Original Effective Date: 07/2018
Current Effective Date: 06/23/2023
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2024
Policy Number: C13432-C

Regranex (becaplermin)

PRODUCTS AFFECTED

Regranex (becaplermin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Diabetic neuropathic ulcers

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. DIABETIC NEUROPATHIC ULCER:
1. Documentation of clinically diagnosed lower extremity chronic neuropathic ulcer that extends into the subcutaneous tissue or beyond (full thickness, e.g., Stage III or IV) or pressure ulcer extending into the subcutaneous tissue (full thickness, e.g., Stage III or IV) AND

2. Prescriber attests that the wound possesses an adequate blood supply
   AND
3. Prescriber attests that the member does not have a neoplasm(s) at site of application
   AND
4. Prescriber attests that Regranex will be used as adjunct treatment to, not a replacement for, good ulcer care including sharp debridement, pressure relief, standard of care moist dressing changes, and prevention and treatment of infection.
   AND
5. Patient has had a trial and failure or contraindication with Santyl (collagenase)

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial Authorization: 5 months, Continuation of Therapy: NA

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a Podiatrist or wound care specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
16 years of age and older

QUANTITY:
3 tubes of 15 grams maximum per the length of authorization (5 months)

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical

DRUG CLASS:
Wound Care - Growth Factor Agents

FDA-APPROVED USES:
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.
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Wound Definitions:
Stage I: Non-blanchable erythema of intact skin
Stage II: Partial thickness skin loss involving epidermis and/or dermis
Stage III: Full thickness skin loss involving damage or necrosis of subcutaneous tissues that may extend down to, but not through, underlying fascia
Stage IV: Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures
Chronic: A wound or condition present for at least 30 days despite standard medical and surgical management

Calculation of dosage: (15 g tube size): To calculate the length of gel applied to the ulcer, measure the greatest length of the ulcer by the greatest width of the ulcer. Tube size and unit of measure will determine the formula used in the calculation.
Recalculate amount of gel needed every 1 to 2 weeks, depending on the rate of change in ulcer area.
Centimeters 15 g tube [ulcer length (cm) × width (cm)] divided by 4 = length of gel (cm)
Inches 15 g tube [length (in) × width (in)] x 0.6 = length of gel (in)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

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. Regranex should be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief, and infection control. The efficacy of Regranex gel has not been established for the treatment of pressure ulcers or venous stasis ulcers.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Regranex (becaplermin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Regranex (becaplermin) include: patients with known neoplasm(s) at the site(S) of application.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Regranex GEL 0.01% (15 grams)

REFERENCES

1. Regranex® prescribing information. Fort Worth, TX: Smith & Nephew, Inc. August 2019

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q2 2023
REVISION- Notable revisions: Age Restrictions	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file