

PRIOR AUTHORIZATION POLICY

POLICY: Dermatology – Anzupgo Prior Authorization Policy

- Anzupgo® (delgocitinib 2% cream – LEO)

REVIEW DATE: 08/27/2025

OVERVIEW

Anzupgo, a Janus kinase (JAK) inhibitor, is indicated for the topical treatment of moderate to severe **chronic hand eczema** in patients ≥ 18 years of age who have had an inadequate response to topical corticosteroids or for whom topical corticosteroids are not advisable.¹

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

Clinical Efficacy

Two pivotal Anzupgo studies enrolled patients ≥ 18 years of age with hand eczema that was present for > 3 months or returned twice or more within the previous 12 month period.² Patients had experienced an inadequate response to treatment with a topical corticosteroid in the previous year (99% of patients), except for patients for whom topical corticosteroids were deemed medically inadvisable (1% of patients). An inadequate response was the failure to maintain clear or almost clear skin despite daily topical corticosteroid application for ≥ 28 days or for the maximum duration recommended by the product prescribing information, whichever was shorter. A potent to very potent topical corticosteroid was required in Europe, while a medium- to ultra-high potency topical corticosteroid was required in Canada. Patients who had previously received treatment with a systemic or topical JAK inhibitor were excluded from study participation. The primary endpoint was evaluated following 16 weeks of treatment.

Guidelines

The European Society of Contact Dermatitis guidelines for the diagnosis, prevention, and treatment of hand eczema (2022) have not been updated since the approval of Anzupgo and list it as a possible future treatment.³ Following secondary prevention strategies, topical corticosteroids are recommended for short-term, first-line treatment of hand eczema. Intermittent, long-term use of topical corticosteroids may be considered for chronic disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Anzupgo cream. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Anzupgo cream as well as the monitoring required for adverse events and long-term efficacy, approval requires Anzupgo cream to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Anzupgo is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Chronic Hand Eczema.** Approve for 4 months if the patient meets ALL of the following (A, B, C, D, and E):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has hand eczema that has been present for > 3 months or has returned at least twice in a year after its initial presentation and subsequent clearance; AND
 - C) According to the prescriber, patient has moderate to severe chronic hand eczema; AND
 - D) Patient meets ALL of the following (i, ii, and iii):
 - i. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
 - ii. This topical corticosteroid was applied daily for at least 28 consecutive days; AND
 - iii. According to the prescriber, inadequate efficacy was demonstrated with this topical corticosteroid therapy; OR
 - E) The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Anzupgo is not recommended in the following situations:

1. **Concurrent Use with other JAK inhibitors.** Use of Anzupgo in combination with other JAK inhibitors is not recommended (see Appendix for examples).¹ Use of other topical or systemic JAK inhibitors was prohibited prior to and during the Anzupgo pivotal studies.² There are no data evaluating combination use of Anzupgo with these therapies; therefore, safety and efficacy of these combinations are unknown.
2. **Concurrent use with Potent Immunosuppressants.** Use of Anzupgo in combination with potent immunosuppressants is not recommended.¹ Use of systemic immunosuppressants was prohibited during the Anzupgo pivotal studies.² There are no data evaluating combination of Anzupgo with these therapies; therefore, safety and efficacy of these combinations are unknown.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Anzupgo[®] cream [prescribing information]. Madison, NJ: LEO; 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, randomized, controlled, double-blind, phase 3 trials. *Lancet*. 2024;404(10451):461-473.
3. Thyssen JP, Schuttelaar MLA, Alfonso JH, et al. Guidelines for diagnosis, prevention, and treatment of hand eczema. *Contact Dermatitis*. 2022;86(5):357-378.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/27/2025

APPENDIX**Table 1. Examples of Other JAK Inhibitors.**

Product	Mechanism of Action
Inrebic [®] (fedratinib tablets)	Inhibition of JAK pathways
Jakafi [®] (ruxolitinib tablets)	Inhibition of JAK pathways
Leqselvi [™] (deuruxolitinib tablets)	Inhibition of JAK pathways
Olumiant [®] (baricitinib tablets)	Inhibition of JAK pathways
Cibinqo [®] (abrocitinib tablets)	Inhibition of JAK pathways
Rinvoq [®] (upadacitinib extended-release tablets)	Inhibition of JAK pathways
Rinvoq [®] LQ (upadacitinib oral solution)	Inhibition of JAK pathways
Xeljanz [®] (tofacitinib tablets, oral solution)	Inhibition of JAK pathways
Xeljanz [®] XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways
Opzelura [®] (ruxolitinib cream)	Inhibition of JAK pathways

JAK – Janus kinase.