

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**REGRANEX (all topical)**  
(becaplermin)

**Status: CVS Caremark Criteria**

**Type: Initial Prior Authorization**

## 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 gel 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 lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have 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/month

For multiple ulcers or an ulcer greater than 2.5 square inches in size:

60 grams/month

### REFERENCES

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew Inc.; August 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed March 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed March 2020.