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

INTERVENTION NOTICE: SOLARAZE® GEL

October 31, 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. At the November 12, 2009 Drug Utilization Review (DUR) Board Meeting, the Board members reviewed Solaraze® (diclofenac sodium) Gel, 3% utilization within the NY Medicaid program.

After considering the clinical presentation, utilization data, and the concerns raised by the membership, including apparent over-utilization and the potential for adverse events, **the Board unanimously recommended quantity and frequency limits for Solaraze® Gel. The Board has recommended that a maximum of one-hundred (100) grams as a ninety-day (90 day) supply be available once a year without prior authorization.**

New York State Medicaid pharmacy claim data indicates that you have written prescription(s) for Solaraze® Gel. Please consider the following information before prescribing Solaraze® Gel, as the DUR Program is concerned that there may be utilization of this medication not consistent with FDA approved labeling.

Documentation in the FDA approved labeling for Solaraze® (diclofenac sodium) Gel 3%, states [1]:

- It is **only** indicated for the topical treatment of actinic keratoses (AK).
- It is applied to lesion areas twice daily. **Normally 0.5 g of gel is used on each 5 cm × 5 cm lesion site.**
- The **recommended duration of therapy** is from **60 days to 90 days.**
- **Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy.** Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Please consider clinical appropriateness and cost effectiveness when prescribing Solaraze® Gel. 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 regarding the prescribing of Solaraze ® Gel.

Thank you for your professional assistance in this matter.

Sincerely,

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

[1] Solaraze 3% Gel (diclofenac sodium) Prescribing Information. PharmaDerm March 2008. Available at: http://www.solaraze.com/solaraze/pdf/solaraze_pi.pdf Accessed July 6, 2010.