

Medical Policy Manual

Approved Revised Policy: Do Not Implement Until 4/30/19

Pneumatic Compression Pumps

DESCRIPTION

Pneumatic compression pumps, also known as limb compression devices in the home setting are proposed treatment options for lymphedema, venous ulcers, and deep venous thromboembolism (DVT) prophylaxis. A variety of pumps are available; they can be single chamber (nonsegmented) or multi-chamber (segmented) and have varying designs and complexity. Newer devices are battery powered to allow freedom of movement to the patient which encourages mobilization. Examples of FDA-cleared devices include: VenaPro™ Vascular Therapy System, Venowave™ VW5, ActiveCare®+S.F.T. System, Restep® DVT System, Kendall SCD™ 700, Compression Pump, Model GS-128, the Sequential Circulator®, PlasmaFlow™, the Lympha-Press® and Lympha-Press Optimal, the Flexitouch™ and Entre™ systems, and the Powerpress Unit Sequential Circulator,

Lymphedema is an abnormal accumulation of lymphatic fluid in subcutaneous tissue. This could be the result of a congenital anomaly or damage to the lymphatic system (e.g., removal of lymph nodes, blockage of lymphatic channels by a tumor, scarring of lymphatic channels from radiation, or as a result of surgery or trauma). Lymphedema can occur immediately following surgery or years later. For individuals with lymphedema who have failed to respond to conservative therapy pneumatic compression pumps applied to the limb may be a treatment option.

Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation and exercise. Pneumatic compression pumps have been proposed as a treatment for venous ulcers.

Major surgery, especially orthopedic surgery, promotes high risk for venous thromboembolism. Pharmacologic prophylaxis is the mainstay of treatment, but some individuals may have contraindications to anticoagulation. For individuals with allergies or comorbidities that would preclude pharmacologic therapies, pneumatic limb compression is a possible option following major surgery such as total hip arthroplasty, total knee arthroplasty, hip fracture surgery, open abdominal, or open-pelvic procedures.

NOTE: This policy **does not** address end-diastolic compression pumps which are a very specialized pneumatic compression pump designed to coordinate the timing of the intermittent boot compression with the QRS complex on the EKG.

POLICY

- The use of pneumatic compression pumps in the home setting for the treatment of lymphedema or prophylactic treatment of deep vein thrombosis (DVT) are considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Pneumatic compression pumps for treatment of venous ulcers are considered **investigational**.
- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered **investigational**.

MEDICAL APPROPRIATENESS

- Pneumatic compression pumps are considered **medically appropriate** if **ANY ONE** of the following are met:

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- Deep venous thromboembolism (DVT) prophylaxis for postoperative use in the home setting following major surgery (e.g. total hip arthroplasty, total knee arthroplasty, hip fracture surgery, open abdominal, or open-pelvic procedures) if **ALL** of the following are met:
 - Intermittent pneumatic device
 - No longer than 14 days
 - Documented contraindication to pharmacological agents (e.g. previous major bleeding [and previous bleeding risk similar to current risk], severe renal failure, concomitant antiplatelet agent, or surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery)
- As a treatment for lymphedema of one or more limbs if **ANY ONE** of the following are met:
 - Nonprogrammable pump, single or multi-chamber, for intractable lymphedema of one or more limbs for documented failure to respond to conservative measures such as limb elevation and use of compression garments
 - Programmable pump, single or multi-chamber if **ALL** of the following:
 - There is documented failure to respond to conservative measures of such as limb elevation and use of compression garments
 - Documentation is present that the individual has characteristics that prevent satisfactory pneumatic compression performance from nonprogrammable pneumatic compression, such as significant scarring or contractures

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

Insufficient quality and quantity of studies were found in the published literature to support the use of home pneumatic compression pumps for venous ulcers or provide comparisons to standard treatment. Therefore, the use of these devices for this purpose remains investigational at this time.

