Clinical Policy: Azelaic Acid (Finacea Topical Foam)

Reference Number: HIM.PA.119
Effective Date: 12.01.17
Last Review Date: 11.26
Line of Business: HIM/ICHRA

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Azelaic acid 15% (Finacea®) topical foam is a naturally-occurring saturated dicarboxylic acid.

FDA Approved Indication(s)

Finacea is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Finacea is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rosacea (must meet all)**:**

1. Diagnosis of rosacea;
2. Age ≥ 18 years;
3. Failure of ≥ 6 consecutive weeks of maximally tolerated doses of one of the following (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated: oral doxycycline or topical metronidazole;*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
4. Member must use generic azelaic acid gel 15%, unless contraindicated or clinically significant adverse effects are experienced;*
   **For Illinois HIM requests, the step therapy requirement above does not apply per IL HB 5395*
5. Dose does not exceed 50 g (1 can) per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

II. Continued Therapy

A. Rosacea (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member must use generic azelaic acid gel 15%, unless contraindicated or clinically significant adverse effects are experienced;*
   **For Illinois HIM requests, the step therapy requirement above does not apply to azelaic acid foam per IL HB 5395*
4. If request is for a dose increase, new dose does not exceed 50 g (1 can) per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace/ICHRA or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole cream, gel and lotion (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75%)	Apply thin film topically to affected area QD for 1% and BID for 0.75%	Not applicable
doxycycline (Oracea®)	40 mg PO once daily in the morning (1 hour before or 2 hours after a meal)	300 mg/day PO; 40 mg PO/day for Oracea

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Rosacea	Apply a thin layer BID to the affected area(s)	Not applicable

VI. Product Availability

Foam (50 g can): 15%

VII. References

1. Finacea Foam Prescribing Information. Madison, NJ: LEO Pharma Inc; December 2020. Available at: https://hcp.finaceafoam.com. Accessed August 6, 2026.
2. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; 2026. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 6, 2026.
3. Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: the 2019 update by the National Rosacea Society expert committee. *J Am Acad Dermatol.* 2020; 82(6): 1501-1510. doi: 10.1016/j.jaad.2020.01.077.
4. Shaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global Rosacea Consensus 2019 panel. *Br J Dermatol* 2020; 182:1090-1091. doi: 10.1111/bjd.18420.
5. Nguyen C, Kuceki G, Birdsall M, Sahni DR, Sahni VN, Hull CM. Rosacea: Practical Guidance and Challenges for Clinical Management. *Clin Cosmet Investig Dermatol*. 2024 Jan 23;17:175-190. doi: 10.2147/CCID.S391705.

6. Del Rosso JQ, Tanghetti E, Webster G, Stein Gold L, Thiboutot D, Gallo RL. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). *J Clin Aesthet Dermatol*. 2020 Jun;13(6 Suppl):S17-S24.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	08.24.22	11.22
4Q 2023 annual review: no significant changes; for Appendix B, removed brand Minocin as NDC is obsolete; references reviewed and updated.	08.02.23	11.23
4Q 2024 annual review: removed redirection to topical ivermectin per non-formulary status; in Appendix B, clarified oral minocycline is used off-label for rosacea; references reviewed and updated	07.31.24	11.24
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	08.08.25	11.25
4Q 2026 annual review: added ICHRA line of business; removed Finacea topical gel dosage form per discontinuation of brand Finacea gel; removed redirection to oral minocycline per non-formulary status; references reviewed and updated.	08.06.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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