

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	RETINOLIDS (TOPICAL)
BRAND NAME* (generic)	(adapalene swab)
	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, Differin Gel 0.1%, Adapalene Topical Solution, 0.1% (swab)

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

Differin Gel 0.3%, Differin Lotion

Differin Gel 0.3% Lotion 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.

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. 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. 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.⁸

The safety and effectiveness of adapalene in pediatric patients below the age of 12 have not been established.¹⁻⁵ Per AAD guidelines, topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children/younger patients and not associated with increased irritation or risk.⁸

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

REFERENCES

- Differin Cream [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2018.
- Differin Gel 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; April 2011.

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3. Differin Gel 0.3% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2018.
4. Differin Lotion 0.1% [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2018.
5. Adapalene Swab Topical Solution 0.1% [package insert]. Doylestown, PA: Rochester Pharmaceuticals; February 2019.
6. Lexi-Comp Online, AHFS Drug Information Online. Hudson, OH: Walters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com>. Accessed June 2019.
7. Micromedex (editorial version). Truven Health Analytics, Greenwood Village, Colorado, USA <http://www.micromedexsolutions.com>. Accessed June 2019.
8. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for Acne Vulgaris Management. *J Am Acad Dermatol*. 2016; 74(5): 945-973.

Written by: UM Development (LS)
 Date Written: 10/1996
 Revised: (LS) 12/1998, 11/1999, 09/2000; (JG) 10/2002; (MG) 10/2003; (TM) 10/2004; (NB) 09/2005, 09/2006; (AM) 08/2007; (MS) 08/2008; (AM) 09/2008; (SE) 09/2009; (MS) 08/2010; (CY) 07/2011; (MS) 08/2012, 10/2012 (extended duration), 06/2013, 06/2014; (RP) 06/2015, (SF) 05/2016 (no dirical changes); (RP) 06/2017 (no dirical changes), 06/2018 (no dirical changes), 06/2019 (Added adapalene swab; renamed criteria to Adapalene; removed MDC-1 designation; shortened DOA to 12 months per Acta integration)
 Reviewed: CRC 01/2004; Medical Affairs (MM) 10/2004, 09/2005, 09/2006; (WF) 08/2007, 08/2008, 09/2008, 09/2009; (KP) 08/2010, 08/2011, 08/2012; (LS) 06/2013; (DQ) 06/2014; (ADA) 06/2015; (DNC) 06/2019
 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

CRITERIA FOR APPROVAL

1 Does the patient have a diagnosis of acne vulgaris?	Yes	No
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Guidelines for Approval

Duration of Approval 12 Months

Set 1

Yes to question(s)	No to question(s)
1	None

Mapping Instructions

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