UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2236-3
Program	Prior Authorization/Medical Necessity – doxepin cream
Medication/Therapeutic Class	Prudoxin® (doxepin)*, Zonalon® (doxepin)*
P&T Approval Date	4/2021, 3/2024, 4/2025
Effective Date	7/1/2025

1. Background:

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

The American Academy of Dermatology guidelines for the care and management of atopic dermatitis recommend topical corticosteroids for patients with atopic dermatitis who have failed to respond to standard nonpharmacologic therapy. The use of topical calcineurin inhibitors (tacrolimus, pimecrolimus) is also recommended in patients who have failed to respond to, or who are not candidates for topical corticosteroid treatment. Doxepin may provide a short-term decrease in pruritus, however has no significant reduction in disease severity or control.

2. Coverage Criteria[a]:

A. Authorization

1. **Prudoxin* or Zonalon*** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

      (1) Diagnosis of moderate pruritus due to atopic dermatitis

      -AND-

      (2) History of failure, contraindication, or intolerance to **one** of the following topical therapies:

         (a) One topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide]
         (b) One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

      -OR-

   b. **Both** of the following:

      (1) Diagnosis of moderate pruritus due to lichen simplex chronicus

      -AND-

(2) History of failure, contraindication, or intolerance to a topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide]

Authorization will be issued for 1 month.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

* Brand Prudoxin and Zonalon are typically excluded from coverage.

4. References:

1. Prudoxin [package insert]. San Antonio, TX: DPT Laboratories, Ltd; June 2017.
2. Zonalon [package insert]. San Antonio, TX: DPT Laboratories, Ltd; June 2017.
3. Eichenfield LF, Tom WL, Berger TG, 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(1):116-32.

Program	Prior Authorization/Medical Necessity – doxepin cream
Change Control	
Date	Change
4/2021	New program.
3/2024	Review with no changes.
4/2025	Annual review with no changes.