

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

Prudoxin cream is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Zonalon

Zonalon Cream is 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*

**Include Rx and OTC products unless otherwise stated.*

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 ointment or Elidel (pimecrolimus) 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 QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
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 intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.*

COVERAGE CRITERIA

Prudoxin, Zonalon ST with Limit, Post PA Policy UDR 04-2024.docx

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Pruritus

Authorization may be granted when the requested drug is being prescribed for the management of moderate pruritus in an adult patient with atopic dermatitis or lichen simplex chronicus when ALL of the following criteria are met:

- The requested drug is being prescribed for short-term use (up to 8 days)
- The patient has experienced an inadequate treatment response to ANY of the following: a topical corticosteroid, topical tacrolimus ointment, Elidel (pimecrolimus), Eucrisa (crisaborole)

QUANTITY LIMITS APPLY

90 grams per 25 days*, 3 month limit 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 intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.*

DURATION OF APPROVAL (DOA)

- 1496-E: DOA: 3 months

REFERENCES

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2. Zonalon [package insert]. Newtown, PA: Prestium Pharma, Inc.; June 2017.
3. Elidel [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
4. Tacrolimus Ointment [package insert]. Melville, NY: Fougere PHARMACEUTICALS INC.; November 2023.
5. Eucrisa [package insert]. New York, NY: Pfizer Inc.; April 2023.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>; Accessed February 13, 2024.
7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/>(cited: 02/13/2024).
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.
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; 75 (3): 494-503.
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