BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 9/21/17**
SECTION: DRUGS	**LAST REVIEW DATE: 9/20/18**
	LAST CRITERIA REVISION DATE: 9/20/18
	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.

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

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

Criteria:

- **ALL** criteria below must be met to be approved for **short-term (up to 8 days**) management:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of moderate pruritus with atopic dermatitis or lichen simplex chronicus

  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 VI 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): ALL** criteria below must be met to be approved for **short-term (up to 8 days**) management:

  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

  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

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

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.

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 to 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.

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
		Spray aerosol	Clobex	0.05
	Diflucortolone valerate (not available in United States)	Ointment, oily cream	Nerisone Forte (United Kingdom, others)	0.3

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

	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
	Fluocinolone acetonide	Ointment	Synalar¶	0.025
	Flurandrenolide	Ointment	Cordran	0.05
	Hydrocortisone valerate	Ointment	Westcort	0.2
	Mometasone furoate	Cream	Elocon	0.1

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

		Lotion	Elocon	0.1
		Solution	Elocon¶	0.1
	Triamcinolone acetonide	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 acetonide	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 acetonide	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
		Foam	Verdeso	0.05
	Fluocinolone acetonide	Cream	Synalar¶	0.01
		Solution	Synalar¶	0.01
		Shampoo	Capex	0.01
		Oil (scalp)$^{\Delta}$	Derma-Smoothe/FS Scalp	0.01
		Oil (body)$^{\Delta}$	Derma-Smoothe/FS Body	0.01

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

	Triamcinolone acetonide	Cream	Kenalog¶, Aristocort¶	0.025
		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
		Cream	Cortaid	0.5
	Hydrocortisone acetate with pramoxine 1% combination	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	1

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

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

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

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

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.