Name of Policy: Lymphedema Pumps/Pneumatic Compression Devices

Policy #: 123
Category: DME

Latest Review Date: September 2014
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures such as compression garments or manual massage. There are a variety of pumps available and they may be single chamber (nonsegmented) or multi-chamber (segmented) and have varying design and complexity.

A lymphedema pump is an intermittent pneumatic compression device that consists of an inflatable garment that wraps around the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. This helps squeeze the lymph fluid through any lymph channels that are present. When the device deflates, blood is allowed to circulate through the area. After many repeated cycles, this device may reduce swelling from lymphedema.

There are three main types of lymphedema pumps that are described below:

- **Type I**: Non-segmented (single chamber nonprogrammable pump) pneumatic compressor (E0650).
- **Type II**: Segmented (multi-chamber nonprogrammable pump) pneumatic compressor without calibrated gradient pressure (no manual control of pressure) (E0651).
- **Type III**: Segmented (multi-chamber) pneumatic compressor with (manually) calibrated gradient pressure (E0652).

A non-segmented pneumatic compressor/single-chamber nonprogrammable pump (E0650) is a device that has a single outflow port on the compressor. The fact that the air from the single tube may be transmitted to a sleeve/appliance with multiple compartments or segments (E0671-E0673) does not affect the coding of the compressor.

A segmented pneumatic compressor (E0651, E0652) is a device that has multiple outflow ports on the compressor that lead to distinct segments of the appliance that inflate sequentially. A segmented device without calibrated gradient pressure (E0651) is one in which either (a) the same pressure is present in each segment or (b) there is a predetermined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of several segments. In an E0651 device the pressure is usually set by a single control on the distal segment. A segmented device with calibrated gradient pressure (E0652) is characterized by a manual control on at least three outflow ports that can deliver an individually determined pressure to each segmental unit. The fact that the tubing and/or appliance are capable of achieving a pressure gradient does not classify the compressor as E0652 because this is not a calibrated gradient pressure.

Single- or multi-chamber programmable pumps are similar to the pumps described above except that it is possible to make manual adjustments in the pressure in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including patients with scarring, contractures or highly sensitive skin, programmable pumps are generally considered to be the preferred option.
The ReidSleeve® (E1399) is a custom-fitted, non-elastic sleeve that provides compression to assist in flow of lymphatic fluid. The sleeve is constructed from specially designed foam and utilizes adjustable bands to provide a wide-range of gradient pressures. The degree of available compression ranges from 20 to 40 mmHg. The high-pressure zones force excess fluid into the areas under lower pressure, forming channels via which the lymphatic fluid can be removed through the lymphatic and venous system. The sleeve is designed to be worn overnight is easily self-applied.

Tribute™ garments are based on principles of physics, fluid dynamics and engineering. The inventions are a method and apparatus designed to create enhanced and directed interstitial movement of excess fluids away from a swollen area of a patient's body, while supporting the restoration of plasma protein tissue concentration and distribution. The garments provide gradient compression that is achieved through high to low pressure ratios created by variations in density, type, size, proportion, and insertion pressure of foam into predetermined pockets or channels created within a proprietary fabric. Using chopped foam of differing sizes and densities gradient compression is produced from distal to proximal and from medial to lateral.

A Compressure bra (E1399) is a gradient compression garment used to treat lymphedema of the breast and trunk.

Intermittent pneumatic foot compression devices are said to act as a pump to improve circulation in the lower extremities. They are used to prevent deep venous thromboses (DVT) and complications of venous stasis in patients after trauma, orthopedic surgery, neurosurgery, or non-ambulatory patients. Recently use of the intermittent pneumatic foot compression device has expanded to ambulatory persons who have chronic venous insufficiency of the legs.

Non-elastic compression garments utilize a non-elastic textile that is fastened by adjustable hooks and loops to provide compression. They can be worn during the day or night. Both custom-made and prefabricated garments are available.

**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.

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.
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 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.

See Policy #515 for Outpatient Use of Limb Pneumatic compression Devices for Venous Thromboembolism Prophylaxis

**Policy:**
**Effective for dates of service on or after February 16, 2014:**
Lymphedema pumps/pneumatic compression devices or compression garments when applied to the limb meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema in the affected limbs resulting from a mastectomy and ordered by the patient’s treating physician.

Single-chamber lymphedema pumps/pneumatic compression devices when applied to the limb meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat true lymphedema not resulting from a mastectomy when all the following criteria are met:
- The lymphedema is associated with functional impairment, e.g., impairment of activities of daily living;
- The patient has tried and been compliant with four weeks of conservative therapy, i.e. elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment;
- The patient’s lymphedema is not improving with conservative measures;
- Photographs or a diagnostic test must document the diagnosis of lymphedema (not required in cases of mastectomy related lymphedema).

Except when as a result of a mastectomy, a single-chamber/non-segmented device (E0650) or multi-chamber/segmented device without manual control of the pressure in each chamber (E0651) is generally sufficient to meet the clinical needs for patients with lymphedema.

A multi-chamber programmable segmented device with manual control of the pressure in each chamber (E0652) when applied to the limb meets medical criteria for coverage only when there is documentation in the patient’s medical record of a condition that will not allow treatment of the lymphedema with E0650 or E0651. Such conditions include a significant
sensitive skin scar or contracture, which make treatment with another device painful or unsafe for the patient.

The **ReidSleeve when applied to the limb meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with **intractable lymphedema** from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

A **Compressure bra meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat **lymphedema of the breast or trunk resulting from treatment of breast cancer**.

The **Tribute™ garment when applied to the limb meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

The use of **lymphedema pumps to treat venous ulcers does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**Intermittent compression devices** which incorporate cold or heat therapy such as the GAME Ready device, **do not** meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

**Lymphedema pumps/pneumatic compression devices** are contraindicated and therefore, **do not meet medical criteria for coverage** for:

- Infection
- Venous or arterial occlusive disease (except venous stasis ulcers as described above)
- Venous thrombosis
- Massive edema secondary to such conditions as congestive heart failure, renal failure, or hepatic insufficiency
- Metastatic disease in the involved extremity

**Lymphedema pumps/pneumatic compression devices** for diabetic neuropathic ulcers and arterial ischemic ulcers **do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **investigational**.

