Topical Doxepin

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Related Coverage Resources

Quantity Limitations

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, 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.

Medical Necessity Criteria

For Employer Group Plans:
Topical doxepin products are considered medically necessary when the following criteria are met:

<table>
<thead>
<tr>
<th>Non-Covered Product</th>
<th>Standard / Performance</th>
<th>Value / Advantage</th>
<th>Cigna Total Savings</th>
<th>Legacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxepin 5% cream</td>
<td>All of the following:</td>
<td></td>
<td></td>
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<tr>
<td>Prudoxin (doxepin 5% cream)</td>
<td>Individual is 18 years of age or older</td>
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<tr>
<td>Zonalon (doxepin 5% cream)</td>
<td>Used for short-term management of ONE of the following:</td>
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<td></td>
<td>Moderate pruritus with atopic dermatitis</td>
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<td></td>
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<tr>
<td></td>
<td>Lichen simplex chronicus</td>
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<tr>
<td></td>
<td>Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for four generic prescription topical corticosteroid formulations</td>
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<tr>
<td></td>
<td>Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for topical tacrolimus</td>
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</tbody>
</table>

Initial and reauthorization is up to 14 days.
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.

Topical doxepin products are considered experimental, investigational or unproven for ANY other use including the following:

- Neuropathic pain

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

*If you're a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

**FDA Approved Indications**

**FDA Approved Indication**

Topical doxepin cream (Prudoxin, Zonalon) is indicated for the short-term (up to 8 days) management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus (thickening of the skin resulting from repeated rubbing, itching, and scratching).

There is no data to establish the safety and efficacy of doxepin when used for greater than 8 days.

The use of topical doxepin cream in pediatric patients is not recommended. Safe conditions for use of topical doxepin cream in children have not been established.

**Recommended Dosing**

**FDA Recommended Dosing**

A thin film of cream should be applied four times each day with at least a 3 to 4 hour interval between applications. There are no data to establish the safety and effectiveness of Zonalon Cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of Zonalon cream for longer than 8 days may result in an increased likelihood of contact sensitization.

The risk for sedation may increase with greater body surface area (BSA) application of doxepin cream (drowsiness is more common when applied to over 10% of BSA).

**Drug Availability**

Doxepin cream is available in 30 gram and 45 gram tubes.

**Background**

**Therapeutic Alternatives**

Therapeutic alternatives to topical doxepin include the following drugs or classes of medication: topical corticosteroids and topical tacrolimus.

**Professional Societies/Organizations**

Guidelines do not recommend or advocate use of topical antihistamines for atopic dermatitis.

**American Academy of Dermatology** guidelines for management of atopic dermatitis do not recommend topical antihistamines (including doxepin) because of the risk of absorption and of contact dermatitis. (Eichenfield, 2014)

**The Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma and Immunology** published a practice parameter in 2012 for atopic dermatitis...
topical antihistamines (including doxepin) are generally not recommended because of potential cutaneous sensitization. (Schneider, 2012)

**Off Label Uses**
AHFS Drug Information 2019 Edition does not support any off-label uses of Prudoxin or Zonalon.

**Experimental, Investigational, Unproven Uses**
There is insufficient evidence to support use of topical doxepin for the treatment of neuropathic pain. A single, double-blind trial of 200 adults with chronic neuropathic pain were randomized to receive one of the following topical treatments: placebo, doxepin 3.3%, capsaicin 0.025%, or combination doxepin 3.3% and capsaicin 0.025% for 4 weeks. Results were available in only 151 patients. Modest, but statistically significant, reductions in the 10-point visual analogue scale were demonstrated with doxepin (0.9), capsaicin (1.12), and combination doxepin/capsaicin (1.07) groups. (McCleane, 2000)

**Comparative Studies**
There are no clinical studies comparing topical doxepin with other therapeutic alternatives.

**References**