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

Lower Extremity Diabetic Neuropathic Ulcers
Authorization may be granted when the requested drug is being prescribed for the treatment of lower extremity diabetic neuropathic ulcers that extends into the subcutaneous tissue or beyond and has an adequate blood supply when ALL of the following criteria are met:

- Good ulcer care practices including initial sharp debridement, pressure relief, and infection control will be performed
- 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 per 25 days*
For multiple ulcers or an ulcer greater than 2.5 square inches in size: 60 grams per 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 intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3-month supplies filled.***

DURATION OF APPROVAL (DOA)

- 186-C: DOA: 20 weeks

REFERENCES

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew Inc.; August 2019.

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2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com.Accessed January 17, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/17/2024).

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