

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

REGRANEX (all topical)
(becaplermin)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Regranex is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.

Limitations of Use:

The efficacy of Regranex has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue [Stage I or II, International Association of Enterostomal Therapy (IAET) staging classification] or ischemic diabetic ulcers.

The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans.

Regranex is not intended to be used in wounds that close by primary intention.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of a lower extremity diabetic neuropathic ulcer that extends into the subcutaneous tissue or beyond and has an adequate blood supply
AND
- Good ulcer care practices including initial sharp debridement, pressure relief, and infection control will be performed
AND
- If additional quantities are being requested, then the requested drug is being prescribed to treat an ulcer greater than 2.5 square inches in size or multiple ulcers

Quantity Limits apply.

30 grams/25 days*

For multiple ulcers or an ulcer greater than 2.5 square inches in size: 60 grams/25 days*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

**** This drug is for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.**

REFERENCES

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew Inc.; August 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed January 30, 2023.

3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed January 30, 2023.