

Pharmacy Policy Bulletin

Title: Becaplermin gel (Regranex®)

Policy #: Rx.01.225

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **becaplermin (Regranex®) gel** as provided under the member's prescription drug benefit.

Description:

Diabetic foot ulcers are a prevalent complication of diabetes mellitus and represent major causes of morbidity and mortality. 15% of all diabetic individuals are affected by foot ulcers during their lifetime and 15-20% of those patients go on to need an amputation. Risk factors for development of diabetic foot ulcers include neuropathy, peripheral vascular disease, and poor glycemic control. Peripheral neuropathy results in patient loss of sensation and can exacerbate the development of ulcerations. Peripheral vascular disease can lead foot tissues to become ischemic. Many wounds go unnoticed and worsen through repetitive pressure because patients are unable to detect trauma to their lower extremities. Multidisciplinary treatment today includes: surgical debridement, dressings promoting a moist wound environment, wound off-loading, vascular assessment, treatment of active infection, and glycemic control.

Regranex® gel is a recombinant human platelet-derived growth factor that promotes cellular proliferation and angiogenesis and thereby improve ulcer healing. Regranex® gel 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® gel is indicated as an adjunct to, and not a substitute for, good ulcer care practices.

Policy:

INITIAL CRITERIA: Becaplermin (Regranex®) gel is approved when BOTH of the following are met:

1. Member has a lower extremity diabetic neuropathic ulcer; and
2. Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief)

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Becaplermin (Regranex®) gel is re-approved when ONE of the following is met:

1. Documentation of lower extremity diabetic neuropathic ulcer at a different treatment site; or
2. Documentation of continued need for treatment beyond 6 months

Reauthorization duration: 6 months

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Pendsey, S. Understanding diabetic foot. Int J Diabetes Dev Ctries 2010; 30:75-9. Accessed April 1, 2022

Armstrong, D., J de Asla, R. Management of diabetic foot ulcers. UpToDate. March 2023. Available from: https://www.uptodate.com/contents/management-of-diabetic-foot-ulcers?search=diabetic%20foot%20ulcer&source=search_result&selectedTitle=1~61&usage_type=default&display_rank=1. Accessed April 17, 2023.

Regranex® (becaplermin gel) [prescribing information]. Fort Worth, TX: Smith & Nephew, Inc.; December 2019. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103691s5134lbl.pdf. Accessed April 17, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand name	Generic name
Regranex®	Becaplermin

Cross References:

Off Label Use Rx.01.33

Policy Version Number:	4.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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