

| 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.

WEB-PEC-0491-16-D

PAGE 1 of 2 09/22/2016

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.

| 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

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.