

Tibsovo

Bahrain · access guide

How to access Tibsovo from Bahrain, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Bahrain patient with IDH1-mutated acute myeloid leukaemia (AML), newly diagnosed in an older or unfit patient, or relapsed/refractory, or IDH1-mutated advanced cholangiocarcinoma, may receive a prescription for Tibsovo (ivosidenib) from their treating oncologist or haematologist. Tibsovo is FDA-approved, developed by Servier (following the acquisition of Agios's oncology portfolio), and is an oral targeted therapy for patients whose tumours carry an IDH1 mutation. In Bahrain, Tibsovo is not yet broadly registered for routine hospital-pharmacy dispensing, which is why your physician may be navigating a named-patient import pathway on your behalf.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

The clinical situation

Tibsovo is a small-molecule inhibitor of mutant IDH1, taken as an oral tablet once daily. Eligibility requires confirmation of an IDH1 mutation on the tumour or bone marrow sample via validated molecular testing. Your treating physician will confirm mutation status, prior line history where relevant, and coordinate baseline and on-treatment monitoring, including ECGs (QTc) and assessment for differentiation syndrome, which is a known class effect of IDH inhibitors in AML. Because Tibsovo is an oral therapy taken at home, the in-country infrastructure requirement is modest once the prescribing team has the monitoring plan in place.

Is Tibsovo legally importable into Bahrain?

Yes, through the National Health Regulatory Authority (NHRA) named-patient import framework. The NHRA route allows a Bahrain-licensed physician to request import of a medicine not locally registered when: (a) the medicine has been approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent locally registered alternative is suitable, (c) the treating physician takes clinical responsibility, and (d) the importing party documents chain of custody. Applications are reviewed by the NHRA Drug Sector.

For a molecularly targeted oncology drug like Tibsovo, where the clinical rationale centres on the IDH1 molecular diagnosis, the named-patient rationale is straightforward to articulate, and NHRA reviewers are familiar with the framework across similar targeted therapies.

How the pathway works, step by step

1. **Consultation with your treating oncologist or haematologist.** The decision to prescribe Tibsovo is a clinical one, supported by IDH1 confirmation and a written rationale.
2. **Molecular report review.** The NGS or targeted IDH1 report confirming the mutation is included in the dossier.
3. **NHRA named-patient application.** Your physician or the hospital's importing pharmacy files the application, including clinical rationale, patient reference, the molecular report, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Tibsovo from authorised distribution.
5. **Ambient shipment.** Tibsovo tablets ship at ambient controlled conditions with chain-of-custody documentation.
6. **Arrival and dispensing.** The hospital pharmacy releases the bottle to the patient with physician instructions for once-daily dosing and monitoring schedule.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming IDH1-mutated AML or cholangiocarcinoma, line history, and Tibsovo as the indicated treatment
- Verification of their Bahrain medical licence (SCFHS / MOH)
- A copy of the molecular diagnostic report confirming IDH1
- Patient identifier (anonymised reference preferred)
- Planned dosing schedule and safety monitoring plan (ECG/QTc, differentiation syndrome surveillance in AML, hepatic monitoring)

Reserve Meds provides a physician documentation kit that bundles the templates NHRA reviewers expect to see, including the molecular-diagnostic attestation and the differentiation-syndrome surveillance plan that NHRA reviewers tend to look for in AML applications.

Costs and timing

Tibsovo's US cash-pay drug-only reference price sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 29,000-33,000 for a 30-day supply, with total course cost driven by duration on therapy. International logistics, NHRA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first dispense after cohort intake opens is 10-21 days from the moment a complete NHRA application is submitted. Refills ship on a rolling basis against your monthly dispensing schedule.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

A culturally-aware note: Ramadan can affect adherence to daily oral oncology therapy. Your physician will advise whether dosing schedule adjustments are appropriate during fasting periods; our concierge team can coordinate refill timing with your hospital's schedule.

Reserve Meds's role

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for NHRA review.
- **Logistics.** Chain-of-custody shipment coordination to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact for your family and your physician through intake, first dispense, and refills.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating physician.

Frequently asked

Is this legal in Bahrain? Yes, when executed through the NHRA named-patient framework with appropriate documentation. Cross-border named-patient import for molecularly targeted oncology is a routine mechanism in Bahrain tertiary centres. See our trust and compliance page.

What if the molecular testing was done abroad? In practice, NHRA reviewers accept molecular reports from accredited international laboratories as part of a named-patient application. Your physician will confirm whether a confirmatory in-country test is also helpful.

AML vs. cholangiocarcinoma, same drug? Yes. Tibsovo is FDA-approved in both settings where IDH1 mutation is confirmed. Dosing is the same; monitoring emphasis differs (differentiation syndrome is an AML-specific concern; hepatic monitoring is relevant in both).

What is differentiation syndrome and how is it managed? Differentiation syndrome is a known class effect of IDH inhibitors in AML, treated promptly with corticosteroids when recognised. Your haematology team will explain recognition and response protocols.

Will private insurance cover this? Cash-pay is the default. Some Bahrain private insurers consider named-patient imports case by case; we supply documentation for your submission but do not process insurance claims directly.

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.

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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