KAISER PERMANENTE®
Mid-Atlantic States

Compression Bandages and Garments and Pneumatic Devices

Medical Coverage Policy

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- Virginia mandates coverage of compression garments for lymphedema regardless of policy limitations or exclusion.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- Compression garments and pneumatic compression devices should be reviewed for Medicare members under the CMS guidelines
- Although "bandages" are excluded from most members' plans, the exclusion refers to single-use wound coverings and not to the reusable bandages used for compression therapy.

I. Benefit Category: Durable Medical Equipment (DME)
Related Medical Coverage Policy: Varicose Veins

II. Therapy: Compression garments and devices
There are two categories of compression therapies with variation in coverage criteria

A. Compression bandages and garments that provide therapeutic compression through snug facilitative application or pressure gradient elastic nature of the materials.

B. Pneumatic Compression Devices, which provide mechanical compression via continuous or intermittent air flow into attached single reservoir or segmented body wraps.

III. Clinical Indications for Coverage of Compression Bandages and Garments

A. Treatment of lymphedema, including:

1. Primary lymphedema from congenital defect (hereditary edema);
2. Secondary lymphedema, acquired and due to lymphatic obstruction or interruption:
3. Lymphedema secondary to cancer or cancer related treatment; including surgery or post radiation treatment fibrosis;
4. Post-mastectomy lymphedema syndrome and other lymphedema, including post mastectomy subclinical edema and other related lymphedema syndrome

B. Treatment of an open venous stasis ulcer;

C. Treatment of chronic venous insufficiency with venous stasis ulcers;

D. Hypertrophic scarring and joint contractures following burn injury or scarring from surgery; or

E. Post amputation compression therapy, e.g., stump wraps, shrinkers, and shapers.

IV. Excluded Conditions and Limitations

A. Contraindicated conditions for Compression Therapies

1. Suspicion or diagnosis of arterial obstruction.
2. Severe peripheral arterial disease;
3. Septic phlebitis or other acute limb infections;
4. Unhealed irradiated soft tissues;
5. Peripheral edema secondary to severe Congestive Heart Failure; or
6. Suspicion of undiagnosed acute DVT

B. Conditions that are generally not medically appropriate for coverage for gradient compression garments but may be appropriate for OTC garments

1. Stasis dermatitis or venous edema;
2. Lipodermatosclerosis;
3. Prevention of thrombosis in immobilized persons;
4. Post thrombotic syndrome and prevention of DVT;
5. Edema following surgery, fracture, burns and other trauma which can be treated with over the counter (OTC) products;
6. Postural hypotension;
7. Severe edema in pregnancy;
8. Edema accompanying paraplegia, quadriplegia, etc.;
9. Venous insufficiency;
10. Varicose veins (see separate KPMAS Medical Coverage Policy for "Varicose Veins");
11. Active malignancy, confirmed or suspected local disease; or
12. Exercise recovery

V. Indications for Compression Bandages and Garments

The member must meet the conditions in section V, A plus the requirements in section V, B for coverage of compression bandages and garments.

A. Covered conditions for pressure gradient compression bandage and garments for face, neck, trunk, and upper and lower extremities include any of the following:

1. The member is actively participating or has successfully completed lymphedema, venous stasis ulcer, or hypertrophic scarring treatment with a lymphedema therapist, certified in instruction, management, education and treatment in the application of compression garments; or
2. The member has been evaluated and there is documentation of treatment for lymphedema, venous stasis ulcer, or hypertrophic scarring treatment in the vascular clinic or wound care clinic;

or

3. The member is being treated for chronic venous insufficiency and has current or history of a venous stasis ulcer; ***and***

B. The member has demonstrated the ability and willingness to comply with their individualized compression therapy.

C. If a member does not meet the above criteria for approval for compression garments, then any request for compression stockings is not a covered benefit. This applies to garments available over the counter with or without a prescription from the ordering provider.

VI Determining type, amount and frequency of INITIAL compression bandages and garments

Either a lymphedema therapist, wound care specialist, or physician may specify the number of initial bandages and garments according to patients' treatment regimens, activity levels, and environments.

