BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 03/05/13**
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	ARCHIVE DATE:

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS

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.

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Description:

This Medical Coverage Guideline addresses the use of limb compression devices for venous thromboembolism prophylaxis in the outpatient setting which includes, but is not limited to: an outpatient hospital, ambulatory surgery center or the home setting. This Medical Coverage Guideline does not address the use of limb compression devices for venous thromboembolism prophylaxis in the inpatient setting.

Limb pneumatic compression devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with specific pressures and cycle times.

Limb pneumatic compression devices are used in the intra-operative and post-operative periods to prevent deep vein thrombosis (DVT) and pulmonary embolism (PE), together known as venous thromboembolism (VTE), in individuals with a contraindication to prophylaxis pharmacologic anticoagulation therapy who are undergoing major orthopedic and other surgeries.

Portable battery-operated devices that have been cleared by the FDA include but are not limited to, Kendall SCD™ 700 Sequential Compression System, VenaPro™ Vascular Therapy System, Venowave™ VW5, ActiveCare®+SFT System and Restep® DVT System.

Prophylaxis pharmacologic anticoagulation therapy is recommended for surgical individuals who are at moderate-to-high risk of postoperative VTE, including DVT and PE. Individuals may be classified as moderate-to high risk of VTE based on the surgical procedure and/or individual characteristics. For some types of surgery (e.g., major orthopedic surgery), there is a particularly high risk of VTE due to the nature of the procedure and the prolonged immobility during and after surgery.

Common individual risk factors for bleeding include increasing age, prior VTE, malignancy, pregnancy and significant comorbidities. Increased risk of bleeding is a relative contraindication to anticoagulation as are adverse effects and allergic reactions.

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Description: (cont.)

A VTE risk assessment tool comparable to the Caprini Risk Factor Assessment or the American College of Chest Physicians (ACCP) Antithrombotic Guidelines are tools that have been used to stratify individuals into a VTE risk category based on their individual risk factors.

The ACCP guidelines on prevention of VTE in orthopedic surgery listed the following general risk factors for bleeding:

- Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- Concomitant antiplatelet agent
- Surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection and revision surgery

The 2016 ACCP guidelines addressing antithrombotic therapy for VTE disease outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for individuals in various risk categories. The following risk factors are assigned one point each. Individuals with no risk factors are categorized as low risk. Moderate risk category includes one risk factor. High risk category includes 2 or more risk factors.

- Age >65 years
- Age >75 years
- Alcohol abuse
- Anemia
- Antiplatelet therapy
- Cancer
- Comorbidity and reduced functional capacity
- Diabetes
- Liver failure
- Metastatic cancer
- Nonsteroidal anti-inflammatory drug
- Poor anticoagulant control
- Previous bleeding
- Previous stroke
- Recent surgery
- Renal failure
- Thrombocytopenia

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Criteria:

For cryopneumatic and cryopneumatic/heat devices, see BCBSAZ Medical Coverage Guideline #O50, *"Durable Medical Equipment"*

Major Orthopedic and Spinal Surgery:

- Limb compression devices for venous thromboembolism (VTE) prophylaxis is considered ***medically necessary*** for individuals with a contraindication to pharmacologic agents (i.e., at risk of bleeding) with documentation of **ALL** of the following:

  1. **ONE** of the following:

     - Total hip arthroplasty (THA)
     - Total knee arthroplasty (TKA)
     - Hip fracture surgery (HFS)
     - Spinal surgery
     - Spinal anesthesia

  2. **ANY** of the following risk factors for bleeding:

     - Previous major bleeding; previous bleeding risk similar to current risk
     - Severe renal failure
     - Concomitant antiplatelet agent
     - Surgical factors, including history of difficult-to-control surgical bleeding or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection and revision surgery

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Criteria: (cont.)

Major Non-Orthopedic Surgery or Non-Major Orthopedic Surgery:

- Limb compression devices for venous thromboembolism (VTE) prophylaxis after major non-orthopedic surgery or non-major orthopedic surgery is considered ***medically necessary*** for individuals at moderate or high risk of venous thromboembolism with a contraindication to pharmacologic agents (i.e., at risk of bleeding) with documentation of **ALL** of the following:

  1. **ANY** of the following risk factors for bleeding:

     - Previous major bleeding; previous bleeding risk similar to current risk
     - Severe renal failure
     - Concomitant antiplatelet agent
     - Surgical factors including history of difficult-to-control surgical bleeding or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection and revision surgery.

  2. **ANY** of the following risk factors for venous thromboembolism:

     - Prior deep vein thrombosis (DVT), pulmonary embolism (PE) or venous thromboembolism (VTE)
     - Hypercoagulable state
     - Open abdominal or open pelvic surgery
     - Abdominal or pelvic surgery for cancer
     - Sepsis or severe infection
     - Age $\geq$ 60
     - Active cancer or cancer treatment
     - Anesthesia $\geq$ 2 hours
     - Bed rest $\geq$ 4 days
     - Surgical complications including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction and pneumonia.

- Limb pneumatic compression devices for venous thromboembolism prophylaxis for periods longer than 30-days post-surgery is considered ***not medically necessary***.

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Criteria: (cont.)

- Limb compression devices for venous thromboembolism prophylaxis for all other indications not previously listed or if above criteria are not met 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.

Resources:

Literature reviewed 04/17/18. 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.

1. 1.01.28 BCBS Medical Policy Reference Manual. Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis, Re-issue date 03/08/2018, issue date 12/13/2012.

2. Daniels AH, Kawaguchi S, Contag AG, et al. Hospital charges associated with "never events": comparison of anterior cervical discectomy and fusion, posterior lumbar interbody fusion, and lumbar laminectomy to total joint arthroplasty. *Journal of neurosurgery. Spine.* Aug 2016;25(2):165-169.

3. Sadaghianloo N, Dardik A. The efficacy of intermittent pneumatic compression in the prevention of lower extremity deep venous thrombosis. *Journal of vascular surgery. Venous and lymphatic disorders.* Apr 2016;4(2):248-256.

4. Smith JS, Fu KM, Polly DW, Jr., et al. Complication rates of three common spine procedures and rates of thromboembolism following spine surgery based on 108,419 procedures: a report from the Scoliosis Research Society Morbidity and Mortality Committee. *Spine.* Nov 15 2010;35(24):2140-2149.

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (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/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 nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' 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 تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة .للتحدث مع مترجم اتصل ب 877-475-4799.

LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, 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 Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

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:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
.[تماس حاصل نمایید.

Assyrian:
ܒ ܫܟܚ، ܡ ܡ ܩܒܝܩܐ ܕܡܨܝܬ ܒܗ، ܫܟܚ ܫܟܚ ܕܐܬ ܐܬ ܕܐܬ ܕ Blue Cross Blue Shield of Arizona، ܫܟܚ، ܫܟܚ ܫܟܚ، ܐܐܐܬ ܕܡܟܫܟܚ
ܐܬܕܬ ܐܐܡܕܫܟܐܬ ܫܟܫܟܐܬ ܫܟܫܟ. ܫܐܐܡܐܬ ܫܟ ܡ ܐܫܕܒܫܬ، ܬܕ ܫܟ ܫܟ ܫܟ ܫܟ ܫܟ 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 prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona
คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799