

Protocol

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

(20217)

Medical Benefit		Effective Date: 02/01/07	Next Review Date: 03/15
Preauthorization	No	Review Dates: 04/07, 05/08, 03/09, 03/10, 03/11, 03/12, 03/13, 03/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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.

Background

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 from groin to toes; and double-walled plastic bags to enclose the treated portion of the leg and to contain the compressed air.

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 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

Related Protocols

Negative Pressure Wound Therapy in the Outpatient Setting

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions

Enhanced External Counterpulsation (EECP)

Policy (Formerly Corporate Medical Guideline)

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 Guideline

End diastolic pneumatic compression boot therapy is typically offered in a series of 40-minute sessions in an office setting.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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.