

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*

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
Prudoxin (doxepin)	90 grams / 25 days	Does Not Apply*
Zonalon (doxepin)	90 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 short-term (up to 8 days) management of moderate pruritus in an adult patient with atopic dermatitis or lichen simplex chronicus

- The patient has experienced an inadequate response to a topical corticosteroid or topical tacrolimus (Protopic) or pimecrolimus (Elidel) or crisaborole (Eucrisa)

Quantity limits apply.

REFERENCES

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5. 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.aad.org/practice-tools/quality-care/clinical-guidelines/atopic-dermatitis/>. Accessed June 2019.
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7. Protopic [package insert]. Parsippany, NJ: LEO Pharma. Inc.; November 2018.
8. Eucrisa [package insert]. New York, NY: Pfizer Inc.; January 2019.
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