Topical Doxepin Prior Authorization with Quantity Limit Criteria Program Summary

This prior authorization applies to Commercial, NetResults A series, NetResults F series and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Topical Doxepin Prior Authorization (PA) and Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. The program will approve for use of the targeted agents when the patient has an FDA labeled indication and the patient's medication history includes the use of a topical corticosteroid, intralesional corticosteroid, or oral antihistamine; or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroid, intralesional corticosteroid, or oral antihistamine. The program will also approve use when the patient has a diagnosis of moderate pruritus associated with atopic dermatitis and the patient's medication history includes the use of a topical calcineurin inhibitor. The program will not allow approval for patients who have an FDA labeled contraindication to the requested agent, nor will it allow for use of more than one targeted agent at a time, nor will it allow for durations longer than 8 days for a single course of therapy. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET AGENTS

Doxepin 5% cream
Prudoxin (doxepin 5% cream)
Zonalon (doxepin 5% cream)

PRIOR AUTHORIZATION TARGET AND QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity Limit
Doxepin 5% cream	90220015103710	M, N, O, Y	45 g every 30 days[a]
Prudoxin 5% cream	90220015103710	M, N, O, Y	45 g every 30 days[a]
Zonalon 5% cream	90220015103710	M, N, O, Y	45 g every 30 days[a]

a – quantity limit is cumulative across agents

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Target Agents will be approved when ALL of the following are met:

1. The patient is an adult
   AND
2. ONE of the following:
   a. The patient has a diagnosis of moderate pruritus associated with atopic dermatitis **AND** ONE of the following:
      i. The patient's medication history includes the use of a topical corticosteroid, intralesional corticosteroid, topical calcineurin inhibitor, or oral antihistamine in the past 90 days
      OR
      ii. The patient has a documented intolerance, FDA labeled

contraindication, or hypersensitivity to topical corticosteroid, intralesional corticosteroid, topical calcineurin inhibitor, or oral antihistamine

OR

b. The patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus **AND** ONE of the following:
    i. The patient's medication history includes the use of a topical corticosteroid, intralesional corticosteroid, or oral antihistamine in the past 90 days
    OR
    ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroid, intralesional corticosteroid, or oral antihistamine

AND

3. ONE of the following:
    a. The patient is not concurrently using another topical doxepin agent
    OR
    b. The patient will discontinue the other topical doxepin agent prior to starting therapy with the requested agent

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 contraindication(s) to the requested agent

AND

6. ONE of the following:
    a. The requested quantity (dose) is NOT greater than the program quantity limit
    OR
    b. BOTH of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 30 days

FDA APPROVED INDICATIONS AND DOSAGE[1-3]

Agents	Indication	Dosage & Administration
Doxepin 5% cream	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*	A thin film of doxepin hydrochloride cream, 5% 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 hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization. Drowsiness is significantly more common in patients applying doxepin cream to over 10% of body surface area.
Prudoxin™ (doxepin) cream 5%	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*	A thin film of doxepin hydrochloride cream, 5% 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 hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization. Drowsiness is significantly more common in patients applying doxepin cream to over 10% of body surface area.
Zonalon® (doxepin) cream 5%	Short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.*	A thin film of doxepin hydrochloride cream, 5% 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 hydrochloride cream, 5% when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin hydrochloride cream, 5% for longer than 8 days may result in an increased likelihood of contact sensitization. Drowsiness is significantly more common in patients applying doxepin cream to over 10% of body surface area.

*Pediatric use is not recommended. There was a case of a 2.5 year old who developed somnolence, grand mal

seizure, respiratory depression, ECG abnormalities, and coma after treatment of doxepin cream.

CLINICAL RATIONALE

Atopic Dermatitis

Recommended topical therapy for atopic dermatitis includes topical corticosteroids, intralesional corticosteroids, as well as topical calcineurin inhibitors. While topical doxepin does provide short-term decrease in pruritus, it is not recommended for atopic dermatitis by the American Academy of Dermatology Association due to the risk of absorption and contact dermatitis.[4] UptoDate lists topical doxepin as an option for treating atopic dermatitis pruritus after sedating and non-sedating antihistamines have failed.[5]

Lichen Simplex Chronicus

The treatment of lichen simplex chronicus centers on the discontinuation of the itch/scratch cycle.[6,7] Topical corticosteroids and intralesional corticosteroids are commonly used therapies.[6,7] Oral antihistamines is a systemic option for less localized pruritus.[6,7] Doxepin is an option for local treatment of pruruitis.[6]

Safety

Doxepin cream is contraindicated in the following:[1]

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention.
- Individuals who have shown previous sensitivity to any of its components.

Prudoxin is contraindicated in the following:[2]

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention.
- Individuals who have shown previous sensitivity to any of its components.

Zonalon is contraindicated in the following:[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

1. Doxepin prescribing information. Renaissance Pharma, Inc. February 2016.
2. Prudoxin prescribing information. Prestium Pharma, Inc. June 2015.
3. Zonalon prescribing information. PharmaDerm. March 2012.
4. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. Journal of the American Academy of Dermatology. 2014 Feb;70(2):338-51.
5. Treatment of atopic dermatitis (eczema). UptoDate. Current through 4/2017. Last updated 4/10/2017. Accessed 5/16/2017.
6. Pruritus: overview of management. UptoDate. Current through 4/2017. Last updated 5/23/2016. Accessed 5/16/2017.
7. Lichen simplex (syn. circumscribed neurodermatitis). Primary Care Dermatology Society. Created 10/2013. Last updated 12/13/2016.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.