup. Postprocedural hospital stay was reduced from a mean of 14 days in the control group to 8.5 days after vertebroplasty, even though physicians who determined the discharge date remained blinded to treatment. In the vertebroplasty group, there were 2 serious adverse events due to sedation and transfer to the radiology table. In the control group, 2 patients developed spinal cord compression; 1 underwent decompressive surgery and the other, not a surgical candidate, became paraplegic.

Vertebroplasty vs Medical Management without Sham Controls

Klazen et al (2010) reported on VERTOS II, an open-label randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium. Of 431 patients eligible for randomization, 229 (53%) had spontaneous pain relief during assessment. Participants with at least 1 painful osteoporotic vertebral fracture of 6 weeks or less in duration were assigned to vertebroplasty or conservative management (i.e., bedrest, analgesia, cast, physical support). The primary outcome was pain relief of 3 points measured on a 10-point VAS at 1 month and 1 year. A sample size of 100 per group was calculated to provide sufficient power to show a 25% difference in pain relief. All analyses were performed using ITT principles. Clinically significant pain relief was defined as a 30% change in VAS score (0-10 scale).

One hundred one subjects were enrolled into the treatment group and 101 into the control arm; 81% completed 12-month follow-up. There were no significant differences in the primary outcome (pain relief of 3 points) measured at 1 month and 1 year. Vertebroplasty resulted in greater pain relief than did medical management through 12 months (<0.001); there were significant between-group differences in mean VAS scores at 1 month (2.6; 1.74 to 3.37; p<0.001) and at 1 year (2.0; 1.13 to 2.80; p<0.001). Survival analysis showed significant pain relief was quicker (29.7 days vs 115.6 days) and was achieved by more patients after vertebroplasty than after conservative management.

Yi et al (2014) assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae). Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, body brace, physical therapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at 1 week for 87.6% of operatively treated patients and at 2 months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and MRI at 6 months and then at yearly intervals until the last follow-up session. At a mean follow-up of 49.4 months (range, 36-80 months), 10.7% of patients had experienced 42 new symptomatic vertebral compression fractures. There was no significant difference in the incidence of new vertebral fractures between the operative (18 total; 9 adjacent, 9 nonadjacent) and conservative (24 total; 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the operative group (9.7 months) than in the nonoperative group (22.4 months).

Leali et al (2016) published a short report on a multicenter RCT enrolling 400 patients with osteoporotic thoracic or lumbar vertebral compression fractures who were treated with vertebroplasty or conservative therapy. Fractures were treated within 2 weeks of pain onset. Details of randomization and rates of follow-up were not reported. At 1 day after treatment, the vertebroplasty group had a reduction in pain scores and improvement in physical function, with VAS pain scores decreasing from 4.8 (maximum, 5.0) to 2.3 (p=0.023) and ODI score improving from 53.6% to 31.7% (p=0.012). Sixty-five percent of patients treated with vertebroplasty had stopped all analgesic use within 48 hours. The conservatively group showed no benefit in the first
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48 hours, but by 6 weeks VAS and ODI scores were described as similar in both groups (specific data not reported). Evaluation of this trial was limited by incomplete reporting.

Yang et al (2016) compared vertebroplasty to conservative therapy in 135 patients over 70 years of age with severe back pain due to an osteoporotic vertebral fracture after minor or mild trauma.31 Vertebroplasty was performed at a mean of 8.4 days after pain onset. Patients in the conservative therapy group were placed on bedrest and analgesics for at least 2 weeks after diagnosis, followed by bracing and assistive devices. All patients receiving vertebroplasty could stand and walk with a brace at 1 day posttreatment while only 12 (23.5%) patients could stand up and walk after 2 weeks of bedrest. The average duration of bedrest from pain onset was 7.8 (SD=4.7) days (range, 2-15 days) in the vertebroplasty group compared to 32.5 (SD=14.3) days (range, 14-60 days) in the conservative therapy group. At 1-year follow-up, there was a similar percentage of additional compression fractures, but a significantly higher complication rate in the conservative therapy group (35.3%) than in the vertebroplasty group (16.1%; p<0.001). Complications included pneumonia, urinary tract infection, deep vein thrombosis, depression, and sleep disorders.

