

Drug and Biologic Coverage Policy



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Becaplermin

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for becaplermin (**Regranex**[®]).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Becaplermin (Regranex) is considered medically necessary when the following are met:

- 1. Diabetic foot ulcer.** Individual meets **BOTH** of the following criteria (A and B):
 - A. Use for the treatment of diabetic neuropathic ulcer of the lower extremity
 - B. Regranex will be used in combination with good wound care practices

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Becaplermin (Regranex) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Regranex is a human platelet-derived growth factor 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 is indicated as an adjunct to, and not a substitute for, good ulcer care practices.¹

Limitations of Use:

- The efficacy of Regranex has not been established for the treatment of pressure ulcers and venous stasis ulcers.
- The effects of Regranex on exposed joints, tendons, ligaments, and bone have not been established in humans.
- Regranex is not intended to be used in wounds that close by primary intention.

The amount of Regranex Gel to be applied will vary depending upon the size of the ulcer area. To calculate the length of gel to apply to the ulcer, measure the greatest length of the ulcer by the greatest width of the ulcer in either inches or centimeters. To calculate the length of gel in inches or centimeters, use the formula shown below:

Tube Size	Formula
15 g tube	Inches = length X width X 0.6
15 g tube	Centimeters = length X width ÷ 4

References

1. Regranex® topical gel [prescribing information]. Fort Worth, TX: Smith & Nephew, Inc.; August 2019.

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