MEDICAL POLICY

POLICY TITLE	END DIASTOLIC PNEUMATIC COMPRESSION BOOT AS A TREATMENT OF PERIPHERAL VASCULAR DISEASE OR LYMPHEDEMA
POLICY NUMBER	MP-6.044

Original Issue Date:	**12/1/2011**
Most Recent Review Date:	**9/18/2018**
Effective Date:	**11/1/2018**

I. POLICY

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End diastolic pneumatic compression boots are considered **investigational** 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. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

Policy Guidelines

End-diastolic pneumatic compression boot therapy is typically offered in a series of 40-minute sessions in an office setting. It is similar to those used for external counterpulsation therapy for chronic refractory angina or congestive heart failure. U.S. Food and Drug Administration (FDA) classifies the circulator boot as an external counterpulsating device.

Cross-references:
MP-2.014 Enhanced External Counterpulsation (EECP)
MP-4.028 Wound & Burn Care & Specialized Treatment Centers
MP-6.013 Pneumatic Compression Devices for Treatment of Lymphedema and Chronic Venous Insufficiency

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO-The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational.

Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

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The end-diastolic pneumatic compression boot includes the following components: a heart monitor to detect the QRS complex of the EKG 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.

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 be arteriosclerosis, worsens with age, smoking, high lipids 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.

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.

Regulatory Status

In January 1980, device "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, the FDA approved a modification to limit the treatment area to the lower leg: The Miniboom. In August 1997, the FDA approved a computerized delay timing based on electrocardiogram.

In May 2009, "The Circulator Boot™" was cleared for marketing by the FDA through the 510(k) process as follows: "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 possible 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

IV. RATIONALE

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SUMMARY OF EVIDENCE

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.

2018 Update
Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

V. DEFINITIONS

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CLAUDICATION is leg pain or numbness that occurs with standing or walking.

LYMPHEDEMA refers to the abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities as a result of obstruction of lymphatic flow causing swelling of the extremities. Lymphedema may be subdivided into two types:

- Primary lymphedema, which has no recognizable etiology; and
- Secondary lymphedema, which has a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels, or congenital anomalies.

Treatment of lymphedema may include the use of pharmaceuticals, mechanical appliances, such as compression garments, bandaging, manual massage, lymphedema pumps, or in rare incidences, surgery.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following codes are considered **investigational** when billed for end diastolic pneumatic compression boots as outlined in the policy section; **therefore, not covered**:

CPT Codes®								
93799	99199							

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IX. REFERENCES

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1. *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.*
2. *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.*
3. *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.*
4. *Dillon RS. Treatment of resistant venous stasis ulcers and dermatitis with the end diastolic pneumatic compression boot. Angiology 1986; 37(1):47-56.*
5. *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.*
6. *Filp JR, Dillon RS. Treatment of end-stage "trash feet" with the end-diastolic pneumatic boot. Angiology 2008; 59(2):214-9*
7. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.02.17, End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema January 2015 (Archived).*

X. POLICY HISTORY

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MP 6.044	**CAC 7/26/2011** New Policy, Adopt BCBSA
	CAC 10/30/12 Minor Revision-Medicare. References updated; no changes to policy statement. Both Medicare and FEP variations were revised. Effective 10/27/2011, Medicare now only covers the indications addressed in NCD 280.6 Pneumatic Compression Devices which include lymphedema and the treatment of chronic venous insufficiency. FEP variation revised to refer to FEP policy manual.
	03/28/2013-Admin code changes
	CAC 11/26/13 Consensus. No change to policy statements. References updated. Rationale section added.
	CAC 11/25/14 Consensus review. No change to the policy statements. References and rationale updated. Codes reviewed, no changes.
	CAC 11/24/15 Consensus review. No change to policy statements. References and rationale reviewed. FEP policy 2.02.17 was archived. Changed variation to reference standard investigational. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to the policy statement.

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	References updated**.** Variations reformatted**.** Coding reviewed.
	12/19/2017 Consensus review. Coding reviewed.
	9/18/18 Consensus review. No change to the policy statement. References reviewed. Rationale revised**.**

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