



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/28/13
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE: 05/27/14
ARCHIVE DATE:

PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY (cont.)

Description:

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

Vesselplasty using Vessel-X®, (MAXXSPINE) and a similar procedure from A-Spine, are variations of vertebroplasty that are reported to eliminate leakage of bone cement by containing the filler in an inflatable vessel. FDA clearance of these devices has not been identified.

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

Criteria:

Vertebroplasty:

- Percutaneous vertebroplasty is considered **medically necessary** for an individual with continual incapacitating pain for the treatment of symptomatic osteoporotic vertebral fractures that have failed a trial of greater than 4 weeks of conservative care ¹ with documentation of **ANY** of the following:
 1. Osteoporotic vertebral fracture(s)
 2. Trauma-related vertebral compression fracture(s)
 3. Steroid-induced vertebral compression fracture(s)

PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY (cont.)

Criteria: (cont.)

- Percutaneous vertebroplasty is considered **medically necessary** for an individual with osteolytic vertebral body fracture with documentation of **ALL** of the following:
 1. Individual has continual incapacitating pain
 2. No evidence of vertebral body destruction
 3. Vertebral body fracture is related to multiple myeloma or metastatic malignancies
 4. Chemotherapy and radiation therapy have failed to relieve the pain
 5. No involvement of the major part of the cortical bone

- Percutaneous vertebroplasty is considered **medically necessary** for vertebral hemangioma with documentation of **ALL** of the following:
 1. Procedure is intended to limit the extent of surgical resection
 2. Procedure is intended as an adjunct to decrease associated surgical blood loss

- Percutaneous vertebroplasty for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient evidence to support improvement of the net health outcome, and
 2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, *but are not limited to*:

- Acute vertebral fractures due to osteoporosis or trauma

Vesselplasty:

- Vesselplasty is considered **experimental or investigational** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY (cont.)

Criteria: (cont.)

Sacroplasty:

- Percutaneous sacroplasty for all indications is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.
- ¹ A trial of conservative care includes, *but is not limited to*, bedrest, immobilization/bracing devices, non-narcotic analgesic medications, narcotic analgesic medications and physical therapy. A trial of conservative care may be contraindicated.

Resources:

Literature reviewed 06/20/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 05/28/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 6.01.25 BCBS Association Medical Policy Reference Manual. Percutaneous Vertebroplasty and Sacroplasty. Re-issue date 05/08/2017, issue date 04/30/2000.
2. Flors L, Lonjedo E, Leiva-Salinas C, et al. Vesselplasty: a new technical approach to treat symptomatic vertebral compression fractures. *AJR Am J Roentgenol*. Jul 2009;193(1):218-226.
3. InterQual ® Care Planning, Procedures. Vertebroplasty or Kyphoplasty.
4. Klingler JH, Sircar R, Deininger MH, Scheiwe C, Kogias E, Hubbe U. Vesselplasty: a new minimally invasive approach to treat pathological vertebral fractures in selected tumor patients - preliminary results. *Rofo*. Apr 2013;185(4):340-350.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínigíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

