Calquence

Saudi Arabia · access guide

How to access Calquence for CLL/SLL or mantle cell lymphoma from Saudi Arabia: 2026 pathway via Saudi haematology and pharmacy supply

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

Saudi Arabia has the deepest adult haematology and lymphoma network in the wider region. King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) Riyadh under the National Guard Health Affairs (NGHA), King Fahd Medical City (KFMC), King Khalid University Hospital, King Fahd Specialist Hospital Dammam, the Dr Sulaiman Al Habib hospital network, and Saudi German Hospitals run programmes that treat chronic lymphocytic leukemia, small lymphocytic lymphoma, and mantle cell lymphoma through the full therapeutic arc: chemo-immunotherapy where appropriate, then targeted oral agents in the Bruton tyrosine kinase (BTK) class. Calquence (acalabrutinib, AstraZeneca) is the selective second-generation BTK inhibitor that has become a default option in CLL and SLL since the November 2019 FDA approval, and in mantle cell lymphoma since the October 2017 accelerated approval, with the January 2025 expansion to newly-diagnosed mantle cell lymphoma in combination with bendamustine plus rituximab. For a Saudi-resident adult with CLL, SLL, or MCL whose treating haematologist is weighing BTK inhibitor therapy, the operational question is no longer whether selective second-generation BTK blockade is reachable: it is whether Calquence is the right fit, which formulation (capsule or maleate tablet), how the prescription is dispensed, what insurance and MoH coverage will and will not cover, and how the twice-daily oral routine fits into a Saudi family's life over years.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies, where the prescribing haematologist conversation happens, how Calquence is dispensed and stored, what the dosing and monitoring look like, what the realistic out-of-pocket exposure band is in SAR, what to monitor (atrial fibrillation, hypertension, second primary malignancies, hepatitis B reactivation), and how the long-term treatment course fits into a Saudi family's life. It is concierge documentation written for a family already in conversation with a treating haematologist who wants the operational reality laid out plainly.

Why Calquence, and why now

Calquence is acalabrutinib, a selective second-generation Bruton tyrosine kinase inhibitor developed by AstraZeneca. The mechanism distinguishes Calquence from the first-generation BTK inhibitor Imbruvica (ibrutinib): Calquence has greater selectivity for BTK and less off-target activity at EGFR, ITK, TEC, and other kinases that drive ibrutinib-class toxicity. The clinical translation in the head-to-head ELEVATE-RR trial in relapsed or refractory CLL was a meaningful reduction in atrial fibrillation (9.4% with acalabrutinib versus 16.0% with ibrutinib), hypertension, major bleeding, and treatment discontinuation for adverse events, with non-inferior progression-free survival.

The FDA approved Calquence for mantle cell lymphoma after one prior therapy in October 2017 (accelerated approval), then for CLL and SLL in November 2019. The newer Calquence Maleate Tablet formulation was approved in August 2022; it has the same 100 mg twice-daily dosing but does not have the pH-dependent absorption of the capsule, so patients on proton pump inhibitors or H2 blockers can take the tablet form without dose timing constraints. The January 2025 approval added newly-diagnosed mantle cell lymphoma in combination with bendamustine and rituximab. SFDA registration status is verified at intake.

For a Saudi-resident adult with CLL, SLL, or MCL whose treating haematologist is weighing BTK inhibitor therapy, Calquence is the selective second-generation option with the strongest head-to-head safety data versus ibrutinib. The conversation about which BTK inhibitor (Calquence, Imbruvica, Brukinsa, or Jaypirca) the patient should start, or whether the patient should start with chemo-immunotherapy or a BCL2 inhibitor combination (venetoclax plus obinutuzumab) instead, is the central clinical decision. This page is the operational layer underneath that conversation.

Reserve Meds does not promote one BTK inhibitor over another. The page describes the Calquence pathway because Calquence is the drug the patient has asked about.

