Proposed Regranex® PA Criteria

Background

The FDA issued a boxed warning on Regranex® gel as a result of a post-marketing retrospective cohort study of medical claims database comparing cancer rates and overall cancer mortality in 1,622 patients exposed to Regranex® gel and 2,809 matched comparators. **There was a five-fold increased risk of cancer mortality in patients who were exposed to three or more tubes of Regranex®**. This was not a single type of cancer, rather deaths from all types of cancer combined were observed. The FDA did **NOT** specify whether this boxed warning is related to the tube size or frequency of use. The only information provided by the FDA and since updated in the Regranex® package insert (PI), refers to "exposure to three or more tubes". Regranex® gel 0.01% is available in two different tube sizes: 2 grams and 15 grams. The amount of gel applied depends on the size of the ulcer. If the diabetic ulcer does not decrease in size by about 30% after ten weeks or complete healing is not achieved within 20 weeks, continuation of therapy must be reassessed.

FHSC Recommendation

Regranex® gel should be prior authorized. Patients must meet the following criteria in order to be approved for Regranex® gel 0.01%.

PA Criteria

A. Diagnosis of lower extremity diabetic ulcers, **AND**
B. Age ≥16 years old, **AND**
C. Quantity/Refill Limit: Original prescription (15 grams maximum/prescription) plus one refill (15 grams maximum/prescription) **OR** a total life-time dose of 30 grams per patient.

References

1. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01845.html. Accessed June 12, 2008.
2. Regranex [package insert]. OrthoMcNeil; Raritan, NJ; May 2008.