

Corporate Medical Policy

End Diastolic Pneumatic Compression Boot

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| File Name: | end_diastolic_pneumatic_compression_boot |
| Origination: | 6/2011 |
| Last CAP Review: | 10/2011 |
| Next CAP Review: | 10/2012 |
| Last Review: | 10/2011 |

Description of Procedure or Service

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.

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.

Regulatory Status

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

End Diastolic Pneumatic Compression Boot

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”

Related Policies:

Enhanced External Counterpulsation (EECP)

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

End diastolic pneumatic compression boots are considered investigational as a treatment of peripheral vascular disease or lymphedema and its associated complications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When End Diastolic Pneumatic Compression Boot is covered

Not Applicable

When End Diastolic Pneumatic Compression Boot 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.

Policy Guidelines

The available evidence 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 lacking.

Billing/Coding/Physician Documentation Information

End Diastolic Pneumatic Compression Boot

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There are no specific CPT codes for this technology; however, the HCPCS code G0166 might be used by some providers.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.17, 4/14/11

Specialty Matched Consultant Advisory Panel review 10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.17, 1/12/12

Policy Implementation/Update Information

6/21/11 New policy implemented. 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. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Policy Statements. (mco)

3/20/12 References updated. No changes to policy statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.