



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** becaplermin

**Brand Name:** Regranex

**Medication Class:** a recombinant human platelet-derived growth factor (rhPDGF)

**FDA Approved Uses:** treatment of lower extremity diabetic neuropathic ulcers that extends into the subcutaneous tissue or beyond.

**Available Dosage Forms:** topical gel 0.01%, 15 gm tube

**Usual Dose:** The amount of gel to be applied will vary depending upon the size of the ulcer area.

**Duration of Therapy:** Until complete healing of ulcer or a maximum of 20 weeks.

**Approximate cost** (based on AWP 2007): \$724.98 per 15gm tube

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond.
- Must have failed standard therapy for at least 2 months (careful-frequent debridement, moist dressing changes and non-weight bearing)
- Failed treatment with a formulary product such as Accuzyme, Ethezyme, Panafil, or Granulex.
- Classification of diabetic wound severity
  - WOCN and NPUAP: Stage III or IV lower extremity diabetic ulcer (extending through the dermis into the subcutaneous tissue or beyond)
  - University of Texas: Diabetic ulcer classified as a grade 2 or 3, stage A (clean, nonischemic, noninfected wounds penetrating to the tendon or capsule or into bone or joint)
  - Wagner: Grade 1 or 2 (partial/full thickness ulcer or probing to tendon or capsule)
- Lower extremity wound must possess an adequate blood supply.
- Must be used as adjunct treatment to, not a replacement for, good ulcer care including sharp debridement, pressure relief, standard of care moist dressing changes, and prevention and treatment of infection.
- Nutritional status must be addressed for any protein and / or calorie malnutrition.
- The wound must be free of infection.

**Contraindications:**

- Hypersensitivity to any component of Regranex.
- Known neoplasms at the site of application



**Not Approved if:**

- For treatment of pressure, venous stasis or other types of non-diabetic related ulcers.
- Patient has any contraindication to the use of Regranex.
- Patient does not meet the above stated criteria.

**Special Considerations:**

- The efficacy of Regranex gel for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I of II, IAET staging classification) or ischemic diabetic ulcers has not been evaluated.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_