

Azelaic Acid Agents

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Azelex (azelaic acid) cream Finacea (azelaic acid) gel

APPROVAL CRITERIA

If the benefit requires prior authorization, requests for azelaic acid agents (Azelex cream) may be approved for the following:

- I. Individual has a diagnosis of acne/acne vulgaris; **AND**
- II. Individual has had a trial and inadequate response to two preferred topical agents for acne/acne vulgaris. Medication samples/coupons/discount cards are excluded from consideration as a trial.

Preferred agents: adapalene (cream, swab, gel, gel pump), clindamycin phosphate (foam, gel, lotion, solution, swab/pads/pledgets), erythromycin (solution, gel, pads/pledgets), tazarotene cream 0.05%, 0.1%, tazarotene gel 0.05%, 0.1%, adapalene/benzoyl peroxide gel, clindamycin/benzoyl peroxide gel, erythromycin/benzoyl peroxide gel, clindamycin/tretinoin gel, tretinoin (gel, cream), tretinoin microsphere (gel, gel pump) except 0.08%..

If the benefit requires prior authorization, requests for azelaic acid agents (Azelex cream, Finacea gel) may be approved for the following:

- I. Individual has a diagnosis of mild-to-moderate inflammatory papulopustular rosacea (AHFS); **AND**
 - A. Individual has had a trial and inadequate response to one preferred generic topical metronidazole agent [metronidazole (all strengths and dose forms), Rosadan 0.75% cream, or Rosadan 0.75% gel]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
 - B. Individual has had a trial of and inadequate response or intolerance to one preferred topical agent for the treatment of rosacea [azelaic acid foam/gel, Zilxi]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
- OR**
- C. Individual has a known topical metronidazole contraindication to use;

AND

- D. Individual has had a trial of and had an inadequate response or intolerance to one preferred agent for the treatment of rosacea [azelaic acid foam/gel, Zilxi]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

- E. If request is for brand provide the clinical necessity of a branded product when generic products are available for the same medical reason and clinical benefit is not expected with a generic product.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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