**Non-elastic gradient compression wrap (A6545) and non-elastic leg binders (A4465), e.g., Circaid Juxta-lite, Circaid T-3 M and Circaid Cures, LegAssist, Caresia Bandage Liners, etc. do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**External intermittent pneumatic compression devices for the feet do not meet** Blue Cross and Blue Shield’s medical criteria for coverage.
**Intermittent compression devices** which incorporate cold or heat therapy such as the GAME Ready device, **do not** meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

**Non-elastic gradient compression wrap (A6545) does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

The use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**End-diastolic pneumatic compression boots do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and 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.

---

**Effective for dates of service on or after November 2, 2012 through February 25, 2014:**

**Lymphedema pumps/pneumatic compression devices or compression garments meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema in the affected limbs **resulting from a mastectomy** and ordered by the patient’s treating physician.

**Single-chamber lymphedema pumps/pneumatic compression devices meet** Blue Cross and Blue Shield of Alabama’s **medical criteria for coverage** when used to treat true lymphedema not resulting from a mastectomy when all the following criteria are met:

- The lymphedema is associated with functional impairment, e.g., impairment of activities of daily living;
- The patient has tried and been compliant with four weeks of conservative therapy, i.e., elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment;
- The patient’s lymphedema is not improving with conservative measures;
- Photographs or a diagnostic test must document the diagnosis of lymphedema (not required in cases of mastectomy related lymphedema).

**Lymphedema pumps/pneumatic compression devices meet** Blue Cross and Blue Shield of Alabama’s **medical criteria for coverage** when used to treat chronic venous insufficiency (CVI) with **venous stasis ulcers that have failed to resolve with six months of intense physician directed conservative therapy**. The therapy should consist of a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

Except when as a result of a mastectomy, a **single-chamber/non-segmented device (E0650)** or **multi-chamber/segmented device without manual control** of the pressure in each chamber (E0651) is generally sufficient to meet the clinical needs for patients with lymphedema or venous stasis ulcers.
A multi-chamber programmable segmented device with manual control of the pressure in each chamber (E0652) meets medical criteria for coverage only when there is documentation in the patient’s medical record of a condition that will not allow treatment of the lymphedema with E0650 or E0651. Such conditions include a significant sensitive skin scar or contracture, which make treatment with another device painful or unsafe for the patient.

The ReidSleeve meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

A Compressure bra meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema of the breast or trunk resulting from treatment of breast cancer.

The Tribute™ garment meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

Lymphedema pumps/pneumatic compression devices are contraindicated and therefore, do not meet medical criteria for coverage for:

- Infection
- Venous or arterial occlusive disease (except venous stasis ulcers as described above)
- Venous thrombosis
- Massive edema secondary to such conditions as congestive heart failure, renal failure, or hepatic insufficiency
- Metastatic disease in the involved extremity

Lymphedema pumps/pneumatic compression devices for diabetic neuropathic ulcers and arterial ischemic ulcers do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Non-elastic gradient compression wrap (A6545) and non-elastic leg binders (A4465), e.g., Circaid Juxta-lite, Circaid T-3 M and Circaid Cures, LegAssist, Caresia Bandage Liners, etc. do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

External intermittent pneumatic compression devices for the feet do not meet Blue Cross and Blue Shield’s medical criteria for coverage.
Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

Non-elastic gradient compression wrap (A6545) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

The use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

End-diastolic pneumatic compression boots do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and 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.

Effective for dates of service on or after May 1, 2012 and prior to November 2, 2012:

Lymphedema pumps/pneumatic compression devices or compression garments meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema in the affected limbs resulting from a mastectomy and ordered by the patient’s treating physician.

Single-chamber lymphedema pumps/pneumatic compression devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat true lymphedema not resulting from a mastectomy when all the following criteria are met:

- The lymphedema is associated with functional impairment, e.g., impairment of activities of daily living;
- The patient has tried and been compliant with four weeks of conservative therapy, i.e. elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment;
- The patient’s lymphedema is not improving with conservative measures;
- Photographs or a diagnostic test must document the diagnosis of lymphedema (not required in cases of mastectomy related lymphedema).

Lymphedema pumps/pneumatic compression devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat chronic venous insufficiency (CVI) with venous stasis ulcers that have failed to resolve with six months of intense physician directed conservative therapy. The therapy should consist of a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

Except when as a result of a mastectomy, a single-chamber/non-segmented device (E0650) or multi-chamber/segmented device without manual control of the pressure in each chamber
(E0651) is generally sufficient to meet the clinical needs for patients with lymphedema or venous stasis ulcers.

A multi-chamber programmable segmented device with manual control of the pressure in each chamber (E0652) meets medical criteria for coverage only when there is documentation in the patient’s medical record of a condition that will not allow treatment of the lymphedema with E0650 or E0651. Such conditions include a significant sensitive skin scar or contracture, which make treatment with another device painful or unsafe for the patient.

The ReidSleeve meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

A Compressure bra meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema of the breast or trunk resulting from treatment of breast cancer.

The Tribute™ garment meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care

Lymphedema pumps/pneumatic compression devices are contraindicated and therefore, do not meet medical criteria for coverage for:

- Infection
- Venous or arterial occlusive disease (except venous stasis ulcers as described above)
- Venous thrombosis
- Massive edema secondary to such conditions as congestive heart failure, renal failure, or hepatic insufficiency
- Metastatic disease in the involved extremity

Lymphedema pumps/pneumatic compression devices for diabetic neuropathic ulcers and arterial ischemic ulcers do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Non-elastic gradient compression wrap (A6545) and non-elastic leg binders (A4465), e.g., Circaid Juxta-lite, Circaid T-3 M and Circaid Cures, LegAssist, Caresia Bandage Liners, etc. do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.
External intermittent pneumatic compression devices for the feet do not meet Blue Cross and Blue Shield’s medical criteria for coverage.

Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

Non-elastic gradient compression wrap (A6545) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Two-phase multi-chamber lymphedema pumps do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

End-diastolic pneumatic compression boots do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and 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.

Effective for dates of services December 28, 2011 through April 30, 2012:
Lymphedema pumps/pneumatic compression devices or compression garments meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema in the affected limbs resulting from a mastectomy and ordered by the patient’s treating physician.

