Copiktra

United Arab Emirates · access guide

How to access Copiktra for r/r CLL/SLL from the UAE: 2026 pathway via the UAE haematology and pharmacy supply | Reserve Meds

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

The UAE has one of the deepest adult haematology and lymphoma service networks in the wider region. Cleveland Clinic Abu Dhabi haematology, Sheikh Shakhbout Medical City (MD Anderson affiliation), Tawam Hospital Al Ain (the federal oncology and haematology reference centre), Burjeel Medical City haematology, Mediclinic City Hospital and Mediclinic Parkview, American Hospital Dubai, NMC Specialty and Aster Hospitals across Dubai and Sharjah, Saudi German Hospital Dubai, and the Dr Sulaiman Al Habib network all run adult haematology services that treat chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) through the full therapeutic ladder: BTK inhibitors (Brukinsa, Calquence, Imbruvica), BCL2 inhibitors (Venclexta with obinutuzumab), and into the PI3K class for patients whose disease has progressed beyond the first two lines. Copiktra (duvelisib, Verastem Oncology) is the oral dual PI3K-delta and PI3K-gamma inhibitor, approved by the FDA in September 2018 for adult patients with relapsed or refractory CLL/SLL after at least two prior therapies, and is the operational option for a UAE-resident adult whose CLL has progressed after a BTK inhibitor and a BCL2 inhibitor.

This page explains how the pathway works in 2026 for a UAE-resident patient: who qualifies, where the prescribing haematologist conversation happens, how Copiktra is dispensed, what Thiqa and commercial insurance will and will not cover, what the four boxed warnings mean operationally, and how the family handles the daily oral routine. It is concierge documentation written for a family already in conversation with a treating haematologist who wants the operational reality laid out plainly.

Why Copiktra, and why now

Copiktra is duvelisib, a small-molecule oral dual inhibitor of phosphoinositide 3-kinase delta (PI3K-delta) and PI3K-gamma. Developed by Verastem Oncology. The mechanism is what distinguishes Copiktra from the rest of the BCR-pathway class: BTK inhibitors (Brukinsa / zanubrutinib, Calquence / acalabrutinib, Imbruvica / ibrutinib) block Bruton tyrosine kinase upstream; BCL2 inhibitors (Venclexta / venetoclax) act on apoptosis; Copiktra blocks the PI3K-delta and PI3K-gamma isoforms, suppressing B-cell receptor signalling and disrupting the tumour microenvironment by acting on regulatory T cells and tumour-associated macrophages. PI3K-delta-only competitors idelalisib (Zydelig, Gilead) and umbralisib (Ukoniq, withdrawn from the US market in 2022) sit in the same class; the class as a whole is challenged on safety, and Copiktra positioning is third-or-later-line CLL after BTK inhibitor failure and BCL2 inhibitor failure.

The FDA approval history matters for context. Copiktra received FDA approval in September 2018 for r/r CLL/SLL after at least two prior therapies, and on the same date received accelerated approval for r/r follicular lymphoma after at least two prior systemic therapies. The follicular lymphoma accelerated approval was voluntarily withdrawn in December 2021 by Verastem following discussions with the FDA about the safety profile and the limited patient population. The CLL/SLL approval remains in force. This page is the operational layer for the CLL/SLL indication.

Reserve Meds does not promote one targeted therapy over another. The page describes the Copiktra pathway because Copiktra is the drug the patient has asked about.

What Copiktra is, in plain language

Copiktra is an oral capsule taken twice daily, continuously. The dose is 25 mg by mouth twice daily (BID). There is no infusion centre, no cold chain, no injection. The capsule is taken with or without food. Patients on a strong CYP3A inhibitor require dose reduction to 15 mg BID; strong CYP3A inducers are avoided.

Pre-treatment is the operational gate. Before the first capsule is dispensed: hepatitis B and hepatitis C serology, HIV testing, cytomegalovirus (CMV) screening, baseline liver function tests, baseline lipid panel, and baseline fasting glucose. Pneumocystis jirovecii pneumonia (PCP) prophylaxis with trimethoprim-sulfamethoxazole (or alternative for sulfa-allergic patients) is initiated before or at start of Copiktra and continued throughout treatment.

