**Note**: Processing may be delayed if information submitted is illegible or incomplete.

If your fax includes the standardized fax form, only the **Member Name**, **DOB**, **ID**, and **Clinical Criteria** need to be completed and faxed as an attachment to process your request.

# ENROLLEE INFORMATION

**Enrollee’s Last Name: Enrollee’s First Name:**

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**Date of Birth: Enrollee’s Medicaid ID (2 letters, 5 numbers, 1 letter):**

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# PRESCRIBER INFORMATION

**Prescriber’s Last Name: Prescriber’s First Name:**

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**Contact Person:**

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**National Provider Identifier (NPI) Number:**

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**Office Phone Number: Office Fax Number:**

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# CLINICAL CRITERIA FOR REGRANEX®

*(This section must be completed before a prior authorization will be issued.)*

**Drug Name:** Regranex®\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Directions:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Quantity[[1]](#footnote-1):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Days’ Supply:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Form continued on next page.)*

**Enrollee’s Last Name: Enrollee’s First Name:**

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# Clinical Criteria (*continued*)

1. Has the patient been diagnosed with a lower extremity diabetic neuropathic ulcer?

[ ]  Yes [ ]  No

1. If **NO**, please provide the diagnosis and rationale for using Regranex® for an off-label indication:

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1. Is becaplermin gel (Regranex®) being used as an adjunct to good ulcer/wound care including debridement, pressure relief, and infection prevention?

[ ]  Yes [ ]  No

1. If the patient has an existing infection at the ulcer/wound site, is the infection being treated?

[ ]  Yes [ ]  No [ ]  N/A

1. Does the patient have a neoplasm at the site of the ulcer, or any known malignancy?

[ ]  Yes [ ]  No

1. If **YES**, please provide rationale for requesting Regranex® which is contraindicated in patients with a known neoplasm at the site of application and should be used with caution in patients with a known malignancy:

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1. To the best of your knowledge, how many 15 gram tubes of becaplermin gel (Regranex®) has this patient used in his/her lifetime?

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1. If **three (3) or more**: What is the clinical rationale for prescribing more than two (2) tubes as there is a five-fold risk of death secondary to malignancy in patients using three (3) or more tubes in their lifetime?[[2]](#footnote-2) *Please complete the below attestation.*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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*(Form continued on next page.)*

**Enrollee’s Last Name: Enrollee’s First Name:**

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# Clinical Criteria (*continued*)

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| --- |
| **WARNING: INCREASED RATE OF MORTALITY SECONDARY TO MALIGNANCY****An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of Regranex® Gel in a post-marketing retrospective cohort study. Regranex® Gel should only be used when the benefits can be expected to outweigh the risks. Regranex® Gel should be used with caution in patients with known malignancy.[[3]](#footnote-3)** |

|  |  |  |
| --- | --- | --- |
| Prescriber Signature (Required)*I attest that Regranex® is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by New York Medicaid.* |  | Date |

**Please complete the below attestation if patient has used three (3) or more tubes in his/her lifetime, the patient has a neoplasm at the site of the ulcer, or has any known malignancy.**

*As the prescriber of Regranex®, I acknowledge that the patient or his/her caregiver has been counseled about the risks, benefits, and appropriate use of Regranex®, including communication of the following safety messages:*

* *An increased risk of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of Gel in a post-marketing retrospective cohort study.*
* *Regranex® Gel should only be used when the benefits can be expected to outweigh the risks.*
* *Regranex® Gel should be used with caution in patients with known malignancy.*

|  |  |  |
| --- | --- | --- |
| Prescriber Signature |  | Date |

**Fax Number:** 1-800-268-2990

**Prior Authorization Call Line:** 1-877-309-9493

**Billing Questions:** 1-800-343-9000

For clinical questions or Clinical Drug Review Program questions, please visit <http://newyork.fhsc.com> or call 1-877-309-9493.

1. Maximum of one 15 gram tube with no refills. [↑](#footnote-ref-1)
2. For patients documented as receiving three (3) or more tubes of Regranex®, prescribers will be requested to fax a signed attestation confirming that the prescriber has made the patient aware of the safety concerns noted in the black box warning. [↑](#footnote-ref-2)
3. Regranex® Gel 0.01% (becaplermin) Prescribing Information. *Ortho-McNeil Pharmaceuticals Inc.* April 2010. Available at <http://www.regranex.com/pdf/PI_Full_Version.pdf>. Accessed January 10, 2011. [↑](#footnote-ref-3)