Single-chamber lymphedema pumps/pneumatic compression devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat true lymphedema not resulting from a mastectomy when all the following criteria are met:
• The lymphedema is associated with functional impairment, e.g., impairment of activities of daily living;
• The patient has tried and been compliant with four weeks of conservative therapy, i.e. elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment;
• The patient’s lymphedema is not improving with conservative measures;
• Photographs or a diagnostic test must document the diagnosis of lymphedema (not required in cases of mastectomy related lymphedema).

Lymphedema pumps/pneumatic compression devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat chronic venous insufficiency (CVI) with venous stasis ulcers that have failed to resolve with six months of intense physician directed conservative therapy. The therapy should consist of a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.
Except when as a result of a mastectomy, a single-chamber/non-segmented device (E0650) or multi-chamber/segmented device without manual control of the pressure in each chamber (E0651) is generally sufficient to meet the clinical needs for patients with lymphedema or venous stasis ulcers.

A multi-chamber programmable segmented device with manual control of the pressure in each chamber (E0652) meets medical criteria for coverage only when there is documentation in the patient’s medical record of a condition that will not allow treatment of the lymphedema with E0650 or E0651. Such conditions include a significant sensitive skin scar or contracture, which make treatment with another device painful or unsafe for the patient.

The ReidSleeve meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

A Compressure bra meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to treat lymphedema of the breast or trunk resulting from treatment of breast cancer.

The Tribute™ garment meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with intractable lymphedema from either axillary radiation therapy or surgery for breast cancer who have not improved with conservative measures of four weeks of elevation, exercise, and massage.

Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

Lymphedema pumps/pneumatic compression devices are contraindicated and therefore, do not meet medical criteria for coverage for:
- Infection
- Venous or arterial occlusive disease (except venous stasis ulcers as described above)
- Venous thrombosis
- Massive edema secondary to such conditions as congestive heart failure, renal failure, or hepatic insufficiency
- Metastatic disease in the involved extremity

Lymphedema pumps/pneumatic compression devices for diabetic neuropathic ulcers and arterial ischemic ulcers do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Non-elastic gradient compression wrap (A6545) and non-elastic leg binders (A4465), e.g., Circaid Juxta-lite, Circaid T-3 M and Circaid Cures, LegAssist, Caresia Bandage Liners, etc. do
not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

External intermittent pneumatic compression devices for the feet do not meet Blue Cross and Blue Shield’s medical criteria for coverage.

Intermittent compression devices which incorporate cold or heat therapy such as the GAME Ready device, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of acute or chronic musculoskeletal injuries or as part of postoperative care.

Non-elastic gradient compression wrap (A6545) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Two-phase multi-chamber lymphedema pumps do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
The most recent literature search was through July 2014.

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema represents a developmental abnormality of the lymphatic system. It can be divided into three forms: lymphedema congenita, lymphedema praecox, and lymphedema tarda, depending on the age at presentation. These conditions are most often sporadic, with no family history, and involve the lower extremity almost exclusively. The primary lymphedemas are rare and occur in 1 of 10,000 individuals.

Secondary lymphedema is acquired and due to an obstruction or interruption in the lymphatic system. Secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, postradiation fibrosis, scarring of lymphatic channels, or congenital anomalies. Patients undergoing surgery for breast cancer that includes node dissection or axillary radiation therapy are at high risk of developing lymphedema.
The goals of lymphedema treatment are to decrease the excess volume as much as possible and maintain the limb at its smallest size. Treatment includes mechanical measures such as compression garments, bandaging, manual massage, pneumatic compression devices (i.e., lymphedema pumps), drugs, or rarely surgery. Comprehensive decongestive therapy combines manual drainage, bandaging, exercises and skin care, and may also include compression garments, dietary recommendations and/or breathing exercises. Rarely, surgery is used as a treatment option.

Dini et al (1998) reported on one randomized trial that demonstrated a trend in favor of pneumatic compression pumps compared with no treatment. They assigned 80 women with postmastectomy lymphedema to either intermittent pneumatic compression or no treatment. Women in the treatment group underwent a two-week cycle of five pump sessions per week, each session lasting two hours, followed by a five-week break, and then another two-week treatment cycle. Although the mean decrease in arm circumference in the treatment group was nearly four times that in the control group (1.9 cm v. 0.5 cm), the post-test differences between the two groups failed to reach statistical significance (p = 0.084), possibly because of the small sample and the large variability in both the initial arm measurements and the circumferential changes within each group.

In 1998, a TEC assessment was published that focused on data that compared the efficacy of the three different types of lymphedema pumps. A comparison of the efficacy of lymphedema pumps to other treatments of lymphedema was not addressed by this assessment. The assessment concluded that the minimal amount of available data were inadequate to validate the superiority of one type of lymphedema pump over another. There were only two trials that included direct comparisons of pump types.

Zanolla et al (1984) compared a single-chamber device and a multi-chamber device without gradient pressures and found no significant difference in efficacy. However, interpretation of this trial is limited by the small number of patients (n=60) and varying range of severity in lymphedema between the treatment groups.

In another trial, Bergen et al (1998) used a multi-chamber device with gradient pressure programmed to simulate the other types of lymphedema pumps. A total of 32 patients were treated with the pump sequentially to simulate the different pump types. While use of the multi-chamber device with gradient pressure was associated with a significant reduction in lymphedema compared to the other simulated pump types, interpretation of this study is limited by lack of appropriate statistical testing, including confidence intervals, and lack of data validating the degree to which the simulated pumps accurately reflect the performance of the true pumps.

There were additional uncontrolled studies in which the heterogeneity in the patient populations, the etiology of lymphedema, the location of lymphedema, and the severity of the illness made it difficult to compare efficacy across the different trials. For example, the efficacy of the pumps may differ in the lower extremities as compared to the upper extremities, or as a function of the etiology of lymphedema, particularly in primary versus secondary forms. Differences in severity of illness may be the most important of these factors affecting outcome. For patients with mild
edema, the response to any form of therapy will likely be more favorable. Furthermore, the manner in which the response is calculated, i.e., percent reduction in edema, is a relative measure and is therefore dependent on the initial level of lymphedema. Therefore, when using this outcome measure to compare results, it is crucial that the underlying severity of illness is similar among groups being compared in order to draw meaningful conclusions. Despite these limitations, results across all of the studies were consistent in showing a substantial improvement in lymphedema following treatment with any of the pumps tested. It is possible to conclude, therefore, that pneumatic compression devices are efficacious to some degree. However, it is not possible to estimate precisely the magnitude of this effect.

