Becaplermin (REGRANEX™) Gel
Criteria for Use
May 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive becaplermin gel.

- ☐ Contraindication: Known neoplasm(s) at the site of application
- ☐ Known hypersensitivity to any component of the product (e.g, parabens)
- ☐ Intended for management of venous stasis or pressure ulcer(s)

Inclusion Criteria

The answers to all the following must be fulfilled in order to meet criteria.

- ☐ Nonsmoking or undergoing treatment for smoking cessation
- ☐ Glycosylated hemoglobin (hemoglobin A1C or HbA1c) < 8 or actions are being taking to improve glycemic control
- ☐ Non-infected lower extremity diabetic ulcer extending to the subcutaneous tissue or beyond with an adequate blood supply to the ulcer
- ☐ Inadequate response to at least 2 months of standard wound therapy (e.g., debridement, moist dressings and non-weight bearing)
- ☐ Committed to 10 weeks of becaplermin gel (reassess after 20 weeks if not completely healed)

Supplementary Information

- Becaplermin gel has not been shown to improve healing of venous stasis or pressure ulcers vs. usual care and therefore should not be used to manage these types of ulcers.
- Malignancies, separate or distant from the application site, have been reported in clinical studies and in post-marketing surveillance. The risks and benefits should be carefully considered before using becaplermin gel in patients with known malignancy.
- Active treatment to improve glycemic control, including referral to Endocrinology if appropriate, should be attempted.
- Patients should be nonsmoking and if not, plans for smoking cessation should be initiated.
- Classification of diabetic wound severity: (All wounds must be free from infection)
    - University of Texas: Diabetic ulcer classified as a grade 2 or 3; stage A (clean, non-ischemic, non-infected 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)
- Identification and removal of the underlying etiology of the wound (e.g. poor fitting shoes, reinforce non-weight bearing, etc.) should be done.
- If present, lower extremity edema should be treated.
- The patient's nutritional status has been addressed for any protein and/or calorie malnutrition.
- Reinforce to patients that application of excessive becaplermin gel has not been shown to be of greater benefit in ulcer healing.
- The provider must calculate an initial amount and recalculate a new amount of becaplermin gel to be applied at every visit (weekly or biweekly intervals), see labeling.
- If the ulcer does not decrease by approximately 30% in size after 10 weeks of therapy, continued treatment with becaplermin should be reassessed. Treatment with becaplermin gel should continue until the ulcer is completely healed or a maximum of 20 weeks.
- If the ulcer has not completely healed after 20 weeks, the benefits/risks of continued treatment with becaplermin gel should be reassessed.
- Patients and care providers must be educated regarding proper application, storage (must be refrigerated) and the potential benefits/risks of becaplermin gel (e.g., Medication Guide and Patient Instructions for Use). An assessment of their ability to properly apply becaplermin gel should be done.
- Patients and care providers need to be educated on proper wound care including dressing changes not involving application of becaplermin gel (second dressing change of the day). They also need to be educated on the **importance** of non-weight bearing measures.

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