SOURCES

American Academy of Orthopaedic Surgeons. (2011). *Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. Evidence-based guideline and evidence report*. Retrieved March 2, 2016 from <http://www.aaos.org>

American College of Chest Physicians. (2012, February). *Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. prevention of venous thromboembolism in orthopedic surgery patients*. Retrieved January 10, 2019 from <http://journal.publications.chestnet.org>

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American College of Chest Physicians. (2016, February). *Antithrombotic therapy for VTE disease*. Abstract retrieved January 10, 2019 from <http://journal.publications.chestnet.org>

American Venous Forum. (August, 2014). Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *Journal of Vascular Surgery*, (60), 3-59.

BlueCross BlueShield Association. Evidence Positioning System. (3:2018). *Pneumatic compression pumps for treatment of lymphedema and venous ulcers*. (1.01.18). Retrieved January 10, 2019 from <http://www.evidencepositioningsystem.com> . (13 articles and/or guidelines reviewed)

BlueCross BlueShield Association. Medical Policy Reference Manual. (3:2018). *Postsurgical outpatient use of limb compression devices for venous thromboembolism prophylaxis*. (1.01.28). Retrieved January 10, 2019 from <http://www.evidencepositioningsystem.com> . (24 articles and/or guidelines reviewed)

Centers for Medicare & Medicaid Services. CMS.gov. (2002) National Coverage Determination (NCD) for *pneumatic compression devices* (280.6). Retrieved March 17, 2017 from <https://www.cms.gov>

Dolibog, P., Franek, A., Taradaj, J., Dolibog, P., Blaszczyk, E., Polak, A., et al. (2014). A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. *International Journal of Medical Science*, 11 (1), 34-43. (Level 4 evidence)

National Institute for Health and Care Excellence. (2014, June). *The geko device for reducing the risk of venous thromboembolism*. Retrieved March 20, 2017 from www.nice.org .

O'Connell, S., Bashar, K., Broderick, B., Sheehan, J., Quondamatteo, F., Walsh, S., et al. (2016). The use of intermittent pneumatic compression in orthopedic and neurosurgical postoperative patients: A systematic review and meta-analysis. *Annals of Surgery*, 263 (5), 888-889. Abstract retrieved March 20, 2017 from PubMed database.

Sadaghianloo, N., & Dardik, A. (2016). The efficacy of intermittent pneumatic compression in the prevention of lower extremity deep venous thrombosis. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*, 4 (2), 248-256. Abstract retrieved March 20, 2017 from PubMed database.

Shoeb, M. and Fang, M. (2013, April) Assessing bleeding risk in patients taking anticoagulants. *Journal of Thrombosis and Thrombolysis*, 35(3), 312-319. (Level 2 evidence)

U. S. Food and Drug Administration. (2008, October). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K082149. Retrieved March 14, 2013 from <http://www.accessdata.fda.gov>

U. S. Food and Drug Administration. (2011, November). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K110276. Retrieved March 8, 2013 from <http://www.accessdata.fda.gov>

Windisch, C., Kolb, W., Kolb, K., Grützner, P., Venbrocks, R., & Anders, J. (2011). Pneumatic compression with foot pumps facilitates early postoperative mobilization in total knee arthroplasty. *International Orthopedics*, 35 (7), 995-1000. (Level 2 evidence)

Winifred S. Hayes, Inc. Medical Technical Directory. (2013, August; last update search November 2018). *Pneumatic compression for prevention of deep vein thrombosis following knee surgery*. Retrieved January 10, 2019 from www.Hayesinc.com/subscribers. (118 articles and/or guidelines reviewed)



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Winifred S. Hayes, Inc. Medical Technical Directory. (2013, July; last update search June 2017). *Intermittent pneumatic compression for peripheral arterial disease*. Retrieved March 28, 2018 from www.Hayesinc.com/subscribers. (47 articles and/or guidelines reviewed)

Zaleska, M., Olszewski, W., & Durlik, M. (2014). The effectiveness of intermittent pneumatic compression in long-term therapy of lymphedema of lower limbs. *Lymphatic Research and Biology*, 12 (2), 103-109. (Level 4 evidence)

EFFECTIVE DATE 4/30/2019

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