APPENDIX to Percutaneous Kyphoplasty, Vertebroplasty and Sacroplasty Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

In the treatment of osteoporosis and malignancy with percutaneous vertebroplasty (PVP), sacroplasty or kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Pain and functional ability are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may be variable and may be associated with a lower health related quality of life. Controlled comparison studies are valuable to demonstrate the clinical effectiveness of these procedures by eliminating any associated non-specific or placebo effects and providing comparison to alternative, conservative therapies.

Percutaneous vertebroplasty or sacroplasty may also be used to treat aggressive hemangioma in an attempt to provide relief of pain and reduction of blood loss associated with surgical treatment.

Vertebroplasty versus Medical Management with Sham Controls

In 2009 Buchbinder et al. reported findings of a randomized trial comparing vertebroplasty to medical management using a sham placebo control (which included local anesthetic) mimicking the vertebroplasty procedure up to the point of cement injection. The study was conducted a 4 centers and provided randomized, double blinded, sham controls designed to determine short term efficacy and safety of vertebroplasty in persons with painful osteoporotic vertebral fractures.

A total of 78 participants with 1 or 2 painful osteoporotic vertebral fractures of duration less than 1 year were assigned to undergo vertebroplasty or sham procedure (e.g., injection of local anesthetic into the facet capsule and/or periosteum). In the study 91% of participants completed 6 months of follow up evaluation. The participants, investigators (other than the radiologists performing the procedure), and outcome assessors were blind to the treatment assignment. Recruitment took place within the practices of both general practitioners and specialists from hospital inpatient and emergency departments. Participants were evaluated at baseline, then with a mailed questionnaire at 1 week and 1, 3, and 6 months after the procedure. The primary outcome was overall pain (over the course of the previous week) measured on a 0 to 10 using a visual analog scale (VAS), with 1.5 representing the minimal clinically important difference. A sample size of 24 per group was calculated to provide 80% power with 2-sided 0.05 to show a 2.5 point post-procedure difference assuming a 3 point standard deviation (SD). All analyses were performed according to intention-to-treat principles. Results are presented as difference from baseline. For the primary outcome of overall pain, the authors reported no significant difference in VAS pain score at 3 months. Results demonstrated reductions in pain and improvements in quality of life in both groups, therefore, the authors concluded vertebroplasty provided no benefit.

In 2010, Masala et al. concluded response or meaningful improvement (2.5 on the VAS) in overall pain at 1, 3, and 6 months tended to be more frequent with vertebroplasty (relative risks (RRs) of 1.2 (95% confidence interval [CI]: 0.7 to 2.0), 1.5 (95% CI: 0.9 to 2.6), and 1.3 (95% CI: 0.8 to 2.1) respectively. However, detecting an increase in clinical response rates often requires larger numbers of patients. For example, detecting an increase in response from 40% (sham) to 60% with 80% power would have required a sample exceeding 200 participants.

Kallmes et al. (2009) conducted a multicenter, randomized, double blind, sham controlled trial in which 131 participants with 1 to 3 painful osteoporotic vertebral fractures were assigned to undergo vertebroplasty or sham procedure (injection of local anesthetic into the facet capsule and/or periosteum). Inclusion criteria was back pain for no more than 12 months and a current pain rating of at least 3 on VAS at baseline. Participants were evaluated at baseline, then again at various time points to 1 year post procedure. In this study 97% completed a 1 month follow up, and 95% completed 3 months. . There was a trend toward a higher clinically meaningful improvement in pain at 1 month (30% reduction from baseline) in the vertebroplasty group (64% versus 48%, respectively; $p = 0.06$). At 3 months, 43% from the control group versus 12% in the vertebroplasty group crossed over ($p < 0.001$). The crossovers did not affect study outcomes, as they occurred after the primary outcome assessment. However, significantly more participants in the control group chose to cross over than in the vertebroplasty group.

