Drug Coverage Decision for BC PharmaCare

About PharmaCare BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	delgoctinib
Brand name	Anzupgo®
Dosage form(s)	20 mg/g topical cream
Manufacturer	LEO Pharma Inc.
Submission type	**New Submission**
Indication reviewed	For the 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.
Canada's Drug Agency (CDA-AMC) Clinical Reimbursement Reviews (CRR)	The Canadian Drug Expert Committee (CDEC) recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDA-AMC website for more details.
The Drug Benefit Council (DBC)	The DBC reviewed clinical and pharmacoeconomic combined reports prepared by the CDA-AMC's CRR on November 13, 2025 , including clinical and pharmacoeconomic evidence review material and the CDEC recommendation. The DBC also considered Patient Input Questionnaire responses from one patient group, as well as patient input provided to the CDA-AMC, a Clinical Practice Review from a specialist, a Budget Impact Assessment, and an Equity Assessment.

Drug Coverage Decision	**Limited Coverage benefit.** **Special Authority drug list - Province of British Columbia**
Date	October 28, 2026
Reason(s)	**Drug coverage decision is consistent with the CDEC recommendation that Anzupgo should be reimbursed for the treatment of moderate to severe CHE in adults for whom topical corticosteroids are inadequate or are not advisable, with conditions including price reduction. The DBC also recommended not to list Anzupgo at the submitted price.** • Evidence from three phase III clinical trials (DELTA 1, DELTA 2, DELTA FORCE) demonstrated that Anzupgo significantly reduced eczema severity and improved symptoms and health-related quality of life compared with an inactive cream and showed comparable or greater efficacy than alitretinoin, the only approved therapy for CHE in Canada. • Anzupgo was generally well tolerated, with mostly mild local reactions and no systemic safety concerns. • Based on the CDA-AMC assessment of the health economic evidence, Anzupgo does not represent good value to the health care system at the public list price. • The Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the manufacturer which were able to address the concerns identified by the DBC and CDEC with respect to the cost-effectiveness and value for money.

The drug review process in B.C.

A manufacturer submits a request to the Ministry of Health (the Ministry).

An independent national organization called Canada's Drug Agency (CDA-AMC) provides evidence-based recommendations to public drug plans across Canada through its reimbursement review process. As part of the CDA-AMC's Clinical Reimbursement Review process, the Canadian Drug Expert Committee (CDEC) makes reimbursement recommendations for non-oncology pharmaceuticals to the participating federal, provincial, and territorial publicly funded drug plans. In developing its recommendations, the CDEC considers:

- whether the drug is safe and effective
- what the drug costs and whether funding it provides good value
- ethical considerations of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by considering:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the CDA-AMC
- the recommendations and reimbursement conditions of the CDEC
- if a Ministry Initiated review, the advice of an independent expert group called the Drug Benefit Council (DBC)
- BC-specific patient input collected through the Your Voice website
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug
- the outcomes of pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with manufacturers

Visit BC PharmaCare and Drug reviews for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.

Appendix

CONFIDENTIAL

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Delgocitinib (Anzupgo®)
LEO Pharma Inc.

Description:

Drug review of **delgocitinib (Anzupgo®)** for the following Health Canada approved indications:

> For the treatment of moderate to severe chronic hand eczema (CHE), including the relief of pain and pruritus, in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable.

In their review, the DBC considered the following: the final reviews completed by Canada's Drug Agency (CDA-AMC) on December 1, 2025, which included clinical and pharmacoeconomic evidence review material and the Canadian Drug Expert Committee (CDEC) recommendations. The DBC also considered Patient Input Questionnaire responses from one patient group, as well as patient input provided to the CDA-AMC, a Clinical Practice Review from a specialist, a Budget Impact Assessment, and an Equity Assessment.

Dosage Forms:

Anzupgo® is available as delgocitinib 20 mg/g topical cream.

