# Clinical Policy: Delgocitinib (Anzupgo)

Reference Number: CP.PHAR.744
Effective Date: 12.01.25
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Delgocitinib (Anzupgo®) is a Janus kinase (JAK) inhibitor.

## FDA Approved Indication(s)

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.

Limitation(s) of use: Use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended.

## Policy/Criteria

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Anzupgo is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Chronic Hand Eczema** (must meet all)**:**

1. Diagnosis of CHE;
2. Member has hand eczema that has persisted for > 3 months or returned twice or more within the last 12 months;
3. Provider attestation that member has moderate to severe hand eczema (*see Appendix D*);
4. Prescribed by or in consultation with a dermatologist or allergist;
5. Age ≥ 18 years;
6. One of the following (a or b):
   a. For Illinois HIM requests only: Failure of one formulary topical corticosteroid, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B)*;
   b. For all other requests: Failure of both of the following (i and ii), unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B)*;*
      i. One formulary topical corticosteroid used for ≥ 2 weeks;
      ii. One of the following (1 or 2):
         1) A second formulary topical corticosteroid used for ≥ 2 weeks;

2) One topical calcineurin inhibitor* used for ≥ 4 weeks;
**Prior authorization may be required for topical calcineurin inhibitors*

7. Anzupgo is not prescribed concurrently with biologic medications (e.g., Dupixent®, Adbry®), biologic disease-modifying antirheumatic drugs (e.g., Humira®, Enbrel®, Taltz®, Stelara®), JAK inhibitors (e.g., Cibinqo®, Opzelura™, Xeljanz®, Rinvoq®, Olumiant®), or potent immunosuppressants (e.g., azathioprine, cyclosporine);
8. Dose does not exceed both of the following (a and b):
   a. One 30-gram tube per 2 weeks;
   b. 60 grams per month.

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Chronic Hand Eczema** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching, no signs of erythema, scaling, hyperkeratosis/lichenification, vesiculation, edema, or fissures;
3. Anzupgo is not prescribed concurrently with biologic medications (e.g., Dupixent, Adbry), biologic disease-modifying antirheumatic drugs (e.g., Humira, Enbrel, Taltz, Stelara), JAK inhibitors (e.g., Cibinqo, Opzelura, Xeljanz, Rinvoq, Olumiant), or potent immunosuppressants (e.g., azathioprine, cyclosporine);

4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. One 30-gram tube per 2 weeks;
   b. 60 grams per month.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
CHE: chronic hand eczema
FDA: Food and Drug Administration
PGA: Physician Global Assessment

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Very High Potency Topical Corticosteroids** | | |
| augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion | Apply topically to the affected area(s) BID | Varies |
| clobetasol propionate 0.05% (Temovate® ) cream, ointment, gel, solution | | |
| diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment | | |
| halobetasol propionate 0.05% (Ultravate®) cream, ointment | | |
| **High Potency Topical Corticosteroids** | | |
| augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion | Apply topically to the affected area(s) BID | Varies |
| diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream | | |
| fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution | | |
| triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment | | |
| **Medium Potency Topical Corticosteroids** | | |
| desoximetasone 0.05% (Topicort ®) cream, ointment, gel | Apply topically to the affected area(s) BID | Varies |
| fluocinolone acetonide 0.025% (Synalar®) cream, ointment | | |
| mometasone 0.1% (Elocon®) cream, ointment, lotion | | |
| triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment | | |
| **Low Potency Topical Corticosteroids** | | |
| alclometasone 0.05% (Aclovate®) cream, ointment | Apply topically to the affected area(s) BID | Varies |
| desonide 0.05% (Desowen®) cream, ointment, lotion | | |
| fluocinolone acetonide 0.01% (Synalar®) solution | | |
| hydrocortisone 2.5% (Hytone®) cream, ointment | | |
| **Topical Calcineurin Inhibitors** | | |
| tacrolimus (Protopic®), pimecrolimus (Elidel®) | Children ≥ 2 years and adults: Apply a thin layer topically to affected skin | Varies |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Very High Potency Topical Corticosteroids** | | |
| | BID. Treatment should be discontinued if resolution of disease occurs. | |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
None reported

*Appendix D: General Information*

- The DELTA 1 and DELTA 2 clinical trials utilized the Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE) to assess and enroll participants with moderate to severe hand eczema (score of 3 or 4). This was defined as at least one clearly perceptible or marked erythema (dull red, deep, or bright red), scaling (thick or coarse scales), or hyperkeratosis/lichenification. Additionally, at least one clustered or high density vesicle, definite or marked edema, or definite or deep fissures was required.
- The Physician Global Assessment (PGA) is a simple tool that involves the evaluation of the intensity of the skin changes and the extent of involvement. PGA defines moderate eczema by the presence of two or more mild to moderate skin changes (erythema, scaling, hyperkeratosis, lichenification, vesiculation, edema, fissures, pruritus, and pain) involving 10% to 30% of the hand surface. Severe eczema is defined by the presence of two or more moderate to severe skin changes (erythema, scaling, hyperkeratosis, lichenification, vesiculation, edema, fissures, pruritus, and pain) involving > 30% of the hand surface.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| CHE | Apply a thin layer twice daily to the affected areas only on the hands and wrists. | 30 g per 2 weeks or 60 g/month |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Delgocitinib (Anzupgo) | Cream: 2%, 30 g and 60 g tubes |

## VII. References

1. Anzupgo Prescribing Information. Madison, NJ: LEO Pharma Inc.: July 2025. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219155s000lbl.pdf. Accessed August 6, 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 Aug 3; 404(10451): 461-473.
3. Gooderham M, Molin S, Bissonnette R, et al. Long-term safety and efficacy of delgocitinib cream for up to 52 weeks in adults with Chronic Hand Eczema: Results of the phase 3 open-label extension DELTA 3 trial following the DELTA 1 and 2 trials. J Am Acad Dermatol. 2025 Jul; 93(1): 95-103.
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6. Eichenfield F, Tom WL, Chamlin SL et al. Guidelines of Care for the Management of Atopic Dermatitis. *J Am Acad Dermatol*. 2014; 70(2): 116-32.
7. Wong JTY, Tsuyuki RT, Cresswell-Melville A, et al. Guidelines for the management of atopic dermatitis (eczema) for pharmacists. *Can Pharm J (Ott)*. 2017;150(5):285-297.
8. Ference JD and Last AR. Choosing topical corticosteroids. *American Family Physician* Journal. 2009; 79(2):135-140.
9. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1):e1-e20.
10. Chu DK, Schnieder L, Asiniasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma, and Immunology Joint Task Force on practice parameters GRADE – and Institute of Medicine- based recommendations.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 08.06.25 | 11.25 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.