STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

August 16, 2010

Dear Prescriber,

The New York State Medicaid Drug Utilization Review (DUR) Program retrospectively reviews the prescribing and dispensing of outpatient prescription medications in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. New York State Medicaid pharmacy claim data indicates that you have written prescription(s) for Regranex® (becaplermin) gel. Please consider the following information before prescribing Regranex®, as the DUR Program is concerned that there may be utilization of this medication that is not consistent with FDA approved labeling.

Documentation in the FDA approved labeling for Regranex® (becaplermin) gel states [1]:

- It is indicated **in patients 16 years and older** for lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply.
- The following black box warning (updated June 2008): **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.**
- 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, continued treatment with Regranex® Gel should be reassessed.**

Regranex® (becaplermin) gel is an agent that is known to be effective and has a role as adjuvant therapy in guidelines for treatment of diabetic ulcers. Despite this, there are documented safety concerns (black box warning) based on an increased rate of mortality secondary to malignancy in patients receiving **3 or more tubes**. Please consider clinical appropriateness and cost effectiveness when prescribing Regranex®. In presenting this information to you, the DUR Program recognizes that safe and effective pharmacotherapy depends on the assessment of the patient's entire clinical profile. We ask that you consider the information provided when prescribing Regranex® gel for your patients.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
DUR Program Manager

[1] Regranex Gel 0.01% (becaplermin) Prescribing Information. *Ortho-McNeil Pharmaceuticals Inc.* May 2008. Available at: http://www.regranex.com/PI_Full_Version.pdf. Accessed June 1, 2010.