

Pharmacy Policy Bulletin: J-1462 Anzupgo (delgocitinib) – Commercial and Healthcare Reform	
Number: J-1462	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-1462-001	Original Date: 09/17/2025
Effective Date: 10/08/2025	Review Date: 09/17/2025

Drugs Product(s):	Anzupgo (delgocitinib)
FDA-Approved Indication(s):	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.

Background:	- Anzupgo (delgocitinib) is a self-administered, topical Janus kinase (JAK) inhibitor. While the exact mechanism of action of Anzupgo is unknown, Anzupgo inhibits the activity of JAK1, JAK2, JAK3, which are involved in recruiting signal transducers and activators of transcription (STAT) to cytokine receptors, which leads to the expression of genes that induce specific biological responses in target cells. CHE - CHE is defined as hand eczema (HE) that lasts for three or more months or relapses twice or more within a year. It affects approximately every one in ten patients worldwide and is a fluctuating disorder characterized by itch and pain; specifically, patients may experience signs such as erythema, scaling, lichenification, hyperkeratosis, vesicles, edema, and fissures on the hands and wrists. - CHE has six main subtypes: irritant contact eczema, allergic contact dermatitis, atopic HE, protein contact eczema, dyshidrotic HE, and hyperkeratotic HE. CHE differs from broader atopic dermatitis (AD) and other forms of eczema such as nummular and xerotic because of its exclusive localization, complex triggers (for example, occupational links), and challenging management (for example, high recurrence). The pathophysiology is characterized by skin barrier dysfunction, inflammation of the skin, and alterations of the skin microbiome, all of which can significantly impact patient quality of life. - According to the 2022 European Society of Contact Dermatitis guidelines for HE, topical therapies, such as emollients and topical corticosteroids (TCS), are the mainstay of treatment for CHE.
--------------------	---

- TCS are recommended first-line for short-term relief of CHE, but because high and super-high potency TCS (for example, mometasone, clobetasol propionate) can inhibit repair of the stratum corneum, inducing skin atrophy and impairing barrier function, long term daily (specifically, off-label) use should be avoided. Furthermore, allergic contact dermatitis caused by a TCS or its vehicle is not uncommon.
- Topical tacrolimus, which is indicated as second-line therapy for short-term and non-continuous chronic treatment of moderate to severe AD, can be used for the atopic HE subtype (or off-label for the others) as a steroid-sparing option for mild to moderate disease and as an alternative in patients with contact allergy to TCS.
- Severity of CHE is defined by the Physician Global Assessment (PGA)
 - Mild: two or more mild skin changes (erythema, scaling, hyperkeratosis, lichenification, vesiculation, edema, fissures, pruritus, and pain) involving < 10 percent of the hand surface
 - Moderate: two or more mild to moderate skin changes (erythema, scaling, hyperkeratosis, lichenification, vesiculation, edema, fissures, pruritus, and pain) involving 10 to 30 percent of the hand surface
 - Severe: two or more moderate to severe skin changes (erythema, scaling, hyperkeratosis, lichenification, vesiculation, edema, fissures, pruritus, and pain) involving >30 percent of the hand surface

Table 1. Preferred Topical Corticosteroid Examples

Medium potency	High potency	Super-high potency
Fluocinolone acetonide 0.025% cream or ointment	Betamethasone dipropionate 0.05% ointment or cream	Betamethasone dipropionate augmented 0.05% ointment
Fluticasone propionate 0.05% cream	Betamethasone valerate 0.1% ointment	Clobetasol propionate 0.05% cream, foam, gel, ointment
Hydrocortisone valerate 0.2% cream or ointment	Desoximetasone 0.25% cream or ointment	Fluocinonide 0.1% cream
Mometasone furoate 0.1% cream, ointment, or solution	Fluocinonide 0.05% ointment, gel, cream, solution	Halobetasol propionate 0.05% cream or ointment
Triamcinolone 0.025% or 0.1% cream, lotion, or ointment	Triamcinolone acetonide 0.5% ointment or cream	

- ICD-10 Code Information:
 - ICD-10: L30 (“other and unspecified dermatitis”) may apply to Anzupgo; however, the prescriber must confirm that the member has a specific diagnosis of CHE.
- Prescribing Considerations:
 - Apply a thin layer of Anzupgo twice daily to affected areas only on the hands and wrists.
 - Anzupgo does not have a limitation on the duration of treatment.
 - Anzupgo does not have significant contraindications to use but does have warnings and precautions for serious infections, non-melanoma skin cancers, immunizations, and potential risks related to JAK inhibition.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Anzupgo may be approved when all of the following criteria are met **(A. through D.)**:

- A.** The member is 18 years of age or older.
- B.** The member has a diagnosis of CHE (no ICD-10 code).
- C.** The member has documentation of one (1) of the following **(1. or 2.)**:
 - 1.** HE persisting for > 3 months
 - 2.** HE recurring ≥ 2 times within a 12-month time frame
- D.** The member has experienced therapeutic failure, contraindication, or intolerance to at least one generic, formulary(1) medium, high, or super-high potency TCS (for example, clobetasol propionate, betamethasone dipropionate).

II. Reauthorization

When a benefit, reauthorization of Anzupgo may be approved when the following criterion is met **(A.)**:

- A.** The prescriber attests that the member has experienced positive clinical response to therapy.

- III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization –

- Commercial and HCR Plans: If approved, up to a 4 month authorization may be granted.

Reauthorization –

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Anzupgo [package insert]. Madison, NJ: LEO Pharma Inc.; July 2025.
2. National Eczema Association. Chronic Hand Eczema 101. Available at: 9661-0027_NEA_Factsheets_Chronic_Hand_Eczema_101.pdf
3. Lee GR, Maarouf M, Hendricks AK, Lee DE, et al. Current and emerging therapies for hand eczema. *Dermatol Ther.* 2019;32(3):e12840.
4. Quaade AS, Simonsen AB, Halling A-S, et al. Prevalence, incidence, and severity of hand eczema in the general population – A systematic review and meta-analysis. *Contact Dermatitis.* 2021;84:361–374.

5. Bissonnette R, Agner T, Molin S, et al. Hand Eczema. Part 1: epidemiology, pathogenesis, diagnosis and work-up. *J Am Acad Dermatol*. 2024 Oct 5:S0190-9622(24)02952-9.
6. Bissonnette R, Agner T, Taylor JS, et al. Hand Eczema. Part 2: Prevention, management, and treatment. *J Am Acad Dermatol*. 2024 Oct 5:S0190-9622(24)02953-0.
7. Weisshaar E. Chronic Hand Eczema. *Am J Clin Dermatol*. 2024 Nov;25(6):909-926.
8. Thyssen JP, Schuttelaar MLA, Alfonso JH, et al. Guidelines for diagnosis, prevention, and treatment of hand eczema. *Contact Dermatitis*. 2022;86(5):357-378.
9. Silverberg JI, Agner T, Baranowski K, Plohberger U, Thoning H, Arbuckle R, Grant L, Skingley G, Bissonnette R. Validation of the Investigator Global Assessment of Chronic Hand Eczema (IGA-CHE): a new clinician reported outcome measure of CHE severity. *Arch Dermatol Res*. 2024 Mar 20;316(4):110.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect Highmark's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

Highmark retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of Highmark. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.