Vertebroplasty versus Medical Management without Sham Controls

The VERTOS II study, reported by Klazen et al. in 2010, was a prospective randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium. Participants with at least 1 painful osteoporotic vertebral fracture, with duration of 6 weeks or less, were assigned to undergo vertebroplasty or conservative management (e.g., bed rest, analgesia, and cast and physical support). The trial was designed to assess the efficacy of vertebroplasty compared to conservative management for the treatment of osteoporotic vertebral compression fractures.

In general, participants were required to be at least 50 years of age or older with a compression fracture with height loss of the vertebral body of at least 15% on x-ray of the spine and located at T5 or lower. Participants were clinically evaluated at baseline then again at intervals of one day, one week, one month, three months, six months and twelve months after treatment. Primary outcome was pain relief at one month and 12 months measured on a ten point VAS scale. A sample size of 100 per group was calculated to provide 80% power with an alpha of 0.05 to show a 25% difference in pain relief. All analyses were performed according to intention to treat principles. Clinically significant pain relief was defined as 30% change on the VAS (0 to10 scale). In this study 101 were enrolled into the treatment group and 101 into the control arm; 81% completed at the twelve month follow up. Except for the primary outcome difference in mean pain score from baseline at three months and 12 months the vertebroplasty group resulted in greater pain relief than did medical management at one month and one year. There were significant differences between groups at one month (2.6; 1.74 to 3.37, $p < 0.0001$) and at one year (2.0; 1.13 to 2.80, $p < 0.0001$). Survival analysis showed significant pain relief was quicker (29.7 versus 115.6 days) and was achieved in more patients after vertebroplasty than after conservative management. Cement leakage in 72% of patients after vertebroplasty was reported, with all patients remaining asymptomatic. At a mean time of 11.4 months follow up, there was no significant difference in number of new fractures between groups, with 18 new fractures in 15 patients who had vertebroplasty compared to 30 new fractures in 21 participants undergoing medical management. By 12 month follow up, 57 of 95 patients (60%) were considered to have sufficient pain relief, with most experiencing sufficient pain relief in the first three months. Comparison by logistic regression analysis with the 38 patients (40%) who still had pain (VAS > 4) at 12 months did not reveal any significant differences between the groups for the clinical and imaging factors that were evaluated.

In 2011, Farrokhi and colleagues reported a randomized trial 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 of the patients 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 the beginning of treatment. Radiological evaluation to measure vertebral body height and correction of deformity was performed before and after treatment and after 36 months of follow up. At one 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 Oswestry 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 patient (2.6%) in the vertebroplasty group and 6 patients (15.4%) 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.

In a 2009 study, Rousing et al. reported on a non-blinded randomized trial in which participants were randomized to either vertebroplasty or conservative management. These participants had no conservative therapy prior to enrolling in the trial. The study enrolled 40 participants with acute fractures and 10 with subacute (2 to 8 weeks). While immediate pain relief was observed in the vertebroplasty group, reductions in pain from baseline to 3 month follow up were similar in the 2 groups. The authors concluded that conservative management should be used in the acute phase. The primary limitations of this study include its small size and incomplete pain assessment at the baseline visit.

The VERTOS I study was a small randomized clinical trial of 34 patients. Voormolen et al. (2009) reported patients had been refractory to medical management for at least 6 weeks and no longer than 6 months. The authors noted that many patients had been referred for vertebroplasty following failed conservative treatment and did not want to be randomized to the optimized medication control group or chose to crossover to vertebroplasty after only 2 weeks of conservative treatment. Thus, the follow up in the study was very short. Vertebroplasty was found to decrease analgesic use (1.9 to 1.2 versus 1.7 to 2.6 in the optimized medication group) and resulted in a 19% improvement in the RMDQ (versus -2% in controls) 2 weeks following the procedure. Excluding 2 patients (11%) who had adjacent vertebral compression fractures by the 2 week follow up, mean VAS scores for pain decreased from 7.1 to 4.4 (versus 7.6 to 6.4 for controls). Patients who crossed over from conservative management to vertebroplasty had improvements after the procedure.