VII. Determining type, amount and frequency of REPLACEMENT compression bandages and garments

Reassessment for replacement compression bandages and garments is required every 2 years by the lymphedema therapist, wound care specialist, or physician to determine continued need. Either a lymphedema therapist, wound care specialist, or physician may specify the number of replacement bandages and garments according to patients' treatment regimens, activity levels, and environments.

A. Daytime and/or Night-Time Garments

1. Daytime compression garments (2 sets for day use) for each affected limb, can be ordered and approved;
2. Nighttime garments, if medically necessary, 1 set for each affected limb, can be ordered and approved;
3. Replacements of more than 1 set or item per limb may be ordered, as appropriate, per the lymphedema therapist, wound care nurse or physician; and
4. We will approve two (2) items, for each limb, initially for reduction phase and for each replacement (maintenance phase).

B. Continuous, 24-hour Use

1. Bandages may be provided by the lymphedema therapist during treatment visits or may be ordered under member's DME benefit, as deemed appropriate by the lymphedema therapist or physician. Bandages and compression garments should be ordered as DME for up to 1 year so that replacements may be approved in the interim without repeated physician order.
   a. Replacement garments will be covered every six months, up to a maximum of two garments per body part, when existing garments are no longer functional, as

determined and documented by the clinician who is treating the patient for the specific diagnoses; *or*

b. Replacement garments may be covered before the six-month period, if after reevaluation by the lymphedema therapist a change in garment type or size is needed to improve therapeutic response.
c. If a member requires multiple garments for the same body part, to allow variation in size or pressure, only one of each size/type will be issued.

2. A reassessment for bandages/compression garments is required every 2 years by the certified lymphedema therapist, physician, or vascular clinic to determine the continued need for replacement items.

VIII Pneumatic Compression Extremity Pump (Night-time / Intermittent Use)

A. Non-Segmented or Segmented Pneumatic Pump without Calibrated Gradient Pressure (manual control)

A single or multi-chamber non-programmable pneumatic compressor is determined to be medically necessary in the home setting when the patient meets the following:

1. A diagnosis of Primary or secondary indicated by ***ALL*** of the following
   a. The member has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings: and
      i. Marked hyperkeratosis with hyperplasia and hyperpigmentation;
      ii. Papillomatosis cutis lymphostatica;
      iii. Deformity of elephantiasis;
      iv. Skin breakdown with persisting lymphorrhea; or
      v. Detailed measurements over time confirming the persistence of the lymphedema
   b. In addition to documented persistence, lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial; and
   c. A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial must include all the following:
      i. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression: and
      ii. Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal, and;
      iii. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression distally, and;
      iv. Regular exercise, and:
      v. Elevation of limb

2. **Chronic Venous Insufficiency with Venous Stasis Ulcers (CVI)**

A single or multi-chamber non-programmable pneumatic compressor is covered for the treatment of CVI of the lower extremities only if the patient has all of the following:

a. Edema in the affected lower extremity, AND;
b. One or more venous stasis ulcer(s), AND;
c. The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating practitioner (see below for trial guidelines).
d. A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all the following:
    i. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.
        1) Adequate compression is defined as
            a) Sufficient pressure at the lowest pressure point to cause fluid movement; and
            b) Sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
    ii. Medications as appropriate (e.g., diuretics and/or other treatment of CHF, etc)
    iii. Regular Exercise
    iv. Elevation of limb
    v. Appropriate wound care for the ulcer

B. Non-segmented (single) or Segmented (multi-chamber) Calibrated Gradient Pressure Pneumatic Pump (Programmable)

A programmable pneumatic compressor is considered medically necessary in the home setting when **ALL** of the following criteria are met:

1. The criteria in section VIII-A must all be *and*
2. Documentation of at least one of the following
    a. The unique characteristics of the patient precludes receiving satisfactory compression therapy with the use of a non-programmable pneumatic device such as hypertrophic scarring and joint contractures following burn injury or significant scarring from surgery; *or*
    b. The member has lymphedema extending onto the head, neck, chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, or:
    c. The patient has no significant improvement, failed to respond or significant symptoms remain after a minimum of four-week therapy with regular, daily, multiple-hour use in home setting of non-programmable pneumatic compressor;

