Topical Doxepin Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
3/20/2023

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 avoidance of soaps with alkaline pH and use of moisturizing agents. 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 symptoms of atopic dermatitis do not improve.(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 and contact dermatitis.(6)
Lichen Simplex Chronicus	Lichen simplex chronicus is a form of chronic neurodermatitis that presents as dry, patchy areas of skin that are scaly and thick.(5,8) 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. Patients typically complain of intense pruritus in the affected areas.(8) The treatment of lichen simplex chronicus centers on the discontinuation of the itch/scratch cycle. Topical corticosteroids and

	topical emollients are commonly used therapies.(5,8) Efficacy of topical calcineurin inhibitors for unresponsive patients has been cited by some studies. Doxepin is also an option for local treatment of pruritis.(8)
Safety	Prudoxin and Zonalon are contraindicated in the following:(1-3) • 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	~~Doxepin prescribing information. Mylan Pharmaceuticals, Inc. May 2017.~~ Reference no longer used.
2	Prudoxin prescribing information. Mylan Pharmaceuticals, Inc. June 2017.
3	Zonalon prescribing information. Mylan Pharmaceuticals, Inc. June 2017.
4	Eichenfield LF, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dermatitis: Part 1: Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol* 2014 Feb;70(2):338-351.
5	Lichen Simplex (syn. Circumscribed Neurodermatitis). Primary Care Dermatology Society. Created October 2013. Last updated March 2019. Available at: http://www.pcds.org.uk/clinical-guidance/lichen-simplex-chronicus. Accessed July 2020.
6	Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of Care for the Management of Atopic Dermatitis: Part 2: Management and Treatment of Atopic Dermatitis with Topical Therapies. *J Am Acad Dermatol* 2014 Jul;71(1):116-132.
7	Eichenfield LF, Ahluwalia J, Waldman A, et al. 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. *J Allergy Clin Immunol* 2017 April;139(4):S49-S57.
8	Charifa A, Badri T. Lichen Simplex Chronicus. [Updated May 2020]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; Jan 2020. Available at: https://www.ncbi.nlm.nih.gov/books/NBK499991/. Accessed July 2020.
9	Elidel prescribing information. Valeant Pharmaceuticals. December 2017.
10	Protopic prescribing information. Astellas Pharma US Inc. May 2012.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Prudoxin ; Zonalon	doxepin hcl cream	5 %	M ; N ; O ; Y	M ; 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	Effective Date
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 %	HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	HIM ; ResultsRx

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'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** 2. 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 used for a minimum of 4 weeks AND a topical calcineurin inhibitor used for a minimum of 6 weeks **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** B. The patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus **AND** ONE of the following:

Module	Clinical Criteria for Approval
	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** C. The patient has another FDA approved indication for the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication **AND** 4. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 1 month NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**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) is greater than 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