Clinical Policy: Azelaic Acid (Finacea Topical Gel/Foam)

Reference Number: HIM.PA.119
Effective Date: 12.01.17
Last Review Date: 11.23
Line of Business: HIM

Revision Log

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

Description
Azelaic acid 15% (Finacea®) topical gel/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.

Limitation(s) of Use:
Efficacy of finacea gel for the treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated.

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, oral minocycline, topical ivermectin*, or topical metronidazole;
   **PA may be required for ivermectin cream.*
4. Member must use generic azelaic acid gel 15%, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 50 g (1 tube or 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) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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.

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;
4. If request is for a dose increase, new dose does not exceed 50 g (1 tube or 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) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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.

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 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 (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75%)	Apply thin film topically to affected area QD for 1% and BID for 0.75%	No maximum dosage information is available.
minocycline (Solodyn®)	IR: 200 mg PO followed by 100 mg PO Q12H ER: 1 mg/kg PO QD	300 mg on day 1, then 200mg/day
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
ivermectin cream 1% (Soolantra®)	Apply a pea-size amount to the affected areas of the face (forehead, chin, nose, each cheek) once daily. Spread as a thin layer, avoiding the eyes and lips.	4 oz/topical application

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.

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)	N/A

VI. Product Availability

Gel (50 g): 15%
Foam (50 g): 15%

VII. References

1. Finacea Foam Prescribing Information. Madison, NJ: LEO Pharma Inc; December 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/207071s002s004lbl.pdf. Accessed August 2, 2023.

2. Finacea Gel Prescribing Information. Madison, NJ: LEO Pharma Inc; November 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021470s017lbl.pdf. Accessed August 2, 2023.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 2, 2023.
4. 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.
5. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.20.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.09.20	11.20
4Q 2021 annual review: added ivermectin 1% cream as an option for failure; added that request should be for generic formulation; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.10.21	11.21
Per March SDC, added requirement that member must use generic azelaic acid gel 15%, added clarification that criteria may also be applied to foam formulation.	03.22.22	05.22
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

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.