Topical Antipruritics

Policy # 00581
Original Effective Date: 01/01/2018
Current Effective Date: 09/09/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Zonalon®‡ (doxepin cream), prudoxin (doxepin cream, generic), and generic doxepin cream to be **eligible for coverage**** when the patient selection criteria are met for the requested drug:

Patient Selection Criteria

Coverage eligibility for Zonalon (doxepin cream), prudoxin (doxepin cream, generic), or generic doxepin cream will be considered when the following criteria are met:

- Patient has a diagnosis of Atopic Dermatitis; AND
    - Patient is 18 years of age or older; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) over-the counter topical antihistamines (i.e., topical diphenhydramine) AND at least TWO prescription generic topical steroid products (medium strength to very high strength), unless there is clinical evidence or patient history that suggests the alternative topical products will be ineffective or cause an adverse reaction to the patient; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) an oral antihistamine (prescription generic or over the counter) unless there is clinical evidence or patient history that suggests the use of an oral antihistamine (prescription generic or over the counter) will be ineffective or cause an adverse reaction to the patient; AND

    - If the request is for Zonalon: Patient has tried and failed (e.g., intolerance or inadequate response) generic doxepin or generic prudoxin for at least one month of therapy, unless there is clinical evidence or patient history that suggests generic doxepin or generic prudoxin will be ineffective or cause an adverse reaction to the patient; OR
- Patient has a diagnosis of Lichen Simplex Chronicus; AND
    - Patient is 18 years of age or older; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO prescription generic topical steroid products (medium strength to very high strength), unless there is clinical evidence or patient history that suggests the alternative products will be ineffective or cause an adverse reaction to the patient; AND
    - If the request is for Zonalon: Patient has tried and failed (e.g., intolerance or inadequate response) generic doxepin or generic prudoxin for at least one month of therapy, unless there is clinical evidence or patient history that suggests generic doxepin or generic prudoxin will be ineffective or cause an adverse reaction to the patient.

*(Note: The patient selection criteria that requires the use of alternative products prior to the requested product are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Zonalon (doxepin cream), prudoxin (doxepin cream, generic), or generic doxepin cream when patients have not tried and failed the listed alternative agents to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Zonalon (doxepin cream), prudoxin (doxepin cream, generic), or generic doxepin cream for any indication other than atopic dermatitis or lichen simplex chronicus OR in patients younger than 18 years of age to be **investigational.***

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Background/Overview

Doxepin 5% cream is available as brand Zonalon, generic prudoxin, and generic doxepin. It is a topical compound with both antihistamine and antidepressant properties that reduces pruritic symptoms associated with atopic dermatitis and lichen simplex chronicus via an unknown mechanism. It is systemically absorbed to a varying degree and can cause drowsiness due to this absorption. These creams are approved for the management of moderate pruritis in adult patients with atopic dermatitis or lichen simplex chronicus.

Atopic dermatitis is a common chronic, pruritic, inflammatory skin disorder also known as eczema. It is common in children, but can occur in patients of all ages. The mainstay of treatment of atopic dermatitis is topical moisturizers and topical corticosteroids (see table below for classification of topical corticosteroids). Doxepin ointment may be used as a second-line agent to relieve pruritus, but its use is limited by allergic contact dermatitis to the drug. Of note, guidelines from the American Academy of Dermatology do not recommend topical antihistamines (including doxepin) for atopic dermatitis due to the risk of absorption and of contact dermatitis.

Lichen simplex chronicus is a secondary skin disorder caused by excessive scratching. It typically results in the formation of lichenified plaques and excoriations. Treatment commonly includes topical corticosteroids (see table below for classification based on potency), but topical doxepin may be used if the patient has a contraindication to the use of topical corticosteroids or they are ineffective.

Topical Corticosteroid Potency

MEDIUM STRENGTH	HIGH STRENGTH	VERY HIGH STRENGTH
betamethasone valerate	amcinonide	augmented betamethasone
desoximetasone	augmented betamethasone	dipriopionate ointment
fluocinolone acetonide	dipropionate cream	clobetasol emollient
fluticasone propionate	apexicon E	clobetasol propionate
hydrocortisone butyrate	betamethasone dipriopionate	clodan
mometasone furoate	betamethasone valerate	cormax
prednicarbate	desoximetasone	diflorasone diacetate
triamcinolone acetonide 0.1%	diflorasone diacetate	halobetasol propionate
	fluocinonide	

trianex triderm	fluocinonide E triamcinolone acetonide 0.5%	

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Doxepin cream is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests a prescription generic topical corticosteroid or over the counter topical antihistamine (depending on indication) will be ineffective or cause an adverse reaction to the patient. In addition, there is evidence that doxepin cream is associated with a risk of adverse effects (drowsiness, contact dermatitis) and it has variable efficacy. Based on review of this data, in the absence of the above mentioned caveats, there is no advantage of using doxepin cream prior to topical corticosteroids or an over the counter topical antihistamine (where applicable based on indication) for the treatment of pruritis associated with atopic dermatitis or lichen simplex chronicus. There is also no advantage of using the generic doxepin or generic prudoxin over the branded Zonalon product.

References

1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014 Feb;70(2):338-51
2. Zonalon. [package insert]. DPT Laboratories, San Antonio, TX Updated October 2014.
3. Prudoxin [package insert]. DPT Laboratories, San Antonio, TX. Update unknown.

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09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. New policy.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Added criteria of 18 years of age or older. Also added requirement for use of oral antihistamine first for atopic dermatitis.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.