PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**RETINOID (TOPICAL)**
BRAND NAME* (generic)	**TAZORAC (ALL TOPICAL) (tazarotene)**
Status: CVS Caremark Criteria	***Ref # 353-A***
Type: Initial Prior Authorization	***Ref # 224-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 plaque psoriasis.
Tazorac Cream 0.1% is also indicated for the topical treatment of acne vulgaris.

Tazorac (tazarotene) Gel
Tazorac Gel 0.05% and 0.1% are indicated for the topical treatment of plaque psoriasis of up to 20% body surface area involvement.
Tazorac Gel 0.1% is also indicated for the topical treatment of mild to moderate facial acne vulgaris.

Limitations of Use
The safety of Tazorac Gel use on more than 20% body surface area has not been established.

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 20 percent of the patient's body surface area
  AND
- The patient has experienced an inadequate treatment response to at least one topical corticosteroid [Note: The patient may continue to use a corticosteroid product (e.g., clobetasol, fluocinonide, mometasone, triamcinolone, etc.).]
  OR
- The patient has experienced an intolerance to at least one topical corticosteroid
  OR
- The patient has a contraindication that would prohibit a trial of topical corticosteroids

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.[1] The criteria do not provide for cosmetic uses of this drug.

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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.[7]

Systemic exposure to tazarotene depends on the extent of body surface area treated. In patients treated topically over sufficient body surface area (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.[4] The compendia state tazarotene cream and gel are used topically in the management of stable plaque psoriasis.[4, 5] Furthermore, psoriasis is classified as mild-to-moderate or as moderate-to-severe. About 65% of patients have mild disease as defined by body surface area involvement and about 35% have moderate-to-severe disease. Mild psoriasis affects up to 3% of the body. Moderate psoriasis affects 3% to 10% of the body's surface and severe psoriasis affects > 10% of the body's surface.[8]

The American Academy of Dermatology and the National Psoriasis Foundation have established guidelines for the treatment of psoriasis. Topical corticosteroids are the most commonly prescribed agents for treating mild to moderate psoriasis. In patients with moderate-to-severe psoriasis, topical corticosteroids may be prescribed as adjunctive therapy along with systemic therapy or phototherapy.[7] Corticosteroids are available in many strengths and formulations, which allows for versatility of use. The choice of the appropriate potency corticosteroid and its vehicle should take into consideration the disease severity, the location being treated, patient preference, as well as the age of the patient. Due to the potential irritancy of topical tazarotene, adding topical corticosteroids to a regimen of tazarotene is an appropriate option. Combination therapy may increase the duration of treatment benefit as well as length of remission. Another potential advantage of using combination tazarotene and a topical corticosteroid is a potential decrease in steroid-induced atrophy.[6] Since topical corticosteroids are the cornerstone of treatment for the majority of patients with psoriasis, Tazorac (tazarotene) will be approved for psoriasis if the patient has had an inadequate treatment response, intolerance or contraindication, to at least one topical corticosteroid.

Avage (tazarotene) Cream is indicated as an adjunctive agent for use in the mitigation (palliation) of facial fine wrinkling, facial mottled hyper- and hypopigmentation, and benign facial lentigines in patients who use comprehensive skin care and sunlight avoidance programs.[3] Since the treatment of these indications is considered cosmetic, this product is not included in the criteria for coverage.

REFERENCES

1. Tazorac Cream [package insert]. Irvine, CA: Allergan, Inc; July 2017.
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6. Menter A, Korman N, Elmets C, et al. Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis. *J Am Acad Dermatol*. 2009; 60: 643-659.
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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 20 percent of the patient's body surface area?	Yes	No
3	Has the patient experienced an inadequate treatment response to at least one topical corticosteroid? [Note: The patient may continue to use a corticosteroid product (e.g., clobetasol, fluocinonide, mometasone, triamcinolone, etc.).] [If yes, then no further questions.]	Yes	No
4	Has the patient experienced an intolerance to at least one topical corticosteroid? [If yes, then no further questions.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of topical corticosteroids?	Yes	No

Mapping Instructions (353-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 36 months	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet any of these conditions: - You have acne vulgaris - You have plaque psoriasis and will use this drug on less than 20 percent of your body Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
3.	Approve, 36 months	Go to 4	
4.	Approve, 36 months	Go to 5	
5.	Approve, 36 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried one topical corticosteroid first, and it did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to topical corticosteroids]

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Guidelines for Approval			
Duration of Approval 12 Months		Duration of Approval 12 Months	
Set 1 Acne		**Set 2 Psoriasis**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	2	1
		3	
Duration of Approval 12 Months		**Duration of Approval 12 Months**	
Set 3 Psoriasis		**Set 4 Psoriasis**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
2	1	2	1
4	3	5	3
			4

Mapping Instructions (224-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet any of these conditions: - You have acne vulgaris - You have plaque psoriasis and will use this drug on less than 20 percent of your body Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
3.	Approve, 12 months	Go to 4	
4.	Approve, 12 months	Go to 5	
5.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried one topical corticosteroid first, and it did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to a topical corticosteroid]

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