entré™ flexitouch®

Medicare Coverage Criteria for Lymphedema

Pneumatic Compression Devices E0651 (Entré) and E0652 (Flexitouch)

How to initiate a Medicare order:

Fax a copy of the patient's medical record face sheet to 866.435.3949. After we have verified Medicare is the patient's primary insurance, a Medicare Specialist will contact you to discuss which pneumatic compression device is appropriate for the patient based upon Medicare's coverage criteria outlined below. They will then work with you to complete the necessary forms and documentation.

Patient's medical records must include the following to meet criteria for either an E0651 or an E0652 device:

☐ **A documented diagnosis of lymphedema**	A diagnosis of lymphedema must be noted within the clinical records, as well as: ☐ Cause of lymphedema, including any history of surgical procedure, cancer, traumatic episodes, or other underlying condition that has interrupted normal lymphatic drainage of the extremity, or if the lymphedema is congenital ☐ Date of onset of swelling
☐ **Objective findings that establish the severity of the condition**	The following are examples of objective findings that require documentation: • Circumferential measurement charts demonstrating significant asymmetrical swelling • Clinician determination of lymphedema Stage (II or III) and Severity (moderate or severe); *Stage I and/or mild lymphedema does not meet criteria* • Documentation of the presence of lymphedema symptoms which may include: – Positive Stemmer's sign – Fibrosis – Papillomas – Lymphatic blisters or weeping – Swelling of dorsum of foot – Skin breakdown, wounds, or ulcerations due to long-term swelling – Repeated infections, with or without hospitalization
☐ **The patient has completed at least 4 weeks of conservative therapies**	Clinical records must demonstrate the patient has been compliant with the following conservative therapies for a minimum of four weeks prior to pneumatic compression treatment: ☐ Appropriate compression bandaging or garment ☐ Elevation ☐ Exercise
☐ **The patient continues to exhibit significant symptoms following conservative therapies**	Clinical records must demonstrate failure of conservative therapies by providing evidence that the patient continues to display significant symptoms. **Documentation must include:** ☐ Measurements that confirm significant edema remains after four weeks ☐ Other symptoms such as fibrosis, recurrent cellulitis infections, or skin breakdown ☐ Clinician determination that the patient is failing to achieve desired results from conservative therapies alone, and has a medical need for pneumatic compression treatment
☐ **Physician oversight**	Physician oversight of all phases of treatment demonstrated by physician notes and/or signed plans of care.

Medicare denies coverage when all questions on the Certificate of Medical Necessity (CMN) are answered "no". Tactile Medical offers self-pay options for patients that do not meet Medicare criteria.

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To speak with a Medicare Specialist, please call our toll-free Medicare hotline at 855.319.9949

Patient's medical records must additionally include the following to meet Medicare criteria for an E0652 device:

☐ **The patient has undergone a trial of a basic* pump**

**A "basic" pump (E0650 or E0651) is defined for these purposes as a noncalibrated pressure pump with no appliances to treat the trunk or chest.*

A less costly basic pump must first be used to determine if it meets the patient's medical need. Documentation must demonstrate the basic pump's level of effectiveness in treating patient's swelling, fibrosis, pain and patient's ability to tolerate prior to E0652 prescription.

Documentation of a basic pump trial should include:

- ☐ Type/make/model of basic pump
- ☐ Pressure settings and treatment plan, which notes duration of use
- ☐ Dates and/or timeframe the pump was utilized; *at least a four-week trial is preferable!*
- ☐ Measurements before and throughout pump trial to demonstrate level of effectiveness in treating patient's swelling
- ☐ Modifications made during the trial to address unique characteristics

☐ **Unique characteristics that prevented satisfactory treatment with basic pump**

The following are examples of possible unique characteristics that prevented satisfactory pneumatic compression treatment with a basic pump.

Documentation should include:

- ☐ Significant fibrosis, scarring, and/or proximal swelling
  - – Do pre- & post-measurements demonstrate increases proximal to where the pump's garments end, or unsatisfactory decreases to the extremity?
  - – Did a fibrotic cuff form following pump use?
  - – Are there new areas of lymphedema after pump use?
  - – Were additional manual lymphatic drainage (MLD) or compression bandaging/garments utilized in conjunction with the basic pump to improve proximal swelling or fibrosis?
- ☐ Pain or intolerance to the pump's pressures
  - – Location and severity of pain
  - – What modifications were made to alleviate pain (e.g., reduced pressures, increased padding)?
  - – Does the patient have a medical condition that may be contributing to the pain?

☐ **Justifications for why a more advanced level of pump (E0652) is medically necessary**

Clinical record should justify why the patient has a medical need for an E0652 level pump that should produce better results than the previously tried basic pump. Medical record should additionally document the specific features the Flexitouch system offers that are medically necessary for the patient.

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