PRIOR AUTHORIZATION POLICY

POLICY: Dermatology – Anzupgo Prior Authorization Policy
- Anzupgo® (delgocitinib 2% cream – LEO)

REVIEW DATE: 08/27/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

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is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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.