Conclusions

Despite the completion of five randomized controlled trials (RCTs), including two with sham control, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. The two randomized, sham controlled trials concluded that vertebroplasty showed no significant benefit above sham for painful osteoporotic fractures. However some uncertainty remains around the interpretation of their 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 is not without controversy, as it might be considered an active control, given that the effect of injecting local anesthetic in the facet capsule and/or periosteum is unknown. Without a clear understanding of the short and long term effects of the injection on pain, questions will remain. Also, both trials were underpowered to observe and compare the proportion of participants experiencing a clinically meaningful difference in pain, which is the most clinically relevant outcome measure. Furthermore, the responder outcome measures in both trials showed trends toward an improvement in the rate of meaningful clinical response, although the differences between groups were not statistically significant.

In contrast, the four RCTs without sham control report that vertebroplasty is associated with significant improvements in pain. Three of the four trials were small, and the studies included populations with different time periods of symptoms and different prior treatments. It is possible

that the effect reported in these non-sham controlled trials is due to a placebo effect, given that these studies were not blinded and the outcome of pain is a subjective, patient reported outcome that is prone to the placebo effect. It is also possible that the differences in these trials represents a true treatment effect, and that the sham control, had a therapeutic effect in reducing short term pain, thus obscuring any impact of vertebroplasty.

Percutaneous Kyphoplasty

Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty. In this procedure, ultra high viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultra high viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

In terms of outcomes, results generally show improvement after kyphoplasty. It has been proposed that kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, one of which is thermal damage to intraosseous nerve fibers given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Coumans et al., (2003) reported statistically significant improvements in several subscores of the short form-36 (SF-36), including physical function, mental health, pain, vitality, and social function. Crandall et al., (2004) showed decreases in the amount of medication use over time and Ledlie et al., (2003) demonstrated a proportional increase of patients fully ambulatory after the procedure. Two non-randomized studies that compared kyphoplasty to conservative management for treatment of osteoporotic fractures showed that patients receiving kyphoplasty had greater improvements in pain and function.

In a study by Moerman et al., (2002) the authors suggest that non-specific or placebo effects can be quite large for an invasive procedure such as kyphoplasty in which there is not blinding. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of results from non-sham controlled trials is questionable.

According to a study conducted by Hrobjartsson et al., (2001) the placebo effect may be substantial, on the order of 6 to 7 millimeters (mm) on a 100-mm scale, for invasive procedures. Even larger placebo effects (10%) were observed in the sham controlled vertebroplasty trials (Buchbinder et al. and Kallmes et al., 2009). In reported cases of chronic pain, mean differences in continuous measures may not be reflective of the percent of patients who have a meaningful clinical response.

The 2008 Blue Cross Blue Shield Association Technology Evaluation Center (TEC Assessment) findings indicated lack of rigorous comparative trials of kyphoplasty, albeit plenty of case study reporting. Since case series studies are subject to many sources of bias and are generally not reliable evidence of efficacy, it was concluded that the evidence for kyphoplasty did not meet TEC criteria.

Other Studies

Although not randomized, there as one other comparative study specifically aimed at patients with acute fracture. Diamond et al. (2006) enrolled 79 consecutive patients with acute vertebral fractures. All patients were offered vertebroplasty, and those who declined followed as a comparison group. The two groups had balanced baseline characteristics. At 24 hours, the group undergoing vertebroplasty (n = 55) had much improved pain compared to the control group (n = 24). However, at 6 weeks and between 6 and 12 months, there were no differences between groups in pain scores. The control group had an identical mean pain score to the vertebroplasty group at the end of follow up. Similar findings were shown for the Barthel index of physical functioning. At long term follow up, there was still slightly higher functioning in the group undergoing vertebroplasty but no difference in the percent improvement from baseline between groups. The authors interpreted these findings as demonstrating that vertebroplasty produced faster resolution of symptoms than conservative management.

