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 Elidel (pimecrolimus) 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.

***QUANTITY LIMIT CRITERIA**

Drug	1 Month Limit* and 3 Month Limit*
Prudoxin (doxepin)	90 grams/25 days
Zonalon (doxepin)	90 grams/25 days

** This drug is indicated for short-term acute use; therefore, the 1 month, 3 month, retail, and mail limits will be the same.*
**The limit criteria apply to both brand and generic, if available.*

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)

Quantity limits apply.

REFERENCES

1. Prudoxin [package insert]. Newtown, PA: Prestium Pharma, Inc.; February 2015.
2. Zonalon [package insert]. Newtown, PA: Prestium Pharma, Inc.; October 2014.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed June 2017.
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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 December 2016.
6. Elidel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; August 2014.
7. Protopic [package insert]. Parsippany, NJ: LEO Pharma. Inc.; June 2016.

