

| Market Applicability |    |    |    |    |    |    |    |
|----------------------|----|----|----|----|----|----|----|
| Market               | DC | GA | KY | MD | NJ | NY | WA |
| Applicable           | X  | X  | X  | X  | X  | X  | NA |

## Doxepin 5% Cream (Prudoxin, Zonalon)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>Quantity Limit | 1 year            |

| Medications                 | Quantity Limit                   |
|-----------------------------|----------------------------------|
| Prudoxin (doxepin 5% cream) | May be subject to quantity limit |
| Zonalon (doxepin 5% cream)  |                                  |

### APPROVAL CRITERIA

Requests for doxepin 5% cream (Prudoxin and Zonalon) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using to treat moderate pruritis associated with atopic dermatitis (AAD 2014); **AND**
- III. Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid; **OR**
- IV. Topical corticosteroid use is not acceptable due to the following concomitant clinical conditions:
  - A. Individual has atopic dermatitis recalcitrant to topical corticosteroids; **OR**
  - B. Individual has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds); **OR**
  - C. Individual has steroid-induced atrophy; **OR**
  - D. Individual has history of long-term or uninterrupted topical steroid use;

#### **AND**

- V. Individual has had a trial of and inadequate response or intolerance to one of the following:
  - A. A topical calcineurin inhibitor; **OR**
  - B. Eucrisa (crisaborole);

#### **OR**

- VI. Individual is 18 years of age or older; **AND**

| Market Applicability |    |    |    |    |    |    |    |
|----------------------|----|----|----|----|----|----|----|
| Market               | DC | GA | KY | MD | NJ | NY | WA |
| Applicable           | X  | X  | X  | X  | X  | X  | NA |

- VII. Individual is using to treat moderate pruritis associated with lichen simplex chronicus;  
**AND**  
VIII. Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid.

Requests for doxepin 5% cream (Prudoxin and Zonalon) may not be approved for the following:

- I. Individual has untreated narrow angle glaucoma; **OR**
- II. Individual has a history of urinary retention.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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>. Accessed: June 17, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Eichenfield L. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. Journal of the American Academy of Dermatology. 2014-01;71:116.
6. Neurodermatitis. American Academy of Dermatology. Available from: <https://www.aad.org/public/diseases/eczema/neurodermatitis#overview>. Accessed June 14, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.