What Calquence is, in plain language

Calquence is an oral capsule or tablet taken twice daily. There is no infusion, no inpatient stay, no specialty-centre administration. The standard dose is 100 mg twice daily, with or without food, approximately 12 hours apart. The capsule formulation has pH-dependent absorption: patients taking proton pump inhibitors should switch to the maleate tablet form or separate the capsule dose from antacid by the prescribing information schedule. The tablet form has no PPI interaction.

This is not a short-course therapy. Calquence is taken for as long as the disease responds and the patient tolerates the drug. Patients with CLL typically remain on Calquence for years; patients with mantle cell lymphoma have a more variable course depending on disease biology and combination regimen.

Eligibility at a Saudi haematologist clinic

For Saudi-resident patients, the major haematology and lymphoma services apply the FDA criteria with local insurance and MoH coverage adaptation:

1. Confirmed indication. CLL or SLL meeting iwCLL treatment criteria; mantle cell lymphoma confirmed by pathology with cyclin D1 expression; for newly-diagnosed MCL, the combination with bendamustine plus rituximab requires the multi-disciplinary tumour board decision. 2. Treatment history. For relapsed or refractory CLL/SLL or MCL, prior therapy documentation. For newly-diagnosed MCL, candidacy for the bendamustine and rituximab combination assessed by the treating haematologist. 3. Adult (18+). No paediatric indication for Calquence. 4. Hepatitis B and HIV screening. HBsAg and anti-HBc are mandatory before BTK inhibitor initiation because of the documented HBV reactivation risk; patients with prior HBV exposure require antiviral prophylaxis and monitoring with hepatology co-management. 5. Pregnancy planning discussion for women of childbearing potential. Effective contraception during treatment and for two days after the last dose. 6. Drug interaction review. Strong CYP3A inhibitors (azole antifungals, clarithromycin, some HIV protease inhibitors) and strong CYP3A inducers (rifampin, carbamazepine, phenytoin) require dose adjustment or alternative. For capsule users on PPIs or H2 blockers, conversion to the maleate tablet form is the cleaner solution. 7. Second primary malignancy counsel. BTK inhibitor class has a documented signal for second primary malignancies, especially non-melanoma skin cancers; annual dermatology review is the standard. 8. Atrial fibrillation and cardiovascular risk review. Baseline ECG and blood pressure check. Patients with pre-existing AF or significant cardiovascular disease require cardiology co-management. 9. Tumour lysis syndrome risk assessment in CLL with high tumour burden; hydration and uric-acid management per institutional protocol.

A Saudi patient should arrive at the BTK inhibitor conversation with the most recent haematology documentation: pathology and immunophenotyping confirming CLL, SLL, or MCL, prior treatment history with response durations and reasons for discontinuation, HBV and HIV serology, baseline ECG and blood pressure, complete blood count with differential, comprehensive metabolic panel, and the insurance preauthorisation paperwork that the prescribing office typically initiates.

The Saudi prescribing and supply picture, plainly

Calquence SFDA registration status is verified at intake. AstraZeneca's MENA commercial supply runs through regional distributors with KFSHRC Riyadh, KAMC, KFMC, KFSHRC Jeddah, King Khalid University Hospital, King Fahd Specialist Hospital Dammam, Dr Sulaiman Al Habib network, and Saudi German Hospitals as the major dispensing centres. Where in-country registration is current, in-country pharmacy dispensing applies. Where a specific indication or the newer maleate tablet formulation has not yet caught up with the FDA label, a named-patient supply pathway covers the case.

