Clinical Policy: Doxepin Hydrochloride Cream (Prudoxin, Zonalon)

Reference Number: HIM.PA.147
Effective Date: 11.17.17
Last Review Date: 02.18 Revision Log
Line of Business: Health Insurance Marketplace

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Doxepin hydrochloride cream, 5%, (Prudoxin™ and Zonalon®) is one of a class of agents known as dibenzoxepin tricyclic antidepressant compounds.

FDA Approved Indication(s)
Prudoxin and Zonalon are indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Policy/Criteria
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Prudoxin and Zonalon are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pruritus (must meet all)**:**

1. Diagnosis of pruritus associated with conditions such as atopic dermatitis (eczema) or lichen simplex chronicus*;
2. Age ≥ 18 years;
3. Trial and failure of ≥ 2 topical therapies (e.g., corticosteroid; antihistamine) in the last six months unless contraindicated or clinically significant adverse effects are experienced (if appropriate, at least one trial should include a topical corticosteroid);
4. Dose does not exceed topical application up to four times daily.

Approval duration: 6 months (1 tube)

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**Lichen simplex chronicus, is a secondary skin condition resulting from excessive scratching associated with a variety of conditions including atopic dermatitis. Complaints of intense pruritus are common.*

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Pruritus (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not received topical doxepin in the last 180 days;
4. If request is for a dose increase, new dose does not exceed topical application up to four times daily.

Approval duration: 6 months (1 tube)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
Not applicable

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Clobetasol propionate, 0.05%	Topical application up to two times daily.	Varies
Desonide, 0.05%	Topical application up to two to four times daily depending on formulation.	
Halcinonide, 0.1% (Halog®)	Topical application up to three times daily.	
OTC topical diphenhydramine 1-2% (e.g., Anti-Itch® Maximum Strength, Anti-Itch®, Benadryl® Itch Stopping, Itch Relief®)	Topical application up to four times daily.	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. References

1. Prudoxin Prescribing Information. Newtown, PA: Prestium Pharma, Inc.; February 2015. Available at https://dailymed.nlm.nih.gov. September 2017.
2. Zonalon Prescribing Information. Malvern, PA: Bioglan Pharma, Inc.; October 2011. Available at https://dailymed.nlm.nih.gov. Accessed September 2017.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
4. Patel T, Yosipovitch G. Therapy of pruritis. Expert Opin Pharmacother. 2010 July; 11(10): 1673-1682.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	11.17.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.