PERCUTANEOUS BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION

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 BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Description:

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with the KIVA® VCF Treatment System are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have 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.

Kienbock's Disease:
A condition of the wrist sometimes caused by trauma.

Percutaneous Balloon Kyphoplasty:
A variant of vertebroplasty 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.

Percutaneous Mechanical Vertebral Augmentation:
The KIVA® VCF Treatment System is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The implant is inserted into the vertebral body over a guide wire and can be customized by changing the coil stack height, with a maximum height of 12 mm. PMMA is injected through the lumen of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. KIVA has been investigated as a technique to reduce cement leakage.

Radiofrequency Kyphoplasty:
A modification of balloon kyphoplasty for vertebral fractures. 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.

Vertebral Body Stenting:
A variant of kyphoplasty which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.
PERCUTANEOUS BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Criteria:

Percutaneous Balloon Kyphoplasty:

- Percutaneous balloon kyphoplasty is considered *medically necessary* for an individual with continual incapacitating pain who has failed a trial of greater than 4 weeks of conservative care¹ 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 balloon kyphoplasty 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 balloon kyphoplasty 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
  - Kienbock’s disease

Percutaneous Mechanical Vertebral Augmentation:

- Percutaneous mechanical vertebral augmentation with Kiva is considered *medically necessary* for an individual with continual incapacitating pain who has failed a trial of greater than 4 weeks of conservative care¹ 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 BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Criteria: (cont.)

Percutaneous Mechanical Vertebral Augmentation: (cont.)

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

- Percutaneous mechanical vertebral augmentation with Kiva 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

- Percutaneous mechanical vertebral augmentation using any other device, *including but not limited to*, vertebral body stenting, 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.

* 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.
PERCUTANEOUS BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Resources:

Literature reviewed 12/20/16. 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.


6. InterQual® Care Planning, Procedures Adult. Vertebroplasty or Kyphoplasty.
PERCUTANEOUS BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

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/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 kweé atah niliiñii Blue Cross Blue Shield of Arizona haada yltºéego binaºídilkidgo éí doodago Háida bíjá aniyeediígil tºáadoo leºé yinaºídilkidgo beehazºânii hóló díí tºáa hazaadºéhí háká aºdoowolgo bee hazºá doo báqºah ilinígoº. Ataº halneºéºgil koºjº bíchºyº hodiilíhin 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 thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أي شخص بخصوص Blue Cross Blue Shield of Arizona، فقد يكون الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة للتحدث مع مرجم اتصل ب 877-475-4799.
PERCUTANEOUS BALLOON KYPHOPLASTY AND PERCUTANEOUS MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 저의 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 얘기하기 위해서는 877-475-4799로 전화하시십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

آگر شما یا کسی که شما به او کمک میکنید، سوال در مورد اطلاعات به زبان خرد را به مرور رایگان دریافت نمایید. اتصال حاصل نمایید.

Assyrian:

کەسی کە نەمەیشئ، یا ھەندێکیە لە یان، ژێر لەوەیە بەڵگەیە کە بەرکەیەنەیە، بەڵگەیە بەرکەیەنەیە، 877-475-4799.

Serbo-Croatian: Ukoliko vi  ili neko kome vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodilacem, nazovite 877-475-4799.

Thai: ถ้าคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เสียเงิน ณ หมายเลขโทรศัพท์ 877-475-4799.