

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)^{10,13-15}

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.