ESC LHIN Integrated Wound Care Program geko™ Device Guideline

Purpose

To provide access to the geko™ device adjunctive therapy for a limited number of appropriate patients with a goal to improve healing for lower leg wounds that have not reduced in size by 30%, utilizing treatment informed by best practice guidelines.

The geko™ device is a wearable, non-invasive, technology that stimulates the Peroneal nerve. The result is a small, localized involuntary muscle contraction. A muscle twitch can be noted. *The device does not produce full-range-of-motion muscle contraction in the same manner as devices using 20 – 50 Hz stimulation.* (Canadian Association of Wound Care, 2016)

Eligibility

Patients eligible for the geko™ device:

- Must be assessed by a wound care specialist (WCS) who has identified that geko™ therapy is appropriate for the patient based on identified inclusion criteria detailed on the 'ESC LHIN Eligibility Checklist and Assessment Tool.'
- Their wound must have been assessed as 'healable' by the WCS with documentation of findings to support that.
- A physician must be involved and agreeable to plan for patients with:
    - a cardiac demand pacemaker
    - an implanted electronically-controlled medical device,
    - a recent history of DVT
    - a history of epilepsy
    - a history of CHF/heart disease
    - who may be pregnant

***Caution** must be exercised with patients with a history of skin irritation or contact dermatitis.

Patients eligible for the geko™ device with a diabetic foot ulcer (DFU) must have:

- A DFU which has been off-loaded and will continue to be off-loaded with an appropriate device (not orthotics) during the course of the therapy
- Received best practice wound treatment for at least four consecutive weeks
- Ulcer reduction < 30% following best practice for four consecutive weeks
- If unable to obtain ABPI (d/t calcification) then TBPI > 0.64 documented
- Documented controlled blood glucose

Patients eligible for the geko™ device with a venous leg ulcer (VLU), arterial leg ulcer (ALU), or mixed VLU/ALU must have:

- Been in compression therapy for a minimum of two weeks with documented ABPI
- Received best practice wound treatment for at least four consecutive weeks
- Wound reduction < 30% following best practice wound treatment for four consecutive weeks
- If Diabetic, documented controlled blood glucose

Ontario

Patients are considered ineligible for geko™ if:

- Under 19 years of age
- ABPI < 0.5 or TBPI < 0.64
- Lymphedema
- Active dermatitis in the application region
- History of non-adherence to care plan/therapy
- Poor adherence to off-loading devices or compression therapy (failure to treat-the-cause)

Goals of Care:

- The geko™ will be authorized to promote a reduction in wound size. If the wound fails to decrease in size over four weeks, geko™ will be discontinued. Other goals of care may include:
  - Reduction of edema
  - Reduction of pain (using a numeric 0-10 pain scale)
  - Tolerance of ideal compression
  - Increase in ambulation

Treatment Protocol:

- Eligibility Checklist and Assessment Tool completed by WCS and submitted to ESC LHIN
  - WCS block of 2 – 1 for assessment, and one at three weeks of geko™ use to determine continuing eligibility, updated APR sent to LHIN at each WCS visit with accurate measurements and signs of wound healing
- Non-Formulary Request Completed and submitted to ESC LHIN
- Patient must have a primary care provider (physician/NP) for medical supervision
- APRs submitted by the SPO every two weeks with accurate measurements, and signs of wound healing are required during the geko™ treatment time
- gekoTM device is worn on the affected leg, six hours per day, six days per week consistently
- Patient is to be independent with application/removal and turning on/off the device by second nursing visit

Reasons to stop geko™ therapy:

- No improvement in wound status at four weeks of treatment – APR by WCS at three weeks of treatment indicating wound progression required
- Wound stalls in spite of best practice wound management
- Active dermatitis in the area of application
- Adverse reaction to geko™ during the treatment period
- Development of a DVT/PE or other contraindication during the treatment period
- Patient is non-adherent to plan of care including self-management strategies such as:
  - Nutritional requirements for wound healing
  - Smoking cessation
  - Blood glucose control
  - Off-loading/compression therapy as indicated

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