CENTENE Corporation

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** becaplermin (Regranex®)
PAGE: 1 of 6	**REFERENCE NUMBER:** NH.PMN.21
EFFECTIVE DATE: 09/06	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/20, 02/15, 12/16, 10/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13, 02/14, 4/16

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Becaplermin is a recombinant human platelet derived growth factor for topical use. The biological activity includes promoting the chemotactic recruitment and proliferation of cells involved in wound repair and enhancing the formation of granulation tissue.

Brand: becaplermin (Regranex®): 0.01% gel

FDA Labeled Indications: Treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply

NOTE: Becaplermin (Regranex®) is not covered for the following indications because it is considered experimental, investigational or unproven according to FDA labeling:

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- pressure ulcers
- venous stasis ulcers
- diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, International Association Enterostomal Therapy (IAET) staging classification)
- ischemic diabetic ulcer

Criteria for Approval:

A. Patient has diabetes; **and**
B. Patient is ≥16 years of age; **and**
C. Diagnosis of Stage III or IV lower extremity diabetic ulcers as defined in the IAET guideline to chronic wound staging (extends through the dermis into the subcutaneous tissue or beyond, and has a good blood supply); **and**
D. Adequate nutritional status (recommend adequate protein intake for serum albumin < 3.5g/dL).

NOTE: Please obtain dimensions of the ulcer prior to the initial approval. Measurement should reflect dimensions of area of greatest length by greatest width of ulcer.

Approval:

Initial Approval: 3 months. Documentation of the size of the ulcer is needed to assess response. Documentation of wound healing in terms of measurement of ulcer size must be submitted for further approval up to a maximum of 20 weeks. Additional justification is needed for continuation of berceplermin if the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks.

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Continued Approval (must meet all as applicable):

A. Member is currently receiving this medication through centene benefit;

B. Member has NOT previously received ≥ 2 tubes

Approval duration: Allow no more than 2 tubes TOTAL per lifetime due to black box warning

Special Instructions
➢ Boxed Warning: An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes. Becaplermin should be used with caution in patients with known malignancy.
➢ Patient should be followed in a wound care program when one is available in the community.
➢ Pregnancy Category C.

References:

1. Regranex® prescribing information, accessed December, 2014. http://www.regranex.com/PI_Full_Version.pdf
2. Becaplermin. Clinical Pharmacology. Accessed November 2015. http://clinicalpharmacology-ip.com/
3. Regranex package insert. Fort Worth, TX: Smith & Nephew Inc.: August 2014. Available at: http://www.regranex.com/pdf/PI_Full_Version.pdf. Accessed December 2015
4. Regranex® monograph, Clinical Pharmacology. Accessed December, 2014. http://www.clinicalpharmacology-ip.com/Forms/search.aspx?s=regranex
5. Agency for Health Care Policy and Research (AHCPR) Treatment of pressure ulcers, clinical

guideline #15. http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=hsahcpr&part=A5124

6. National Pressure Ulcer Advisory Panel's (NPUAP) Updated Pressure Ulcer Staging System, Medscape on-line, posted 11/06/2007. http://www.medscape.com/viewarticle/556483_6
7. Update of Safety Review: Follow-up to the March 27, 2008, Communicatio about the Ongoing Safety Review of Regranex (becaplermin), June 6, 2008, Accessed December 2014. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm072148.htm
8. Facts and Comparisons accessed January 11, 2014:http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandchcp13133&quick=631532%7c5&search=631532%7c5&isstemmed=True&NDCmapping=-1&fromTop=true#firstMatch

Revision Log	
Revision	**Date**
Updated the "FDA Labeled Indications" and quantity limits in the "Approval" section.	02/10
Updated reference section to reflect current literature search.	02/10
Added Age Limit ≥ 16 years. References updated.	02/11
Updated reference section to reflect current literature search.	02/12
Update Criteria for Approval item F from "Adequate nutritional status (recommend serum albumin > 3.5g/dl)" to	02/12

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"Adequate nutritional status (recommend adequate protein intake for serum albumin < 3.5g/dL)".	
Added beyond "beyond and have an adequate blood supply" to the FDA indication according to drug labeling	02/13
Added "initial sharp debridement, pressure relief, and infection control" to approval criteria C to describe acceptable treatment.	02/13
Added "measurement should reflect dimensions of area of greatest length by greatest width of ulcer" to approval criteria to specifically define the required measurement.	02/13
Updated reference section to reflect current literature search.	02/13
Updated reference section to reflect current literature search.	02/14
Updated reference section to reflect current literature search	02/15
Added additional justification is needed for continuation of berceplermin	06/15
Removed "Chronic Ulcer present > 8 weeks, not responding to current wound care including initial sharp debridement, pressure relief, and infection control" from Criteria for approval. Removed "Documentation of proper and adequate wound care, wound devoid of infection" from criteria for approval. Added Continued Approval (must meet all as applicable): A. Member is currently receiving this medication through centene benefit; B. Member has NOT previously received ≥ 2 tubes **Approval duration: Allow no more than 2 tubes TOTAL per lifetime due to black box warning.** Updated reference section to reflect current literature search	4/16
Annual Review, No changes	12/16
Annual Review, No Changes	10/17

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POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

NOTE: The electronic approval is retained in Compliance 360.