



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

864-3126 or emailed to Pharmacyprecert@azblue.com. Incomplete forms or forms without the chart notes will be returned.

Criteria:

- **Criteria for initial therapy:** Doxepin hydrochloride 5% cream, Prudoxin (doxepin hydrochloride 5%) cream, and Zonalon (doxepin hydrochloride 5%) cream is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual is 18 years of age or older
 2. A confirmed diagnosis of moderate pruritus with atopic dermatitis or lichen simplex chronicus for **short-term (up to 8 days)** management
 3. Individual has tried, failed, or has contraindication to **at least two** of the medium to high potency corticosteroids for the body such as:
 - Fluocinolone 0.025%
 - Triamcinolone 0.1%
 - Betamethasone dipropionate 0.05%

OR

Individual has tried, failed, or has contraindication to **at least two** of the low potency corticosteroids group for face and skin folds such as:
 - Desonide 0.05%
 - Fluocinolone acetonide 0.01%
 - Triamcinolone 0.025%
 4. There are **NO** contraindications.
 - Contraindications include:
 - Patients with untreated narrow angle glaucoma
 - Tendency to urinary retention

Initial approval duration: 1 month

- **Continuation of coverage (renewal request):** Doxepin hydrochloride 5% cream, Prudoxin (doxepin hydrochloride 5%) cream, and Zonalon (doxepin hydrochloride 5%) cream is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. The individual has benefited from therapy but remains at high risk
 2. As this is for short term use, minimum of 3 months have passed between prior uses



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

Renewal duration: 1 month

Description:

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.

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.

Doxepin has an anticholinergic effect; 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.

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.

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

Potency group	Corticosteroid	Vehicle type/form	Trade names (United States)	Available strength(s), percent (except as noted)	
Super-high potency	Betamethasone dipropionate, augmented	Ointment, optimized	Diprolene	0.05	
		Lotion	Diprolene	0.05	
		Gel	Diprolene	0.05	
	Clobetasol propionate		Ointment	Temovate	0.05
			Cream	Temovate	0.05
			Cream, emollient base	Temovate E	0.05
			Gel	Temovate	0.05
			Lotion	Clobex	0.05
			Foam aerosol	Olux-E	0.05
			Foam aerosol (scalp)	Olux	0.05
			Shampoo	Clobex	0.05
			Solution (scalp)	Temovate, Cormax	0.05

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

		Spray aerosol	Clobex	0.05
	Diflucortolone valerate (not available in United States)	Ointment, oily cream	Nerisone Forte (United Kingdom, others)	0.3
	Fluocinonide	Cream	Vanos	0.1
	Flurandrenolide	Tape (roll)	Cordran	4 mcg/cm ²
	Halobetasol propionate	Ointment	Ultravate	0.05
		Cream	Ultravate	0.05
		Lotion	Ultravate	0.05
High potency	Amcinonide	Ointment	Cyclocort, Amcort	0.1
	Betamethasone dipropionate	Ointment	Diprosone	0.05
		Cream, augmented formulation (AF)	Diprolene AF	0.05
	Desoximetasone	Ointment	Topicort	0.25
		Cream	Topicort	0.25
		Gel	Topicort	0.05
	Diflorasone diacetate	Ointment	ApexiCon, Florone	0.05
		Cream, emollient	ApexiCon E	0.05
	Fluocinonide	Ointment	Lidex	0.05
		Gel	Lidex	0.05
		Cream anhydrous	Lidex	0.05
		Solution	Lidex	0.05
	Halcinonide	Ointment	Halog	0.1
		Cream	Halog	0.1
	Amcinonide	Cream	Cyclocort, Amcort	0.1
		Lotion	Amcort	0.1
	Betamethasone dipropionate	Cream, hydrophilic emollient	Diprosone	0.05
	Betamethasone valerate	Ointment	Valisone	0.1
		Foam	Luxiq	0.12
	Desoximetasone	Cream	Topicort LP	0.05
	Diflorasone diacetate	Cream	Florone	0.05
	Diflucortolone valerate (not available in United States)	Cream, oily cream, ointment	Nerisone (Canada, United Kingdom, others)	0.1
	Fluocinonide	Cream aqueous emollient	Lidex-E	0.05
Fluticasone propionate	Ointment	Cutivate	0.005	
Mometasone furoate	Ointment	Elocon	0.1	
Triamcinolone acetonide	Ointment	Kenalog	0.5	
	Cream	Triderm, Aristocort HP	0.5	
Medium potency	Betamethasone dipropionate	Spray	Sernivo	0.05
	Clocortolone pivalate	Cream	Cloderm	0.1

