

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Regranex Gel (becaplermin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Regranex (becaplermin) 0.01% Gel	N/A

APPROVAL CRITERIA

Requests for Regranex (becaplermin) may be approved if the following criteria are met:

- I. Individual has a diagnosis of diabetic neuropathic ulcer of the lower extremities, including legs, ankles, and feet, that is stage 3 or 4 of the International Association for Enterostomal Therapy (IAET) guide to chronic wound staging; **AND**
- II. Individual is using as adjunctive therapy with good ulcer care practices including, but not limited to sharp debridement of the ulcer.

Note: Regranex gel (becaplermin) has a black box warning regarding an increased rate of mortality secondary to malignancy. A post marketing retrospective cohort study observed increased rates of mortality in individuals treated with 3 or more tubes of Regranex. Regranex should only be used when the benefits outweigh the risks. Regranex should be used with caution in individuals with known malignancy.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.