

azelaic acid 15% gel

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Azelaic acid gel is a topical agent used in the treatment of rosacea. Rosacea is a skin condition primarily affecting the face and can present as redness, swelling, inflammation that includes papules and pustules, dilated blood vessels that appear on the surface of the skin, and rhinophyma (characterized by an enlarged, red nose). Treatment of rosacea can vary depending on the symptoms involved. The first-line treatment of the inflammatory papules and pustules involve topical agents such as metronidazole and azelaic acid gel.

Definitions

"Papule" is a raised area of the skin, usually pink or red, that occurs in conditions such as rosacea and dermatitis.

"Pustule" is a bump on the skin that contains pus or liquid.

“Rosacea” is a skin condition primarily affecting the face and can present as redness, swelling, inflammation that includes papules and pustules, dilated blood vessels that appear on the surface of the skin, and rhinophyma (characterized by an enlarged, red nose).

Medical Necessity Criteria for Authorization

The Plan considers **azelaic acid 15% gel** medically necessary when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member is using the requested medication for the treatment of inflammatory papules and pustules of mild to moderate rosacea; **AND**
3. The member is unable to use, or has adequately tried and failed topical metronidazole for a minimum one (1) month trial.

If the above prior authorization criteria are met, azelaic acid 15% gel will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Azelaic acid 15% gel for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Austin E, Nguyen JK, Jagdeo J. Topical Treatments for Melasma: A Systematic Review of Randomized Controlled Trials. *Journal of Drugs in Dermatology*. Published 01 Nov 2019, 18(11).
2. Azelex (azelaic acid) [prescribing information]. Exton, PA: Almirall, LLC; June 2019.
3. Bolognia, J., Jorizzo, J. L., & Schaffer, J. V. (2017). *Dermatology*. Philadelphia: Elsevier Saunders.
4. Dahl MV, Jarratt M, Kaplan D, et al. Once-daily topical metronidazole cream formulations in the treatment of the papules and pustules of rosacea. *J Am Acad Dermatol*. 2001;45(5):723.
5. Draelos, Zoe Diana. Examining 15% Azelaic Acid Foam for the Treatment of Folliculitis: A Pilot Study. *J Clin Aesthet Dermatol*. 2020 Apr; 13(4): 3638.
6. Elsa Fitria Apriani, Yeva Rosana, and Iskandarsyah Iskandarsyah. Formulation, characterization, and in vitro testing of azelaic acid ethosome-based cream against *Propionibacterium acnes* for the treatment of acne. *J Adv Pharm Technol Res*. 2019 Apr-Jun; 10(2): 7580. doi: 10.4103/japtr.JAPTR_289_18.
7. Finacea (azelaic acid) foam [prescribing information]. Madison, NJ: LEO Pharma Inc; December 2020.
8. Finacea (azelaic acid) gel [prescribing information]. Madison, NJ: LEO Pharma Inc; November 2021.

9. Habif TP, Chapman MS, Dinulos JG, Zug KA. Skin disease: diagnosis and treatment. Elsevier Health Sciences; 2017 Sep 4.
10. Hashim PW, Chen T, Harper JC, Kircik LH. The Efficacy and Safety of Azelaic Acid 15% Foam in the Treatment of Facial Acne Vulgaris. *Journal of Drugs in Dermatology*, 01 Jun 2018, 17(6):641-645.
11. Hoffman LK, Del Rosso JQ, Kircik LH. The Efficacy and Safety of Azelaic Acid 15% Foam in the Treatment of Truncal Acne Vulgaris. *Journal of Drugs in Dermatology*. Published 01 Jun 2017, 16(6):534-538.
12. Kirsch, Brandon et al. Evaluating the Efficacy, Safety, and Tolerability of the Combination of Tazarotene, Azelaic Acid, Tacrolimus, and Zinc Oxide for the Treatment of Melasma: A Pilot Study. *J Clin Aesthet Dermatol*. 2019 May; 12(5): 4045. Published online 2019 May 1.
13. Lebwohl MG, Heymann WR, Coulson IH, Murrell DF. SPEC–Treatment of Skin Disease, Comprehensive Therapeutic Strategies. Elsevier Health Sciences; 2021 Sep 17.
14. Liu, Haibo. Topical azelaic acid, salicylic acid, nicotinamide, sulphur, zinc and fruit acid (alpha hydroxy acid) for acne. Version published: 01 May 2020.
<https://doi.org/10.1002/14651858.CD011368.pub2>
15. Maghfour, Jalal. Treatment of keratosis pilaris and its variants: a systematic review. *Journal of Dermatological Treatment*. Published online: 14 Sep 2020.
<https://doi.org/10.1080/09546634.2020.1818678>
16. Maier LE. Management of rosacea. UpToDate [Online]. Updated February 24, 2020. Accessed August 10, 2020.
17. Searle, Tamara et al. The versatility of azelaic acid in dermatology. *Journal of Dermatological Treatment*. Published online: 04 Aug 2020. <https://doi.org/10.1080/09546634.2020.1800579>
18. St. Surin-Lord, Sharleen. Topical Treatment of Truncal Acne with Tretinoin Lotion 0.05% and Azelaic Acid Foam. *Case reports in Dermatological Medicine* Volume 2020, Article ID 5217567
<https://doi.org/10.1155/2020/5217567>
19. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74(5):945-973.e33. [http://www.jaad.org/article/S0190-9622\(15\)02614-6/pdf](http://www.jaad.org/article/S0190-9622(15)02614-6/pdf).

Clinical Guideline Revision / History Information

Original Date: 11/05/2020

Reviewed/Revised: 10/14/2021, 12/01/2021, 06/23/2022, 06/29/2023