Section Summary: Percutaneous Vertebroplasty for Vertebral Compression Fractures of less than 6 Weeks Old
In a sham-controlled randomized trial, where no anesthetic was injected into the periosteum, there was a significant benefit of vertebroplasty in patients who had severe pain of less than 6 weeks in duration following vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain, earlier improvements in function, and reductions in the duration of bedrest compared to conservatively managed patients.

Percutaneous Sacroplasty
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 (2008) is an observational cohort study of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short-axis technique.32 Patients had a mean age of 75.9 years, a mean duration of symptoms of 34.5 days (range, 4-89 days), and a mean VAS score of 8.1 at baseline. Improvements in VAS scores were measured at 30 minutes and 2, 4, 12, 24, and 52 weeks postprocedure. At each interval, statistically significant improvements over baseline were observed and maintained through 52 weeks.

The largest series identified is a 2013 retrospective multicenter analysis of 204 patients with painful sacral insufficiency fractures and 39 patients with symptomatic sacral lesions treated with the short-axis or long-axis technique.33 One hundred sixty-nine patients had bilateral sacral insufficiency fractures and 65 patients had additional fractures of the axial skeleton. VAS scores 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 1 case of radicular pain due to extravasation of cement requiring surgical decompression.

There are several retrospective reviews with about 50 patients each. One from 2014 has described a series of 57 patients treated with sacroplasty for sacral insufficiency fractures.34 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 were available for 45 (79%) patients, 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 outcomes data, 37 (82%) had experienced a numeric or descriptive decrease from initial pain of at least 30%.

There are complications related to 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.\textsuperscript{35} Performing sacroplasty only on zone 1 fractures can minimize these risks.\textsuperscript{36}

**Section Summary: Percutaneous Sacroplasty**

No RCTs on percutaneous sacroplasty for sacral insufficiency were identified. The available evidence includes 1 prospective cohort study with 52 patients and a retrospective series with 243 patients. 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 small size 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.

**Summary of Evidence**

For individuals who have symptomatic osteoporotic vertebral fractures of between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes 2 randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and systematic reviews of these RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. A 2016 meta-analysis, which included the 2 sham-controlled trials, found that vertebroplasty showed no significant benefit above sham for painful osteoporotic fractures, although alternative interpretations are possible. These studies have some methodologic issues, including the choice of sham procedure and the potential effect of the sham procedure having a therapeutic effect by reducing pain. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of patients with chronic pain. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and other nonblinded RCTs comparing vertebroplasty with conservative management. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option, and symptoms will resolve in a large percentage of patients with conservative treatment only. However, a sham-controlled randomized trial in patients who had severe pain of less than 6 weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain and reductions in the duration of bedrest. Given the high morbidity associated with extended bedrest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes a prospective cohort study and a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. No RCTs have been reported. The available evidence includes a prospective cohort study and a retrospective series with 243 patients. These studies have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional literature has mostly reported immediate improvements following the procedure. However, due to the small size of the evidence base, the harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine the effects of the technology on health outcomes.
Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests from Blue Cross Blue Shield Association, input was received from 2 physician specialty societies and 3 academic medical centers in 2014. Focused input was sought on the treatment of acute vertebral fractures when there is severe pain that has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after 6 weeks of conservative treatment. Clinical input on these issues was mixed.

2008 Input

In response to requests from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies and 2 academic medical centers in 2008. Unsolicited input was received from a sixth physician specialty society. All reviewers disagreed with the proposed policy and provided references in support of the use of vertebroplasty.

Practice Guidelines and Position Statements

American College of Radiology et al

In 2012, joint practice guidelines on the performance of vertebral augmentation were published by the American College of Radiology (ACR), the American Society of Neuroradiology (ASN), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of Neurointerventional Surgery (SNIS). Methods to achieve internal vertebral body stabilization included vertebroplasty, balloon kyphoplasty, radiofrequency ablation and coblation, mechanical void creation, and injection of bone graft material or bone substitutes. ACR, ASN, ASSR, SIR, and SNIS considered vertebral augmentation to be an established and safe procedure and provided guidelines for appropriate patient selection, qualifications and responsibilities of personnel, specifications of the procedure, equipment quality control, and quality improvement and documentation. These guidelines addressed vertebral augmentation in general and referred to all percutaneous techniques used.

