



Kansas City

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

Policy Number: 2.02.17

Origination: 1/2008

Last Review: 2/2014

Next Review: 2/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for end diastolic pneumatic compression boot as described below. Their use is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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.

Considerations

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.

Description of Procedure or Service

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.

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 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, “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 possible 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

Rationale

This policy was created in 2003 and updated periodically with searches of the MEDLINE database. The most recent literature update was performed through December 20, 2013.

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.

References

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.

Billing Coding/Physician Documentation Information

92971	Cardioassist-method of circulatory assist; external
93041	Rhythm EKG, 1-3 leads; tracing only without interpretation and reports
93799	Unlisted cardiovascular service or procedure
99354	Prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management service)
99355	Prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)
99356	Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient Evaluation and Management service)

- 99357** Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)
- 99358** Prolonged evaluation and management service before and/or after direct patient care; first hour
- 99359** Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (List separately in addition to code for prolonged service)
- 99211** Office or outpatient visit for the evaluation of an established patient that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.
- E0675** Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
- G0166** External counterpulsation, per treatment session

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 counterpulsation device, and thus this HCPCS code might possibly be used by some providers to report the boot therapy. The unlisted CPT code 93799 (unlisted cardiovascular service or procedure) might be used for this service.

Codes E0667, E0668, E0669, E0671, E0672 or E0673 may be seen on claims for home therapy. When submitted for the indications outlined in the policy statements above, these related codes would also be considered investigational.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- 1/1/08 New policy; considered investigational
- 8/1/08 Policy updated to include discussion of rapid compression for the treatment of arterial insufficiency; this treatment is considered investigational. The title of the policy was changed from *End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema* to *Pneumatic Compression Devices as a Treatment of Peripheral Vascular Disease or Lymphedema*.
- 1/1/09 No policy statement changes.
- 1/1/10 No policy statement changes.
- 9/1/10 Policy statement revised removing pneumatic compression devices for treatment of peripheral arterial occlusive disease/arterial insufficiency. Title of policy changed from *Pneumatic Compression Devices as a Treatment of Peripheral Vascular Disease or Lymphedema* to *End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema*.
- 1/1/11 No policy statement changes.
- 1/1/12 No policy statement changes.
- 1/1/13 No policy statement changes.
- 1/1/14 No policy statement changes.
- 2/1/14 No policy statement changes. Added CPT codes that were missing.

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