In 2011, Edidin et al. reported mortality risk in Medicare patients who had vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty or medically managed. This study was industry funded. Using the United States Centers for Medicare and Medicaid Services (CMS) data set, the researchers identified 858,978 patients who had vertebral compression fractures between 2005 and 2008. The data set included 119,253 kyphoplasty patients and 63,693 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow up (up to 4 years). Cox regression was used to evaluate the joint effect of multiple covariates, which included gender, age, race/ethnicity, patient health status, type of diagnosed fracture, site of service, physician specialty, socioeconomic status, year of diagnosis, and census region. After adjusting for co-variates, patients in the operated cohort (vertebroplasty or kyphoplasty) were found to have a higher adjusted survival rate (60.8%) than patients in the non-operated cohort (50.0%) and were 37% less likely to die. The adjusted survival rates for vertebroplasty or kyphoplasty were 57.3% and 62.8%, respectively, a 23% lower relative risk for kyphoplasty. As noted by the authors, a causal relationship cannot be determined from this study.

Evidence from observational studies were generally consistent in showing significant decreases in pain from an initial pre operative level of 8 to 9 on a VAS to a rating of 2 to 4, typically within 1 day of receiving the procedure. Such pain relief appeared to be lasting in the limited studies reporting long term outcomes (Layton et al., 2007).

Safety and Efficacy

A systematic review of the safety and efficacy of vertebroplasty in malignancy was reported by Chew et al. in 2011. Thirty relevant studies were identified; totaling 987 patients this review included 1 randomized controlled trial and 7 prospective studies. Most centers reported treating no more than 4 vertebrae per session. Pain reduction ranged between 20% to 79%. Five deaths were attributable to vertebroplasty, 2 from chest infections following general anesthesia, 1 from a cement pulmonary embolus, and 2 from sepsis after emergency spinal decompression. Another 19 patients suffered a serious complication related to the procedure, with 13 requiring emergency spinal decompression. Reports of complications occurred in studies with a mean cement volume of more than 4 ml, suggesting a possible association between the volumes of cement injected and adverse events.

Percutaneous Vertebroplasty Regulatory Status

Vertebroplasty is a surgical procedure and, as such, is not subject to United States Food and Drug Administration (FDA) approval. In 2005, PMMA bone cement products such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. The use of PMMA in sacroplasty continues to represent 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 only. In 2004, the FDA issued a Public Health Web Notification addressing issues related to complications associated with the use of bone cement products and bone fillers in treating compression fractures of the spine. The most frequent safety issue is leakage of the cement outside of the vertebral body. Studies reported occurrence between 19% and 72% in patients undergoing these procedures for pain management and vertebral stability (Layton et al., 2007).

Percutaneous Sacroplasty

Sacroplasty is an evolving technique with numerous methods (short axis, long axis, balloon assisted short axis, and iliosacral screws). No randomized trials of sacroplasty have been reported. Published evidence is mostly from case reports (Garant et al., Layton et al., Sciubba et al., and Smith et al.) and small case series (all but one enrolling fewer than 13 patients).

In 2008 Frey et al. reported the largest experience is a prospective observational cohort study of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short axis technique. Patients had a mean age of 75.9 years and a mean duration of symptoms of 34.5 days (range: 4 to 89 days) and mean VAS score of 8.1 at baseline. Improvement on the VAS scale was measured at 30 minutes and two, four, 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, adverse outcomes associated with sacroplasty have not been adequately studied. There are complications of cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of PMMA into the pre-sacral 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 (Zaman et al., 2006). According to Denis et al., (2008) these risks can be minimized by performing sacroplasty on Zone One fractures only.

Practice Guidelines and Position Statements

In 2010, the American Academy of Orthopedic Surgeons (AAOS) Board of Directors approved a new clinical practice guideline on the treatment of osteoporotic spinal compression fractures. The Board 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.” In coming out with a strong recommendation, the committee expressed their confidence that future evidence is unlikely to overturn the existing evidence.

In 2006, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) published a statement on the safety and efficacy of balloon vertebroplasty for vertebral compression fractures. The statement supports 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, treat symptomatic vertebral hemangioma and painful vertebral body tumors (metastases or myeloma). Recommendations included the normal arrangements are in place for consent, audit, and clinical governance. The guidance recommends that the procedure be limited to patients whose pain is refractory to more conservative treatment.

