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

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<tr>
<th>Section</th>
<th>Original Policy Date</th>
<th>Last Review Status/Date</th>
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<tbody>
<tr>
<td>Medicine</td>
<td>12:2013</td>
<td>Reviewed with literature search/12:2013</td>
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### Issue
12:2013

### Description

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 (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.
Regulatory Status

In January 1980, “The Circulator Boot™” (Circulator Boot Corporation, Malvern, PA) was cleared for marketing by the U.S. Food and Drug Administration (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 Miniboot.

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

In May 2009, “The Multicrus Circulator Boot™” was cleared for marketing by the 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
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.

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 FDA classifies the circulator boot as an external counterpulsating device, and thus this HCPCS code might possibly be used by some providers to the boot therapy. The unlisted CPT code 99199 (unlisted special service, procedure or report) might be used for this service.

Rationale
This policy was created in 2003 and 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, if necessary (see policy Nos.1.01.16, 2.01.16).

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 Filip 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.

References:

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.

<table>
<thead>
<tr>
<th>Codes</th>
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<th>Description</th>
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<tbody>
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<td>CPT</td>
<td>92971</td>
<td>Cardioassist-method of circulatory assist; external</td>
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<tr>
<td></td>
<td>93041</td>
<td>Rhythm EKG - one to three leads; tracing only without interpretation and reports</td>
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<tr>
<td></td>
<td>99354–99357</td>
<td>Prolonged physician services with direct (face to face) patient contact</td>
</tr>
<tr>
<td></td>
<td>99358–99359</td>
<td>Prolonged physician services without direct (face to face) contact</td>
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<tr>
<td></td>
<td>99211</td>
<td>Office or outpatient visit for the evaluation of an established patient by non-physician</td>
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<tr>
<td>ICD-9 Diagnosis</td>
<td>Investigational for all codes</td>
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<tr>
<td>HCPCS</td>
<td>G0166</td>
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<tr>
<td></td>
<td>External counterpulsation, per treatment session</td>
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<td>Phlebitis and thrombophlebitis code range</td>
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<td>Varicose veins of lower extremities with inflammation code range</td>
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<td>I83.202-I83.209; I83.212-I83.219; I83.222-I83.229</td>
<td>Varicose veins of lower extremities with both ulcer and inflammation code range</td>
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<td>I89.0</td>
<td>Lymphedema, not elsewhere classified</td>
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<td>ICD-10-PCS (effective 10/1/14)</td>
<td>ICD-10-PCS codes are only used for inpatient services. There is no specific ICD-10-PCS code for this procedure.</td>
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External Counterpulsation Therapy, Peripheral Artery Disease