

## STEP THERAPY POLICY

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

**REVIEW DATE:** 05/11/2022

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### 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.<sup>1-3</sup>

Doxepin has H<sub>1</sub> and H<sub>2</sub> histamine receptor blocking actions, but the exact mechanism by which it exerts its antipruritic effect is unknown.<sup>1-3</sup> 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 of Dermatology published guidelines for the management and treatment of atopic dermatitis with topical therapies in 2014.<sup>4</sup> Moisturizers and emollients are recommended as first-line treatment. For disease that is not controlled by moisturizers alone, a topical corticosteroid should be used. Topical corticosteroids have been shown to decrease acute and chronic signs of atopic dermatitis. For maintenance therapy, a low-potency corticosteroid is recommended, and intermediate- and high-potency corticosteroids are recommended for the treatment of clinical exacerbations over short periods of time. Use of topical doxepin has demonstrated a short-term reduction in pruritus in some cases, but with no significant reduction in disease severity or control. In addition, topical doxepin can cause allergic contact dermatitis, local stinging and burning, and sedation.

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

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

Potency/Group	Examples
<b>Super-high potency (Group 1)</b>	augmented betamethasone dipropionate 0.05% gel, lotion, ointment; clobetasol propionate 0.05% cream, cream (emollient base), foam aerosol, gel, lotion, ointment, shampoo, solution (scalp), spray aerosol; fluocinonide 0.1% cream; flurandrenolide 4 mcg/cm <sup>2</sup> tape; halobetasol propionate 0.05% cream, lotion, ointment.
<b>High potency (Group 2)</b>	amcinonide 0.1% ointment; betamethasone dipropionate 0.05% cream (augmented), ointment; clobetasol propionate 0.025% cream; desoximetasone 0.25% cream, ointment, spray; desoximetasone 0.05% gel; diflorasone diacetate 0.05% cream (emollient), ointment; fluocinonide 0.05% cream, gel, ointment, solution; halcinonide 0.1% cream, ointment; halobetasol propionate 0.01% lotion.

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

Potency/Group	Examples
<b>High potency (Group 3)</b>	amcinonide 0.1% cream, lotion; betamethasone dipropionate 0.05% cream (hydrophilic emollient); betamethasone valerate 0.1% ointment; betamethasone valerate 0.12% foam; desoximetasone 0.05% cream; diflorasone diacetate 0.05% cream; fluocinonide 0.05% cream (aqueous emollient); fluticasone propionate 0.005% ointment; mometasone furoate 0.1% ointment; triamcinolone acetonide 0.5% cream, ointment.
<b>Medium potency (Group 4)</b>	betamethasone propionate 0.05% spray; clocortolone pivalate 0.1% cream; fluocinolone acetonide 0.025% ointment; flurandrenolide 0.05% ointment; hydrocortisone valerate 0.2% ointment; mometasone furoate 0.1% cream, lotion, ointment, solution; triamcinolone acetonide 0.1% cream, ointment; triamcinolone acetonide 0.05% ointment; triamcinolone acetonide 0.2 mg aerosol spray.
<b>Lower-mid potency (Group 5)</b>	betamethasone dipropionate 0.05% lotion; betamethasone valerate 0.1% cream; desonide 0.05% gel, ointment; fluocinolone acetonide 0.025% cream; flurandrenolide 0.05% cream, lotion; fluticasone propionate 0.05% cream, lotion; hydrocortisone butyrate 0.1% cream, lotion, ointment, solution; hydrocortisone probutate 0.1% cream; hydrocortisone valerate 0.2% cream; prednicarbate 0.1% cream (emollient), ointment; triamcinolone acetonide 0.1% lotion; triamcinolone acetonide 0.025% ointment.
<b>Low potency (Group 6)</b>	aclometasone dipropionate 0.05% cream, ointment; betamethasone valerate 0.1% lotion; desonide 0.05% cream, foam, lotion; fluocinolone acetonide 0.01% cream, oil, shampoo, solution; triamcinolone acetonide 0.025% cream, lotion.
<b>Least potent (Group 7)</b>	hydrocortisone 2.5% cream, ointment, solution; hydrocortisone 2% lotion; hydrocortisone 1% cream, gel, lotion, ointment, solution, spray; hydrocortisone 0.5% cream, ointment; hydrocortisone acetate 2.5% cream; hydrocortisone acetate 2% lotion.

\* 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. 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):116-132.
5. Lichen simplex chronicus: <https://emedicine.medscape.com/article/1123423-treatment?src=refgatesrc1>. Updated February 15, 2019. Accessed on May 2, 2019.

6. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=>. Accessed on May 9, 2022. Search terms: doxepin, corticosteroid.