Guidelines published in 2006 from the American College of Radiology (ACR) consider percutaneous vertebroplasty appropriate for painful osteoporotic or neoplastic vertebral compression fracture(s) refractory to medical therapy. It is noted that when fewer than 95% of percutaneous vertebroplasty in an institution are performed for the above indication, it should prompt a review of practices related to selection of patients for this procedure. The guidelines also list *absolute contraindications* of:

- Asymptomatic vertebral body compression fractures, including patient improving on medical therapy
- Non-fractured vertebral levels
- Prophylaxis in osteoporotic patients (unless being performed as part of a research protocol)
- Osteomyelitis of the target vertebra
- Myelopathy originating at the fracture level
- Uncorrectable coagulopathy
- Allergy to bone cement or opacification agent

Relative contraindications are listed as:

- Radiculopathy in excess of local vertebral pain caused by a compressive syndrome unrelated to vertebral collapse (occasionally preoperative percutaneous vertebroplasty can be performed before a spinal decompressive procedure)
- Asymptomatic retropulsion of a fracture fragment causing significant spinal canal compromise
- Asymptomatic tumor extension into the epidural space
- Ongoing systemic infection

The ACR published updated guidelines on the management of vertebral compression fractures in 2010. While generally supportive of vertebroplasty and kyphoplasty in specified conditions, the guidelines state,

> Conservative management is the first-line and gold standard treatment of painful vertebral compression fractures; most patients with osteoporotic vertebral compression fractures, even without medication, have spontaneous resolution of pain within 4 to 6 weeks from the initial onset of pain.

From the inception of vertebral augmentation in the late 1980s, its minimally invasive procedures have been reserved for patients who have failed conservative therapy. Failure can be defined as pain refractory to oral medications (Non-steroidal anti-inflammatory drugs [NSAIDs]

and/or narcotic) over 6 to12 weeks. However, failure can also be defined as contraindications to such medications or a requirement for parenteral narcotics and hospital admission.

Summary

Vertebroplasty and kyphoplasty have been investigated as interventions to providing 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 or metastatic malignancies). The results of clinical vetting performed by Blue Cross Blue Shield Association (BCBSA) in 2008 indicated uniform support for the use of vertebroplasty and kyphoplasty in painful osteoporotic fractures. After consideration BCBSA concluded the consistent results of numerous case series, including large prospective reports, together with the results of clinical vetting, were sufficient to determine that vertebroplasty and kyphoplasty are reasonable treatment options in patients with vertebral fractures who fail to respond to conservative treatment (at least six weeks with analgesics, physical therapy, and rest).

The BCBSA has literature updates performed after 2008, including two sham-controlled trials, have raised questions about the efficacy of vertebroplasty and kyphoplasty for osteoporotic fractures. These trials can be interpreted as showing vertebroplasty and kyphoplasty as ineffective. However, alternate interpretations are possible. There are methodological issues with these studies, including but not limited to the choice of sham procedure, and the potential effect of the sham procedure having a therapeutic effect by reducing pain.

The BCBSA statement also stated there is insufficient clinical evidence to permit conclusions on the use of vertebroplasty or kyphoplasty for acute fractures. The statement acknowledges the VERTOS II trial as a well performed study, however suggests results should be replicated and verified.

For acute vertebral 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 (Diamond et al., 2006). Based on the clinical evidence, the BCBSA recommendation regarding use of vertebroplasty and/or kyphoplasty for acute osteoporotic fractures is considered investigational.

According to the BCBSA sacroplasty is under development. Varying techniques, patient indications, and small numbers of treated patients leaves uncertainty regarding the impact of sacroplasty on health outcomes and does not permit conclusion on its use for sacral insufficiency fractures or other indication. Given the evidence based opinion of BCBSA, sacroplasty is considered investigational.

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)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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.

