

ANZUPGO (delgocitinib) cream

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Chronic Hand Eczema

Anzupgo is a Janus kinase (JAK) inhibitor 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 of Use: Use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Chronic Hand Eczema (CHE)

Authorization of 12 months may be granted for treatment of moderate to severe CHE when all of the following criteria are met:

- A. Member is 18 years of age or older
- B. Medication is prescribed by, or in consultation with, a dermatologist or allergist/immunologist
- C. Documentation that member has a confirmed diagnosis of chronic hand eczema (CHE) that has persisted for more than three months or recurred two or more times within a 12- month time frame after the initial occurrence with complete clearances between relapses
- D. Documentation of moderate to severe disease activity, with signs and symptoms of pruritus (itching), burning, stinging, erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, and/or lichenification (epidermal thickening)
- E. Documentation that the member experienced an inadequate treatment response to at least one medium or higher potency topical corticosteroid, or a medium or higher potency topical corticosteroid is NOT advisable for the member. Contraindications, adverse effects and/or intolerance must be documented.
- F. Documentation that the member experienced an inadequate treatment response or intolerance to tacrolimus ointment. Contraindications, adverse effects and/or intolerance must be documented.
- G. Member is not immunocompromised
- H. Anzupgo will not be used concomitantly with any therapeutic biologic drug, any targeted synthetic drug, Opzelura (ruxolitinib) cream, Vtama (tapinoraf) cream, Zoryve (roflumilast) cream, systemic JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members requesting continuation of therapy when the following criteria are met:

- A. Documentation that member has achieved or maintained a positive clinical response evidenced by low disease activity (i.e., clear or almost clear skin), or clinical improvement in signs and symptoms of CHE [e.g.,

improvement in erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), or pruritus (itching)]

- B. Medication continues to be prescribed by, or in consultation with, a dermatologist or allergist/immunologist
- C. Anzupgo will not be used concomitantly with any therapeutic biologic drug, any targeted synthetic drug, Opzelura (ruxolitinib) cream, Vtama (tapinoraf) cream, Zoryve (roflumilast) cream, systemic JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine.

IV. QUANTITY LIMIT

Anzupgo has a quantity limit of 30 grams per 2 weeks.

V. REFERENCES

1. Anzupgo [package insert]. Madison, NJ: LEO Pharma Inc.; July 2025.
2. Thyssen JP, Schuttelaar MLA, Alfonso JH, et al. Guidelines for diagnosis, prevention, and treatment of hand eczema. *Contact Dermatitis*. 2022; 86(5): 357-378.