Clinical Policy: Becaplermin (Regranex)

Reference Number: CP.PMN.21
Effective Date: 09.01.06
Last Review Date: 02.19
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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.

Limitation(s) 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 gel on exposed joints, tendons, ligaments, and bone have not been established in humans.
- Regranex gel 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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. Request does not exceed 1 tube.

Approval duration: 1 tube

B. Other diagnoses/indications

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not previously received ≥ 2 tubes of Regranex;
4. Request does not exceed 1 tube.

Approval duration: 1 tube (lifetime benefit of 2 tubes total)

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: 1 tube (lifetime benefit of 2 tubes total); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically 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 – 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): increased rate of mortality secondary to malignancy (observed in patients treated with 3 or more tubes of Regranex in a postmarketing retrospective cohort study)

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 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	See regimen

VI. Product Availability

Gel: 0.01% becaplermin in 15 g tube

VII. References

1. Regranex Prescribing Information. Fort Worth, TX: Smith & Nephew, Inc.; August 2014. Available at: https://www.regranex.com. Accessed November 1, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated reference section to reflect current literature search	02.15	02.15
Converted to new template. Removed criteria F as the requirement of this criteria is unclear with regards to albumin level. Clarify that the ulcer should be lower extremity ulcer	08.15	08.15
Removed criteria that cannot be enforced at a PBM level: presence of ulcer for > 8 weeks, ulcer stage requirement for stages III and IV of the IAET guide to chronic wound staging, failure of wound care, including initial sharp debridement, pressure relief, and infection control; documentation of proper and adequate wound care, wound devoid of infection; Added limit of 2 tubes per lifetime due to black box warning for increased mortality beyond in patients who have used 3 or more tubes; Added black box warning detail to background section; Updated reference section to reflect current literature search.	11.15	02.16
Converted to new integrated template. Removed age restriction as that is not an absolute contraindication per the PI. Added requirement that request may not exceed 1 tube at a time. On re-auth, added that member must be responding positively to therapy. Added workflow document. Updated references.	11.16	02.17
1Q18 annual review: - No significant changes. - Age added per safety guidance endorsed by Centene Medical Affairs. - References reviewed and updated.	11.20.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.12.18	02.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.