BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/19/13
LAST REVIEW DATE: 01/21/14
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

END-DIASTOLIC PNEUMATIC COMPRESSION BOOT AS A TREATMENT OF PERIPHERAL VASCULAR DISEASE OR LYMPHEDEMA

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

End-diastolic pneumatic compression is a timed, sequential inflation during the end-diastolic portion of the cardiac cycle and 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 Circulator Boot™ device is equipped with a heart monitor to detect the QRS complex of the EKG and time boot compressions during diastole, therefore, not compressing the leg during contraction and arterial inflow. End-diastolic pneumatic compression may also be known as external counterpulsation or intermittent pneumatic compression (IPC) and has been investigated as a technique to promote peripheral circulation to treat peripheral vascular disease (PVD) and its complications, including venous stasis ulcers, dermatitis and osteomyelitis and soft tissue infections. It has also been investigated in the treatment of lymphedema.

END-DIASTOLIC PNEUMATIC COMPRESSION BOOT AS A TREATMENT OF PERIPHERAL VASCULAR DISEASE OR LYMPHEDEMA (cont.)

Criteria:

- End-diastolic pneumatic compression for treatment of the following indications are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

  These indications include, *but are not limited to:*

  - Claudication pain
  - Ischemic lesions
  - Lymphedema
  - Necrotizing cellulitis
  - Peripheral vascular disease
  - Stasis dermatitis
  - Thrombophlebitis
  - Venous stasis ulcers

Resources:

Resources prior to 02/19/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.02.17 BCBS Medical Policy Reference Manual. End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema. Re-issue date 01/09/2014, issue date 10/09/2003.

FDA 510K Summary for Circulator Boot System:

- FDA-approved indication: Used to treat peripheral arterial disease, lymphedema, ischemic lesions, claudication pain, necrotizing cellulites, venous stasis ulcers, stasis dermatitis and thrombophlebitis.