

delgocitinib (Anzupgo[®])

Policy # 00950

Original Effective Date: 01/01/2026

Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider delgocitinib (Anzupgo[®])[‡] for the treatment of chronic hand eczema to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for delgocitinib (Anzupgo) will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of moderate to severe chronic hand eczema; AND
- Patient is 18 years of age or older; AND
- Patient has hand eczema that has been present for more than 3 months OR has returned twice or more within the last 12 months; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) treatment with TWO prescription topical corticosteroids of medium, medium-high, high, and/or super high potency for at least two consecutive weeks EACH unless there is clinical evidence or patient history that suggests the use of TWO prescription topical corticosteroids of medium, medium-high, high, and/or super high potency topical corticosteroids will be ineffective or cause an adverse reaction to the patient. Examples of medium, medium-high, high, or super-high potency prescription topical corticosteroids include betamethasone valerate, desoximetasone, fluocinolone acetonide, fluticasone propionate, mometasone furoate, triamcinolone acetonide 0.1%, trianex, triderm, amcinonide, augmented betamethasone dipropionate cream, apexicon E, betamethasone dipropionate, betamethasone valerate, desoximetasone, diflorasone diacetate, fluocinonide, fluocinonide E, triamcinolone acetonide 0.5%, augmented betamethasone dipropionate ointment, clobetasol emollient, clobetasol propionate, clodan, cormax, diflorasone diacetate, and halobetasol propionate; AND
- Requested medication will be applied only to affected areas of the hands and wrists; AND
- Requested medication will NOT be used in combination with therapeutic biologics (such as dupilumab [Dupixent][®])[‡], other Janus kinase (JAK) inhibitors (such as tofacitinib [Xeljanz/XR][®], upadacitinib [Rinvoq][®])[‡], or potent immunosuppressants (such as azathioprine or cyclosporine).

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Continuation

- Patient has received an initial authorization; AND
- Requested medication will NOT be used in combination with therapeutic biologics (such as dupilumab [Dupixent]), other Janus kinase (JAK) inhibitors (such as tofacitinib [Xeljanz/XR], upadacitinib [Rinvoq]), or potent immunosuppressants (such as azathioprine or cyclosporine); AND
- Patient has demonstrated a clinically meaningful beneficial response to Anzupgo therapy as compared to their baseline status (before Anzupgo therapy) as evidenced by at least TWO of the following:
 - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
 - Reduction in the frequency or intensity of pruritus
 - Reduction in the frequency of disease exacerbations/flare
 - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.).

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the continued use of delgocitinib (Anzupgo) when the patient has not demonstrated a clinically meaningful beneficial response to Anzupgo therapy as compared to their baseline status to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers use of delgocitinib (Anzupgo) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Anzupgo is a Janus kinase (JAK) inhibitor indicated for the topical treatment of moderate to severe chronic hand eczema (CHE) in adults aged 18 years and older who have had an inadequate response to topical corticosteroids or for whom topical corticosteroids are not advisable; use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended. Anzupgo should be applied twice daily (BID) as a thin layer to affected areas of skin on the hands and wrists only, with a maximum usage of 30 grams per 2 weeks or 60 grams per month. The product is available as a 2% cream in 30 gram and 60 gram tubes.

Hand eczema is a common inflammatory skin condition affecting the hands and wrists, with a one-year prevalence of about 10% and lifetime impact on roughly 14.5% of the general population. It is more frequent in women, peaking between ages 19 and 29, while incidence in men increases with

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age. Chronic hand eczema is defined as lasting at least three months or recurring twice in a year, and symptoms range from itching, pain, and burning to acute lesions like erythema and vesicles, and chronic changes such as scaling and fissures. Severity varies, but over one-third of patients experience moderate to severe disease, which can significantly affect quality of life. Multiple subtypes exist, including irritant contact dermatitis, atopic hand eczema, hyperkeratotic, vesicular, and allergic contact dermatitis, often overlapping in individual patients. Risk factors include atopic dermatitis, genetic mutations, contact allergies, occupational exposures, and environmental conditions. While guidelines recommend topical corticosteroids as first-line therapy, other recommended treatments include tacrolimus ointment, phototherapy, cyclosporine A, methotrexate, azathioprine, and acitretin capsules for specific subtypes or refractory cases. Anzupgo is the first and only FDA-approved medication specifically for chronic hand eczema, and US guidelines have not yet incorporated its use.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Anzupgo was approved in July 2025 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Anzupgo was demonstrated in two pivotal randomized, double-blind, vehicle-controlled trials (Trial 1 and Trial 2), each lasting 16 weeks and enrolling a total of 960 adult patients with moderate to severe chronic hand eczema who had an inadequate response to, or for whom topical corticosteroids were not advisable. In these studies, patients were randomized to receive either Anzupgo cream or vehicle (placebo) applied twice daily to affected areas. The primary endpoint in both studies was the proportion of patients achieving treatment success, defined as a rating of “clear” or “almost clear” skin with at least a 2-grade improvement from baseline on a validated Investigator’s Global Assessment for Chronic Hand Eczema (IGA-CHE) scale. Results showed that a significantly greater proportion of patients treated with Anzupgo achieved treatment success compared to those receiving vehicle. In Trial 1, 19.7% of Anzupgo-treated patients achieved treatment success, versus 9.9% for vehicle. In Trial 2, 29.1% of patients treated with Anzupgo achieved treatment success at week 16, compared to 6.9% in the vehicle group. Key secondary endpoints included a ≥ 4 -point reduction in weekly average Hand Eczema Symptom Diary (HESD) itch and pain scores, and improvements in the Hand Eczema Severity Index (HECSI). At Week 16, 47.1% (Trial 1) and 47.2% (Trial 2) of Anzupgo patients achieved a ≥ 4 -point improvement in HESD itch score, compared to 23.0% and 19.9% in the vehicle groups, respectively. For HESD pain, 49.1% (Trial 1) and 48.6% (Trial 2) of Anzupgo patients achieved a ≥ 4 -point improvement, versus 27.5%

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and 22.7% for vehicle. Regarding HECSI, 49.2% (Trial 1) and 49.5% (Trial 2) of Anzupgo patients achieved HECSI-75 ($\geq 75\%$ improvement from baseline) at Week 16, compared to 23.5% and 18.2% in the vehicle groups; HECSI-90 ($\geq 90\%$ improvement) was achieved by 29.5% (Trial 1) and 31.0% (Trial 2) of Anzupgo patients, versus 12.3% and 8.8% for vehicle. Anzupgo also led to greater improvements in Dermatology Life Quality Index (DLQI) scores.

References

1. Anzupgo [package insert]. Leo Pharma Inc. Madison, New Jersey. Updated July 2025.
2. Anzupgo Drug Evaluation. Express Scripts. Updated August 2025.

Policy History

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12/04/2025 Medical Policy Committee review

12/10/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 12/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.