DESCRIPTION: The mechanism of action of diclofenac sodium in the treatment of actinic keratoses (AK) is unknown. The contribution to efficacy of individual components of the vehicle has not been established.

INDICATION(S): Solaraze® (diclofenac sodium) Gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

The recommended dosage Solaraze® Gel is applied to lesion areas twice daily. It is to be smoothed onto the affected skin gently. The amount needed depends upon the size of the lesion site. Assure that enough Solaraze® Gel is applied to adequately cover each lesion.

Solaraze® (diclofenac sodium) Gel is contraindicated in patients with a known hypersensitivity to diclofenac, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium.

REASONS FOR PA: Cost Potential for misuse Toxicity

CRITERIA for APPROVAL: 1. Patient has a diagnosis of actinic keratoses 2. Is 18 years of age or older 3. Has had a trial and failure of (masoprocol, 5-fluorouracil, cyclosporine, retinoids, trichloroacetic acid/lactic acid/peel, 50% glycolic acid peel)

REASONS for DENIAL 1. Patient does not meet above criteria

RENEWAL CRITERIA: Patient has demonstrated a response to therapy

BENEFIT APPROVAL: approval for a period of 3 months; recommended duration of therapy is 60-90 days

References: Solaraze, Package Insert Manufactured by Almirall Hermal GmbH D-21465 Reinbek, Germany; for PharmaDerm Melville, NY 11747 January 2012