

**Drug Therapy Guidelines:  
Wound Healing Agent  
Regranex<sup>®</sup> (becaplermin)**

*Effective Date: 11/20/07*

*Committee Review Date: 11/28/00, 11/27/01,  
11/19/02, 12/16/03, 11/16/04, 11/15/05,  
10/15/06, 11/5/07*

**Policy Statements:**

**Non-Formulary or Prior Authorization drugs will require an appropriate trial of a Formulary agent(s) based on clinical criteria. Members with a closed Formulary (2 Tier) prescription benefit are limited to use of Formulary agents only. A therapeutic trial of samples of a Non-Formulary or Prior Authorization agent will not be accepted as appropriate.**

**Please be sure to list all therapies that have been previously tried on the request form so that your request can be processed in a timely manner.**

**What it Does and How it is Used:**

- Regranex<sup>®</sup> 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. This medication is to be used as an adjunct to, and not a substitute for, good ulcer care practices.
- Regranex<sup>®</sup> is a platelet derived growth factor used as debridement adjunct for the treatment of diabetic ulcers that occur on the lower limbs and feet, a costly recombinant DNA product in which careful patient selection is important to obtaining optimal outcomes. Patients who are poor candidates for Regranex<sup>®</sup> therapy include those who are non-compliant with good wound care, not capable of following the regimen, and those who have ulcers without adequate blood supply.

**Rationale for Prior Authorization:**

To provide coverage for Regranex<sup>®</sup> for the treatment of non-healing, lower-extremity diabetic neuropathic ulcer; to avoid exposure to cost related to the use of Regranex<sup>®</sup> therapy in conditions where it is not indicated.

**Benefit Design:**

Coverage is determined through a prior authorization process for every claim.

**Prior Authorization Criteria:**

Coverage for Regranex<sup>®</sup> is provided in accord with the following conditions:

- a) Non-healing lower extremity diabetic ulcer only of at least 8 weeks duration that has failed other conventional therapies
- AND
- b) In the absence of active infection at the ulcer site
- AND

- c) Ulcer size is not > 10 cm<sup>2</sup> (no clear clinical evidence of efficacy exists for treatment of larger foot ulcers)

AND

- d) Adequate blood supply to the ulcer (by physician assessment or transcutaneous oxygen tension of  $\geq$  30 mmHg)

Regranex® will not be approved for coverage in non-diabetic ulcers until clinically significant efficacy is established.

Notes:

- In a randomized, double-blind study of Regranex® gel (100mcg/g once daily for 16 weeks) in patients with Stage III or IV pressure ulcers, the incidence of complete ulcer closure was 15% (28/189) in the becaplermin group and 12% in the vehicle control group. The difference was not statistically significant.
- In two small, randomized, double-blinded studies of Regranex® gel (100mcg/g once daily for 16 weeks) in patients with venous stasis ulcers, the combined incidence of complete closure was 46% (30/65) in the becaplermin group and 39% (26/67) in the vehicle control group. The difference was not statistically significant.

#### **Coverage Duration:**

Coverage is provided for 20 weeks. It is recommended that if the ulcer has not decreased in size by at least 30% after 10 weeks of therapy or complete healing has not occurred in 20 weeks, reassessment of continuation is warranted.

Dosage/Application:

- Dosage must be calculated based on ulcer size. The amount of gel to use in inches = ulcer length in inches x ulcer width in inches x 0.6. The amount of gel to use in centimeters = ulcer length in cm x ulcer width in cm / 4. The dosage must be recalculated as the ulcer heals.
- Twice daily dressing changes are required. The first change is to apply the product and the second to remove it 12 hours later.
- The product must be refrigerated and can not be left at room temperature for more than 20 minutes. If left at room temperature > 20 minutes but <3 days, it must be refrigerated immediately and used within 30 days.

#### **References:**

1. Lexi-Comp Inc, Becaplermin Monograph, <http://www.crlonline.com> (accessed October 5, 2005).
2. Micromedex. BECAPLERMIN Most recent revision: 6/2004. (accessed October 5, 2005).
3. Piascik P Use of Regranex® gel for diabetic foot ulcers. J Am Pharm Assoc 1998 Sept-Oct;38(5):628-30
4. Rees RS Becaplermin gel in the treatment of pressure ulcers. Wound Repair Regen 1999 May-Jun;7(3) 141-7
5. Regranex® [Product Information]. Raritan, NJ: OrthoMcNeil. Last Updated March 1999.
6. Sibbald RG, Torrance G, Hux M, Attard C, Milkovich N. Cost-effectiveness of becaplermin for non-healing neuropathic diabetic foot ulcers. Ostomy Wound Manage. 2003 Nov;49(11):76-84.
7. US Food and Drug Administration information on Regranex® gel, <http://www.fda.gov/cder/foi/appletter/2005/103691s5015ltr.pdf> (Accessed 10/5/05)