

# Initial Prior Authorization Topical Retinoids

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Altreno	tretinoin
Atralin	tretinoin
Avita	tretinoin
Retin-A	tretinoin
Retin-A Micro	tretinoin
Twynéo	tretinoin/benzoyl peroxide
Veltin	clindamycin/tretinoin
Ziana	clindamycin/tretinoin

## Indications

### FDA-approved Indications

#### Atralin, Avita, Retin-A

Atralin, Avita, and Retin-A are indicated for topical treatment of acne vulgaris. The safety and efficacy of this product in the treatment of other disorders have not been established.

#### Altreno (tretinoin) lotion 0.05%, Twynéo

Altreno (tretinoin) lotion 0.05% and Twynéo are indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Reference number(s)
355-A, 237-A

## Retin-A Micro

Retin-A Micro is a retinoid indicated for topical application in the treatment of acne vulgaris.

## Veltin, Ziana

Veltin gel 1.2%/0.025% and Ziana gel are indicated for the topical treatment of acne vulgaris in patients 12 years and older.

## Compendial Uses

Keratosis follicularis (Darier's disease, Darier-White disease)<sup>10,13-15</sup>

# Coverage Criteria

## Acne Vulgaris

Authorization may be granted when the patient has a diagnosis of acne vulgaris

## Keratosis Follicularis

Authorization may be granted when the patient has a diagnosis of keratosis follicularis (Darier's disease, Darier-White disease)

# Continuation of Therapy

## Acne Vulgaris

Authorization may be granted when the patient has a diagnosis 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, patient satisfaction, etc.)

## Keratosis Follicularis

Authorization may be granted when the patient has a diagnosis of keratosis follicularis (Darier's disease, Darier-White disease) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement

## Duration of Approval (DOA)

- 355-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 36 months
- 237-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

## References

1. Altreno [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
2. Atralin [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2024.
3. Avita Cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
4. Avita Gel [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2018.
5. Retin-A [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.
6. Retin-A Micro [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2023.
7. Twynéo [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; August 2022.
8. Veltin [package insert]. Malvern, PA: Almirall, LLC; June 2019.
9. Ziana [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
10. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed July 3, 2024.
11. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/02/2024).
12. 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.
13. NIH National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. Darier disease. <https://rarediseases.info.nih.gov/diseases/6243/darier-disease>. Accessed July 3, 2024.
14. Keratosis Follicularis National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/keratosis-follicularis/>. Accessed July 3, 2024.
15. Engin B, Kutlubay Z, Erkan E, et al. Darier disease: A fold (intertriginous) dermatosis. *Clin Dermatol*. 2015;33(4):448-451.