

Reference number(s)

351-C

Initial Prior Authorization with Quantity Limit Adapalene

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
adapalene (all other brands)	adapalene
Differin	adapalene

Indications

FDA-approved Indications

Differin Cream 0.1%, Adapalene Gel 0.1%, Adapalene Topical Solution 0.1% (swab), Adapalene Topical Solution 0.1%

Differin Cream 0.1%, Adapalene Gel 0.1%, Adapalene Topical Solution 0.1% (swab), and Adapalene Topical Solution 0.1% are indicated for the topical treatment of acne vulgaris.

Differin Gel 0.3%, Differin Lotion 0.1%

Differin Gel 0.3% and Differin Lotion 0.1% are indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

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Coverage Criteria

Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgairs when the following criteria is met:

• If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires additional quantities.

Continuation of Therapy

Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgairs when All of the following criteria are met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, patient satisfaction, etc.).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires additional quantities.

Quantity Limits Apply

Quantity Limit

Please Note: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

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.

Medication	COLUMN A (Lower Limit) 4 Week Limit	COLUMN B (Lower Limit) 12 Week Limit	COLUMN C (Upper Limit) 4 Week Limit	COLUMN D (Upper Limit) 12 Week Limit
Adapalene topical solution	120 mL / 21 days	360 mL / 63 days	240 mL / 21 days	720 mL / 63 days

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	COLUMN A (Lower Limit)	COLUMN B (Lower Limit)	COLUMN C (Upper Limit)	COLUMN D (Upper Limit)
Medication	4 Week Limit	12 Week Limit	4 Week Limit	12 Week Limit
Adapalene topical solution (swab)	28 swabs / 21 days	84 swabs / 63 days	56 swabs / 21 days	168 swabs / 63 days
Differin cream 0.1% (adapalene cream)	45 grams / 21 days	135 grams / 63 days	90 grams / 21 days	270 grams / 63 days
Adapalene gel 0.1%	45 grams / 21 days	135 grams / 63 days	90 grams / 21 days	270 grams / 63 days
Differin gel 0.3% (adapalene gel)	45 grams / 21 days	135 grams / 63 days	90 grams / 21 days	270 grams / 63 days
Differin lotion 0.1% (adapalene lotion)	59 mL / 21 days	177 mL / 63 days	118 mL / 21 days	354 mL / 63 days

Duration of Approval (DOA)

• 351-C: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

- 1. Adapalene Gel 0.1% [package insert]. Scottsdale, AZ: PruGen Pharmaceuticals; June 2015.
- 2. Adapalene Topical Solution 0.1% [package insert]. Doylestown, PA: Rochester Pharmaceuticals; July 2021.
- 3. Adapalene Topical Solution 0.1% Swab [package insert]. Doylestown, PA: Rochester Pharmaceuticals; January 2025.
- 4. Differin Cream 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; October 2022.
- 5. Differin Gel 0.3% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; December 2023.
- 6. Differin Lotion 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; April 2023.
- 7. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed July 16, 2025.
- 8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/16/2025).
- 9. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024;90(5):1006.e1-1006.e30.
- 10. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132.

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- 11. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021;84(2):432-470.
- 12. Burn Triage and Treatment Thermal Injuries. Available at: https://chemm.hhs.gov/burns.htm. Accessed July 3, 2024.