

**Prudoxin® (doxepin cream)
Zonalon® (doxepin cream)
Topical doxepin 5% cream
Effective 01/01/2023**

Plan	<input checked="" type="checkbox"/> MassHealth (UPPL) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations			
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Prudoxin (doxepin cream) and Zonalon (doxepin cream) are indicated for the short-term (up to eight days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

No PA	Drugs that require PA
Various topical and systemic agents that are available without PA may be used.	Prudoxin® (doxepin cream)*
	Zonalon® (doxepin cream)*
	Doxepin 5% cream

*Authorized generic available. Both brand and authorized generic require PA.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization will be granted when **ALL** the following criteria has been met and documentation has been submitted:

1. Diagnosis of moderate to severe pruritus
2. Member is ≥ 18 years of age



3. Provider documentation of inadequate response or adverse reaction to **THREE** of the following or contraindication to **ALL** of the following:
 - a. Capsaicin cream
 - b. Lidocaine patch
 - c. One potent or superpotent topical corticosteroid
 - d. Systemic therapy (See Appendix)
 - e. Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
4. **ONE** of the following:
 - a. Request is for ≤ 45 grams per month
 - b. **ALL** of the following:
 - i. Request is for > 45 grams per month
 - ii. Provider documentation of inadequate response or adverse reaction to at least one systemic therapy
 - iii. Medical necessity for exceeding quantity limits
5. If the request is for BRAND name Prudoxin® or Zonalon®, the prescriber must also provide medical records documenting an inadequate response or an adverse reaction to the therapeutically equivalent generic doxepin cream

Continuation of Therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 3 months.
2. Reauthorizations will be granted for 6 months.
3. The following quantity limits apply:

Prudoxin cream	45 grams per 30 days
Zonalon cream	45 grams per 30 days
Doxepin cream 5%	45 grams per 30 days

Appendix

Systemic therapies for the treatment of pruritus
<ul style="list-style-type: none"> • Antihistamines at various doses • Oral doxepin • Mirtazapine 7.5 mg to 15 mg at night • Serotonin-norepinephrine reuptake inhibitors (SNRIs)/selective serotonin reuptake inhibitors (SSRIs) <ul style="list-style-type: none"> ○ Paroxetine 10 mg to 40 mg per day ○ Fluvoxamine 25 mg to 150 mg per day ○ Sertraline 75 mg to 100 mg per day • Anticonvulsants <ul style="list-style-type: none"> ○ Gabapentin 100 mg to 3,600 mg per day ○ Pregabalin 150 mg to 300 mg per day • Opioid receptor agonists/antagonists <ul style="list-style-type: none"> ○ Naltrexone 12.5 mg to 50 mg per day ○ Butorphanol 1 to 4 mg intranasally per day

- Aprepitant 80 mg per day
- Thalidomide 100 mg at night

References

1. Fazio SB, Yosipovitch, GY. Pruritus: Therapies for generalized pruritus. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 24]. Available from: <https://www.uptodate.com/contents/pruritus-overview-of-management>.
2. Prudoxin® (doxepin) [package insert]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2017 Jun.
3. Zonalon® (doxepin) [package insert]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2017 Jun.

Review History

09/21/2022 – Reviewed and Created for Sept P&T; matched MH UPPL.

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