

DRUG POLICY

Anzupgo® (delgocitinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial requests:
 - a. Chart notes and medical record documentation of hand eczema persisting for more than 3 months or recurring more than or equal to 2 times within a 12-month time frame.
 - b. Chart notes, medical record documentation, and claims history of prerequisite therapies (including topical calcineurin inhibitors and topical corticosteroids) including dosage, duration, and response to therapy. If prerequisite therapy is not advisable, documentation of why topical calcineurin inhibitors and/or topical corticosteroids are not advisable for the patient.

2. Continuation requests: Documentation (e.g., chart notes) that the patient has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

Prescriber Specialties (initial approvals only)

The requested medication must be prescribed by or in consultation with one of the following:

1. Dermatologist
2. Allergist/immunologist

Criteria for Initial Approval

Chronic Hand Eczema

1. Authorization of **6 months** may be granted to adult members for the topical treatment of moderate to severe chronic hand eczema when ALL of the following criteria are met:
 - A. The requested drug is NOT being prescribed in combination with any other janus kinase (JAK) inhibitors or potent immunosuppressants.
 - B. Member has had hand eczema persisting for more than 3 months or recurring more than or equal to 2 times within a 12-month time frame.
 - C. Member has had an inadequate treatment response to both of the following:
 - i. A medium potency to super-high potency topical corticosteroid (TCS) (see Appendix), or the use of topical corticosteroids is not advisable for the patient (e.g., due to contraindications, prior intolerances).
 - ii. A topical calcineurin inhibitor (TCI) (e.g., tacrolimus), or the use of a topical calcineurin inhibitor is not advisable for the patient (e.g., due to contraindications, prior intolerances).

Continuation of Therapy

Chronic Hand Eczema

1. Authorization of **12 months** may be granted to adult members for the topical treatment of moderate to severe chronic hand eczema when ALL of the following criteria are met:
 - A. The requested drug is NOT being prescribed in combination with any other janus kinase (JAK) inhibitors or potent immunosuppressants.
 - B. The patient has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of chronic hand eczema (e.g., redness, swelling, dry skin, erosions, oozing/crusting, itching).

Other

Anzupgo® (delgocitinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Anzupgo® (delgocitinib) 2% topical cream	60 grams per 30 days	Apply a thin layer twice daily, to the affected areas only on the hands and wrists. <i>Do not use more than 30 grams per 2 weeks or 60 grams per month.</i>

Appendix

Relative potency of select topical corticosteroid products			
Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
III. High potency (group 3)	Halobetasol propionate	Lotion	0.01%
	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%

		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment, Cream, Lotion	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream, ointment	0.1% and 0.05%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, Lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Anzupgo [package insert]. Madison, NJ: LEO Pharma Inc.; July 2025.
- 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 February 2026. <https://clinicaltrials.gov/study/NCT04871711>.
- 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 February 2026. <https://clinicaltrials.gov/study/NCT04872101>.
- 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.
- 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 February 2026.

POLICY HISTORY

Policy #: 05.06.08

Original Effective Date: December 9, 2025

Reviewed: August 2026

Revised:

Current Effective Date: December 9, 2025