

STEP THERAPY POLICY

- POLICY:** Topical Doxepin Step Therapy Policy
- Generic doxepin cream 5% (Mylan, generic)
 - Prudoxin™ (doxepin hydrochloride cream 5% – Mylan, generic)
 - Zonalon® (doxepin hydrochloride cream 5% – Mylan, generic)

REVIEW DATE: 05/22/2024

OVERVIEW

Topical doxepin cream 5% (Prudoxin™, Zonalon®, generics) is indicated for the short-term (up to 8 days) **management of moderate pruritus** in adults with atopic dermatitis or lichen simplex chronicus.¹⁻³

Doxepin has H₁ and H₂ histamine receptor blocking actions, but the exact mechanism by which it exerts its antipruritic effect is unknown.¹⁻³ There are no data to establish the safety and effectiveness of doxepin cream when used for > 8 days. Furthermore, chronic use (beyond 8 days) may result in higher systemic levels and increased likelihood of contact sensitization.

Guidelines/Recommendations

The American Academy and American College of Allergy, Asthma and Immunology Joint Task Force guidelines for atopic dermatitis (eczema) [2023] recommend moisturizers as first line therapy for mild disease.⁴ For refractory atopic dermatitis, guidelines recommend the addition of topical corticosteroids. Topical doxepin is not addressed in the guidelines.

Topical corticosteroids are the current treatment of choice for lichen simplex chronicus because they decrease inflammation and itch while concurrently softening the hyperkeratosis.⁵ Alternatives to topical corticosteroids include topical doxepin.

Table 1. Topical Corticosteroids, Classified According to Potency* (Adapted from Facts/Comparisons).⁶

Table 1 (continued). Topical Corticosteroids, Classified According to Potency* (Adapted from Facts/Comparisons).⁶

* This table may not include all available topical corticosteroids (strength or formulation).

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are for 2 months in duration.

Automation: A patient with a of two Step 1 Products within the 130-day look-back period are excluded from Step Therapy.

Step 1: generic prescription topical corticosteroids (see Table 1)

Step 2: Doxepin cream, Prudoxin cream, Zonalon cream

CRITERIA

1. If the patient has tried two Step 1 Products, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Doxepin hydrochloride cream, 5% [prescribing information]. San Antonio, TX: DPT Laboratories; May 2017.
2. Prudoxin™ (doxepin hydrochloride) cream, 5% [prescribing information]. San Antonio, TX: DPT Laboratories; June 2017.
3. Zonalon® (doxepin hydrochloride cream, 5% [prescribing information]. San Antonio, TX: DPT Laboratories; June 2017.
4. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel, Chu DK, Schneider L, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. *Ann Allergy Asthma Immunol.* 2024;132(3):274-312.
5. Lichen simplex chronicus: <https://emedicine.medscape.com/article/1123423-treatment?src=refgatesrc1>. Updated August 20, 2020 . Accessed on May 16, 2024.
6. Facts and Comparisons® Online. Wolters Kluwer; © 2024 UpToDate, Inc. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=>. Accessed on May 16, 2024. Search terms: doxepin, corticosteroid.