DOCUMENTATION CHECKLIST FOR PNEUMATIC COMPRESSION DEVICES

Policy References:

- Local Coverage Determination (L33829)
- Policy Article (A52488)
- National Coverage Determination (280.6)

Documentation References:

- Standard Documentation Requirements Policy Article (A55426)

The supplier must be able to provide all these items upon request:

- ☐ Standard Written Order (SWO)
- ☐ Beneficiary Authorization
- ☐ Proof of Delivery (POD)
- ☐ Continued Need
- ☐ Continued Use
- ☐ Financial Attestation Statement - signed and dated stating the licensed/certified medical professional (LCMP) has no financial relationship with the supplier
- ☐ Medical records from treating practitioner must include enough information to support that coverage criteria have been met prior to the date of service, including, but not limited to:
  - ☐ The patient's diagnosis and prognosis;
  - ☐ Symptoms and objective findings, including measurements which establish the severity of the condition;
  - ☐ The reason the device is required, including the treatments which have been tried and failed; and
  - ☐ The clinical response to an initial treatment with the device
    - ☐ The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.
- ☐ Four-week trial
- ☐ Treating practitioner concurrence when LCMP performs the assessment/evaluation

Lymphedema

For pneumatic compression devices (PCD) coded E0650 or E0651 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria for I - lymphedema or II - chronic venous insufficiency with venous stasis ulcers (CVI) are met.

For PCDs coded as E0652 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria in III - lymphedema extending onto the chest, trunk and/or abdomen are met.

Pneumatic Compression Devices (E0650 or E0651)

A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all the following three requirements are met:

- ☐ The beneficiary has a diagnosis of lymphedema as defined above, and
- ☐ The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
  - ☐ Marked hyperkeratosis with hyperplasia and hyperpigmentation,
  - ☐ Papillomatosis cutis lymphostatica,
  - ☐ Deformity of elephantiasis,
  - ☐ Skin breakdown with persisting lymphorrhea,
  - ☐ Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
- ☐ In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial. (See below for trial guidelines.)

Four-Week Trial for Lymphedema

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- ☐ Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
- ☐ 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. The compression used must not create a tourniquet effect at any point.

- ☐ The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- ☐ Regular exercise
- ☐ Elevation of the limb

☐ When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive failure.

☐ The medical necessity determination for a PCD by the treating practitioner must include symptoms and objective findings, including measurements, to establish the severity of the condition.

The documentation by the treating practitioner of the medical necessity of a pneumatic compression device must include:

- ☐ The patient's diagnosis and prognosis;
- ☐ Symptoms and objective findings, including measurements which establish the severity of the condition;
- ☐ The reason the device is required, including the treatments which have been tried and failed; and
- ☐ The clinical response to an initial treatment with the device

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner, or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

Chronic Venous Insufficiency with Venous Stasis Ulcers (CVI)

A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all of the following:

- ☐ Edema in the affected lower extremity
- ☐ One or more venous stasis ulcer(s)
- ☐ 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.)

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- ☐ Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression

  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. The compression used must not create a tourniquet effect at any point.

  The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- ☐ Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- ☐ Regular exercise
- ☐ Elevation of the limb
- ☐ Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no significant improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

Pneumatic Compression Devices (E0652)

A PCD coded as E0652 is covered for both treatment of lymphedema extending onto the chest, trunk and/or abdomen when all of the following are met:

- ☐ The beneficiary has lymphedema of an extremity as defined above
- ☐ The coverage criteria for an E0650 or E0651 are met
- ☐ The beneficiary has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial.

Four-Week Trial for Lymphedema Extending onto the Chest, Trunk and/or Abdomen

A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:

- [ ] At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- [ ] Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
- [ ] 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. The compression used must not create a tourniquet effect at any point.
- [ ] The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- [ ] Regular exercise
- [ ] Elevation where appropriate
- [ ] Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- [ ] Evaluation of diet and implementation of any necessary change
- [ ] Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- [ ] Correction (where possible) of anemia and/or hypoprotenemia

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.