Type	Number	Description
CPT	0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), 1 or more needles
	0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), 2 or more needles
	22520	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic
	22521	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; lumbar
	22522	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)
	22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic
	22524	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); lumbar
	22525	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); each additional thoracic or lumbar

Type	Number	Description
	72291	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under fluoroscopic guidance
	72292	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under CT guidance
HCPC	S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
	S2361	Each additional cervical vertebral body (list separately in addition to code for primary procedure)
ICD9 Procedure	81.65	Percutaneous vertebroplasty
	81.66	Percutaneous vertebral augmentation
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Compression Fracture - A fracture caused by the compression of one bone, especially a vertebra, against another.

Inflatable Bone Tamp - an orthopedic balloon designed to inflate in cancellous bone while resisting puncture.

Osteolytic - Dissolution or destruction of bone caused by disease, infection or inadequate blood supply.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Kyphoplasty
- Radiofrequency-Targeted Vertebral Augmentation (RF-TVA)
- Sacroplasty
- Vertebroplasty

References

- American College of Orthopedic Surgeons (AAOS). (2010). Clinical practice guidelines: Treatment of osteoporotic spinal compression fractures. Retrieved March 15, 2012 from http://www.aaos.org/Research/guidelines/SCFguideline.asp.
- American College of Radiology (ACR). (2006). Practice guideline for the performance of percutaneous vertebroplasty. Retrieved March 15, 2012 from: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/head-neck/percutaneous_vertebroplasty.aspx.
- American College of Radiology (ACR). (2010). Practice Guidelines: Appropriateness criteria for management of vertebral compression fractures. Retrieved March 15, 2012 from http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonInterventionalRadiology/Management-of-Vertebral-Compression-Fractures.aspx.
- Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008; 23(Tab 5):1-36.
- Blue Cross Blue Shield Association. Medical Policy Reference Manual. 6.01.38 (March 2012).
- Blue Cross Blue Shield Association. Medical Policy Reference Manual. No. 6.01.25 (March 2012).
- Buchbinder R, Osborne RH, Ebeling PR et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med 2009; 361(6):557-568.
- Chew C, Craig L, Edwards R et al. Safety and efficacy of percutaneous vertebroplasty in malignancy: A systematic review. Clin Radiol. 2011; 66(1):63-72.
- Coumans JV, Reinhardt MK, Lieberman IH et al. Kyphoplasty for vertebral compression fractures: One year clinical outcomes from a perspective study. J Neurosurg. 2003; 99(1 Suppl):44-50.
- Crandall D, Slaughter D, Hankins PJ et al. Acute versus chronic vertebral compression fractures treated with kyphoplasty: Early results. Spine J. 2004; 4(4):418-424.
- Denis F, Davis S, Comfort T et al. Sacral fractures: An important problem. Retrospective analysis of 236 cases. Clin Orthop Relat Res. 1988; 227:67-81.
- Diamond TH, Bryant C, Browne L et al. Clinical outcomes after acute osteoporotic vertebral fractures: A two year non-randomized trial comparing percutaneous vertebroplasty with conservative therapy. Med J Aust 2006; 184(3):113-117.

