Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PMN.21	**Effective Date: 01/2018** **Revision Date: 01/2021**
Policy Name: Becaplermin (Regranex)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:**

Clinical Policy: Becaplermin (Regranex)

Reference Number: PA.CP.PMN.21
Effective Date: 01/2018
Last Review Date: 01/2021

Coding Implications
Revision Log

Description
Becaplermin (Regranex®) is a human platelet-derived growth factor.

FDA approved indication
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, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.

Limitations of use:
- The efficacy of Regranex gel has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers.
- The effects of Regranex on exposed joints, tendons, ligaments, and bone have not been established in humans.
- Regranex is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness ® that Regranex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diabetic Neuropathic Ulcers (must meet all)**:**
1. Diagnosis of diabetes with lower extremity neuropathic ulcer(s);
2. Age ≥ 16 years;
3. Number of tubes being requested is no greater than the quantity of whole tubes sufficient to meet dosing regimen outlined in package labeling based on size of wound being treated.

Approval duration: 6 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Diabetic Neuropathic Ulcers (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Number of tubes being requested is no greater than the quantity of whole tubes sufficient to meet dosing regimen outlined in package labeling based on size of wound being treated.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: 6 months; or
2. Refer to PA.CP. PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP. PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known neoplasm(s) at the site(s) of application
- Boxed warning(s): none reported

Appendix D: General Information

- In November 2018, the FDA removed the boxed warning for increased rate of mortality secondary to malignancy, which was originally observed in patients treated with 3 or more tubes of Regranex in a postmarketing retrospective cohort study. This removal was based on the results of two additional postmarketing retrospective studies, which both demonstrated no increased risk of cancer death with Regranex.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Diabetic neuropathic ulcers	One application topically to ulcer(s) left in place for 12 hours once daily until complete healing has occurred; amount applied will vary depending upon the size of the	See regimen

Indication	Dosing Regimen	Maximum Dose
	ulcer area – for a 15 g tube, the length of gel to be applied daily can be calculated using the following: • Inches: ulcer length x ulcer width x 0.6 • Centimeters: ulcer length x ulcer width ÷ 4	

VI. Product Availability

Gel: 0.01% becaplermin in 15 g tube

IV. References

1. Regranex Prescribing Information. Fort Worth, TX: Smith & Nephew, Inc.; December 2018. Available at: https://www.regranex.com. Accessed October 26, 2020.

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	
1Q 2020 annual review: based on new clinical data demonstrating no increase in cancer mortality risk and the FDA's subsequent removal of the boxed warning, modified quantity restriction from 2 tubes/lifetime to 1 tube/30 days and modified approval durations from 1 tube to 6 months; age limit added (≥ 16 years); references reviewed and updated.	01/2020	
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021	