C. Exclusions

An intermittent pneumatic compression device is considered experimental and investigational for treatment of the following condition as evidence is inconclusive, insufficient, or poor to support its' efficacy and/or safety. This is not an exhaustive list:

1. Critical limb ischemia;
2. Peripheral arterial occlusive disease and arterial insufficiency (ABI<0.9);
3. Intermittent claudication;
4. Post-thrombotic syndrome;
5. Restless leg syndrome;
6. Prevention of thrombosis following surgery;
7. Truncal edema;
8. Treatment of venous ulcers except for the condition cited in section VIII A, 1-d; *and*
9. Advanced Congestive Heart Failure or Right Sided CHF (NYHA Class III or IV)
10. Metastatic liver or bone cancer with ascites, not under hospice care
11. All other indications except those cited in section VIII A and B of the policy

IX. Repair or Replacement of compression pumps

The garments attached to pneumatic compression pumps are worn for fewer hours over time. Therefore, they are replaced less frequently than continuous use garments. The attached garments and the pneumatic compression pump have separate assessment and replacement requirements.

A. Reassessment for both the compression garment and the pump is required every 2 years by the lymphedema therapist, treating physician, wound care nurse or vascular clinic to determine continued need before replacements can be approved. The evaluation of therapeutic results must include documentation that:

1. The compression device is effective in maintaining the size of the affected extremity;
2. The compression device is effective in reducing hypertrophic scarring and joint contractures of affected extremity;
3. The compression device is effective in reducing venous insufficiency with venous stasis ulcers.

B. Pneumatic compression machines are generally replaced every 3 years per manufacturer's specifications when documentation is provided for the minimum manufacturer's inspection, as indicated below:

1. When the lymphedema therapist or physician recommends a change in therapy earlier than 3 years, the following criteria apply:
   a. Excessive change in girth or excessive damage from drainage whereas the garment is no longer effective; or
   b. Upon recommendation by manufacturer or supplier that device is beyond repair.

C. Repairs of lymphedema pumps are limited to restoration to a serviceable condition. Replacement of a Member owned lymphedema pump and/or sleeve is covered if any of the following criteria are

met:

1. When necessitated by irreparable damage not due to misuse, intentional or non-intentional; or
2. The cost of repairs to the device and/or sleeve would exceed the purchase price.

X. Description

Adequate compression is the application of pressure to the affected extremity or other appropriate body part though a device by administering a prescribed amount of sufficient pressure at the lowest pressure point to cause fluid movement and sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The pressure applied must not create a tourniquet effect at any point.

Pneumatic Compression Device (PCD) is an electric device consisting of a pneumatic sleeve connected to a pump that uses compressed air to intermittently fill the inflatable garments (arm, leg, trunk, chest) and apply varying degrees of pressure to the affected limb, propelling the excess lymph fluid out of the extremity through the lymphatic system into the general circulation. Some of the most common types of pneumatic compression pumps are as follows:

A. **Non-programmable Pneumatic Pump**

1. **Non-segmented (single/uni-chamber) or non-sequential non-programmable pump** is a compressor consisting of a single chamber that inflates at one time, applying uniform pressure along the affected limb**.**

2. **Segmented (multi-chamber) or sequential non-programmable pump** is a compressor consisting of multiple chambers (ranging from 2 to 12 or more chambers) that inflates and deflates sequentially, applying either a fixed or same pressure in each compartment or manual control, also known as pressure gradient in each of the several segments. It may or may not have the ability to manually control the amount of pressure (also known as pressure gradient) in each segment as described below.

3. **Segmented pneumatic pump without calibrated gradient pressure** is a compressor that could either:
   a. Apply the same pressure in each segment or chamber; or
   b. Apply a pre-determined pressure gradient in successive segments but the pressure on each individual compartment cannot be adjusted individually.

B. **Non-segmented (single) or Segmented (multi-chamber) programmable pneumatic pump** is a compressor device which has similar features to the non-programmable pump except the ability to program the pressure adjustments such as peak-pressures and pressure-time on each individual compartment, including pattern, length and timing or frequency of the inflation cycles.

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*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.