Original Effective Date: 12/11/2025
Current Effective Date: 12/11/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 04/2026
Policy Number: C29884-A

Anzupgo (delgocitinib)

PRODUCTS AFFECTED

Anzupgo (delgocitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to Severe Chronic Hand Eczema (CHE)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MODERATE TO SEVERE CHRONIC HAND ECZEMA (CHE):
   1. Documented diagnosis of moderate to severe chronic hand eczema (CHE) such as atopic dermatitis, contact dermatitis, allergic dermatitis, etc.
      AND

2. Documentation that the body surface area (BSA) affected is the hands only OR documentation that treatment area will be limited to the hands only
   AND
3. Documentation of hand eczema persisting for greater than 3 months or recurring at least two times within 12-month time frame
   AND
4. Documentation of inadequate response, serious side effects, or contraindication to TWO of the following: topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus)
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., eczematous lesions, pruritus, frequency and duration of flares)

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE CHRONIC HAND ECZEMA (CHE):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation that member's condition has improved based upon the prescriber's assessment of disease control and clinical improvements while on therapy (e.g., improvements in severity of eczematous lesions, decrease in pruritus severity, decrease in frequency or duration of flares)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum of 30 grams/2 weeks

PLACE OF ADMINISTRATION:

The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical

DRUG CLASS:

Atopic Dermatitis - Janus Kinase (JAK) Inhibitors

FDA-APPROVED USES:

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.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

Topical Steroids by Potency

Very High Potency

Betamethasone dipropionate (augmented)
Clobetasol
Diflorasone diacetate ointment
Halobetasol

High Potency

Amcinonide
Betamethasone dipropionate
Desoximetasone gel, ointment, or cream 0.25% or more
Diflorasone diacetate cream
Fluocinolone cream 0.2% or more
Fluocinonide
Halcinonide
Triamcinolone 0.5% or more

Medium Potency

Beclomethasone
Betamethasone benzoate
Betamethasone valerate
Hydrocortisone acetate
Clobetasone
Clocortolone
Desoximetasone cream less than 0.25%
Diflucortolone
Fluocinolone ointment or topical solution or cream less than 0.2%
Flurandrenolide 0.025% or more
Fluticasone
Hydrocortisone butyrate
Hydrocortisone valerate
Mometasone
Prednicarbate
Triamcinolone less than 0.5%

Low Potency

Alclometasone
Desonide
Dexamethasone
Flumethasone
Flurandrenolide less than 0.025%
Hydrocortisone

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Chronic hand eczema (CHE) is a chronic, inflammatory skin condition characterized by redness, itching, scaling, fissuring, and pain localized to the hands and wrists. It affects approximately 10% of adults globally and poses a significant burden on daily functioning and quality of life. Standard first-line treatment consists of emollients and topical corticosteroids; however, long-term corticosteroid use is limited by side effects such as skin atrophy, and many patients experience inadequate response or contraindications to corticosteroids.

Anzupgo (delgocitinib) is the first and only FDA-approved topical pan-JAK inhibitor indicated for moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable. By inhibiting JAK1, JAK2, JAK3, and tyrosine kinase 2 (TYK2), topical delgocitinib offers a non-steroidal, targeted anti-inflammatory treatment that addresses the underlying cytokine-mediated pathology of CHE.

The FDA approval was based on data from two pivotal Phase 3 trials, DELTA 1 (NCT04871711) and DELTA 2 (NCT04872101), which demonstrated statistically significant improvements at Week 16 in both clinician-assessed outcomes (Investigator's Global Assessment for CHE treatment success: 20% vs. 10% in DELTA 1, and 29% vs. 7% in DELTA 2 compared to placebo) and patient-reported outcomes (≥4-point reductions in itch and pain; itch: 47% vs. 20-23%; pain: 49% vs. 23-28%). Durability of response and safety were confirmed in the 36-week open-label extension trial (DELTA 3). The safety profile is favorable, with adverse events such as application site reactions, pruritus, and minor skin infections reported in ≤1% of patients; systemic exposure is minimal.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Anzupgo (delgocitinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Anzupgo (delgocitinib) include: Avoid use of Anzupgo in patients with an active or serious infection, avoid vaccination with live vaccines immediately prior to, during, and immediately after Anzupgo treatment.

Exclusions/Discontinuation:

Do not use concurrently with other JAK inhibitors or potent immunosuppressants.

OTHER SPECIAL CONSIDERATIONS:

Instruct patients to apply a thin layer of Anzupgo, twice daily, to the affected areas only on the hands and wrists.
Do not use more than 30 grams per 2 weeks. Anzupgo is for topical use only. Not for oral, ophthalmic, or intravaginal use.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover*

claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Anzupgo CREA 20MG/GM 30-gram tube

REFERENCES

1. Anzupgo (delgocitinib) cream, for topical use [prescribing information]. Madison, NJ: LEO Pharma Inc; July 2025.
2. Bissonnette R, Warren RB, Pinter A, et al. Efficacy and safety of delgocitinib cream in adults with moderate to severe chronic hand eczema (DELTA 1 and DELTA 2): results from multicentre, randomised, controlled, double-blind, phase 3 trials. Lancet. 2024;404(10451):461-473. doi:10.1016/S0140-6736(24)01027-4 [PubMed 39033766]
3. Mense, S.A., et al. A practical approach to chronic hand eczema. Dermatol Ther (Heidelb) 15, 1953–1971 (2025). doi:10.1007/s13555-025-01433-y
4. Quaade AS, et al. Chronic hand eczema: A prevalent disease in the general population associated with reduced quality of life and poor overall health measures. Contact Dermatitis. 2023;89(6):453–463. doi:10.1111/cod.14407
5. Ruff SMD, et al. The association between atopic dermatitis and hand eczema: a systematic review and meta-analysis. Br J Dermatol. 2018;178(4):879–888. doi:10.1111/bjd.16147
6. Thaçi D, Gooderham M, Lovato P, Madsen DE, Soehoel A, Bissonnette R. Systemic exposure and bioavailability of delgocitinib cream in adults with moderate to severe chronic hand eczema. J Eur Acad Dermatol Venereol. Published online June 17, 2025. doi:10.1111/jdv.20777 [PubMed 40525591]
7. Thyssen JP, et al. Guidelines for diagnosis, prevention, and treatment of hand eczema. Contact Dermatitis. 2022;86(5):357–378. doi:10.1111/cod.14035
8. Weidinger, Stephan et al. Hand eczema. Lancet. 2024;404(10470):2476–2486. doi:10.1016/S0140-6736(24)01810-5

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2025