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

	Fluocinolone acetone	Ointment	Synalar	0.025
	Flurandrenolide	Ointment	Cordran	0.05
	Hydrocortisone valerate	Ointment	Westcort	0.2
	Mometasone furoate	Cream	Elocon	0.1
		Lotion	Elocon	0.1
		Solution	Elocon	0.1
	Triamcinolone acetone	Cream	Kenalog	0.1
		Ointment	Kenalog	0.1
		Aerosol spray	Kenalog	0.2 mg per 2 second spray
Lower-mid potency	Betamethasone dipropionate	Lotion	Diprosone	0.05
	Betamethasone valerate	Cream	Beta-Val, Valisone	0.1
	Desonide	Ointment	DesOwen, Tridesilon	0.05
		Gel	Desonate	0.05
	Fluocinolone acetone	Cream	Synalar	0.025
	Flurandrenolide	Cream	Cordran	0.05
		Lotion	Cordran	0.05
	Fluticasone propionate	Cream	Cutivate	0.05
		Lotion	Cutivate	0.05
	Hydrocortisone butyrate	Ointment	Locoid	0.1
		Cream	Locoid, Locoid Lipocream	0.1
		Lotion, spray	Cortizone 10 maximum	0.1
		Lotion	Locoid	0.1
		Solution	Locoid	0.1
	Hydrocortisone probutate	Cream	Pandel	0.1
	Hydrocortisone valerate	Cream	Westcort	0.2
	Prednicarbate	Cream, emollient	Dermatop	0.1
Ointment		Dermatop	0.1	
Triamcinolone acetone	Lotion	Kenalog	0.1	
	Ointment	Kenalog	0.025	
Low potency	Alclometasone dipropionate	Ointment	Aclovate	0.05
		Cream	Aclovate	0.05
	Betamethasone valerate	Lotion	Beta-Val, Valisone	0.1
	Desonide	Cream	DesOwen, Tridesilon	0.05
Lotion		DesOwen, LoKara	0.05	

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

		Foam	Verdeso	0.05
	Fluocinolone acetonide	Cream	Synalar	0.01
		Solution	Synalar	0.01
		Shampoo	Capex	0.01
		Oil (scalp)	Derma-Smoothe/FS Scalp	0.01
		Oil (body)	Derma-Smoothe/FS Body	0.01
		Triamcinolone acetonide	Cream	Kenalog, Aristocort
	Lotion		Kenalog	0.025
Least potent	Hydrocortisone (base, ≥2%)	Ointment	Hytone	2.5
		Cream	Hytone, Nutracort	2.5
		Lotion	Hytone, Ala Scalp, Scalacort	2.5 or 2
		Solution	Texacort	2.5
	Hydrocortisone (base, <2%)	Ointment	Cortaid, Hytone, Nutracort	1
		Cream	Cortaid, Hytone, Synacort	1
		Lotion	Aquanil HC, Sarnol-HC, Cortizone 10	1
		Spray	Cortaid	1
		Solution	Cortaid, Noble, Scalp relief	1
		Ointment	Cortaid	0.5
	Hydrocortisone acetate with pramoxine 1% combination	Cream	Cortaid	0.5
		Ointment	Pramosone	1 or 2.5
		Cream	Pramosone, Analpram-HC	1 or 2.5
		Lotion	Pramosone, Analpram-HC	1 or 2.5
			Aerosol foam	Epifoam

Resources:

Doxepin Hydrochloride. Package Insert. Revised by manufacturer 7/2015. Accessed 9/05/17.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=03107529-561a-4408-b319-94b245b3117b>

Prudoxin. Package Insert. Revised by manufacturer 6/2015. Accessed 9/05/17, 7/19/18.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9756deca-4d3f-4b8f-bbdc-5f3d61793c34>

Zonalon. Package Insert. Revised by manufacturer 3/2015. Accessed 9/05/17, 7/19/18.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ea3b314f-473f-45cb-bab2-8a89ef632030>



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 8/15/19
LAST CRITERIA REVISION DATE: 8/15/19
ARCHIVE DATE:

DOXEPIN HYDROCHLORIDE cream 5%
PRUDOXIN™ (doxepin hydrochloride) cream 5%
ZONALON® (doxepin hydrochloride) cream 5%

Doxepin Hydrochloride. Package Insert. Revised by manufacturer 2/2016. Accessed 7/19/18.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=03107529-561a-4408-b319-94b245b3117b>

UpToDate: Pruritus: Overview of management. Current through Jul 2018. https://www.uptodate-com.mwu.idm.oclc.org/contents/pruritus-overview-of-management?search=lichen%20simplex%20chronicus&source=search_result&selectedTitle=1~36&usage_type=default&display_rank=1

UpToDate: Pruritus: Etiology and patient evaluation. Current through Jul 2018. https://www.uptodate-com.mwu.idm.oclc.org/contents/pruritus-etiology-and-patient-evaluation?sectionName=Systemic%20disorders&topicRef=5576&anchor=H690865&source=see_link#H690830

UpToDate: Overview of dermatitis (eczema). Current through Jul 2018. https://www.uptodate-com.mwu.idm.oclc.org/contents/overview-of-dermatitis-eczema?search=atopic%20dermatitis&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4

UpToDate: Treatment of atopic dermatitis (eczema). Current through Jul 2018. https://www.uptodate-com.mwu.idm.oclc.org/contents/treatment-of-atopic-dermatitis-eczema?search=atopic%20dermatitis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
