Brukinsa

Oman · access guide

How to access Brukinsa from Oman, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Oman patient with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenstrom macroglobulinemia, mantle cell lymphoma after at least one prior therapy, marginal zone lymphoma after at least one anti-CD20-based regimen, or relapsed or refractory follicular lymphoma (in combination with obinutuzumab) may receive a prescription for Brukinsa (zanubrutinib) from their treating hematologist. Brukinsa is FDA-approved in the United States and manufactured by BeiGene. It is a second-generation Bruton tyrosine kinase (BTK) inhibitor administered by oral capsule. Local availability of Brukinsa in Oman can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through DGPADC remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Brukinsa is a second-generation covalent BTK inhibitor. Mechanism: a small-molecule irreversible inhibitor of Bruton tyrosine kinase, designed for sustained BTK occupancy and improved selectivity over first-generation BTK inhibitors. Dosing: 160 mg orally twice daily or 320 mg orally once daily, per FDA labeling. Baseline workup per FDA labeling includes CBC with differential, hepatitis B serology, baseline ECG, lipid panel, and bleeding history review. Other important warnings include serious infections including opportunistic infections and hepatitis B reactivation, hemorrhage, cytopenias, atrial fibrillation and flutter, second primary malignancies including non-melanoma skin cancer, and tumor lysis syndrome. Your hematologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Brukinsa legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient and personal-use import framework, coordinated through a Oman-licensed treating facility's pharmacy. The Oman has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The DGPADC named-patient route allows a Oman-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating hematologist.** The prescribing decision is clinical. Your hematologist documents the indication, prior therapies where relevant, and rationale for Brukinsa.
2. **Baseline screening.** CBC with differential, hepatitis B serology, baseline ECG, lipid panel, and bleeding history review are confirmed and documented.
3. **DGPADC named-patient application.** Your hematologist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from BeiGene's authorised distribution under DSCSA chain-of-custody.
5. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your hematologist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis (CLL/SLL, WM, MCL, MZL, or r/r FL with planned obinutuzumab combination), prior therapies where relevant, and Brukinsa as the indicated next step
- Verification of their Oman medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (160 mg orally twice daily or 320 mg orally once daily, per FDA labeling)
- A monitoring plan covering CBC at regular intervals, atrial fibrillation surveillance, infection vigilance, and hepatitis B reactivation monitoring

Reserve Meds provides a physician documentation kit tailored for BTK inhibitor therapies, including the templates DGPADC reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a typical month of dosing of Brukinsa sits in an indicative 2026 band of approximately USD 16,000 to 19,000. International logistics, DGPADC documentation handling, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Brukinsa specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for DGPADC review, including BTK inhibitor class templates.
- **Logistics.** Internationally tracked shipment to your named dispensing facility with tamper-evident packaging.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating hematologist, and dispensing sits with the licensed Oman pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Oman tertiary centers.

Will my private health insurance cover this? Cash-pay is the default posture. Some Oman private insurers (Daman, AXA, Mednet-administered plans) reimburse named-patient imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

How does Brukinsa compare to Imbruvica and Calquence? All three are covalent BTK inhibitors. Brukinsa has shown reduced atrial fibrillation rates relative to ibrutinib in head-to-head CLL data and a favorable cardiovascular safety profile. Choice between them is a clinical decision your hematologist will make based on cardiac history, drug interactions, and indication.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Oman tertiary centers (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, American Hospital Dubai, and Mediclinic City Hospital) have encountered. Our documentation kit is written for first-time applicants and tracks what DGPADC reviewers commonly ask for.

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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.
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