In 2010, the McMaster University Evidence-based Practice Center, under contract with the Agency for Healthcare Research and Quality (AHRQ), published a technology assessment on diagnosis and treatment of secondary lymphedema that included discussion of pneumatic compression pumps. The authors identified a total of ten studies: six moderate-to-high-quality randomized controlled trials, two low-quality randomized controlled trials (RCTs), and two observational studies. There was a high degree of heterogeneity between studies: seven types of lymphedema pumps were used, pumps were compared to six different alternative interventions (including compression bandages, laser, and massage), and five studies used pumps in combination with other interventions. Due to the relatively small number of studies and high degree of variability in study design, the authors concluded that there was insufficient evidence to determine whether one type of IPC device and sleeve was more effective than another type.

The literature search did not identify any studies that examined whether treating the truncal area in addition to the affected limb improves the outcomes of pneumatic compression pump treatment.

It has been suggested that a failure to treat the trunk may be harmful to patients, for example, leading to the development of new areas of edema in the genitals, abdomen, hips, or chest. The AHRQ evidence review included an evaluation of harms associated with treatments for lymphedema. They found that therapy-specific adverse effects occurred in less than 1% of patients. This includes infection, arm thrombosis, and headache with elevated blood pressure; the appearance of new areas of edema was not mentioned as an adverse effect reported in trials.

Six trials compared the addition of massage, including manual lymphatic drainage (a specialized type of massage performed by a trained therapist), to more conservative treatments such as bandaging or physical therapy. Five of the six studies included women with arm lymphedema after breast cancer treatment. Only one of these five studies found that massage led to greater reduction in arm volume than more conservative therapy. The sixth trial, which addressed lymphedema after ankle surgery, found significantly greater reduction in volume when manual lymph drainage massage was added to standard physical therapy versus physical therapy alone.

Representative RCTs using FDA-cleared devices are described below.
Johansson et al (1998) published an RCT that was conducted at a single center in Sweden. Twenty-eight women with unilateral postoperative arm lymphedema (at least 10% greater volume in the affected arm) following breast cancer surgery were randomly assigned to receive
manual lymph drainage (MLD) or sequential pneumatic compression (SPC). The pump utilized was the Lympha-Press which had 9 compression cells. All patients initially received two weeks of treatment with a compression sleeve. A total of 24 women completed the initial treatment and the two-week course of MLD or SPC, 12 in each group. Patients in each group experienced a decrease in volume of the arm during treatment; there was a 15% reduction in the manual lymph drainage group and 7% in the sequential pneumatic compression group; the difference between groups was not statistically significant. The study was small and may not have had sufficient statistical power.

Szuba et al (2002) published an article that evaluated the Sequential Circulator lymphedema pump, a 4-chamber device, in two RCTs conducted in the U.S. among women with breast cancer.

Study 1
The study evaluated initial treatment of women with unilateral lymphedema (an increase of at least 20% in the volume of the swollen arm compared to the normal arm) who had completed cancer therapy at least 12 weeks earlier. Twelve women were randomly assigned to 10 days of outpatient treatment with decongestive lymphatic therapy (a multidisciplinary approach consisting of manual lymph drainage, compression bandaging, and massage) plus use of a lymphedema pump 30 minutes a day at 40-50 mm Hg, and 11 were randomly assigned to decongestive lymphatic therapy alone. At the two-week follow-up, there was a statistically significant greater reduction in volume of the edematous arm in the group assigned to pump use (45%) compared to the non-pump group (26%), p<0.05. The difference in volume reduction between groups was not significantly different at 40 days at the end of Phase II; there was a mean reduction of 30% in the pump group and 27% in the non-pump group.

Study 2
The study included women who had received a course of decongestive lymphatic therapy at least one month and less than one year prior to enrollment. Twenty-seven women were randomly assigned; the average duration of lymphedema was 60 months, and the average time from surgery was 114 months. Thirty days of self-administered conservative therapy alone (i.e., lymphatic massage and use of a compression garment) was compared to conservative therapy plus 60 minutes per day of lymphedema pump use. Patients assigned to use lymphedema pumps were supplied with a device for home use. After a month of treatment, patients could cross-over to the other intervention. The authors did not report the number of patients in each treatment group but stated that 25 women completed the study and two voluntarily withdrew. During the month of treatment that included pump use, there was a mean volume reduction in the affected limb of 86 mL; there was no apparent effect of treatment order. In contrast, during the month of self-administered conservative treatment alone, there was a mean increase in volume of 33 mL. There were no adverse responses to maintenance treatment with the lymphedema pump; in Study 1, the authors reported that only one of 11 patients experienced headache and a modest increase in blood pressure during pump use.

Wilburn et al (2006) published a pilot randomized crossover study in ten women with breast-cancer-associated lymphedema of the arm (at least 10% increased volume in the affected limb) after initial treatment with intensive decongestive physical therapy. Women were assigned, in
random order, to self-administered treatment with the Flexitouch™ or massage, one hour daily for 14 days; they then switched to the other treatment. There was a washout phase of one week before each treatment period during which patients used only a compression garment. The difference in arm volume was significantly greater after treatment with the Flexitouch™ (mean decrease of 207 mL) than after self-massage (mean increase of 52 mL), p=0.007. The authors state that the positive response to the Flexitouch™ device in this preliminary trial warrants additional testing in larger studies.

In addition to the studies described above, a 2009 RCT by Pilch et al, in Poland, compared lymphedema pumps in terms of number of chambers and cycle times. Fifty-seven women with lymphedema of the arm following breast cancer treatment were randomly assigned to one of four treatments: 1) one-to-one cycle of compression and interval (90s: 90s) with a single chamber sleeve (n=17); 2) one-to-one cycle of compression and interval (90s: 90s) with a three-chamber sleeve (n=9); 3) three-to-one cycle of compression and interval (45s: 15s) with a single chamber sleeve (n=11); or 4) three-to-one cycle of compression and interval (45s: 15s) with a three-chamber sleeve (n=20). Patients in all groups received 25 intermittent pneumatic compression treatments, performed five days a week for five weeks. Two models of Flowtron pumps (Huntleigh Healthcare, UK) were used. (These pumps appear to be FDA-cleared for prevention of deep vein thrombosis.) The mean percent edema post-treatment was 29% in Group 1, 35% in Group 2, 34% in Group 3, and 28% in Group 4. Overall, there was not a significant difference among groups. However, percent edema was significantly lower in Group 3 (45s cycle with a three compartment sleeve) than Group 4 (45s cycle with a single compartment sleeve) (p=0.040).