This is not a fixed-duration therapy. Copiktra is continued until disease progression or unacceptable toxicity. Median duration of treatment in the pivotal trial was approximately 9 months.

Eligibility at a UAE haematologist clinic

For UAE-resident patients, the haematology services apply the FDA criteria with local insurance adaptation:

1. Confirmed diagnosis of relapsed or refractory CLL or SLL with at least two prior therapies, one of which must include a BTK inhibitor and a BCL2 inhibitor in the appropriate sequence. 2. Adult (18+). No paediatric label for Copiktra. 3. Hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody, HIV serology, and CMV serology all reviewed at intake. Active HBV or HIV requires infectious disease co-management before Copiktra. 4. PCP prophylaxis initiated. TMP-SMX is the default; alternatives for sulfa-allergic patients arranged at intake. 5. Baseline liver function tests within normal range or stable. Active or chronic hepatic dysfunction is a relative contraindication. 6. Baseline fasting glucose and lipid panel. Hyperglycemia is a known Copiktra adverse event; pre-existing diabetes requires endocrinology co-management. 7. No active serious infection. Active untreated infection is a hard contraindication. 8. No severe pre-existing colitis or inflammatory bowel disease. Severe diarrhoea or colitis is one of the four boxed warnings. 9. No severe pre-existing pneumonitis or interstitial lung disease. Pneumonitis is one of the four boxed warnings. 10. No history of severe cutaneous adverse reaction (TEN, SJS, DRESS) to any prior therapy. Severe cutaneous reactions are one of the four boxed warnings. 11. Drug interaction review. Strong CYP3A inhibitors require dose reduction to 15 mg BID; strong CYP3A inducers should be avoided.

A UAE patient should arrive at the Copiktra conversation with the most recent haematology documentation: current CBC with differential, peripheral smear, flow cytometry, FISH and karyotype if available, complete treatment history including BTK inhibitor and BCL2 inhibitor exposure with response durations and reasons for failure, recent imaging, hepatitis and HIV serology, baseline LFTs and lipid panel and fasting glucose, and the Thiqa or commercial-insurance preauthorisation paperwork.

The UAE prescribing and supply picture, plainly

Copiktra UAE EDE registration status is verified at intake. Verastem Oncology's MENA commercial supply runs through regional distributors. Where in-country registration is complete, in-country pharmacy dispensing applies. Where registration has not yet caught up, a named-patient US-import pathway covers the case. The pathway is:

1. Prescribing physician: a board-certified UAE adult haematologist at Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, Tawam Hospital Al Ain, Burjeel Medical City, Mediclinic City Hospital, American Hospital Dubai, NMC Specialty, Aster Hospitals, Saudi German Hospital Dubai, or the Dr Sulaiman Al Habib network. The boxed-warning awareness and the prior-line documentation are what gate the dispensing decision. 2. Pharmacy dispensing: hospital pharmacy under haematology supervision for the first cycle and for any patient with active infection risk or hepatic concern. Community pharmacy with cold-chain capability handles maintenance dispensing for stable patients. 3. Insurance pre-authorisation: Thiqa coverage for Emirati nationals has historically extended to oral oncology agents on a case-by-case basis with documented severity and prior-therapy failure. Daman and the major commercial insurers (Oman Insurance, AXA Gulf, MetLife, Cigna, others) require similar documentation. Documented BTK inhibitor and BCL2 inhibitor prior trial-and-failure is the gating evidence. `[VERIFY: current UAE EDE registration status at intake.]` 4. PCP prophylaxis dispensing: TMP-SMX or alternative dispensed alongside Copiktra; the prescribing office initiates this before the first Copiktra capsule. 5. Ongoing monitoring: weekly LFTs for the first three months, then every two weeks for the next three months, then monthly. CBC monthly. Fasting glucose monthly. Lipid panel quarterly. Diarrhoea grading at every visit; grade 3 or greater diarrhoea prompts immediate discontinuation. Pulmonary symptom check at every visit; new cough, dyspnoea, or hypoxia prompts immediate chest imaging and pulmonology review.

