BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 10/21/25**
SECTION: DURABLE MEDICAL EQUIPMENT (DME)	**LAST REVIEW DATE: 10/21/25**
	CURRENT EFFECTIVE DATE: 10/21/25
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2026	**ARCHIVE DATE:**

NONPNEUMATIC COMPRESSION DEVICES

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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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NONPNEUMATIC COMPRESSION DEVICES

Description:

Nonpneumatic compression devices are medically prescribed lightweight, portable, battery-powered garments designed to deliver active compression, while allowing the individual to remain completely mobile during treatment. The nonpneumatic compression device consists of a garment that applies compression and the controller responsible for programming the garment's compression settings. Nonpneumatic compression devices are proposed as a treatment for individuals with lymphedema, venous insufficiency, intermittent claudication, deep vein thrombosis, venous ulcers, and to reduce wound healing time.

A number of nonpneumatic compression devices are available with varying compression techniques such as sequential, non-sequential, sequential calibrated gradient pressure, and peristaltic wave compression.

The Venowave™ VW5 is a nonpneumatic, non-sequential, peristaltic wave compression device. The device was cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) pathway in 2008 with an updated clearance in June 2024 for modifications to the contraindications for use. The contraindication was updated and specified to be "Venowave device should not be used to treat individuals who have open or freshly healed ulcers or other wounds or otherwise fragile skin between the knee and the ankle of the leg to be treated" and the labeling was updated to reflect the new contraindication. The Venowave VW5 series of devices are designed to be worn below the knee strapped firmly to the calf. The device consists of compact, battery-operated peristaltic pumps that generate a wave-form motion, resulting in compression of the calf and consequently, an increased upward volumetric displacement of venous and lymph fluid. The device is intended to induce improved vascular and lymphatic flow of the lower limbs. The Venowave devices are indicated for the treatment of lower extremity conditions such as lymphedema, venous insufficiency, varicose veins, intermittent claudication, and deep vein thrombosis.

The Koya Dayspring™ is a nonpneumatic, sequential calibrated gradient pressure compression device. The device received FDA 510(k) clearance in 2020 with newer models cleared in 2021, Dayspring, and 2024, Dayspring Lite. Dayspring series of devices consist of two main components: a controller and garment. The garment is powered by an active smart compression technology that is calibrated, instant-acting, and silent. The technology uses a Nickel Titanium (Ni-Ti) shape-memory alloy programmed by the controller. A liner is worn under the garment to prevent direct individual contact with the garment. The garment is wrapped around the individual's affected area so that the device fits snugly. The device has independently controlled sections in each limb. The controller can be programmed to provide graduated sequential compression therapy to the affected area over a range of 0-100 mmHg. The device is powered by a rechargeable Lithium-ion battery pack. Dayspring devices were developed to provide individuals with untethered access and a functional range of motion and mobility. A mobile phone application can be used to program and individualize pressures; start, stop, and pause therapy; and track device usage. Dayspring devices are indicated for the treatment of lymphedema, post mastectomy edema, venous insufficiency, reducing wound healing time, venous stasis ulcers, arterial and diabetic leg ulcers, lipedema, and phlebolymphedema.

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Criteria:

- Nonpneumatic compression devices (sequential, non-sequential, calibrated gradient pressure, or peristaltic wave) for all indications are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting

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

  - Lymphedema
  - Venous insufficiency
  - Wound healing

Resources:

Literature reviewed 10/21/25. We do not include marketing materials, poster boards or non-published literature in our review.

1. Barfield M, Winokur R, Berland T, et al. Results from a comparative study to evaluate the treatment effectiveness of a nonpneumatic compression device vs an advanced pneumatic compression device for lower extremity lymphedema swelling (TEAYS study). *J Vasc Surg Venous Lymphat Disord*. Jan 2025;13(1):101965. doi:10.1016/j.jvsv.2024.101965

2. Barnhart H, Maldonado T, Rockson SG. Various Therapies for Lymphedema and Chronic Venous Insufficiency, Including a Multimodal At-Home Nonpneumatic Compression Treatment. *Adv Skin Wound Care*. Apr 1 2024;37(4):212-215. doi:10.1097/asw.0000000000000091

