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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	July 1, 2014
Subject:	Regranex	**Page:**	1 of 4

Last Review Date: June 13, 2024

Regranex

Description

Regranex (becaplermin)

Background
Regranex is a recombinant form of human platelet-derived growth factor which is applied directly to diabetic foot and leg ulcers that are not healing. The recombinant form of platelet growth factor has a biologic activity that is much like that produced naturally by the body. Growth factors cause cells to divide more rapidly. Regranex promotes the chemotactic recruitment and proliferation of cells involved in wound repair and enhancing the formation of granulation tissue (1).

Regulatory Status
FDA-approved indication: Regranex contains becaplermin, a human platelet-derived growth factor that 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 (1).

Limitations of Use:

- Regranex 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 the subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers (1).

- The effects of Regranex on exposed joints, tendons, ligaments, and bone have not been established in humans (1).

- Regranex is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention (1).

Malignancies distant from the site of application have occurred in Regranex users. Regranex should only be used when the benefits can be expected to outweigh the risks. Regranex should be used with caution in patients with known malignancy (1).

Regranex is contraindicated in patients with known neoplasm(s) at the sites(s) of application (1).

Regranex should not be used for more than 20 weeks if wound has not completely healed (1).

Safety and effectiveness of Regranex in pediatric patients below the age of 16 years have not been established (1).

Related policies
Santyl

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Regranex may be considered **medically necessary** if the conditions indicated below are met.

Regranex may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnoses

Patient must have **ALL** of the following:

1. Diabetes
2. Lower extremity neuropathic ulcers

a. That extend into the subcutaneous tissue or beyond with adequate blood supply

AND NONE of the following:

1. Neoplasm(s) at the sites(s) of application
2. Use in pressure ulcers, venous stasis ulcers, or ischemic diabetic ulcers
3. Exposed joints, tendons, ligaments, and bone (at application site)
4. Use in wounds that close by primary intention (such as suturing or gluing)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 tubes per 20 weeks

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Regranex promotes the chemotactic recruitment and proliferation of cells involved in wound repair and enhancing the formation of granulation tissue in lower extremity diabetic neuropathic ulcers that extended to subcutaneous tissue and beyond. Regranex should only be used when the benefits can be expected to outweigh the risks. Regranex should be used with caution in patients with known malignancy. Safety and effectiveness of Regranex in patients under the age of 16 years have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Regranex while maintaining optimal therapeutic outcomes.

References

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew, Inc.; August 2019.

Policy History

Date	Action
June 2014	New addition to PA
September 2015	Annual editorial review.
December 2016	Annual editorial review and reference update Policy number change from 9.14.06 to 5.90.06
September 2017	Annual review
March 2018	Addition of quantity limit of 3 tubes
June 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review and reference update
September 2021	Annual review
September 2022	Annual review, Per SME and PI update, removed reference to boxed warning in regulatory
September 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.