In some situations, including in patients with scarring, contractures or highly sensitive skin, programmable pumps are generally considered to be the preferred option.

Although complications of compressive therapy have not generally been reported, there have been warnings that the generated pressures might damage skin lymphatics and that the residual proteins, which remain after forceful fluid displacement, can induce secondary inflammation and accelerate fibrosclerotic changes. In addition, a ring of fibrous tissue can form over time above the sleeve of the pneumatic pump and further compromise lymphatic outflow. The use of any form of compressive therapy does require a sufficient arterial blood supply to the limb. In cases of limb ischemia, compressive therapy can compromise arterial blood flow and promote severe ischemia and necrosis. Isolated cases of induced or aggravated lymphangitis and peroneal nerve palsy have also been reported as complications of sequential pneumatic compression.

**Compression Sleeves**

The mechanism of action of compression sleeves is unclear. It is likely that the garments aid in reducing swelling by lessening the amount of edema formed within the involved arm. It remains unclear whether garments actually reduce the existing edema within the limb. The sleeves also lend a measure of protection against external incidental trauma, such as burns and lacerations. They may also protect against intrinsic trauma to the limb that occurs as a result of chronically increased interstitial pressures. It has been suggested that this increased pressures is exerted against the skin and other subcutaneous tissues that aid in maintaining interstitial fluid homeostasis. Compliance with compression garments is difficult for patients because even
customized garments can be uncomfortable, unsightly, and laborious to put on. Patient education may improve compliance.

A literature search was performed through June 2011. The literature review addresses two main questions: the efficacy and safety of pneumatic compression pumps compared to alternative treatments for lymphedema and the relative efficacy of different types of pumps. Due to the FDA-approval of new two-phase multichambered lymphedema pumps that treat the truncal area in addition to the affected limb, there has recently been interest in the evidence on truncal clearance as part of lymphedema treatment. The literature search did not identify any comparative studies that examined whether treating the truncal area in addition to the affected limb improves the outcomes of pneumatic compression pump treatment more than only treating the limb.

Rinder et al (2008) conducted a study to compare treatment protocol adherence, satisfaction and perceived changes in emotional and functional status between patients with lymphedema using the Flexitouch system. A total of 155 patients were included in the study—93 with cancer related symptoms and 62 with noncancer-related lymphedema. Surveys were completed prior to treatment, during the maintenance phase of treatment and upon completion of the therapy. Participants with cancer symptoms as well as the noncancer group were found to be satisfied with the system, perceived it to be effective and reported improvement in physical and emotional status. However, several limitation of the study are noted; only 65% of the total participants completed post-therapy questionnaires, the findings in the study were self-reported, and there was not a control group.

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, if necessary.

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. 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.

The literature search identified 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. 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, six improved, and two 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.

In 2012, Oremus and colleagues published an updated systematic review on conservative treatments for secondary lymphedema. The authors identified a total of 36 of English-language studies, 30 of which were RCTs and six were observational studies. Since RCTs evaluated intermittent pneumatic compression. Studies findings were not pooled. The authors reported that two RCTs showed that IPC was superior to decongestive therapy or self-massage but three other RCTs failed to show that IPC was superior to a different type of conservative treatment of lymphedema. In addition, the authors identified one RCT comparing types of IPC devices. This study, Pilch et al (2009) found that a 3-chamber IPC sleeve was superior to a one-chamber sleeve for reducing edema.

In 2010, Hammond and Mayrovitz published a non-controlled study of five patients with breast cancer treatment-related lymphedema in the upper extremity and trunk that had been referred to a lymphedema clinic for treatment. Four out of five of the patients had been unsuccessful in controlling lymphedema symptoms at home. Patients received in-clinic exercise, short-stretch compression bandaging and/or compression garments for the affected arm. The in-home therapy included exercise, skin care, dietary and nutritional recommendations, short-stretch bandaging and use of the Flexitouch (FT) system.

Arm circumferences were measured using either an automated device or manually with a tape measure at 4-cm intervals along the arm beginning at the wrist. In addition to the quantitative measures, patients provided subjective impressions of their experience and the therapist made clinical observations regarding changes in fibrosis, range of motion and mobility, compliance with at-home treatment, and other parameters. Affected limb volumes of four of the five patients decreased after two months of in-clinic therapy supplemented with FT. The range of arm reduction was from 2.2% to 7.4%. Reduction in trunk circumferences ranged from 1.5cm to 4 cm. Patients reported that self-treatment with FT was effective without undue interference in their daily lives. Limitations of this study include the small number of participants and no control group using other types of lymphedema devices for comparison.

Two industry-sponsored RCTs were published in 2012 that included women with breast cancer who had documented post-surgical upper-extremity lymphedema. Fife and colleagues compared treatment with the Flexitouch™ system to the Biocompression Systems Sequential Circulator. Participants needed to have at least 5% edema volume in the upper extremity at the time of study enrollment. A total of 36 women from three centers were included, 18 in each group. Participants used the devices for home treatment of one hour per day for 12 weeks in addition to standard care e.g. wearing compression garments. The Biocompression Systems device utilized an arm garment only whereas the Flexitouch device utilized three garments and treated the full upper extremity (arm, chest, and truncal quadrant). Outcome assessment was conducted by experienced lymphedema therapists; blinding was not reported. Edema outcomes were available for all participants and local tissue water analysis for 28 of 36 (78%) of participants.
Key outcomes at the end of the 12-week treatment period are as follows:

<table>
<thead>
<tr>
<th></th>
<th>Flexitouch</th>
<th>Sequential Circulator</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected arm value (ml)</td>
<td>2,952 ± 724</td>
<td>3,013 ±773</td>
<td>0.141</td>
</tr>
<tr>
<td>Edema volume (ml)</td>
<td>438 ± 344</td>
<td>537 ± 293</td>
<td>0.050</td>
</tr>
<tr>
<td>Edema volume (%)</td>
<td>18.2 ± 14.0</td>
<td>21.0 ± 10.7</td>
<td>0.047</td>
</tr>
<tr>
<td>Local tissue water (TDC*)</td>
<td>33.8 ± 7.6</td>
<td>33.5 ± 6.6</td>
<td>0.049</td>
</tr>
</tbody>
</table>

*TDC: arm tissue dielectric constant

At the p<0.05 level, there was a statistically significant difference in edema volume and tissue water at 12 weeks between groups, favoring treatment with the Flexitouch system. If the p-value was adjusted for the two primary outcome variables (edema volume and local tissue water) or the four reported outcome variables, differences would not be statistically different. The study was limited by its small sample size, missing data on the local tissue water outcome and unclear blinding of outcome assessment. Also, the outcomes reported were primarily volume of fluid removed, which is an intermediate outcome. It is unclear whether the difference in volume of fluid removed would translate to clinically meaningful differences in symptoms, functional status, and/or quality of life.

Ridner and colleagues conducted a RCT comparing treatment with the Flexitouch System of the arm-only versus the arm, chest and trunk in women with breast cancer who had arm lymphedema. To be eligible for participation, there needed to have a 2 cm difference in girth on the affected arm compared to the unaffected arm. A total of 47 patients were enrolled; five patients were withdrawn in the course of the study, leaving 21 patients in each treatment group. Participants completed training in using the device and were observed in the laboratory to insure they used proper technique; the remainders of the sessions were conducted at home. Patients in the experimental group (arm, chest and trunk treatment) were told to perform 30 daily sessions of one-hour each; patients in the control group (arm-only) were told to perform 30 daily treatments of 36 minutes each. Final outcome assessment took place at the end of the 30-day outcomes were blinded to the patient’s treatment group. There were no statistically significant differences between groups in efficacy outcomes. For example, change in the volume of the affected arm was -2.66 ml in the experimental group and -0.38 ml in the control group, p=0.609. In addition, the mean number of symptoms reported at the end of the study was 10.0 in the experimental group and 6.0 in the control group (p=0.145).

**Intermittent Cooling and Compression (Cryopneumatic) Regimens**

A multicenter randomized trial with 280 total knee arthroplasty patients compared the GameReady cryopneumatic device versus ice packs with static compression. Upon discharge from the hospital, the treatments were given at the same application cycle of one hour on and 30 minutes off. Compliance rates were similar for the two groups. Blinded evaluation of 187 patients (67% of patients had complete evaluations) found no significant difference between the groups in visual analog score (VAS) for pain, range of motion, six-minute walk test, timed up and go test, or knee girth under this more typical icing regimen. Narcotic consumption was decreased from 680 mg to 509 mg morphine equivalents over the first two weeks (14 mg less per day), and patient satisfaction was increased with the cryopneumatic device.
Waterman et al reported a randomized controlled trial of the GameReady device in 36 patients with ACL reconstruction. Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least three times per day and return to the clinic at 1, 2, and 6 weeks postoperatively. Compliance during the first two weeks was not significantly different between the two groups (100% for GameReady and 83% for icing). The primary outcome measure (VAS) was not comparable at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm short form-36, SF-36, or single assessment numerical evaluation (SANE) scores. A greater percentage of patients treated with the GameReady device discontinued narcotic use by six weeks (83% vs. 28%).

**Lymphedema pumps compared to alternative treatment**

A small RCT from Turkey, published in 2012, studied women with breast cancer-related lymphedema. The authors did not specify the IPC device that was used. The trial manual lymphatic drainage in combination with compression bandages (n=15) or in combination with pneumatic compression (n=15). Total arm volume decreased by a mean of 529 ml (14.9%) in the compression bandage group and 439 mL (12.2%) in the IPC group; the difference between groups was not statistically significant. Findings were similar on other outcomes.

A 2014 systematic review by Shao et al addressed pneumatic compression pumps for treatment of breast cancer-related lymphedema. The authors identified seven RCTs; most compared decongestive lymphatic therapy alone with decongestive lymphatic therapy plus lymphedema pump therapy. A pooled analysis of data from the three RCTs suitable for meta-analysis did not find a statistically significant difference in the percent of volume reduction with and without use of lymphedema pumps (mean difference [MD]=4.51, 95% CI, -7.01 to 16.03). Data from the other four trials were not included in the meta-analysis.

**Arterial and Venous Disease**

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The majority of venous ulcers are located over the medial malleolus, with the remainder located elsewhere on the leg or foot. Either or both legs may be affected. One study found the left leg involved in 44% of cases, the right leg in 35%, and both legs in 21% of cases. Venous ulcers are large, often larger than ulcers of non-venous origin. Venous ulcers may be single or multiple and, if left untreated, can involve the entire circumference of the leg. Chronic non-healing leg ulceration can be debilitating. Approximately one million Americans have ulceration due to superficial venous disease, and approximately 100,000 are disabled because of their condition.

Treatment goals for patients with chronic venous insufficiency include reduction of edema, alleviation of pain, improvement of lipodermatosclerosis, healing of ulcers, and prevention of recurrence. Recently, use of the intermittent pneumatic compression devices has expanded to ambulatory persons who suffer from chronic venous insufficiency (CVI) of the legs and consequent edema, stasis dermatitis, ulcerations, and cellulitis.
The compression pump reduces venous stasis by promoting venous blood flow and has been shown to enhance fibrinolytic activity. Compression therapy must continue after the ulcer is healed, often for the duration of the patient's lifetime.

There is no evidence that intermittent pneumatic compression devices are superior to gradient compression stockings in preventing complications of chronic venous disease. Compliance with gradient compression stockings has been shown to be essential to their effectiveness; the stockings do not work unless they are worn. There are no studies, however, that have demonstrated that compliance with intermittent pneumatic compression devices is significantly greater than compliance with gradient compression stockings.

