I. POLICY

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.

*Cross-reference*
- MP-2.014 Enhanced External Counterpulsation (EECP)
- MP-4.028 Wound & Burn Care & Specialized Treatment Centers (Including Surgical Dressings)
- MP-6.013 Pneumatic Compression Pumps for Treatment of Lymphedema and Chronic Venous Insufficiency
- MP-8.001 Physical Medicine and Specialized Physical Medicine Treatments
### II. PRODUCT VARIATIONS

- **[N]** = No product variation, policy applies as stated
- **[Y]** = Standard product coverage varies from application of this policy, see below

<table>
<thead>
<tr>
<th>Policy Variation</th>
<th>Description</th>
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<tbody>
<tr>
<td>Capital Cares 4 Kids</td>
<td>[N] Indemnity</td>
</tr>
<tr>
<td>PPO</td>
<td>[N] SpecialCare</td>
</tr>
<tr>
<td>HMO</td>
<td>[N] POS</td>
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<tr>
<td>SeniorBlue HMO*</td>
<td>[Y] FEP PPO*</td>
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<tr>
<td>SeniorBlue PPO*</td>
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</tbody>
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*Refer to Noviatas Solutions Local Coverage Determination (LCD) L31686 Services That Are Not Reasonable and Necessary which states: Procedure code 99199 will be denied as not reasonable and necessary when reported for end diastolic pneumatic compression therapy services other than what is covered per NCD 280.6 Pneumatic Compression Devices which include lymphedema and the treatment of chronic venous insufficiency with venous stasis ulcers.

### Lymphedema

Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

### Chronic Venous Insufficiency with Venous Stasis Ulcers

Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

**Refer to FEP Medical Policy Manual MP-2.02.17 End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema. The FEP Medical Policy manual can be found at:** [www.fepblue.org](http://www.fepblue.org)

### III. DESCRIPTION/BACKGROUND

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 by 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:*

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>END DIASTOLIC PNEUMATIC COMPRESSION BOOT AS A TREATMENT OF PERIPHERAL VASCULAR DISEASE OR LYMPHEDEMA</th>
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<tbody>
<tr>
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<td>MP-6.044</td>
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<tr>
<td>POLICY TITLE</td>
<td>END DIASTOLIC PNEUMATIC COMPRESSION BOOT AS A TREATMENT OF PERIPHERAL VASCULAR DISEASE OR LYMPHEDEMA</td>
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</tr>
<tr>
<td>POLICY NUMBER</td>
<td>MP-6.044</td>
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</tbody>
</table>

- 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

This policy is updated periodically with searches of the MEDLINE database. The most recent literature update was performed through November 2012.

As noted in other policies focusing on treatment of cutaneous ulcers, randomized controlled trials (RCTs) are particularly important to isolate the contribution of any one therapy to an overall program of wound management, which typically includes sharp debridement of necrotic tissue, non-weight bearing, adequate nutrition, and antibiotic therapy,

**Literature Review**

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 2,177 episodes of foot and leg lesions (with a variety of etiologies) with the circulator boot. (1) While the author reported that there was “deterioration” in a greater proportion of control (i.e., 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. (2-5)

Updated searches of the MEDLINE database identified only one 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. (6) 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.

V. DEFINITIONS

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

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 for benefit information.

VII. DISCLAIMER
Capital’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 considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VIII. CODING INFORMATION

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:

<table>
<thead>
<tr>
<th>CPT Codes®</th>
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<tr>
<td>92971</td>
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<tr>
<td>93041</td>
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<td>93799</td>
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<td>99199</td>
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</table>


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

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>G0166</td>
<td>EXTERNAL COUNTERPULSATION, PER TREATMENT SESSION</td>
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</table>

<table>
<thead>
<tr>
<th>ICD-9-CM Diagnosis Code*</th>
<th>Description</th>
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</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code*</th>
<th>Description</th>
</tr>
</thead>
</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.
IX. REFERENCES


2. Dillon RS. Improved hemodynamics shown by continuous monitoring of electrical impedance during external counterc pulsation 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.


X. POLICY HISTORY

<table>
<thead>
<tr>
<th>MP 6.044</th>
<th>CAC 7/26/2011 New Policy, Adopt BCBSA</th>
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</thead>
<tbody>
<tr>
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<td>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.</td>
</tr>
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<td></td>
<td>03/28/2013-Admin code changes-skb</td>
</tr>
<tr>
<td></td>
<td>CAC 11/26/13 Consensus. No change to policy statements. References updated. Rationale section added.</td>
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</tbody>
</table>

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