



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, generic)

REVIEW DATE: 09/03/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 (generic).^{1,4} Prudoxin (generic) is available in a 45 gram tube and Zonalon (generic) is available in a 30 gram (brand only) and 45 gram tubes.

Additional Information

Topical antihistamines are no longer recommended for the treatment of atopic dermatitis.² The treatment of lichen simplex chronicus centers on the discontinuation of the itch-scratch cycle.⁵ 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.³ 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 and 2.25 grams would cover 9% of the patient's BSA.

POLICY STATEMENT

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 the duration noted below.

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, generic)	30 gram tube (brand only) 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.

Topical Antipruritics – Doxepin Products Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol.* 2023;89(1):e1-e20.
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 6, 2024.
4. Prudoxin® 5% cream [prescribing information]. Morgantown, WV: Mylan; June 2017.
5. Fazio SB, Yosipovitch G. Pruritus: Therapies for localized pruritus. Last updated July 2024. 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=machineLearning&selectedTitle=1~43&display_rank=1#H171003115. Accessed on August 6, 2024.
6. SCORing Atopic Dermatitis Calculator (SCORAD 0.9.0). Available at: <https://www.mdapp.co/scoring-atopic-dermatitis-scorad-calculator-396/>. Accessed on August 6, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Generic to brand Zonalon added to the policy.	08/15/2023
Annual Revision	No criteria changes.	09/03/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.