Enjaymo

Bahrain · access guide

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

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

A Bahrain patient with cold agglutinin disease (CAD) and a history of haemolytic anaemia may be evaluated by their treating haematologist for Enjaymo (sutimlimab-jome). Enjaymo is FDA-approved in the United States and manufactured by Sanofi. It is a humanised monoclonal antibody that selectively inhibits the classical complement pathway at C1s, the pathway relevant to CAD-driven haemolysis. Where Enjaymo is not on a Bahrain hospital formulary, a named-patient import pathway via the NHRA is the legitimate route.

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

The clinical situation

Enjaymo is administered as a weight-based IV infusion on a loading dose schedule (weeks 0 and 1), followed by maintenance every 2 weeks. Patient selection is based on documented CAD diagnosis, a history of transfusion in the past 6 months, and ongoing haemolysis. Like other complement-pathway inhibitors, Enjaymo carries labeled guidance around encapsulated-organism vaccination before therapy begins. Your treating haematologist confirms CAD diagnosis (DAT positive for C3d, cold agglutinin titre, haemolysis markers), transfusion history, vaccination status, and the monitoring plan per FDA labeling.

Is Enjaymo 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 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 ultra-rare haematology indications like CAD, NHRA reviewers are accustomed to named-patient applications, and tertiary centres in Riyadh, Jeddah, and elsewhere coordinate infusion logistics as part of standard practice.

How the pathway works, step by step

1. **Consultation with your treating haematologist.** CAD diagnosis confirmation (DAT C3d, cold agglutinin titre, haemolysis labs), transfusion history, and clinical rationale.
2. **Pre-treatment vaccination.** Meningococcal, pneumococcal, and Hib vaccinations per labeling, typically at least 2 weeks before first dose.
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.
5. **Cold-chain shipment.** Enjaymo ships at 2-8°C with continuous temperature monitoring.
6. **Arrival and infusion scheduling.** The infusion facility administers on the loading-then-biweekly schedule, weight-adjusted dosing.

What documentation your physician needs

Your physician will typically need to provide:

- Clinical rationale letter confirming CAD diagnosis, supporting lab evidence, transfusion history, and Enjaymo as the indicated treatment
- Verification of their Bahrain medical licence
- Patient identifier and weight-based dose plan
- Vaccination documentation
- Planned loading and every-2-week maintenance regimen

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

Costs and timing

Enjaymo's US cash-pay drug-only reference price is weight-driven and is a high-cost ultra-rare-disease therapy. Annualised treatment cost is commonly quoted in a broad indicative range of USD 500,000+; individual infusion costs depend on weight tier. 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, plus vaccination lead time. Maintenance doses ship on a rolling biweekly 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

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Enjaymo 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.** 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 haematologist.

Frequently asked

Is this legal in Bahrain? Yes, when executed through the NHRA named-patient / personal-use framework with appropriate documentation.

How is Enjaymo different from other complement inhibitors? Enjaymo targets C1s in the classical pathway, which is the specific pathway driving CAD-associated haemolysis. C5 inhibitors (Soliris, Ultomiris) act downstream across all complement pathways. The C1s-specific mechanism is why Enjaymo is the labeled option for CAD.

What about the vaccination requirement? It is load-bearing. Encapsulated-organism vaccination per labeling is completed before therapy starts.

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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