Recommendations:

1. The Drug Benefit Council (DBC) recommends not to list delgocitinib (Anzupgo®) at the submitted price.

Of Note:

- The DBC recognizes that there is an unmet need for treatment for CHE in patients who have had an inadequate response to, or cannot use, topical corticosteroids, and that other available treatment options (i.e., phototherapy, corticosteroids and oral alitretinoin) may be difficult to access or are associated with significant safety concerns.

Reasons for the Recommendation:

1. **Summary**

- Results from three phase III randomized controlled trials (RCTs) evaluating the efficacy and safety of delgocitinib cream 20 mg/g in adults with moderate to severe CHE demonstrated that delgocitinib significantly reduced eczema severity and improved symptoms and health-related quality of life (HRQoL) compared with an inactive cream and also showed comparable or greater efficacy than alitretinoin.
- Clinical trial data indicates that delgocitinib was generally well tolerated, with most adverse events (AEs) being mild to moderate local application site reactions. Compred with alitretinoin, delgocitinib likely results in fewer AEs and severe AEs, although the magnitude and clinical importance of this effect are uncertain.
- At the manufacturer list price, delgocitinib is associated with higher costs to the health care system than alitretinoin and phototherapy. The cost-effectiveness of delgocitinib is highly uncertain when considering all potential treatment options, and there is insufficient evidence to justify a cost premium for delgocitinib over alitretinoin.

2. **Clinical Efficacy**

- The DBC considered the CDA-AMC systematic review, which included three phase III RCTs that evaluated the efficacy and safety of delgocitinib cream 20 mg/g in adults with moderate to severe CHE.
- Two vehicle-controlled trials, DELTA 1 (N = 487) and DELTA 2 (N = 473), assessed whether delgocitinib improved Investigator Global Assessment of Chronic Hand Eczema (IGA-CHE) treatment success and Hand Eczema Severity Index (HECSI) scores over 16 weeks compared to vehicle cream.
- An active-controlled trial, DELTA FORCE (N = 513), compared delgocitinib to oral alitretinoin over 24 weeks in patients with severe CHE, with primary and key secondary outcomes including change in HECSI score,

IGA-CHE treatment success, HECSI-75 and HECSI-90, and patient-reported measures such as the Hand Eczema Symptom Diary (HESD) itch score and Dermatology Life Quality Index (DLQI).

- In DELTA 1 and DELTA 2, delgocitinib cream 20 mg/g twice daily demonstrated superior efficacy to vehicle at week 16 across clinician-reported and patient-reported outcomes.
- IGA-CHE treatment success was achieved in 64 of 325 patients (19.7%) receiving delgocitinib versus 16 of 162 patients (9.9%) receiving vehicle in DELTA 1, and in 91 of 313 patients (29.1%) receiving delgocitinib versus 11 of 159 patients (6.9%) receiving vehicle in DELTA 2.
- More patients treated with delgocitinib had HECSI-75 responses versus those receiving vehicle (49.2% versus 23.5% in DELTA 1, 49.5% versus 18.2% in DELTA 2), and more patients treated with delgocitinib had HECSI-90 responses versus those receiving vehicle (29.5% versus 12.3% in DELTA 1, 31.0% versus 8.8% in DELTA 2). The mean percentage reduction from baseline in HECSI score also favoured delgocitinib in both DELTA 1 and DELTA 2.
- A 4-point or greater reduction in HESD itch was reported 47.1% of patients receiving delgocitinib versus 23.0% receiving vehicle in DELTA 1, and 47.2% of those receiving delgocitinib versus 19.9% receiving vehicle in DELTA 2.
- In terms of quality of life (QoL), DLQI improvement of 4 points or greater was reported in 74.4% of patients receiving delgocitinib versus 50.0% receiving vehicle in DELTA 1, and 72.2% of patients receiving delgocitinib versus 45.8% receiving vehicle in DELTA 2. Mean DLQI score improved by –7.6 and –7.0 with delgocitinib in DELTA 1 and DELTA 2, respectively, compared to –3.9 and –3.1 in the vehicle groups; the mean difference was –3.6 in DELTA 1 and –3.9 in DELTA 2. HEIS scores also improved more with delgocitinib than with vehicle in DELTA 1 trial and DELTA 2. All effects across these outcomes in DELTA 1 and DELTA 2 were considered clinically meaningful.
- In DELTA FORCE, delgocitinib demonstrated greater efficacy than oral alitretinoin 30 mg once daily. At week 12, IGA-CHE treatment success was achieved in 27.2% of patient receiving delgocitinib versus 16.6% receiving alitretinoin. Mean change from baseline in HECSI score was –67.6 versus –51.5 at week 12 and –69.6 versus –45.1 at week 24, favouring delgocitinib. HECSI-90 responses were achieved in 38.6% of patients receiving delgocitinib versus 26.0% receiving alitretinoin. The observed

