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Topical Doxepin Cream

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following topical doxepin cream 5% products:

- doxepin 5% cream
• Prudoxin™ (doxepin) 5% cream
• Zonalon® (doxepin) 5% cream

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Topical doxepin cream 5% (Prudoxin, Zonalon, generics) is considered medically necessary when the following are met:

1. Moderate to severe pruritus associated with atopic dermatitis or lichen simplex chronicus. Individual meets the following criteria (A and B):
A. Individual is age 18 years or older

B. Individual meets the preferred covered alternative(s) criteria as indicated in the table below

**Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.**

**Employer Group Non-Covered Products and the Preferred Covered Alternatives:**

<b>Non-Covered Product</b>	<b>Criteria</b>
<b>doxepin</b> 5% cream	There is documentation of the following criterion (A):  A. The individual has had an inadequate response, contraindication, or is intolerant to <b>FIVE</b> generic prescription topical corticosteroid formulations (see <a href="#">Table 1</a> ).
<b>Prudoxin</b> (doxepin) 5% cream	There is documentation of the following criterion (A):  A. The individual has had an inadequate response, contraindication, or is intolerant to <b>FIVE</b> generic prescription topical corticosteroid formulations (see <a href="#">Table 1</a> ).
<b>Zonalon</b> (doxepin) 5% cream	There is documentation of the following criterion (A):  A. The individual has had an inadequate response, contraindication, or is intolerant to <b>FIVE</b> generic prescription topical corticosteroid formulations (see <a href="#">Table 1</a> ).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Topical doxepin cream 5% (Prudoxin, Zonalon, generics) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response

## Authorization Duration

Initial and reauthorization approval is: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

## Background

### 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.
<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>	alclometasone 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).

## 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 August 20, 2020 . Accessed on April 7, 2023.
6. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=>. Accessed on April 7, 2023. Search terms: doxepin, corticosteroid.

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