

# PRIOR AUTHORIZATION CRITERIA

**DRUG CLASS** RETINOID (TOPICAL)

**BRAND NAME\***  
(generic)

**TAZORAC (ALL TOPICAL)**  
(tazarotene)

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

**REG**  
**Ref # 2815-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**

### **Tazorac (tazarotene) Cream**

Tazorac Cream 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis.  
Tazorac Cream 0.1% is also indicated for the topical treatment of patients with acne vulgaris.

### **Tazorac (tazarotene) Gel**

Tazorac Gel 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Tazorac Gel 0.1% is also indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

The efficacy of Tazorac Gel in the treatment of acne previously treated with other retinoids or resistant to oral antibiotics has not been established.

### **Limitations of Use**

The safety of Tazorac Gel use on more than 20% body surface area has not been established in psoriasis or acne.

## **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

**OR**

- The requested drug is being prescribed for plaque psoriasis to treat less than or equal to 20 percent of the patient's body surface area

## **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. Tazorac Cream 0.05% and 0.1% are indicated for the topical treatment of plaque psoriasis and Tazorac Cream 0.1% is also indicated for the topical treatment of acne vulgaris. Tazorac Gel 0.05% and 0.1% are indicated for the topical treatment of plaque psoriasis of up to 20% body surface area involvement and Tazorac Gel 0.1% is also indicated for the topical treatment of mild to moderate facial acne vulgaris.<sup>1-2</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

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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.<sup>5</sup>

Systemic exposure to tazarotene depends on the extent of body surface area treated. In patients treated topically over sufficient body surface area (BSA) (over 35 or 20% of body surface area when used as a cream or gel, respectively, in psoriasis patients), systemic exposure to tazarotene could be of the same magnitude as in orally treated animals. Although systemic exposure anticipated in the treatment of the face alone may be less as a result of the more limited area of application of the drug, it is not known what level of exposure produces teratogenic effects in humans.<sup>3</sup> The compendia state tazarotene cream and gel are used topically in the management of stable plaque psoriasis.<sup>3,4</sup> While the severity of psoriasis is defined in part by the total body surface area (BSA) involved, with less than 3% BSA considered mild, 3% to 10% BSA considered moderate, and greater than 10% considered severe disease, psoriasis can be severe irrespective of BSA, when it has serious emotional consequences or when it occurs in select locations, including, but not restricted to, the hands, feet, scalp, face, genital area, or when it causes intractable pruritus.<sup>6</sup>

## REFERENCES

1. Tazorac Cream [package insert]. Irvine, CA: Allergan, Inc; July 2017.
2. Tazorac Gel [package insert]. Irvine, CA: Allergan, Inc; April 2018.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed March 8, 2021.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed March 8, 2021.
5. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016; 74:945-73.
6. Elmetts C, Korman N, Prater E, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapies and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021; 84:432-70.

Written by: UM Development (SF)  
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## CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of acne vulgaris? [If yes, then no further questions.]	Yes	No
2	Is the requested drug being prescribed for plaque psoriasis to treat less than or equal to 20 percent of the patient's body surface area?	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 months	Go to 2	
2.	Approve, 12 months	Deny	<p>You do not meet the requirements of your plan.</p> <p>Your plan covers this drug when you meet any of these conditions:</p> <ul style="list-style-type: none"> <li>- You have acne vulgaris</li> <li>- You have plaque psoriasis and will use this drug on less than or equal to 20 percent of your body</li> </ul> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>