Compression therapy can exacerbate ischemic disease and therefore is contraindicated in the treatment of peripheral arterial disease or arterial ulcers. However, preliminary published evidence suggests that modified compression therapy may be effective in improving arterial blood flow and improve healing of ischemic ulcers when offered in a supervised healthcare setting. The evidence for pneumatic compression devices for the treatment of arterial ischemic ulcers consists of one study. Vella et al treated 29 patients with ischemic leg ulcers with circular boot pneumatic compression therapy. The 29 patients had transcutaneous oxygen pressures of less than 20 mmHg at the ulcer site. Nineteen patients had a favorable outcome following circular boot therapy. A favorable outcome was documented if the wound healed completely, the ulcer decreased in size, or the affected limb improved sufficiently to allow successful revascularization. The remaining ten patients failed to receive benefit from therapy and went on to amputation or the ulcer increased in size. The evidence for pneumatic compression therapy for ischemic arterial ulcers is limited, therefore, conclusions concerning safety and effectiveness cannot be drawn.

A search of the literature failed to show that intermittent pneumatic foot compression devices are superior to gradient compression stockings in preventing complications of chronic venous disease.

**Venous Ulcers**

A Cochrane review by Nelson et al, updated in 2014, addressed intermittent pneumatic compression pumps for treating venous leg ulcers. The review identified a total of nine RCTs. Five trials compared pneumatic compression pumps plus continuous compression with continuous compression alone, two trials compared compression pumps with continuous compression (stockings or bandages), one trial compared compression pumps with wound dressings only, and one trial compared two intermittent pneumatic compression regimens. In a meta-analysis of three of the five trials evaluating the incremental benefit of pneumatic compression pumps over continuous compression alone, there was a significantly higher rate of healing with combined treatment, risk ratio (RR)=1.31, 95% CI, 1.06 to 1.63. Two of these three trials were considered to have a high risk of bias e.g., not blinded and had unclear allocation concealment. There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the two trials comparing intermittent pneumatic compression with continuous compression with stockings or bandages found statistically significant between-group differences in healing rates.
A 2014 RCT by Dolibog et al was published after the Cochrane review literature search. The study included 147 patients with venous ulcers. It compared five types of compression therapy: intermittent pneumatic compression using a twelve-chamber Flowtron device, stockings, multilayer bandages, two-layer bandages, and Unna boots. All patients received standard drug therapy and the compression interventions lasted two months. The rate of complete healing at the end of treatment was similar in three of the treatment groups: 16 of 28 patients (57%) in the pneumatic compression group, 17 of 30 (57%) in the stockings group, and 17 of 29 (59%) in the multi-layer bandage group. On the other hand, rates of healing were much lower in the other two groups: five of 30 (17%) in the two-layer bandage group and six of 30 (20%) in the Unna boot group. A 2013 pilot study by Dolibog et al included in the Cochrane review, had similar findings.

In 2013, an additional RCT including 70 patients was published by Dolibog and colleagues in Poland. The study was single-blind; outcome assessment was blinded. All patients had received standard medical treatment (drug therapy and gauze dressings changed once a day) for two months prior to study participation. There were a total of six treatment groups. Patients were stratified by wound type, superficial venous reflux alone versus superficial plus segmental deep venous reflux. Within each of these groups, patients were randomized to one of three compression treatments: intermittent pneumatic compression (using a Flowtron device), stockings or compression short-stretch bandages. The primary study outcome, proportion of wounds healed at 15 days, was significantly higher in the intermittent pneumatic compression and stockings groups than in the bandage groups. The proportion of wounds healed did not differ significantly with pneumatic compression versus stockings. For example, among patients with isolated superficial vein insufficiency, the proportion of ulcers healed was 25% in the intermittent compression group, 27% in the stockings group and 10% in the bandages group. Similar results were found for the outcome of percentage reduction in wound area.

The evidence is insufficient to conclude whether lymphedema pumps improve healing of venous ulcers. Overall, there are few trials that reported on the most relevant clinical comparisons i.e., pneumatic compression as an adjunct to optimal wound care compared to optimal wound care alone. In many studies, it is difficult to ascertain whether optimal wound care was provided in the control group and whether enrolled patients had failed optimal wound care prior to enrollment in the study. Moreover, many of the studies have methodological limitations such as a lack of blinding or a failure to report on complete ulcer healing. The literature is characterized by a high degree of heterogeneity among studies in the types of pumps used, the protocols for pneumatic compression, the comparison groups, and control interventions. The pumps used in the trials varied, and some were older devices used in the 1980s and 1990s. This creates challenges in classifying the types of devices used. Moreover, it is difficult to compare the pumps in the trials to currently available lymphedema pumps, since all but two of the studies were published at least ten years ago and some were from the late 1980s/early 1990s. The most recent study, published in 2013, did not find a significant difference in the wound healing rate with intermittent pneumatic compression compared to compression stockings, although outcomes were better with both of these interventions than with compression bandages.
Summary
The available evidence from randomized controlled trials suggests that use of pneumatic compression pumps may be effective at reducing limb volume in patients with lymphedema who fail to respond to conservative therapy. There is insufficient evidence from comparative trials that one type of pump is more effective than another for lymphedema patients. Therefore, nonprogrammable lymphedema pumps are considered medically necessary, and programmable pumps are considered medically necessary only for patients unable to use the standard pumps. There is insufficient evidence that treating the truncal area in addition to the limb affected by lymphedema improves the outcomes of pneumatic compression pump treatment more than only treating the limb. Therefore, use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs is considered investigational.

There is insufficient evidence on whether intermittent pneumatic compression pumps improve healing of venous ulcers. The available studies have methodological limitations such as lack of blinding and inadequate randomization. Moreover, the literature is characterized by a high degree of heterogeneity among studies in the types of pumps used, the protocols for pneumatic compression, the comparison groups, and control interventions. Thus, use of lymphedema pumps for the treatment of venous ulcers is considered investigational.

Practice Guidelines and Position Statements
The Women's Health and Cancer Rights Act of 1998 was passed on October 21, 1998, includes provisions for coverage of physical complications at all stages of mastectomy including lymphedemas.

In 2001, Health Canada issued breast cancer treatment guidelines that included information on management of lymphedema related to breast cancer. Recommendations include encouraging long-term consistent use of compression garments and offers practical advice on skin care, exercise, and body weight. The guideline states that one trial demonstrated a trend in favor of pneumatic compression pumps and that further randomized trials are needed to determine whether pneumatic compression provides additional benefit beyond that offered by compression garments.