1. **Prescribing physician**: a board-certified Saudi haematologist or medical oncologist with lymphoma experience, ideally within a multi-disciplinary lymphoma programme. KFSHRC Riyadh and Jeddah, KAMC Riyadh under NGHA, KFMC, King Khalid University Hospital, King Fahd Specialist Hospital Dammam, Dr Sulaiman Al Habib network, and Saudi German Hospitals are the major centres. 2. **Pharmacy dispensing**: hospital pharmacy if prescribed in the specialty outpatient setting; some patients dispense through community pharmacy with the prescribing physician's coordination. Capsules and tablets are stored at room temperature. 3. **Insurance and MoH coverage**: MoH coverage for Saudi nationals has historically extended to BTK inhibitor therapy in CLL and MCL with documented indication and treatment history. CCHI-regulated commercial insurance (Bupa Arabia, Tawuniya, MedGulf, others) requires similar documentation. `[VERIFY: current SFDA registration status for Calquence Maleate Tablet at intake.]` 4. **Ongoing monitoring**: haematology follow-up at week 2, week 4, then monthly for the first 6 months, then every 3 months. Complete blood count, comprehensive metabolic panel, blood pressure, and HBV viral load (if applicable) at each visit. Annual dermatology review for second primary malignancy surveillance.

Cost band and insurance positioning

US list price for Calquence is approximately USD 15,000 to 17,500 per month at WAC. Annual cost at list price is approximately USD 175,000 to 210,000. At 2026 indicative cross rates, the SAR-equivalent annual cost band is approximately SAR 656,000 to 788,000 at list price.

MoH coverage for Saudi nationals reduces out-of-pocket exposure substantially for covered patients. CCHI-regulated commercial covers vary; the prescribing haematologist's office is the gating step for preauthorisation. The financial conversation needs to start before the first dispensing, not after.

What to expect on Calquence, week-by-week

Week 0: Baseline workup completed (HBV, HIV, ECG, blood pressure, CBC, CMP, dermatology baseline if applicable). First Calquence dose dispensed.

Week 1 to 2: Headache is very common in the first 1 to 2 weeks (more than 30% of patients), typically transient and responsive to paracetamol or caffeine. Mild diarrhoea is also common. Most patients report these settle by week 4.

Week 2 to 4: First haematology follow-up. CBC to assess neutrophil and platelet trajectory. Blood pressure check. Adverse event review.

Month 2 to 6: Monthly haematology follow-up. Response assessment by imaging or clinical exam per indication-specific schedule. Disease response usually becomes apparent by month 3 to 6.

Month 6 onwards: Every-3-month haematology follow-up for stable responders. Annual dermatology review. Ongoing CBC, CMP, and blood pressure monitoring.

Year 1 onwards: Long-term maintenance for as long as the disease responds and the patient tolerates the drug.

When Calquence is the wrong drug

For a Saudi patient with active untreated hepatitis B without antiviral prophylaxis and hepatology co-management, with severe uncontrolled hypertension, with significant pre-existing atrial fibrillation that has not been optimised by cardiology, during pregnancy when effective contraception cannot be ensured, or where strong CYP3A inhibitor or inducer therapy cannot be modified, the operational pathway shifts:

- **Other BTK inhibitors (Imbruvica / ibrutinib, Brukinsa / zanubrutinib, Jaypirca / pirtobrutinib)**: each has a distinct safety profile; the treating haematologist may prefer one over another based on patient comorbidities. - **BCL2 inhibitor combination (venetoclax plus obinutuzumab or rituximab)**: fixed-duration alternative to indefinite BTK inhibitor therapy in CLL, with different toxicity profile and tumour lysis syndrome considerations. - **Chemo-immunotherapy (bendamustine plus rituximab, FCR, R-CHOP for MCL induction)**: where targeted therapy is contraindicated or not yet warranted.

Reserve Meds does not promote one BTK inhibitor over another, and does not push a default treatment class. If the conversation with the treating haematologist points toward a different BTK inhibitor, a BCL2 combination, or chemo-immunotherapy, 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 Saudi Calquence case we build the documentation pack with the treating haematologist office, confirm SFDA registration status per formulation and the appropriate dispensing pathway, run the insurance and MoH coverage conversation alongside the clinical preauthorisation, coordinate the supply logistics for ongoing dispensing, organise baseline screening (HBV, HIV, ECG, blood pressure, dermatology baseline) that the prescribing office requires, and stay with the case through the first year 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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