3. Davies MG. Management of symptomatic peripheral artery disease: Claudication. In: Collins KA, Givens J, eds. *UpToDate*. UpToDate; 2025. Accessed September 24, 2025. https://www.uptodate.com/contents/management-of-symptomatic-peripheral-artery-disease-claudication

4. Galili O, Mannheim D, Rapaport S, Karmeli R. A novel intermittent mechanical compression device for stasis prevention in the lower limbs during limited mobility situations. *Thromb Res*. 2007;121(1):37-41. doi:10.1016/j.thromres.2007.02.015

5. Hettrick H, Ehmann S, McKeown B, Blebea J. Selecting Appropriate Compression for Lymphedema Patients. Position Statement of the American Vein & Lymphatic Society. Accessed September 24, 2025. https://www.myavls.org/assets/pdf/white-paper/Compression_for_Lymphedema-6-18-24-revision.pdf

6. O'Donnell MJ, McRae S, Kahn SR, et al. Evaluation of a venous-return assist device to treat severe post-thrombotic syndrome (VENOPTS). A randomized controlled trial. *Thromb Haemost*. Mar 2008;99(3):623-9. doi:10.1160/th07-09-0546

7. Rao A, Berland T, Mullick A, Maldonado TS, Blumberg SN. A novel non-pneumatic compression device results in reduced foot and ankle swelling in patients with venous and lymphatic edema. *Vascular*. Dec 4 2024:17085381241305898. doi:10.1177/17085381241305898

8. Rockson SG, Karaca-Mandic P, Nguyen M, et al. A non-randomized, open-label study of the safety and effectiveness of a novel non-pneumatic compression device (NPCD) for lower limb lymphedema. *Sci Rep*. Aug 17 2022;12(1):14005. doi:10.1038/s41598-022-17225-9

9. Rockson SG, Karaca-Mandic P, Skoracki R, et al. Clinical Evaluation of a Novel Wearable Compression Technology in the Treatment of Lymphedema, an Open-Label Controlled Study. *Lymphat Res Biol*. Apr 2022;20(2):125-132. doi:10.1089/lrb.2020.0126

10. Rockson SG, Skoracki R. Effectiveness of a Nonpneumatic Active Compression Device in Older Adults with Breast Cancer-Related Lymphedema: A Subanalysis of a Randomized Crossover Trial. *Lymphat Res Biol*. Dec 2023;21(6):581-584. doi:10.1089/lrb.2022.0085

11. Rockson SG, Whitworth PW, Cooper A, et al. Safety and effectiveness of a novel nonpneumatic active compression device for treating breast cancer-related lymphedema: A multicenter randomized, crossover trial (NILE). *J Vasc Surg Venous Lymphat Disord*. Nov 2022;10(6):1359-1366.e1. doi:10.1016/j.jvsv.2022.06.016

12. Sobieraj-Teague M, Hirsh J, Yip G, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. *J Thromb Haemost*. Feb 2012;10(2):229-35. doi:10.1111/j.1538-7836.2011.04598.x

13. U.S. Food and Drug Administration (FDA). 510(k) Summary: Dayspring K210885. 2025. Accessed September 24, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210885.pdf

14. U.S. Food and Drug Administration (FDA). 510(k) Summary: Dayspring K223228. 2025. Accessed September 24, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223228.pdf

15. U.S. Food and Drug Administration (FDA). 510(k) Summary: Dayspring Lite K212287. 2025. Accessed September 24, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212287.pdf

16. U.S. Food and Drug Administration (FDA). 510(k) Summary: Koya Dayspring K193288. 2025. Accessed September 24, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193288.pdf

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17. U.S. Food and Drug Administration (FDA). 510(k) Summary: Venowave VW5 K232640. 2025. Accessed September 24, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232640.pdf

Coding:

HCPCS: E0677, E0678, E0679, E0680, E0681, E0682, E0683

History:	Date:	Activity:
Medical Policy Panel	10/21/25	Approved guideline
Medical Director (Dr. Raja, Dr. Sutanto)	09/23/25	Development
Medical Director (Dr. Raja, Dr. Sutanto)	07/03/25	Development
Medical Director (Dr. Raja)	05/01/25	Development

Policy Revisions:

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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 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 hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. 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.

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Multi-Language Interpreter Services:

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:

[illegible] Blue Cross Blue Shield of Arizona [illegible] 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