Cost band

US list price for Copiktra is approximately USD 16,000 to 23,000 per month at WAC, depending on prescription. Annual cost at list price is approximately USD 200,000 to 280,000. At 2026 indicative cross rates, the AED-equivalent annual cost band is approximately AED 735,000 to 1,030,000 at list price. Insurance preauthorisation reduces out-of-pocket exposure substantially for covered patients; cash-pay exposure depends on the dispensing pharmacy's regional pricing.

For Emirati nationals with Thiqa coverage, the financial pre-authorisation conversation needs to start before the first dispensing, not after. Daman and other commercial covers vary; the prescribing physician's office is the gating step.

What to expect on Copiktra, week-by-week

Week 0 to 2: First capsule taken at home after the prescribing haematologist office confirms PCP prophylaxis is in place and baseline labs are clean. Patient takes 25 mg BID with or without food. Diarrhoea, when it occurs, typically begins in the first 2 to 6 weeks.

Week 2 to 12: Weekly LFTs. Transaminase elevation is common; grade 1 to 2 elevation is managed with continued treatment plus monitoring; grade 3 or higher prompts dose hold and haematology review. Diarrhoea is graded at every contact; grade 1 to 2 is managed with loperamide and hydration plus dose hold consideration; grade 3 or higher prompts immediate Copiktra discontinuation and infectious workup (rule out CMV colitis, C. difficile, immune-mediated colitis). CBC monthly to monitor for neutropenia and lymphopenia.

Week 12 to 24: LFTs every two weeks, then monthly if stable. Diarrhoea vigilance continues. Pulmonary symptom check at every contact. Fasting glucose monthly. Lipid panel at week 12 and quarterly thereafter.

Week 24 onwards: Disease assessment. Patients with response continue on Copiktra until progression or unacceptable toxicity. Patients without response transition to next line of therapy.

Ongoing: Boxed-warning vigilance does not relax. Infection vigilance (fever, cough, dyspnoea), diarrhoea/colitis vigilance, pneumonitis vigilance, and cutaneous reaction vigilance (any new rash) continue throughout treatment. PCP prophylaxis continues for the duration of Copiktra and for the post-treatment period per haematologist guidance.

When Copiktra is the wrong drug

For a UAE patient where BTK inhibitor (Brukinsa, Calquence, Imbruvica) and BCL2 inhibitor (Venclexta) are still viable options that have not been fully trialled, where the patient has a severe pre-existing infection risk (uncontrolled HBV, active HIV, recent serious opportunistic infection), where there is a severe pre-existing colitis or inflammatory bowel disease history, where there is a severe pre-existing pneumonitis or interstitial lung disease history, where there is a history of severe cutaneous adverse reaction (TEN, SJS, DRESS) to any prior therapy, or where there is significant hepatic dysfunction, the operational pathway shifts away from Copiktra:

- BTK inhibitors (Brukinsa, Calquence, Imbruvica) as the first-line and second-line oral targeted option. - BCL2 inhibitor (Venclexta) with obinutuzumab or rituximab as the alternative second-line or third-line option. - Allogeneic stem cell transplant for selected fit patients with high-risk CLL who have exhausted targeted options; cross-border to KFSHRC Riyadh is the regional reference. - Clinical trial enrolment for novel agents.

Reserve Meds does not promote one targeted therapy over another. The page above describes the Copiktra pathway because Copiktra is the drug the patient has asked about. If the conversation with the treating haematologist points toward a BTK inhibitor, a BCL2 inhibitor, allogeneic transplant, or clinical trial enrolment, the operational pathway shifts accordingly.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a UAE Copiktra case we build the documentation pack with the treating haematologist office, confirm UAE EDE registration status and the appropriate dispensing pathway, run the insurance pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the supply logistics for ongoing dispensing, organise PCP prophylaxis and baseline screening that the prescribing office requires, and stay with the case through the first six months of dosing with handoff to the local prescriber for ongoing surveillance. Clinical decisions remain with your treating haematologist.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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