These 5 societies also published a joint position statement on percutaneous vertebral augmentation in 2014. The statement indicated that percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in accordance with public standards. The document also stated that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering patients’ quality of life.

In a 2014 quality improvement guideline from SIR, failure of medical therapy was defined as follows:

1. “For a patient rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;
2. For a patient with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or
3. For any patient with a weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.”
American Academy of Orthopaedic Surgeons
In 2010, the American Academy of Orthopaedic Surgeons (AAOS) approved practice guidelines on the treatment of osteoporotic spinal compression fractures. AAOS approved a strong recommendation against the use of vertebroplasty for patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.” With this recommendation, AAOS expressed its confidence that future evidence is unlikely to overturn the existing evidence. As a note, these recommendations were based on a literature review through September 2009; therefore, the 2010 Klazen trial was not included in the systematic review.

National Institute for Health and Care Excellence
The U.K.’s National Institute for Health and Care Excellence (NICE) concluded in its 2003 guidance on percutaneous vertebroplasty that the current evidence on the safety and efficacy of vertebroplasty for vertebral compression fractures appeared “adequate to support the use of this procedure” to “provide pain relief for people with severe painful osteoporosis with loss of height and/or compression fractures of the vertebral body....” The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A 2013 NICE guidance indicated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty “are recommended as options for treating osteoporotic vertebral compression fractures” in persons having “severe, ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management” and whose “pain has been confirmed to be at the level of the fracture by physical examination and imaging.”

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. This guidance indicated that vertebroplasty or kyphoplasty should be considered for “patients who have vertebral metastases and no evidence of MSCC [metastatic spinal cord compression] or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
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<tr>
<td>NCT02370628</td>
<td>Vertebroplasty in the treatment of acute fracture trial (The VITTA Trial)</td>
<td>495</td>
<td>Apr 2018</td>
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</tbody>
</table>

NCT: National Clinical Trial.

References


13. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008;Volume 23:Tab 5.


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):
- History and physical and/or consultation notes including:
  - Reason for procedure
  - Description of prior treatment and response (including time frame of treatment)
  - Imaging report(s)

**Post Service**
- Procedure report

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>0200T</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>0201T</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
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### Type Code Description

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<tr>
<th>Type</th>
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<th>Description</th>
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<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
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<tr>
<td>22512</td>
<td>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)</td>
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### HCPCS

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### ICD-10 Procedure

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<tr>
<td>0PU33JZ</td>
<td>Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0PU34JZ</td>
<td>Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0PU43JZ</td>
<td>Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0PU44JZ</td>
<td>Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<tr>
<td>0QU03JZ</td>
<td>Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0QU04JZ</td>
<td>Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<tr>
<td>0QU13JZ</td>
<td>Supplement Sacrum with Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0QU14JZ</td>
<td>Supplement Sacrum with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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### ICD-10 Diagnosis

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<td>All Diagnoses</td>
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### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>02/14/2001</td>
<td>New Policy Adoption Policy for Vertebroplasty</td>
<td>Medical Policy Committee</td>
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<tr>
<td>10/24/2001</td>
<td>New Policy Adoption Policy for Kyphoplasty</td>
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<tr>
<td>11/05/2002</td>
<td>Policy Revision Addition of the FDA notification to description</td>
<td>Administrative Review</td>
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<tr>
<td>10/01/2005</td>
<td>Policy Name Change Policy review, title modifications</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>12/01/2006</td>
<td>BCBSA Medical Policy adoption MPC adopted BCBSA MPP review for Percutaneous Vertebroplasty 4:2006 &amp; Percutaneous Kyphoplasty</td>
<td>Medical Policy Committee</td>
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<tr>
<td>10/15/2007</td>
<td>Policy Revision Policy changed based on expert input and evidence review. Approved</td>
<td>Medical Policy Committee</td>
</tr>
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</table>
Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence.
over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.