

# PRIOR AUTHORIZATION CRITERIA

**DRUG CLASS** RETINIDS (TOPICAL)

**BRAND NAME\***  
(generic)

(adapalene)

**DIFFERIN**  
(adapalene)

**Status: CVS Caremark Criteria**  
**Type: Initial Prior Authorization**

**Ref # 351-A**

*\* 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**

**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.

## **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of acne vulgaris

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Adapalene is indicated for the topical treatment of acne vulgaris.<sup>1-8</sup>

The American Academy of Dermatology (AAD) guidelines state that the topical therapy of acne vulgaris includes the usage of agents that are available over the counter or via prescription. Therapy choice may be influenced by age of the patient, site of involvement, extent and severity of disease, and patient preference. Topical therapies may be used as monotherapy, in combination with other topical agents or in combination with oral agents in both initial control and maintenance. Commonly used topical acne therapies include benzoyl peroxide, salicylic acid, antibiotics, combination antibiotics with benzoyl peroxide, retinoids, retinoid with benzoyl peroxide, retinoid with antibiotic, azelaic acid, and sulfone agents. A topical retinoid alone is a first-line treatment option for mild acne vulgaris. Topical retinoids are also considered to be a first-line treatment option for mild, moderate or severe acne vulgaris when used as combination therapy with benzoyl peroxide, oral antibiotics, and/or topical antibiotics. Topical retinoids are important in addressing the development and maintenance of acne and are recommended as monotherapy in primarily comedonal acne, or in combination with topical or oral antimicrobials in patients with mixed or primarily inflammatory acne lesions. Using multiple topical agents that affect different aspects of acne pathogenesis can be useful; combination therapy should be used in the majority of patients with acne.<sup>9</sup>

The safety and effectiveness of adapalene in pediatric patients below the age of 12 have not been established.<sup>1-6</sup> Per AAD guidelines, topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children. Current data show that retinoids in younger patients are effective and are not associated with increased irritation or risk.<sup>9</sup>

These criteria do not provide for cosmetic uses of this drug.

## REFERENCES

1. Adapalene Gel 0.1% [package insert]. Mahwah, NJ: Glenmark Pharmaceuticals Inc., USA; September 2014.
2. Adapalene Topical Solution 0.1% [package insert]. Canton, MS: Allegis Holding LLC; March 2020.
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4. Differin Cream 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; November 2011.
5. Differin Gel 0.3% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2018.
6. Differin Lotion 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2018.
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8. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed July 13, 2021.
9. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for the Management of Acne Vulgaris. *J Am Acad Dermatol*. 2016;74(5):945-973.

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Date Written: 10/1996

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External Review: 02/2004, 12/2004, 12/2005, 12/2006, 02/2008, 04/2009, 12/2009, 02/2011, 02/2012, 12/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021

## CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of acne vulgaris?	Yes	No
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### Mapping Instructions

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 months	Deny	<p>You do not meet the requirements of your plan.</p> <p>Your plan covers this drug when you have acne vulgaris.</p> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>