differences in HESD itch reduction greater than or equal to 4 points, DLQI, and HEIS were smaller and consistently favoured delgocitinib, but were not judged to be clinically meaningful.
- For detailed information on the systematic review of delgocitinib please see the CDEC Final Recommendation at: https://www.cda-amc.ca/delgocitinib.

3. Safety
- In the vehicle-controlled studies (DELTA 1 and DELTA 2), the proportion of patients experiencing at least 1 adverse event (AE) was similar between groups: 45.2% with delgocitinib versus 50.6% with vehicle in DELTA 1, and 45.5% versus 44.7% in DELTA 2. Most AEs were mild to moderate.
- In the active-controlled DELTA FORCE study, AEs occurred in 76.1% of patients receiving oral alitretinoin versus 49.4% of patients receiving delgocitinib. Notable AEs such as headache (32.4% versus 4.0%), nausea (5.7% versus 0.4%), dry skin (3.6% versus 1.2%), and hypercholesterolemia (3.6% versus 0%) occurred more frequently with alitretinoin than with delgocitinib.
- Serious adverse events (SAEs) were infrequent across all studies, occurring in ≤ 2.0% of patients receiving delgocitinib in all trials, compared to ≤ 4.9% of patients receiving alitretinoin in DELTA FORCE. No deaths occurred in any of the trials.
- AEs leading to treatment discontinuation were rare with delgocitinib (≤ 1.2%) but notably higher with alitretinoin (10.1%) in DELTA FORCE. No AEs of special interest occurred in the delgocitinib groups, while 1 patient in the alitretinoin group experienced deep vein thrombosis.
- For detailed information on the safety and tolerability of delgocitinib, please see the CDEC Final Recommendations at the links above.

4. Economic Considerations
- CDEC reported that no definitive conclusions can be drawn regarding the overall relative efficacy or cost-effectiveness of delgocitinib when considering other appropriate comparators. CDEC determined that there is not enough evidence to justify a greater annual cost for Anzupgo compared with alitretinoin.

5. Of Note

- The DBC considered patient input from one patient group, Eczema Society of Canada. Patients reported that CHE is characterized by extremely itchy, painful, inflamed, dry, and scaly patches of skin on the palms, fingertips, web spaces and dorsal surfaces of the hands that can flake, crack, and bleed.
- CHE profoundly affects quality of life because people's hands are constantly used in tasks of daily living such as dressing, washing, and cooking. Intimacy, family dynamics, and relationships may be affected by CHE. CHE can also disproportionately impact individuals in certain professions whose hands may be exposed to irritants or who may have to wash their hands frequently as a requirement of their occupation.
- Topical corticosteroids are the most common treatments for CHE but possess multiple known side effects from long-term use. Many patients with CHE do not experience an adequate response to corticosteroids.
- Alitretinoin is an approved oral retinoid treatment for CHE but is associated with severe adverse effects (including headache, nausea, and hair loss in women), is teratogenic, requires frequent blood monitoring, and does not work for all patients. Phototherapy is also used to treat CHE but is only available in a small number of centers and is difficult to access for people in rural and remote areas.