

Policy Name:	Azelaic Acid	Policy #:	585P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Azelex and Finacea.

Statement of the Policy

Health Alliance Medical Plans will approve the use of azelaic acid products (Azelex and Finacea) when the following criteria have been met.

Criteria

1. Azelex for Acne Vulgaris

- 1.1 Diagnosis of acne
- 1.2 Trial and failure of two generic topical or oral agents; OR contraindication to all topical and oral agents.
 - topical agents such as tretinoin and adapalene
 - oral agents like tetracycline, minocycline, doxycycline

2. Finacea for Rosacea

- 2.1 Diagnosis of rosacea
- 2.2 Failure, intolerance, or contraindication to topical metronidazole cream, gel, or lotion
- 2.3 Failure, intolerance, or contraindication to doxycycline

3. Approval Period

- 3.1 Approval time: 12 months

4. Managed Dose Limit

- 4.1 All topical skin products have a Managed Dose Limit (MDL) in place allowing only the smallest package size of each product to process
- 4.2 Requests for larger package sizes will require documentation of medical necessity, including the following:
 - At least two previous paid claims for the product in the smallest package size within the previous month

CPT Codes

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HCPCS Codes

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References

1. Azelex (azelaic acid) [prescribing information]. Exton, PA: Almirall, LLC; June 2019.
2. Finacea (azelaic acid) gel [prescribing information]. Madison, NJ: LEO Pharma Inc; November 2021.
3. 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.
4. Thiboutot D, Anderson R, Cook-Bolden F, et al. *J Am Acad Dermatol.* Standard management options for rosacea: the 2019 update by the National Rosacea Society expert committee [published online February 6, 2020].

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.