

# MEDICAL POLICY



<b>SUBJECT: END-DIASTOLIC PNEUMATIC COMPRESSION (e.g., CIRCULATOR BOOT)</b>	<b>EFFECTIVE DATE: 02/21/01</b> <b>REVISED DATE: 05/16/02, 06/16/05</b> <b>ARCHIVED: 07/17/03-06/16/05, 03/16/06</b> <b>EDITED DATE: 04/04/07, 04/17/08, 04/16/09, 04/22/10, 04/21/11, 04/19/12, 04/18/13, 04/17/14, 04/16/15, 04/21/16, 04/20/17, 04/19/18</b>
<b>POLICY NUMBER: 1.01.31</b> <b>CATEGORY: Technology Assessment</b>	<b>PAGE: 1 OF: 2</b>
<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul>	

## **POLICY STATEMENT:**

Based upon our criteria and assessment of the peer-reviewed literature, end-diastolic pneumatic compression for the assistance of arterial and venous circulation in the lower extremity has not been proven to be medically effective and is considered **investigational**.

*Refer to Corporate Medical Policy #1.01.17 Pneumatic Compression Devices/Lymphedema Pump.*

*Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.*

## **POLICY GUIDELINES:**

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity

## **DESCRIPTION:**

End-diastolic pneumatic compression or circulator boot has been investigated as a non-invasive technique to promote the peripheral circulation and thus treat peripheral vascular disease and its complications, including venous stasis ulcers, dermatitis, osteomyelitis, and soft tissue infections. The technique has also been investigated in the treatment of lymphedema.

The device is designed to help increase the circulation to the extremities. A double walled plastic bag is placed over the leg of the patient and then placed inside a rigid “plastic” boot. The boot is then attached to a valve system, which is connected to an air supply. The boot is then attached to a valve monitor that times the compression cycle to occur with the end portion of the heart cycles. Timed, sequential inflation during the end diastolic portion of the cardiac cycle is designed both to allow maximal arterial flow into the leg and to expel venous blood and lymphatic fluid. End diastolic pneumatic compression boot therapy is typically offered in a series of multiple 40-minute sessions in an office setting.

This policy addresses only end-diastolic pneumatic compression (Circulator Boot).

## **RATIONALE:**

The Circulator Boot has received clearance for marketing from the U.S. Food and Drug Administration (FDA) through the 510(k) approval process. The FDA classifies the Circulator Boot as an external counter-pulsating device and it is specifically labeled for the following indications:

- I. Peripheral arterial disease,
- II. Ischemic lesions,
- III. Claudication pain,
- IV. Necrotizing cellulites,
- V. Venous stasis ulcers,
- VI. Stasis dermatitis,
- VII. Chronic lymphedema,
- VIII. Thrombophlebitis.

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The evidence is lacking to demonstrate that this treatment is beneficial to the general population of patients with peripheral vascular disease or lymphedema and their associated complications, including but not limited to ischemic lesions, claudication pain, necrotizing cellulitis, venous stasis ulcers, stasis dermatitis, chronic lymphedema, or thrombophlebitis. It remains unclear whether the circular boot would lead to better health outcomes when compared to standard treatment of these patients.

**CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**                      No specific codes

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**HCPCS:**                No specific codes

**ICD 9:**                    Experimental/Investigational for all codes

**ICD10:**                 Experimental/Investigational for all codes

**REFERENCES:**

BlueCross BlueShield Association. End diastolic pneumatic compression boot as a treatment of peripheral vascular disease or lymphedema. Medical Policy Reference Manual Policy #2.02.17. archived 2014 Jan 11.

\*Dillon RS. Fifteen years experience in treating 2177 episodes of foot and leg lesions with the circulator boot. Angiol 1997;48(5 pt 2):S17-34.

\*Vella A. Circulator boot therapy alters the natural history of ischemic limb ulcerations. Vascul Med 2000;5:21-5.

\*Key article

**KEY WORDS:**

Circulator boot, End diastolic pneumatic compression device

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, End Diastolic Pneumatic Compression Boot is not addressed in National or Regional Medicare coverage determinations or policies.