Topical Doxepin Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
1/1/2024	1/1/2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Prudoxin® (doxepin) 5% cream*	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus	*generic available	2
Zonalon® (doxepin) 5% cream*	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus	*generic available	3

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Atopic Dermatitis	Atopic dermatitis is a chronic, pruritic, inflammatory skin disease. Clinical features include skin dryness, erythema, oozing and crusting, and lichenification. Pruritus is responsible for much of the disease burden for patients. The goals of treatment are to reduce symptoms of pruritus and dermatitis, prevent exacerbations, and minimize therapeutic risks.(4) Initial nonpharmacological therapy for atopic dermatitis, as recommended by American Academy of Dermatology (AAD) guidelines, is use of moisturizing agents. Moisturizers are the cornerstone of atopic dermatitis therapy as an important component of maintenance treatment and for the prevention of flares. Recommended topical therapy for atopic dermatitis, indicated when nonpharmacologic interventions have failed, includes topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI).(6,7) Proactive, once to twice weekly application of mid-potency TCS for up to 40 weeks has not demonstrated adverse events in clinical trials. AAD notes that mid- to higher-potency topical corticosteroids are appropriate for short courses to gain rapid control of symptoms, but long-term management should use the least-potent corticosteroid that is effective. TCIs (e.g., pimecrolimus, tacrolimus) are recommended by the AAD as second-line therapy, and are particularly useful in selected clinical situations such as recalcitrance to steroids; for sensitive areas (face, anogenital, skin folds); for steroid-induced atrophy; and when there is long-term uninterrupted topical steroid use.(6) Prescribing information for Elidel® (pimecrolimus) cream and Protopic® (tacrolimus) ointment indicate evaluation after 6 weeks if signs and symptoms of atopic dermatitis persist.(9,10) While topical doxepin does provide short-term decrease in pruritus, it is not recommended for atopic dermatitis by the

	AAD guidelines due to the risk of absorption, contact dermatitis, and noting that studies have shown no significant reduction in disease severity or control.(6)
Lichen Simplex Chronicus	Lichen simplex chronicus (LSC) is a common form of chronic neurodermatitis that presents as localized dry, patchy areas of skin that are scaly and thick. The plaques form as a result of constant and repeated scratching and/or rubbing of specific areas. The root of the disorder may be both a primary symptom reflective of a psychological component, or secondary to other cutaneous issues such as eczema or psoriasis. The treatment of LSC centers on breaking the itch-scratch cycle. Reducing inflammation is another cornerstone to treatment. As LSC is usually localized, topical agents are often used with high-potency topical corticosteroids considered first-line for treatment.(1,8).
Safety	Prudoxin and Zonalon are contraindicated in the following:(2,3) • Patients with untreated narrow angle glaucoma or a tendency to urinary retention • Individuals who have shown previous sensitivity to any of its components

REFERENCES

Number	Reference
1	Ju, T., Vander Does, A., Mohsin, N., & Yosipovitch, G. (2022). Lichen simplex chronicus itch: An update. Acta Dermato-Venereologica, 102. https://doi.org/10.2340/actadv.v102.4367
2	Prudoxin prescribing information. Mylan Pharmaceuticals, Inc. June 2017.
3	Zonalon prescribing information. Mylan Pharmaceuticals, Inc. June 2017.
4	Eichenfield, L. F., Tom, W. L., Chamlin, S. L., Feldman, S. R., Hanifin, J. M., Simpson, E. L., Berger, T. G., Bergman, J. N., Cohen, D. E., Cooper, K. D., Cordoro, K. M., Davis, D. M., Krol, A., Margolis, D. J., Paller, A. S., Schwarzenberger, K., Silverman, R. A., Williams, H. C., Elmets, C. A., … Sidbury, R. (2014). Guidelines of care for the management of atopic dermatitis (Section 1). Journal of the American Academy of Dermatology, 70(2), 338–351. https://doi.org/10.1016/j.jaad.2013.10.010
5	Reference no longer used
6	Eichenfield, L. F., Tom, W. L., Berger, T. G., Krol, A., Paller, A. S., Schwarzenberger, K., Bergman, J. N., Chamlin, S. L., Cohen, D. E., Cooper, K. D., Cordoro, K. M., Davis, D. M., Feldman, S. R., Hanifin, J. M., Margolis, D. J., Silverman, R. A., Simpson, E. L., Williams, H. C., Elmets, C. A., … Sidbury, R. (2014). Guidelines of care for the management of atopic dermatitis (Section 2). Journal of the American Academy of Dermatology, 71(1), 116–132. https://doi.org/10.1016/j.jaad.2014.03.023
7	Eichenfield, L. F., Ahluwalia, J., Waldman, A., Borok, J., Udkoff, J., & Boguniewicz, M. (2017). Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology guidelines. Journal of Allergy and Clinical Immunology, 139(4), S49–S57. https://doi.org/10.1016/j.jaci.2017.01.009
8	Charifa, A., Badri, T., & Harris, B. W. (2023, May 2). Lichen Simplex Chronicus. In StatPearls [Internet]. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK499991/
9	Elidel prescribing information. Bausch Health Companies Inc. September 2020.
10	Protopic prescribing information. Leo Pharma Inc. February 2019.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	45	Grams	30	DAYS	Quantity Limit is cumulative across agents		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Target Agent** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of moderate pruritus associated with atopic dermatitis AND ONE of the following: 1. The patient has tried and had an inadequate response to BOTH a topical corticosteroid AND a topical calcineurin inhibitor **OR** 2. The patient has an intolerance or hypersensitivity to a topical corticosteroid AND a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval

C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

5. The prescriber has provided documentation that ALL topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following:

1. The patient has tried and had an inadequate response to ONE topical corticosteroid **OR**
2. The patient has an intolerance or hypersensitivity to ONE topical corticosteroid **OR**
3. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
5. The prescriber has provided documentation that ALL topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has another FDA approved indication for the requested agent **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. If the request is for one of the following brand agents with an available generic (listed below), then ONE of the following:

Brand	Generic
Prudoxin cream Zonalon cream	doxepin hydrochloride cream 5%

   A. The patient has an intolerance or hypersensitivity to the generic that is not expected to occur with the brand agent **OR**
   B. The patient has an FDA labeled contraindication to the generic that is not expected to occur with the brand agent **OR**
   C. The prescriber has provided information to support the use of the requested brand agent over the generic **AND**
4. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication **AND**
5. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 1 month

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 1 month