In 2001, Medicare National coverage issued a decision memo for lymphedema pumps which stated the following:

“A pneumatic compression device will not be covered as initial therapy for lymphedema in the home setting. A patient must first undergo a four-week trial of conservative therapy, which includes the use of an appropriate compression garment, exercise and elevation. This garment does not need to be custom-fabricated; however, it does need to be a graduated compression stocking/sleeve. A pneumatic compression device is covered if a physician determines after such a trial that there has been no significant improvement or if significant symptoms remain…”

A 2009 Technology Assessment Report by the McMaster University Evidence-based Practice Center for AHRQ had the following conclusions regarding treatment of secondary lymphedema: “…there was no evidence concerning the optimal criteria to initiate or stop treatment. While the studies suggested that most treatments did reduce the size of the lymphatic
limb, there was too much heterogeneity in terms of treatments, inclusion and exclusion criteria, and treatment protocols to suggest the optimality of one type of treatment over another. Despite the multiplicity of inclusion and exclusion criteria, the studies did not contain reports of treatment benefits in any subgroup of patients.” The report did not have specific recommendations on use of lymphedema pumps.

A 2009 consensus statement from the international Union of Phlebology stated that sequential pneumatic compression is an effective treatment for primary lymphedema and is particularly useful in situation in which lymphedema is best treated by physical passive therapy e.g., elderly and disabled patients.

**Key Words:**

**Approved by Governing Bodies:**
Several pneumatic compression pumps indicated for primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of devices with these indications that are intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (Medmark Technologies, LLC, Perkasie, PA); the Sequential Circulator® (Bio Compression Systems, Inc., Moonarchie, NJ); and the Lympha-Press® and Lympha-Press Optimal (Mego Afek, Israel), the Flexitouch™ system (Tactile Medical, formerly Tactile Systems Technology, Inc.) and the PowerPress Unit Sequential Circulator (Hanuri Distribution, Inc, Chatsworth, CA).

Several pneumatic compression devices are cleared by the FDA for treatment of venous stasis ulcers. Examples include the Model GS-128, Lympha-Press, Flexitouch®, and PowerPress Unit listed above as well as Nanotherm™ (ThermoTek, Inc.), CTU676(R) (Compression Technologies), and Recovery+™ (Pulsar Scientific).
**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Special benefit consideration may apply. Refer to member’s benefit plan. Pre-certification requirements: Not applicable.

**Current Coding:**

**HPCPS codes:**

**Pumps:**
- **Single-chamber pumps:** E0650 Pneumatic compressor, non-segmental home model
- **Multi-chamber pumps:** E0651 Pneumatic compressor, segmental home model without calibrated gradient pressure

**Multi-chamber programmable pumps:**
- E0652 Pneumatic compressor, segmental home model with calibrated gradient pressure

**Appliances:**
- A4465 Non-elastic binder for extremity
- A6545 Gradient compression wrap, non-elastic, below knee, 60-50 mm hg, each
- **E0650 is used in conjunction with any of the following appliances:**
  - E0655 Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
  - E0656 Segmental pneumatic appliance for use with pneumatic compressor, trunk
  - E0657 Segmental pneumatic appliance for use with pneumatic compressor, chest
  - E0660 Non-segmental pneumatic appliance for use for pneumatic compressor, full leg
  - E0665 Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
  - E0666 Non-segmental pneumatic appliance for use with pneumatic compressor, half leg
  - E0667 Segmental pneumatic appliance for use with pneumatic compressor, full leg
  - E0668 Segmental pneumatic appliance for use with pneumatic compressor, full arm
  - E0669 Segmental pneumatic appliance for use with pneumatic compressor, half leg
  - E0670 Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk (Effective January 1, 2013)
  - E0671 Segmental gradient pressure pneumatic appliance, full leg
E0672  Segmental gradient pressure pneumatic appliance, full arm
E0673  Segmental gradient pressure pneumatic appliance, half leg
E1399  Durable medical equipment; miscellaneous

**E0651** may be used with any of the following appliance codes:
- E0656: Segmental pneumatic appliance for use with pneumatic compressor, trunk
- E0657: Segmental pneumatic appliance for use with pneumatic compressor, chest
- E0667: Segmental pneumatic appliance for use with pneumatic compressor, full leg
- E0668: Segmental pneumatic appliance for use with pneumatic compressor, full arm
- E0669: Segmental pneumatic appliance for use with pneumatic compressor, half leg

**E0652** may be used with any of the following appliance codes:
- E0671: Segmental gradient pressure pneumatic appliance, full leg
- E0672: Segmental gradient pressure pneumatic appliance, full arm
- E0673: Segmental gradient pressure pneumatic appliance, half leg

**References:**
6. 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.
7. 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.


23. McDonagh PF. Current cardiovascular concepts on the use of compression to manage chronic venous insufficiency. WOUNDS 1993: 5(2); 89-96.


26. Medicare National Coverage Decision. Decision Memo for Lymphedema Pumps (CAG-00016N). Available online at: 


Policy History:
Medical Policy Group, January 1993
Medical Policy Group, September 1995
TEC Assessment, July 1998
Medical Policy Group, September 1999
Medical Policy Group, May 2000
Medical Policy Group, June 2003 (2)
Medical Policy Administration Committee, June 2003
Available for comment July 1-August 14, 2003
Medical Policy Group, June 2005 (1)
Medical Policy Group, July 2005 (2)
Medical Policy Administration Committee, July 2005
Available for comment July 28-September 10, 2005
Medical Policy Group, June 2006 (2)
Medical Policy Administration Committee, June 2006
Available for comment July 5-August 14, 2006
Medical Policy Group, August 2006 (2)
Medical Policy Administration Committee, August 2006
Available for comment August 15-September 28, 2006
Medical Policy Group, October 2006 (2)
Medical Policy Administration Committee, October 2006
Available for comment November 3-December 17, 2006
Medical Policy Group, October 2007 (2)
Medical Policy Administration Committee, November 2007
Available for comment November 17-December 31, 2007
Medical Policy Group, December 2008 (2)
Medical Policy Administration Committee, January 2009
Available for comments, December 17, 2008-January 30, 2009
Medical Policy Group, May 2011(2): Updated Description, Key Points, and References
Medical Policy Group, June 2011(2): Updated Policy, Key Words
Medical Policy Administration, June 2011
Available for comment June 23 – August 28, 2011
This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.