STEP THERAPY CRITERIA

BRAND NAME
(generic)

PRUDOXIN
(doxepin)

ZONALON
(doxepin)

Status: CVS Caremark Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Prudoxin and Zonalon are indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

INITIAL STEP THERAPY with QUANTITY LIMIT*
If the patient has filled a prescription for at least a 7 day supply of a generic topical corticosteroid **AND** at least a 7 day supply of topical tacrolimus (Protopic) or pimecrolimus (Elidel) or Eucrisa (crisaborole) within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.* If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

*If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

INITIAL LIMIT CRITERIA*

Drug	1 Month Limit*	3 Month Limit*
Prudoxin (doxepin)	45 grams / 25 days	Does Not Apply*
Zonalon (doxepin)	45 grams / 25 days	Does Not Apply*

** The duration of 25 days is used for a 30-day fill period to allow time for refill processing.*
** These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.*

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for management of moderate pruritus in an adult patient with atopic dermatitis or lichen simplex chronicus
  AND

- The requested drug being prescribed for short-term use (up to 8 days)
  AND
- The patient has experienced an inadequate response to a topical corticosteroid or topical tacrolimus (Protopic) or pimecrolimus (Elidel) or crisaborole (Eucrisa)

Quantity Limits apply.

POST QUANTITY LIMITS FOR APPROVAL

90 grams/25 days.*

**The duration of 25 days is used for a 30-day fill period to allow time for refill processing.*

REFERENCES

1. Prudoxin [package insert]. Newtown, PA: Prestium Pharma, Inc.; June 2017.
2. Zonalon [package insert]. Newtown, PA: Prestium Pharma, Inc.; June 2017.
3. Elidel [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
4. Protopic [package insert]. Madison, NJ: LEO Pharma. Inc.; February 2019.
5. Eucrisa [package insert]. New York, NY: Pfizer Inc.; April 2020.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed June 16, 2021.
7. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed June 16, 2021.
8. Eichenfield L, Tom W, Berger T, et al. Guidelines of Care for the Management of Atopic Dermatitis Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol* 2014;71:116-32. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4326095/. Accessed June 2020.
9. Paller AS, Tom WL, et. al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *J Am Acad Dermatol.* 2016 Jul 11; 75 (3) 494-503.e4