



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema

Policy # 00404

Original Effective Date: 03/19/2014
Current Effective Date: 03/19/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers end-diastolic pneumatic compression boots as a treatment of peripheral vascular disease or lymphedema and its associated complications, including but not limited to ischemic lesions, claudication pain, necrotizing cellulitis, venous stasis ulcers, stasis dermatitis, chronic lymphedema, or thrombophlebitis, to be **investigational.***

Background/Overview

End-diastolic pneumatic compression has been investigated in the treatment of peripheral vascular disease, venous stasis, and lymphedema. Timed, sequential inflation during the end-diastolic portion of the cardiac cycle is applied to a boot enclosing the foot or ankle, or extending from the toes to the groin, and is designed both to allow maximal arterial flow into the leg and to expel venous blood and lymphatic fluid.

Poor lower extremity circulation can be associated with compromised arterial flow, impaired venous return or both. When oxygen demand exceeds the supply to the lower extremity, such as during physical activity, claudication pain can result. Small amounts of oxygen deprivation over a chronic period will lead to skin breakdown and poor healing capacity. Peripheral artery disease, typically caused by arteriosclerosis, worsens with age, smoking, high lipid levels, and diabetes. Venous stasis and lymphedema compress small arterioles and shunt blood from these areas.

Therapeutic approaches to peripheral artery disease include risk factor modification, control of diabetes; hypertension; and hyperlipidemia, aspirin and other antiplatelet therapies, and progressive exercise. Percutaneous or open surgical procedures can reestablish arterial flow. Approaches to venous stasis include compression and elevation.

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The end-diastolic pneumatic compression boot includes the following components: a heart monitor to detect the QRS complex of the electrocardiogram (ECG) and to appropriately time boot compressions in the end portion of the heart cycle; a rapid action valve assembly capable of both pressurizing and exhausting the boots; rigid, adjustable long boots to enclose the leg from groin to toes; and double-walled plastic bags to enclose the treated portion of the leg and to contain the compressed air.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In January 1980, "The Circulator Boot™"‡ (Circulator Boot Corporation, Malvern, PA) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for treatment of leg vascular diseases and congestive heart failure.

In May 1984, FDA approved a modification to limit the treatment area to the lower leg: The Miniboot.

In August 1997, FDA approved a computerized delay timing based on electrocardiogram.

In May 2009, "The Multicrus Circulator Boot™"‡ was cleared for marketing by FDA through the 510(k) process (K082134). This boot is adjustable in all three dimensions of length, height, and width. The clearance notes that the Circulator Boot System alone—or in combination with other drug or device therapies—may be prescribed by the physician to treat:

Poor arterial flow in extremities associated with:

- Ischemic ulcers
- Rest pain or claudication (pain with walking)
- Threatened gangrene
- Insufficient blood supply at amputation site
- Persisting ischemia after embolectomy or bypass surgery
- Pre- and postarterial reconstruction to improve runoff

Diabetes complicated by the above or other conditions possibly related to arterial insufficiency including:

- Nocturnal leg cramps
- Necrobiosis diabetorum

Venous disease (once risk of emboli minimized)

- Prophylaxis of deep vein thrombophlebitis
- Edema and induration associated with chronic venous stasis
- Venous stasis ulcers

Athletic injuries:

- "Charlie horses," pulled muscles, and edematous muscles

Rationale/Source

Randomized controlled trials that focus on the treatment of cutaneous ulcers are particularly important to isolate the contribution of any single therapy to an overall program of wound management, which typically includes sharp debridement of necrotic tissue, non-weight bearing, adequate nutrition, and antibiotic therapy.



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Searches of the literature identified several published articles on end-diastolic compression boot therapy authored by a single investigator, Richard Dillon, and all of them uncontrolled case series. In the largest case series, Dillon reported on 15 years of experience in treating 2177 episodes of foot and leg lesions (with a variety of etiologies) with the circulator boot. While the author reported that there was "deterioration" in a greater proportion of control (ie, initially uninvolved) legs compared to the treated leg, the heterogeneous group of patients and the lack of randomization limit interpretation of these data. Other published studies consist of small case series with the same limitations.

Updated literature searches identified only 1 report that was authored by Filp and Dillon of a series of 27 patients (41 legs) with cholesterol-embolization syndrome (CES) treated between 1997 and 2005. The alternate therapy offered to most patients at the time of referral was limb amputation. After a median interval of 11 months (range, 3-32 months) after initiation of therapy, 33 legs were totally healed, 6 improved, and 2 amputated. One patient died of causes unrelated to CES or use of the circulator boot. Another improved and discontinued treatment before he was totally healed. The authors concluded that the circulator boot seems to be the only effective therapy for CES. No comparison to alternative interventions at the time of treatment is possible, and treatment, particularly for cutaneous ulcers associated with vascular insufficiency, has continued to evolve since the patients in this study were treated.

Summary

End-diastolic pneumatic compression has been investigated in the treatment of peripheral vascular disease, venous stasis, and lymphedema. The available evidence, which consists of case series, is insufficient to determine if there is a role for end-diastolic pneumatic compression therapy in the treatment of peripheral vascular disease or lymphedema and its associated complications. Randomized controlled trials comparing outcomes with currently available treatments are required. Therefore, the treatment is considered investigational.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema , 2.02.17, 1:2014.
2. Dillon RS. Fifteen years of experience in treating 2177 episodes of foot and leg lesions with the circulator boot. *Angiology* 1997; 48(5 pt 2):S17-34.
3. Dillon RS. Improved hemodynamics shown by continuous monitoring of electrical impedance during external counterpulsation with the end-diastolic pneumatic boot and improved ambulatory EKG monitoring after 3 weeks of therapy. *Angiology* 1998; 49(7):523-35.
4. Dillon RS. Effect of therapy with the pneumatic end-diastolic leg compression boot on peripheral vascular test and on the clinical course of peripheral vascular disease. *Angiology* 1980; 31(9):614-38.
5. Dillon RS. Treatment of resistant venous stasis ulcers and dermatitis with the end diastolic pneumatic compression boot. *Angiology* 1986; 37(1):47-56.
6. Dillon RS. Successful treatment of osteomyelitis and soft tissue infections in ischemic diabetic legs by local antibiotic injections and the end-diastolic pneumatic compression boot. *Ann Surg* 1986; 204(6):643-9.
7. Filp JR, Dillon RS. Treatment of end-stage "trash feet" with the end-diastolic pneumatic boot. *Angiology* 2008; 59(2):214-9.



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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPSC	G0166
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

Policy History

Original Effective Date: 03/19/2014

Current Effective Date: 03/19/2014

03/06/2014 Medical Policy Committee review

03/19/2014 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 03/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

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