BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.90.27

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	February 17, 2017
Subject:	Doxepin Cream 5%	**Page:**	1 of 6

Last Review Date: March 12, 2021

Doxepin Cream 5%

Description

Doxepin Cream 5% (Prudoxin, Zonalon)

Background
Doxepin cream is a topical medication used for the short-term treatment of pruritus (itching of the skin) due to atopic dermatitis (eczema) or lichen simplex chronicus (thickening of skin due to prolonged itching and scratching). Although doxepin does have H1 and H2 histamine receptor blocking actions, the exact mechanism by which doxepin exerts its antipruritic effect is unknown. Possible adverse reactions include, but are not limited to: drowsiness, urinary retention, increased pruritus, and contact sensitization (1-2).

Regulatory Status
FDA-approved indications: Doxepin cream 5% is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus (1-2).

Doxepin has an anticholinergic effect and significant plasma levels of doxepin are detectable after topical doxepin cream application, the use of doxepin cream is contraindicated in patients with untreated narrow angle glaucoma or a tendency to urinary retention (1-2).

A thin film of doxepin 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 doxepin cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided (1-2).

Doxepin cream 5% criteria was created with dosing above FDA recommended limits in order to help existing patients that have been taking doses above the FDA recommended limits to safely taper down their doses to the appropriate levels. This will allow physicians time to work with their patients in creating a custom taper that is safe and provides adequate relief from pruritus.

The safety and effectiveness of doxepin cream 5% in pediatric patients under 18 years of age has not been established (1).

Related policies
Fluticasone powder, Mometasone powder, Topical Anti-inflammatories

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Doxepin cream 5% may be considered **medically necessary** in patients with moderate pruritus and if the conditions indicated below are met.

Doxepin cream 5% may be considered **investigational** in children under 18 years of age and all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Moderate pruritus, due to atopic dermatitis (eczema) or lichen simplex chronicus

AND the following:

1. Inadequate response, intolerance or contraindication to **ONE** medication in **EACH** of the following categories:
    a. Topical antihistamine (see Appendix I)
    b. **High** potency topical corticosteroid (see Appendix II)

2. Physician agrees to taper patient's dose to the FDA recommended dose, and after tapered will only use for short-term pruritus relief (up to 8 days)
    a. Patients using over 60 grams of topical doxepin in 90 days be required to taper to 60 grams topical doxepin within 90 days

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

Age 18 years of age or older

Quantity 60 grams every 90 days

Prior - Approval Limits

Quantity 180 grams for 90 days

Duration 3 months

Rationale

Summary

Doxepin cream is a topical medication used for the short-term treatment of pruritus (itching of the skin) due to atopic dermatitis (eczema) or lichen simplex chronicus (thickening of skin due to prolonged itching and scratching). Although doxepin does have H1 and H2 histamine receptor blocking actions, the exact mechanism by which doxepin exerts its antipruritic effect is unknown. There are no data to establish the safety and effectiveness of doxepin cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of doxepin cream 5% while maintaining optimal therapeutic outcomes.

References

1. Zonalon Cream [package insert]. San Antonio, TX: DPT Laboratories Ltd.; June 2017.
2. Prudoxin Cream [package insert]. San Antonio, TX: DPT Laboratories Ltd. June 2017.

Policy History

Date	Action
February 2017	Addition to PA
June 2017	Annual review
August 2017	Addition of inadequate response, intolerance or contraindication to ONE medication in EACH of the following categories: topical antihistamine (see Appendix I) and high potency topical corticosteroid (see Appendix II)
September 2017	Annual review
December 2018	Annual review
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

APPENDIX I

Drug	Dosage Form
Diphenhydramine	Cream
Phenyltoloxamine	Lotion/ Cream
Tripelennamine	Cream
Phendiamine	Cream

APPENDIX II

Relative Potency of Selected Topical Corticosteroid			
	Drug	**Dosage Form**	**Strength**
I.	***Very high potency***		
	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
	Diflorasone diacetate	Ointment	0.05%
	Halobetasol propionate	Cream, Ointment	0.05%
II.	***High potency***		
	Amcinonide	Cream, Lotion,	0.1%
	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone	Cream, Ointment	0.05%
	Betamethasone valerate	Ointment	0.1%
	Desoximetasone	Cream, Ointment	0.25%
		Gel	0.05%
	Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
	Fluocinonide	Cream, Ointment, Gel	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
III.	***Medium potency***		
	Betamethasone	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Clocortolone pivalate	Cream	0.1%
	Desoximetasone	Cream	0.05%
	Fluocinolone acetonide	Cream, Ointment	0.025%
		Cream, Ointment,	0.05%

III.	Flurandrenolide	Tape	4 mcg/cm^2
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
	Hydrocortisone butyrate	Ointment, Solution	0.1%
	Hydrocortisone valerate	Cream, Ointment	0.2%
	Mometasone furoate	Cream, Ointment,	0.1%
	Prednicarbate[2]	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
		Cream, Ointment, Lotion	0.1%
IV.	***Low potency***		
	Alclometasone dipropionate	Cream, Ointment	0.05%
	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Lotion	0.25%
		Cream, Ointment, Lotion,	0.5%
		Cream, Ointment, Lotion,	1%
		Cream, Ointment,	2.5%
	Hydrocortisone acetate	Cream, Ointment	0.5%
		Cream, Ointment	1%