

# Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit

## Anzupgo

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Anzupgo	delgocitinib

### Indications

#### FDA-approved Indications

Anzupgo is indicated for the topical treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable.

#### Limitations of Use

Use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended.

### Initial Step Therapy with Quantity Limit

Include Prescription (Rx) and Over-the-counter (OTC) products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then a quantity limit will apply. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a PA is required.

## Initial Limit Quantity

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Anzupgo (delgocitinib)	60 grams / 25 days	180 grams / 75 days

Table 1: Examples of Medium or Higher Potency Topical Corticosteroids<sup>4</sup>

Potency	Drug
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
Medium Potency	betamethasone valerate cream/lotion 0.1%/foam 0.12%
Medium Potency	clocortolone pivalate cream 0.1%
Medium Potency	desonide lotion, ointment 0.05%
Medium Potency	desoximetasone cream 0.05%
Medium Potency	fluocinolone acetonide cream/ointment/kit 0.025%
Medium Potency	flurandrenolide cream/ointment/lotion 0.05%
Medium Potency	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
Medium Potency	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
Medium Potency	hydrocortisone probutate cream 0.1%
Medium Potency	hydrocortisone valerate cream/ointment 0.2%
Medium Potency	mometasone furoate cream/lotion/solution 0.1%
Medium Potency	prednicarbate cream/ointment 0.1%

Potency	Drug
Medium Potency	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion 0.025%
Medium Potency	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
High Potency	betamethasone dipropionate cream/ointment 0.05%
High Potency	betamethasone dipropionate augmented cream/lotion 0.05%
High Potency	betamethasone valerate ointment 0.1%
High Potency	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%
High Potency	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
High Potency	halcinonide cream/ointment 0.1%
High Potency	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%
High Potency	mometasone furoate ointment 0.1%
High Potency	triamcinolone acetonide aerosol solution 0.147 mg/g
High Potency	triamcinolone acetonide cream/ointment 0.5%
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
Very High Potency	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
Very High Potency	diflorasone diacetate ointment 0.05%
Very High Potency	flurandrenolide tape 4mcg/cm <sup>2</sup>
Very High Potency	halobetasol propionate cream/ointment/lotion/kit 0.05%
Very High Potency	fluocinonide cream 0.1%

## Coverage Criteria

### Chronic Hand Eczema

Authorization may be granted when the requested drug is being prescribed for the topical treatment of moderate to severe chronic hand eczema in an adult patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with other janus kinase (JAK) inhibitors or potent immunosuppressants.
- The patient meets ONE of the following:

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7117-E

- The patient has experienced an inadequate treatment response to a medium or higher potency topical corticosteroid.
- A medium or higher potency topical corticosteroid is NOT advisable for the patient.

## Continuation of Therapy

### Chronic Hand Eczema

Authorization may be granted when the requested drug is being prescribed for the topical treatment of moderate to severe chronic hand eczema in an adult patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with other janus kinase (JAK) inhibitors or potent immunosuppressants.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)].

## Quantity Limits Apply

60 grams per 25 days or 180 grams per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

## Duration of Approval (DOA)

- 7117-E: Initial therapy DOA: 5 months; Continuation of therapy DOA: 12 months

## References

1. Anzupgo [package insert]. Madison, NJ: LEO Pharma Inc.; July 2025.
2. Efficacy and Safety of Delgocitinib Cream in Adults with Moderate to Severe Chronic Hand Eczema (DELTA 1). ClinicalTrials.gov identifier: NCT04871711. Updated April 8, 2025. Accessed July 29, 2025. <https://clinicaltrials.gov/study/NCT04871711>.
3. Efficacy and Safety of Delgocitinib Cream in Adults with Moderate to Severe Chronic Hand Eczema (DELTA 2). ClinicalTrials.gov identifier: NCT04872101. Updated April 8, 2025. Accessed July 29, 2025. <https://clinicaltrials.gov/study/NCT04872101>.

Reference number(s)
7117-E

4. Eichenfield LF, Tom WL, 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.
5. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. December 26, 2024. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed July 28, 2025.