

## Ultomiris

Bahrain · access guide

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

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

A Bahrain patient with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), or generalised myasthenia gravis (gMG) may receive a prescription for Ultomiris (ravulizumab) from their treating haematologist, nephrologist, or neurologist. Ultomiris is FDA-approved in the United States and manufactured by Alexion (AstraZeneca Rare Disease). It is a long-acting complement C5 inhibitor that enables an 8-week maintenance dosing interval, compared with the every-2-week schedule of its predecessor eculizumab. Access is coordinated with the manufacturer's controlled-distribution model and physician-training expectations; the named-patient pathway respects those parameters while solving supply and formulary gaps.

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

## The clinical situation

Ultomiris is administered as an IV infusion, a loading dose on day 1, a maintenance dose on day 15, then every 8 weeks (weight-based dosing). Like other complement inhibitors, it carries a US boxed warning regarding life-threatening meningococcal infections; meningococcal vaccination or antibiotic prophylaxis is a gating step before therapy begins, and enrolment in the US REMS program is required. Outside the US, equivalent manufacturer risk-minimisation measures apply. Your treating physician confirms diagnosis, vaccination status, prior therapy history, and the monitoring plan per FDA labeling.

## Is Ultomiris legally importable into Bahrain?

Yes, through the National Health Regulatory Authority (NHRA) named-patient / personal-use import framework. The pathway allows a Bahrain-licensed physician to import a medicine not locally registered for the specific indication when: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent registered alternative fits, (c) the physician takes clinical responsibility, and (d) chain of custody is documented.

For ravulizumab specifically, international access respects the manufacturer's controlled-distribution program and physician-registration expectations tied to the meningococcal-infection risk profile.

## How the pathway works, step by step

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1. **Consultation with your treating physician.** Diagnosis confirmation (flow cytometry for PNH, clinical/serology criteria for aHUS, antibody testing for gMG), and clinical rationale.
2. **Meningococcal vaccination / prophylaxis.** Vaccination at least 2 weeks before first dose, or antibiotic cover per labeling.
3. **NHRA named-patient application.** The physician or hospital pharmacy files the application.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner, aligned with the manufacturer's controlled-distribution model.
5. **Cold-chain shipment.** Ultomiris ships at 2-8°C with continuous temperature monitoring.
6. **Arrival and infusion scheduling.** The infusion facility administers on the load-maintenance-every-8-weeks schedule.

## What documentation your physician needs

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Your physician will typically need to provide:

- Clinical rationale letter confirming indication, diagnostic evidence, prior therapies, and Ultomiris as the indicated treatment
- Verification of their Bahrain medical licence
- Patient identifier, weight-based dose plan
- Meningococcal vaccination documentation or prophylaxis plan
- Planned induction and every-8-week maintenance regimen

Reserve Meds provides a physician documentation kit that bundles the templates NHRA reviewers expect to see for complement inhibitors.

## Costs and timing

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Ultomiris's US cash-pay drug-only reference price is weight-driven, with a single weight-adjusted maintenance dose commonly falling in a broad indicative range of roughly USD 90,000-130,000; annualised cost is in the multi-hundred-thousand range. International cold-chain logistics, NHRA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for first dose after cohort intake opens is 7-14 days from the moment a complete application is submitted (vaccination lead time may extend this). Maintenance doses ship on a rolling every-8-week basis.

*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.*

## Reserve Meds's role

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody and aligned with the manufacturer's controlled-distribution program.
- **Documentation.** Regulatory package for your physician and for NHRA review.
- **Logistics.** Cold-chain, temperature-monitored shipment.
- **Concierge case lead.** A named point of contact.

**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

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**Is this legal in Bahrain?** Yes, when executed through the NHRA named-patient / personal-use framework with appropriate documentation and respect for the manufacturer's controlled-distribution expectations.

**Why Ultomiris instead of Soliris?** Ultomiris's 8-week dosing interval is a major quality-of-life difference, reducing infusion visits from 26 per year to about 6-7. Your physician will consider clinical profile, infusion logistics, and patient preference.

**What about the meningococcal warning?** It is load-bearing. Vaccination at least 2 weeks before first dose, or prophylaxis, is required per labeling.

**Will private insurance cover this?** Cash-pay is the default. Some Bahrain insurers reimburse named-patient imports for ultra-rare-disease therapies on escalated review; 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.

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### **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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