

QUANTITY LIMIT CRITERIA

BRAND NAME*
(generic)

(imiquimod cream 5%)

Status: CVS Caremark® Criteria
Type: Quantity Limit

Ref # 2959-H

**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

Actinic Keratosis

Imiquimod Cream is indicated for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults.

Superficial Basal Cell Carcinoma

Imiquimod Cream is indicated for the topical treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured.

The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of Imiquimod Cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.

External Genital Warts

Imiquimod Cream is indicated for the treatment of external genital and perianal warts/condyloma acuminata in patients 12 years old and older.

Limitations of Use

Imiquimod cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

Unevaluated Populations

The safety and efficacy of imiquimod Cream in immunosuppressed patients have not been established. Imiquimod Cream should be used with caution in patients with pre-existing autoimmune conditions. The efficacy and safety of Imiquimod Cream have not been established for patients with Basal Cell Nevus Syndrome or Xeroderma Pigmentosum.

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

Drug	4 Week Limit*	12 Week Limit*
Imiquimod cream 5 percent	24 packets / 21 days	72 packets / 63 days

**The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*

REFERENCES

1. Imiquimod Cream 5% [package insert]. Allegan, Michigan: Padagis; July 2022.

Imiquimod 5 Percent Limit 2959-H 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. 106-58428| 021423

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed May 15, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/15/2024).
4. NCCN Clinical Practice Guidelines in Oncology. Basal Cell Skin Cancer. Version 3.2024, March 1, 2024. https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

Written by: UM Development (DFW)
Date Written: 06/2019
Revised: (CJM) 07/2020 (no clinical changes); (CJH) 07/2021 (Added brand Aldara to target box and limit, updated document title); (DRS) 07/2022 (no clinical changes), 07/2023 (no clinical changes); (NS) 06/2024 (removed Aldara)
Reviewed: Medical Affairs (AN) 06/2019, (CHART) 07/30/2020, 08/05/2021, 07/28/2022, 07/27/2023, 06/27/2027
External Review: 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 09/2024

Imiquimod 5 Percent Limit 2959-H 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. 106-58428| 021423