

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Topical Antipruritics – Doxepin Products Drug Quantity Management Policy – Per Days
- Prudoxin® (doxepin hydrochloride cream 5% – Mylan, generic)
 - Zonalon (doxepin hydrochloride cream 5% – Mylan)

REVIEW DATE: 08/10/2022

OVERVIEW

Doxepin topical cream, an H₁ and H₂ histamine receptor blocker, is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with **atopic dermatitis or lichen simplex chronicus**.^{1,4}

Dosing

A thin film of doxepin cream should be applied four times each day with at least a 3 to 4 hour interval between applications.^{1,4} There are no data to establish the safety and effectiveness of doxepin cream when used for greater than 8 days. Chronic use beyond 8 days may result in higher systemic levels and should be avoided. Use of doxepin 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 application. Drowsiness is significantly more common in patients applying doxepin cream to over 10% of body surface area; therefore, patients with greater than 10% of body surface area affected should be particularly cautioned concerning possible drowsiness and other systemic adverse effects of doxepin.

Availability

Doxepin 5% cream is available as Prudoxin (generic) and Zonalon.^{1,4} Prudoxin (generic) is available in a 45 gram tube and Zonalon is available in a 30 gram and 45 gram tubes.

Additional Information

Topical antihistamines are not generally recommended for the treatment of atopic dermatitis due to the risk of contact dermatitis.⁵ The treatment of lichen simplex chronicus centers on the discontinuation of the itch-scratch cycle.⁷ Commonly used therapies include topical corticosteroids under occlusion and intralesional corticosteroids.

The clinical presentation of atopic dermatitis differs depending on age at presentation.⁵ In infants, the face, scalp, trunk, and extremities are most often impacted. Older children present with patches on flexural surfaces, and adults present with patches on extremities. The SCORing Atopic Dermatitis (SCORAD) index is the most widely used validated clinical tool to classify atopic dermatitis severity based on affected body surface area (BSA) and intensity of the lesions.^{2,3,6} The head and neck are considered 9% of BSA, each upper limb is 9% of BSA (18% total), each lower limb is 18% BSA (36% total), anterior tuck is 18% of BSA, back is 18% of BSA, and genitals are 1% of BSA. When determining the amount of a topical corticosteroid to apply, a standard measure, the fingertip unit (FTU), is often used.⁴ One FTU is the amount of product that is squeezed out of a standard tube along an adult's fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total BSA. Therefore, although not a corticosteroid, it is assumed that 1 g of topical doxepin would cover 4% of the patient's BSA. Because atopic dermatitis in adults commonly affects the extremities (9% each for arms, and 18% each for leg), 2.25 grams of topical doxepin would cover 9% of the patients BSA.

POLICY STATEMENT

08/10/2022

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This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of the topical doxepin products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 days
Prudoxin® (doxepin hydrochloride 5% cream, generic)	45 gram tube	90 grams*	225 grams*
Zonalon® (doxepin hydrochloride 5% cream)	30 gram tube 45 gram tube	90 grams*	225 grams*

*This is enough drug to cover 9% of the body surface area when applying four times daily for 8 days per month. A quantity of 72 grams per 30 days would supply a quantity sufficient to cover 9% of BSA (e.g., one upper extremity limb) for one 8-day treatment course (2.25 grams applied four times per day [9 grams/day]). A quantity of 216 grams per 90 days would supply a quantity sufficient to cover 9% BSA for three 8-day treatment courses. Due to the package sizing of topical doxepin products, a quantity of 90 grams per 30 days at retail and 225 grams at home delivery will be covered without prior authorization.

CRITERIA

1. If the patient has atopic dermatitis or lichen simplex chronicus and is treating greater than 9% of body surface area, approve a one-time override for the quantity requested not to exceed 180 grams at retail or 450 grams at home delivery.
2. If the patient has atopic dermatitis or lichen simplex chronicus and requires two 8-day treatment periods per 30-days, approve a one-time override for the quantity requested not to exceed 180 grams at retail or 315 grams at home delivery.

Note: For home delivery this quantity will accommodate two 8-day treatment periods per 30 days, and one 8-day treatment period per 30-days for 60 days (total of 90 days).

EXCLUSIONS

1. No overrides are recommended for use in compounded formulations.

REFERENCES

1. Zonalon® 5% cream [prescribing information]. Morgantown, WV: Mylan; June 2017.
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3. Frazier W and Bhardwaj N. Atopic dermatitis: diagnosis and treatment. *Am Fam Phys*. 2020;101:590-598. Available at: <https://www.aafp.org/pubs/afp/issues/2020/0515/p590.html>. Accessed on August 5, 2022.
4. Prudoxin® 5% cream [prescribing information]. Morgantown, WV: Mylan; June 2017.
5. Fazio SB, Yosipovitch G. Pruritis: Therapies for localized pruritus. Last updated July 2021. In T.W. Post, P. Rutgeerts, & S. Grover (Eds.), *UptoDate*. Available from: https://www.uptodate.com/contents/pruritus-therapies-for-localized-pruritus?search=lichen%20simplex%20chronicus§ionRank=1&usage_type=default&anchor=H45580783&source=macLineLearning&selectedTitle=1~43&display_rank=1#H171003115. Accessed on August 5, 2022.
6. SCORing Atopic Dermatitis Calculator (SCORAD 0.9.0). Available at: <https://scorad.corti.li/>. Accessed on August 5, 2022.

