

# Topical Immunomodulators Effective 05/01/2025

Plan	<ul><li>☐ MassHealth UPPL</li><li>☒ Commercial/Exchange</li></ul>	Duo ayon Tuno	☐ Prior Authorization
Benefit	<ul><li>☑ Pharmacy Benefit</li><li>☐ Medical Benefit</li></ul>	Program Type	<ul><li>☐ Quantity Limit</li><li>☑ Step Therapy</li></ul>
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact Information	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

#### Overview

Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of sale. If the prescription does not meet the initial step therapy requirements, the prescription will deny with a message indicating that prior authorization (PA) is required. Refer to the criteria below and submit a PA request for the members who do not meet the initial step therapy requirements at the point of sale.

### **Initial Step-Therapy Requirements:**

First-Line: Medications listed as first-line are covered without prior-authorization.

**Second-Line:** Second-line medications will pay if the member has filled at least two first-line medications or a second-line medication within the past 180 days.

### **Coverage Guidelines**

FIRST-LINE	SECOND-LINE
Generic corticosteroids (see appendix below)	Nujo 0.1% (tacrolimus) solution
Pimecrolimus 1% cream	
Tacrolimus 0.03% and 0.1% ointment	

For all medications, authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

#### OR

If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member meets the following criteria:

1. Member meets ONE of the following:

- a. The member has previously tried at least TWO (2) first-line (medium, high, or very high potency topical corticosteroids, pimecrolimus 1% cream, tacrolimus 0.03% and 0.1% ointment) medications AND has had a documented side effect, allergy, or treatment failure with all trialed agents
- b. Member is continuing treatment with a second-line medication

## Limitations

- 1. Approvals will be granted for 12 months
- 2. The following quantity limits apply:

Medication Name	Quantity Limit
Nujo solution	60 grams per 30 days
Pimecrolimus cream	30 grams per 30 days
Tacrolimus 0.03%, 0.1% ointment	30 grams per 30 days

## **Appendix**

<u>Topical Corticosteroid Reference (not all inclusive)</u>

Very High Potency	Dosage Form	Strength
augmented betamethasone dipropionate (Diprolene)	Ointment	0.05%
clobetasol propionate (Temovate, Olux)	Cream, Gel, Ointment, Sol, Foam	0.05%
diflorasone diacetate (Psorcon)	Ointment	0.05%

High Potency	Dosage Form	Strength
amcinonide	Cream, Lotion, Ointment	0.1%
augmented betamethasone dipropionate (Diprolene AF)	Cream	0.05%
Betamethasone dipropionate	Cream, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone (Topicort)	Cream, Ointment	0.25%
Desoximetasone (Topicort)	Cream, Gel	0.05%
diflorasone diacetate (Psorcon)	Cream	0.05%
Fluocinonide	Cream, Gel, Ointment, Solution	0.05%
Fluocinonide emollient base	Cream	0.05%
Triamcinolone acetonide (Kenalog)	Cream, Ointment	0.5%

Medium Potency	Dosage Form	Strength
Betamethasone dipropionate (Diprosone)	Lotion	0.05%
Betamethasone valerate	Cream, Lotion	0.1%
Desoximetasone (Topicort LP)	Cream	0.05%
Fluocinolone acetonide (Synalar)	Cream, Ointment	0.025%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate (Elocon)	Ointment	0.1%
Triamcinolone acetonide (Kenalog)	Cream, Lotion, Ointment	0.025%
Triamcinolone acetonide (Kenalog)	Cream, Lotion, Ointment	0.1%

#### References

1. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis. Section 2: Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71:116-32.



- 2. Elidel (pimecrolimus) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
- 3. Hanifin JM, Cooper KD, Ho VC, Kang S, Krafchik BR, Margolis DJ, et al. Guidelines of Care for Atopic Dermatitis. J Am Acad Dermatol. 2004 Mar;50(3):391-404.
- 4. Lebwohl M, Freeman AK, Chapman MS, et al. Tacrolimus ointment is effective for facial and intertriginous psoriasis. J Am Acad Dermatol 2004; 51:723.
- 5. Margolis DJ, Abuabara K, Hoffstad OJ, Wan J, Raimondo D, Bilker WB. Association between malignancy and topical use of pimecrolimus. JAMA Dermatol. 2014. Doi:10.1001/jamadermatol.2014.4305
- 6. National Psoriasis Foundation. Psoriasis [webpage on the internet]. 2014. Available at: http://www.psoriasis.org/psoriasis
- 7. Protopic (tacrolimus) [prescribing information]. Madison, NJ: LEO Pharma Inc; February 2019.
- 8. Weston WL, Howe W. Treatment of atopic dermatitis (eczema). In: Basow DS (Ed). UpToDate [database on the internet]. 2015. Available at: http://www.utdonline.com/utd/index/do

#### **Review History**

06/27/05 - Updated

04/24/06 - Reviewed

04/23/07 - Reviewed

04/28/08 - Reviewed

04/27/09 - Updated

04/26/10 - Updated

04/25/11 - Updated

04/23/12 - Reviewed

04/22/13 - Reviewed

04/28/14 – Updated

03/09/15 – Tacrolimus generic

04/27/15 - Reviewed

04/25/16 - Reviewed

06/26/17 – Updated

02/26/18 - Reviewed

02/20/19 - Updated

11/16/2020 - Updated; separated out MH vs. Comm/Exch criteria due to MH partial unified formulary.

02/08/2023 – Reviewed and Updated for Feb P&T; added new drug Nujo as a second line agent. Effective 05/01/2023

07/10/2024 – Reviewed and Updated for July P&T; updated prior authorization criteria to mirror the step therapy edit; clarified that members are considered new to the Plan if they joined within the previous 90 days; effective 08/01/2024.

02/12/2025 – Reviewed and updated for February P&T. Updated policy to indicate that tacrolimus and pimecrolimus will be covered without prior authorization. Updated criteria for second-line agent to allow for approval if the member is continuing treatment with the agent. Effective 05/01/2025.

