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

Plaque Psoriasis

Tazorac cream 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis.

Acne Vulgaris

Tazorac cream 0.1% is also indicated for the topical treatment of patients with acne vulgaris.

Tazorac (tazarotene) Gel

Plaque Psoriasis

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.

Acne Vulgaris

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

Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgaris.

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the treatment of plaque psoriasis when ALL of the following criteria are met:

- The plaque psoriasis affects less than or equal to 20 percent of the patient's body surface area (BSA)
- The patient meets ONE of the following:

- 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.).]
- The patient has experienced an intolerance to at least ONE topical corticosteroid
- The patient has a contraindication that would prohibit a trial of ALL topical corticosteroids

CONTINUATION OF THERAPY

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

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, etc.)

Plaque Psoriasis
Authorization may be granted when the requested drug is being prescribed for the treatment of plaque psoriasis when ALL of the following criteria are met:

- The plaque psoriasis affects less than or equal to 20 percent of the patient's body surface area (BSA)
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear or almost clear outcome, patient satisfaction, etc.)

DURATION OF APPROVAL (DOA)

- 224-A:
  - Acne Vulgaris: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months
  - Plaque Psoriasis: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
- 353-A:
  - Acne Vulgaris: Initial therapy DOA: 4 months; Continuation of therapy DOA: 36 months
  - Plaque Psoriasis: Initial therapy DOA: 3 months; Continuation of therapy DOA: 36 months

REFERENCES

1. Tazorac Cream [package insert]. Exton, PA: Almirall, LLC.; August 2019.
2. Tazorac Gel [package insert]. Exton, PA: Almirall, LLC; August 2019.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 29, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/29/2024).
5. Elmets 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.
6. 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.

Written by:	UM Development (GP)
Date Written:	08/1997
Revised:	UM Development (LS) 12/1998; (MG) 12/2002, 12/2003; (TM) 11/2004; (NB) 09/2005, 09/2006; (AM) 08/2007; (MS) 08/2008; (AM) 09/2008; (SE) 09/2009; (TM) 09/2010; (MS) 08/2011, 08/2012, 06/2013, 10/2013, 03/2014, 03/2015; (CF) 03/2016 (no clinical changes), (SE) 06/2016 (created separate Med D); (CF) 09/2016 (removed gender, no clinical changes); (RP/JK) 03/2017; (KC) 03/2018 (combined 353-A, 224-A, no clinical changes), (JK) 03/2019 (no clinical changes), (SF) 03/2020 (no clinical changes), 03/2021 (no clinical changes); (VLS) 03/2022 (no clinical changes); (KMB) 03/2023 (added COT for psoriasis & initial DOA), 07/2023 (added COT for acne), 03/2024 (no clinical changes), 06/2024 (no clinical changes)

Reviewed: CRC: 12/2002, 1/2004, CDPR/Medical Affairs: (MM) 11/2004, 09/2005, 09/2006; (WF) 08/2007, 08/2008, 09/2008, 09/2009; (KP) 09/2010, 08/2011, 08/2012; (DC) 06/2013; (KP) 10/2013; (LS) 03/2014; (KU) 03/2015; (LMS) 04/2017, (CHART) 03/26/2020, 03/25/2021, 03/31/2022, 03/30/2023, 07/27/2023, 03/28/2024, 06/27/2024
External Review: 02/2004, 12/2004, 12/2005, 12/2006, 02/2008, 04/2009, 12/2009, 02/2011, 02/2012, 12/2012, 10/2013, 06/2014, 06/2015, 06/2016, 10/2016, 06/2017, 06/2018, 06/2019, 06/2020, 06/2021, 06/2022, 06/2023, 10/2023, 06/2024, 09/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the topical treatment of acne vulgaris? [If Yes, then go to 2. If No, then go to 4.]	Yes	No
2	Is the request for continuation of therapy? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, etc.)? [No further questions]	Yes	No
4	Is the requested drug being prescribed for the treatment of plaque psoriasis? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the plaque psoriasis affect less than or equal to 20 percent of the patient's body surface area (BSA)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is the request for continuation of therapy? [If Yes, then go to 10. If No, then go to 7.]	Yes	No
7	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. If No, then go to 8.]	Yes	No
8	Has the patient experienced an intolerance to at least ONE topical corticosteroid? [If Yes, then no further questions. If No, then go to 9.]	Yes	No
9	Does the patient have a contraindication that would prohibit a trial of ALL topical corticosteroids? [No further questions]	Yes	No
10	Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear or almost clear outcome, patient satisfaction, etc.)? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 4	

2.	Go to 3	Approve, 4 Months	
3.	Approve, 12 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Efficacy]
4.	Go to 5	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for acne vulgaris and plaque psoriasis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
5.	Go to 6	Deny	Your plan only covers this drug if you have plaque psoriasis that covers less than or equal to 20 percent of your body. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Disease severity]
6.	Go to 10	Go to 7	
7.	Approve, 3 Months	Go to 8	
8.	Approve, 3 Months	Go to 9	
9.	Approve, 3 Months	Deny	Your plan only covers this drug if you have tried a topical corticosteroid and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]

10.	Approve, 12 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Efficacy]