Medical Exception and Medical Necessity Checklist

Anzupgo® (delgocitinib) cream 2%

A medical exception letter can be used to request coverage when ANZUPGO® (delgocitinib) is not on formulary, if a formulary decision has not yet been made, or if ANZUPGO is subject to an NDC block. Further, you may also consider submitting a letter that demonstrates the medical necessity of ANZUPGO for your patients. The checklist below provides suggestions for the type of information to include when a letter of medical exception and medical necessity is appropriate.

This is not an instructional guide, and information provided is not intended to be a substitute for, or an influence on, your independent medical judgment.

Patient information, diagnosis, and ICD-10-CM code(s)

- Patient name, date of birth, insurance information, and claim number should be included at the beginning of the letter for quick reference
- Include patient's diagnosis and appropriate ICD-10-CM code(s):

  Diagnosis: ANZUPGO is indicated for adults with moderate-to-severe Chronic Hand Eczema (CHE).[1]

  Example ICD-10-CM code(s)*:

Atopic dermatitis:	Allergic contact dermatitis:	Irritant contact dermatitis:	Protein contact dermatitis:	Acute, recurrent vesicular (dyshidrosis):	Hand dermatitis:
L20.89, L20.9	L23.0-L23.9	L24.0-L24.B3	L25.0-L25.9	L30.1	L30.8

Rationale for treatment

- Provide your rationale, based on your clinical discretion, for prescribing ANZUPGO (i.e., has your patient experienced a lack of response to other treatments? Are side effects to other treatments outweighing the benefits? Are first-line treatments not advisable for your patient?)[1]

Severity of condition and patient's symptoms

- Include details on the chronicity (i.e., Chronic Hand Eczema [CHE] >3 months or relapsed ≥2x within a year) and severity (i.e., if available, consider including results of an outcome measure used to document the severity) of your patient's CHE[1,2]
- Consider mentioning other details related to the impact of CHE on your patient's productivity and QoL
- Additional information about your patient's history, such as a high-risk occupation, comorbidities, allergies, etc., may also help strengthen your rationale for prescribing ANZUPGO

Treatment history

- Be sure to provide a list of previous treatments, including start and stop dates, reasons for discontinuation, and contraindications
- Confirm ANZUPGO will not be used with other JAK inhibitors (including topicals) or potent immunosuppressants[2]

Enclosures

Enclosures can provide important evidence to support the medical necessity of ANZUPGO for your patient.
These may include:

- ANZUPGO Prescribing Information
- Clinical trial publication(s)
- Clinical notes/medical records
- Documentation of age-appropriate vaccinations as recommended by current immunization guidelines, including herpes zoster vaccinations[1]
- Peer-reviewed literature
- Photos showing the severity of your patient's condition, indicating the therapy used at the time photos were taken
- Front-and-back copies of your patient's insurance card(s)

Click or scan the QR code for a Sample Letter of Medical Exception and Medical Necessity and other access resources.

Anzupgohcp.com/access-and-resources/resources

INDICATION

ANZUPGO is 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.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infections

ANZUPGO may increase the risk of infections. Eczema herpeticum was observed in a subject treated with ANZUPGO. Serious and sometimes fatal infections have been reported in patients receiving oral or topical JAK inhibitors. Avoid use of ANZUPGO in patients with an active or serious infection. Consider the risks and benefits of treatment prior to initiating ANZUPGO in patients with chronic or recurrent infection, who have been exposed to tuberculosis, with a history of a serious or an opportunistic infection, or with underlying conditions that may predispose them to infection.

Please see additional Important Safety Information on the next page and full Prescribing Information and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Serious Infections (cont'd)
Closely monitor patients for the development of signs and symptoms of infection during and after treatment with ANZUPGO. Interrupt treatment with ANZUPGO if a patient develops a serious infection. Do not resume ANZUPGO until the infection resolves or is adequately treated.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical trials with ANZUPGO. If a patient develops herpes zoster, consider interrupting ANZUPGO treatment until the episode resolves.

The impact of ANZUPGO on chronic viral hepatitis reactivation is unknown. Consider viral hepatitis screening and monitoring for reactivation in accordance with clinical guidelines before starting therapy and during therapy with ANZUPGO. If signs of reactivation occur, consult a hepatitis specialist. ANZUPGO is not recommended for use in patients with active hepatitis B or hepatitis C.

Non-melanoma Skin Cancers
Non-melanoma skin cancers, including basal cell carcinoma, have been reported in subjects treated with ANZUPGO. Periodic skin examinations of the application sites are recommended for all patients, particularly those with risk factors for skin cancer. Advise patients to avoid sunlamps and minimize exposure to sunlight by wearing sun-protective clothing or using broad-spectrum sunscreen.

Immunizations
Prior to ANZUPGO treatment, complete all age-appropriate vaccinations as recommended by current immunization guidelines, including herpes zoster vaccinations. Avoid vaccination with live vaccines immediately prior to, during, and immediately after ANZUPGO treatment.

Potential Risks Related to JAK Inhibition
It is not known whether ANZUPGO may be associated with the observed or potential adverse reactions of JAK inhibition. In a large, randomized, postmarketing safety trial of an oral JAK inhibitor in combination with methotrexate in rheumatoid arthritis (RA), patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events (MACE), overall thrombosis, deep venous thrombosis (DVT), pulmonary embolism (PE), and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. ANZUPGO is not indicated for use in RA.

Treatment with oral and topical JAK inhibitors has been associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides.

ADVERSE REACTIONS

Adverse reactions reported in ≤1% of subjects were application site pain, paresthesia, pruritus, erythema, and bacterial skin infections, including finger cellulitis, paronychia, other skin infections, leukopenia, and neutropenia.

USE IN SPECIFIC PATIENT POPULATIONS

Lactation
To minimize potential infant exposure, advise breastfeeding women to avoid direct contact with the nipple and surrounding area immediately after applying ANZUPGO to the hands and/or wrists.

Please see full Prescribing Information and Medication Guide.

ICD-10-CM=*International Classification of Diseases, 10th Revision, Clinical Modification*; JAK=Janus kinase; NDC=National Drug Code; QoL=quality of life.

*The coding information in this resource is provided for informational purposes only and is subject to change. The ICD-10-CM codes listed may not apply to all patients or to all health plans; it is the responsibility of the healthcare provider to select the appropriate ICD-10-CM code(s) and submit claims that accurately reflect the services and products furnished to a specific patient.

References: 1. ANZUPGO Prescribing Information. LEO Pharma. **2.** Bissonette 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, randomised, controlled, double-blind, phase 3 trials. *Lancet*. 2024;404(10451)(suppl index):1-33. doi:10.1016/S0140-6736(24)01027-4