

Clinical Pharmacy Program Guidelines for Regranex

Program	Prior Authorization
Medication	Regranex® (becaplermin gel)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

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. Regranex should be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief, and infection control. The efficacy of Regranex gel has not been established for the treatment of pressure ulcers or venous stasis ulcers.

Regranex has black box warnings for mortality due to cancer and new primary malignancies. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. Authorization

1. **Regranex** will be approved based on the following:
 - a. Patient has a lower extremity diabetic neuropathic ulcer

Authorization will be issued for 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

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

Program	Prior Authorization/Notification - Regranex
Change Control	
Date	Change
3/2013	New policy applicable to the Michigan line of business
6/2015	Updated policy to include Rhode Island and Ohio as an in-scope plan
6/2016	Updated policy template. Policy now applies to all lines of business.
7/2017	Annual review. Removed automated step language from background. Updated reference.
8/2018	Annual review. No changes.
10/2018	Updated criteria to allow for Diagnosis to Drug Match for diabetic ulcers.
9/2019	Annual review. Reference updated.
9/2020	Annual review. Added Additional Clinical Rules section and updated references.