

Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2020

Prior Authorization: Regranex

Products Affected: Regranex (becaplermin) 0.01% topical gel

Medication Description: Becaplermin, rhPDGF-BB, is approved for use as a topical wound healing agent to treat lower extremity, neuropathic, diabetic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. Becaplermin and endogenous platelet-derived growth factor (PDGF) have similar activity such as the promotion of chemotactic recruitment and proliferation of cells involved in wound repair and the enhancement of granulation tissue formation. Regranex has black box warnings for mortality due to cancer and new primary malignancies.

Covered Uses: 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.

Exclusion Criteria:

1. Patients with known neoplasm(s) at the site(s) of application
2. The treatment of pressure ulcers, venous stasis ulcers, 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.

Required Medical Information:

1. Diagnosis
2. Wound type and location
3. Current treatment regimen

Age Restrictions: 16 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 20 weeks

Other Criteria:

1. The patient has a diagnosis of Diabetes; AND
2. The patient has chronic lower extremity diabetic neuropathic ulcer(s) that extend into the subcutaneous tissue or beyond, classification examples are included but not limited to the following:
 - a. WOCN and NPUAP: Stage III or IV lower extremity diabetic ulcer (extending through the dermis into the subcutaneous tissue or beyond); OR
 - b. University of Texas: Diabetic ulcer classified as a grade 2 or 3, stage A (clean, nonischemic, non-infected wound penetrating to the tendon or capsule or into bone or joint); OR
 - c. Wagner: Grade 1 or 2 (partial/full thickness ulcer or probing to tendon or capsule); AND
3. The ulcer(s) has an adequate blood supply; AND
4. Regranex is being used as an adjunct to, and not a substitute for, good ulcer care practices; including initial sharp debridement, pressure relief and infection control.

References:

1. Product Information: REGRANEX[®] topical gel, becaplermin topical gel. Smith & Nephew Inc (per FDA), Fort Worth, TX, 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	Policy Update	Adopted EH Template and Criteria; CCI P&T Review History: 3/04, 12/05, 12/06, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 8/16, 8/17, 7/18 CCI Revision Record: 8/17, 7/18	All	10/21/2019