

# Azelex Cream

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Azelex (azelaic acid) cream	May be subject to quantity limit

## **APPROVAL CRITERIA**

If the benefit requires prior authorization, requests for 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%..

### **OR**

- III. 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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