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: 09/13/2021

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.***

Policy Guidelines

End-diastolic pneumatic compression boot therapy is typically offered in a series of 40-minute sessions in an office setting. There are no specific CPT codes for this technology, but a series of CPT codes may be used to describe the individual components of the overall therapy, similar to those used for external counterpulsation therapy for chronic refractory angina or congestive heart failure. See the coding section for further detail. In 2000, HCPCS code G0166 (external counterpulsation, per treatment session) was introduced to describe external counterpulsation as a treatment of chronic refractory angina. However, the U.S. Food and Drug Administration (FDA) classifies the circulator boot as an external counterpulsating device, and thus this HCPCS code might possibly be used by some providers for the boot therapy. The unlisted CPT code 93799 (unlisted cardiovascular service or procedure) might be used for this service.

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.

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 post-arterial reconstruction to improve runoff

Diabetes complicated by the above or other conditions possibly related to arterial insufficiency including:
- Nocturnal leg cramps
- Necrobiosis diabeticorum

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

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Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

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.

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-Archived policy, December 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.

Policy History

Original Effective Date: 03/19/2014
Current Effective Date: 09/13/2021

03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. New policy.
08/06/2015	Medical Policy Committee review
08/19/2015	Medical Policy Implementation Committee approval. No change to coverage.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. No change to coverage.
08/09/2018	Medical Policy Committee review. Recommend archiving policy.
08/15/2018	Medical Policy Implementation Committee approval. Decided not to archive. No change to coverage.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged

Next Scheduled Review Date: 08/2022

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 2020

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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	93799
HCPCS	G0166
ICD-10 Diagnosis	All related diagnosis

*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);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.