PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic) (diclofenac sodium gel 3%)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 621-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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*
**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.***

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.

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

Written by: UM Development (CT)
Date Written: 01/2010
Revised: (MS) 02/2011 (new MDC-1 created from Silverscript), 09/2011; (CT) 08/2012; (MS) 06/2013, 06/2014; (RP) 06/2015; (MS) 06/2016; (TM) 06/2017 (add limit, revise duration); (SF) 06/2018 (no clinical changes); (DFW) 06/2019 (removed MDC designation from title/document); (ME) 06/2020 (no clinical changes); (RP) 05/2021 (added t/f question); (VLS) 05/2022 (no clinical changes); (KMB) 06/2023 (added COT); (NS) 06/2024 (no clinical changes)
Reviewed: Medical Affairs (KP) 01/2010, 02/2011, 09/2011, 08/2012; (LS) 06/2013; (DC) 06/2014, 06/2015; (ME) 06/2016, (AN) 06/2017, (AN) 06/2019, (CHART) 06/25/20, 07/01/2021, (CHART) 06/30/2022, 06/29/2023, 06/27/2024
External Review: 03/2010, 05/2011, 02/2012, 12/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 09/2024

CRITERIA FOR APPROVAL

1	Is the requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] being prescribed for the treatment of actinic keratoses (AK)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is the request for continuation of therapy? [If Yes, then go to 3. If No, then go to 4.]	Yes	No
3	Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of actinic keratosis lesions cleared, patient/prescriber satisfaction, etc.)? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
4	Has the patient experienced an inadequate treatment response, intolerance, OR does the patient have a contraindication to ONE of the following: A) imiquimod 5 percent cream, B) fluorouracil cream or solution? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient require MORE than the plan allowance of 100 grams per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 100 grams per 25 days.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for actinic keratoses (AK). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 4	

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

3.	Go to 5	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
4.	Go to 5	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried imiquimod 5 percent cream or fluorouracil cream/solution, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
5.	Deny	[PA approved for 3 month(s). Approve 100 grams per 25 days* no 3-month supplies.]. Approve, 3 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (100 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]

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