- Edidin AA, Ong KL, Lau E et al. Mortality risk for operated and non-operated vertebral fracture patients in the medicare population. J Bone Miner Res. 2011; 26(7):1617-1626.
- Farrokhi MR, Alibai E, Maghami Z et al. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. J Neurosurg Spine 2011; 14(5):561-569.
- Frey ME, Depalma MJ, Cifu DX et al. Percutaneous sacroplasty for osteoporotic sacral insufficiency fractures: A prospective, multicenter, observational pilot study. Spine J. 2008; 8(2):367-373.
- Garant M. Sacroplasty: A new treatment for sacral insufficiency fracture. J Vasc Interv Radiol. 2002; 13(12):1265-1267.
- Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. N Engl J Med. 2001; 344(21):1594-1602.
- Kallmes DF, Comstock BA, Heagerty PJ et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med 2009; 361(6):569-579.
- Klazen CA, Lohle PN, de Vries J et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): An open label randomized trial. Lancet 2010; 376(9746):1085-1092.
- Layton, KF, Thielen, KR, Koch, CA et al. Vertebroplasty, first 1000 levels of a single center: Evaluation of the outcomes and complications. Am J Neuroradiol. 2007; 28:683-689.
- Ledlie JT, Renfro M. Balloon kyphoplasty: One year outcomes in vertebral body height restoration, chronic pain, and activity levels. J Neurosurg. 2003; 98(1 Suppl):36-42.
- Masala S, Massari F, Assako OP et al. Is 3T-MR spectroscopy a predictable selection tool in prophylactic vertebroplasty? Cardiovasc Intervent Radiol 2010; 33(6):1243-1252.
- Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. Ann Intern Med. 2002; 136(6):471-476.
- National Institute for Health and Clinical Excellence (NICE). (2006, April). Guidance on balloon kyphoplasty for vertebral compression fractures. Retrieved March 15, 2012 from: http://www.nice.org.uk/nicemedia/pdf/IPG166A4Updated.pdf.
- Rousing R, Andersen MO, Jespersen SM et al. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute osteoporotic vertebral fractures: Three months follow up in a clinical randomized study. Spine (Phila Pa 1976). 2009; 34(13):1349-1354.
- Sciubba DM, Wolinsky JP, Than KD et al. CT fluoroscopically guided percutaneous placement of transiliosacral rod for sacral insufficiency fracture: Case report and technique. Am J Neuroradiol. 2007; 28(8):1451-1454.
- Smith DK, Dix JE. Percutaneous sacroplasty: Long-axis injection technique. Am J Roentgenol. 2006; 186(5):1252-1255.
- United States Food and Drug Administration. (FDA). (2004, May). Public Health Web Notification: Complications Related to the Use of Bone Cement and Bone Void Fillers in Treating Compression Fractures of the Spine. Updated May 2004. Retrieved March 16, 2012 from

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062126.htm.
- United States Food and Drug Administration. (2005, December). 510 (k) Summary: Spine-Fix Biomimetic Bone Cement. Retrieved March 16, 2012 from: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K043593.pdf.
- Voormolen, MH, Mali, WP, Lohle, P et al. Percutaneous vertebroplasty compared with optimal pain medication treatment: Short term clinical outcome of patients with subacute or chronic painful osteoporotic vertebral compression fractures. The VERTOS study. Am J Neuroradiol. 2007; 28(3):555-560.
- Zaman FM, Frey M, Slipman CW et al. Sacral stress fractures. Curr Sports Med Rep. 2006; 5(1):37-43.

Policy History

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

Effective Date	Action	Reason
2/14/2001	New Policy Adoption Policy for Vertebroplasty	Medical Policy Committee
10/24/2001	New Policy Adoption Policy for Kyphoplasty	Medical Policy Committee
11/5/2002	Policy Revision Addition of FDA notification to description	Administrative Review
3/1/2005	Policy Revision MPC Adoption CTAF Consent review of BCBSA TEC 2004 Vol. 24, No. 12 & 13. Policy Updated.	Medical Policy Committee
10/1/2005	Policy Name Change Policy review, title modifications	Administrative Review
12/1/2005	Policy Revision MPC Adoption CTAF Consent review of BCBSA TEC Vol.20, No. 6 & 7. Policy Updated.	Medical Policy Committee

Effective Date	Action	Reason
12/1/2006	BCBSA Medical Policy adoption MPC adopted BCBSA MPP review for Percutaneous Vertebroplasty 4:2006 & Percutaneous Kyphoplasty	Medical Policy Committee
10/15/2007	Policy Revision Policy changed based on expert input and evidence review. Approved under certain conditions (see policy for details).	Medical Policy Committee
6/19/2009	Policy Revision	Medical Policy Committee
7/06/2012	Policy title change from Percutaneous Kyphoplasty and Vertebroplasty with position change	Medical Policy Committee
7/13/2012	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

An Independent Member of the Blue Shield Association