PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

REGRANEX (all topical)
(becaplermin)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 186-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
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, International Association of Enterostomal Therapy (IAET) staging classification] or ischemic diabetic ulcers.

The effects of becaplermin 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.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
  AND
- Good ulcer care practices including initial sharp debridement, pressure relief, and infection control will be performed
  AND
- If additional quantities are being requested, then the requested drug is being prescribed to treat an ulcer greater than 2.5 square inches in size or multiple ulcers

Quantity Limits apply.

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Regranex gel 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 is not a substitute for good ulcer care practices which includes initial sharp debridement, pressure relief and infection control.[1]

The effects of Regranex Gel on the incidence of and time to complete healing in lower extremity diabetic ulcers were assessed in four randomized controlled clinical studies. All study participants had lower extremity diabetic neuropathic ulcers that extended into the subcutaneous tissue or beyond [Stages III and IV of the International Association of Enterostomal Therapy (IAET) guide to chronic wound staging] with an adequate blood supply. Patients were treated until complete healing, or for a period of up to 20 weeks. Patients were considered a treatment failure if their ulcer did not show an approximate 30% reduction in initial ulcer area after eight to ten weeks of Regranex Gel therapy.[1-3]

Dosing for Regranex is calculated by multiplying the length of the ulcer in inches by the width of the ulcer in inches by a constant of 0.6. This equation determines the length of gel in inches to be applied to the ulcer. The weight of Regranex is 0.65 grams per inch of length. An amount of 1 gram per day is sufficient to treat an ulcer up to 2.5 square inches. In the four clinical trials that evaluated the efficacy of Regranex, 95% of the ulcers treated measured in area up to 10 square centimeters or 1.55 square inches.[1] A limit of 30 grams per month will apply to patients who meet the prior authorization criteria.

For patients that have an ulcer greater than 2.5 square inches or for patients that have multiple ulcers, a limit of 60 grams per month will apply.

The efficacy of Regranex gel for the treatment of non-diabetic ulcers has not been established.

REFERENCES

1. Regranex [package insert]. Fort Worth, TX: Smith & Nephew Inc.; August 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 22, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed February 22, 2021.

Written by:	UM Development (SE)
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Reviewed:	Medical Affairs (KP) 12/2009, 08/2010, 08/2011; (LB) 08/2012; (LMS) 07/2013, (DC) 07/2014 (KRU) 07/2015; (ME) 07/2016; (CHART) 04/16/2020, 03/25/2021 External Review: 03/2010, 12/2010, 12/2011, 10/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 06/2018, 06/2019, 06/2020, 06/2021

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply? [If no, then no further questions.]	Yes	No
2	Will good ulcer care practices including initial sharp debridement, pressure relief, and infection control be performed? [If no, then no further questions.]	Yes	No
3	Coverage is provided for up to 30 grams per month. Is MORE than this quantity needed to manage the patient's ulcer(s)? [If no, then no further questions.]	Yes	No
4	Is the requested drug being prescribed to treat an ulcer greater than 2.5 square inches in size OR multiple ulcers? [If no, then no further questions.] [RPh Note: If no, then deny and enter a partial approval for 30 grams / 25 days of the requested drug.]	Yes	No
5	Does the patient require MORE than the plan allowance of 60 grams per month? [RPh Note: If yes, then deny and enter a partial approval for 60 grams / 25 days of the	Yes	No

requested drug.]

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You have lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond - You have an adequate blood supply to the tissue Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have good ulcer care practices including: - Sharp debridement - Pressure relief - Infection control Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
3.	Go to 4	Approve, 20 weeks, 30 grams/25 days*	
4.	Go to 5	Deny	You have requested more than the quantity allowed by your plan. Current plan approved criteria cover up to 30 grams/month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 20 weeks. Your request for additional quantities of the requested drug and strength has been denied. Your plan covers additional quantities of this drug when you meet any of these conditions: -You have an ulcer greater than 2.5 square inches in size -You have multiple ulcers Your request has been denied based on the information we have. [Short Description: Over max quantity and patient does not meet requirements for additional quantities]
5.	Deny	Approve, 20 weeks, 60 grams/25 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 60 grams/month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 20 weeks. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

** The duration of 25 days is used for a 30-day fill period to allow time for refill processing.*

**** This drug is for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.***