PRIOR AUTHORIZATION CRITERIA

BRAND NAME*

(generic) (diclofenac sodium gel 3%)

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Diclofenac sodium topical gel is indicated for the topical treatment of actinic keratoses (AK).

COVERAGE CRITERIA

Actinic Keratosis (AK)

Authorization may be granted when the requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] is being prescribed for the treatment of actinic keratosis (AK) when the following criteria is met:

• The patient experienced an inadequate treatment response, intolerance, OR has a contraindication to ONE of the following: imiquimod 5 percent cream, fluorouracil cream or solution

CONTINUATION OF THERAPY

Actinic Keratosis (AK)

Authorization may be granted when the requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] is being prescribed for the treatment of actinic keratosis (AK) when the following criteria is met:

• The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of actinic keratosis lesions cleared, patient/prescriber satisfaction, etc.)

QUANTITY LIMITS APPLY

100 grams per 25 days*

DURATION OF APPROVAL (DOA)

621-C: DOA: 3 months

REFERENCES

- 1. Diclofenac Gel 3% [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; August 2023.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 21, 2024.
- 3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/21/2024).
- 4. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 1.2024. November 9, 2023. NCCN.org. Accessed May 31, 2024.
- 5. Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. *J Am Acad Dermatol.* 2021;85:e209-e233.

Diclofenac Sodium Gel 3 Percent PA with Limit Policy UDR 07-2024.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428A 021423

^{*}The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

^{**} These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.