Enjaymo access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Enjaymo (sutimlimab-jome), Sanofi's humanized monoclonal antibody targeting complement protein C1s (classical complement pathway inhibitor), through the SFDA Personal Importation Program.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the Saudi Arabia country research module with the Enjaymo drug module to describe the path families actually walk.

Quick orientation

Enjaymo (sutimlimab-jome) is Sanofi's classical complement pathway inhibitor and the first therapy approved by the FDA specifically for hemolysis in adults with cold agglutinin disease. It received FDA approval in February 2022. For Saudi Arabia patients with confirmed cold agglutinin disease and clinically significant hemolysis, this page describes the SFDA Personal Importation Program pathway and what families should expect.

Why this drug is hard to source in Saudi Arabia

Cold agglutinin disease is a rare autoimmune hemolytic anemia, and the KSA patient population is small. Enjaymo is a newer, ultra-rare disease therapy that has not had broad SFDA registration uptake for the standard small-population commercial reason. Even at KFSH&RC and the other major tertiary centers, the local pharmacy is unlikely to stock sutimlimab routinely; the case typically requires patient-specific import. The PIP route is the lawful path for the treating hematologist to bring Enjaymo in for a named patient.

The SFDA Patient Import Permit (PIP) pathway applied to Enjaymo

The Saudi Food and Drug Authority's Personal Importation Program is the federal pathway that allows an SCFHS-licensed physician to import a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Enjaymo (sutimlimab-jome) holds FDA approval since

2022 for hemolysis in adults with cold agglutinin disease (CAD), which places it squarely within the framework's scope.

The application is filed through the dispensing institution's import pharmacy (or, where the institution does not hold internal import-pharmacy capability, through an SFDA-licensed specialty importer in Riyadh or Jeddah). The standard package contains the clinical justification letter from the treating physician, the SCFHS license verification, the anonymized patient identifier, the full product details for Enjaymo including 1,100 mg per 22 mL intravenous infusion (50 mg/mL), weight-based dosing every two weeks after a loading dose schedule, with cold-chain handling at 2 to 8 degrees Celsius documented in the file, the destination dispensing facility license, and the chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy. The SFDA portal at sfda.gov.sa handles regulatory transactions, and named-patient activity increasingly routes through the agency's Ghad digital platform.

Where Enjaymo gets dispensed in the Kingdom

The major Saudi institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network; King Saud University Medical City and the academic medical centers; King Khalid University Hospital; Dr. Sulaiman Al Habib Medical Group (HMG) across multiple Riyadh, Jeddah, and Eastern Province facilities; the Saudi German Hospital network; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. Smaller hospitals typically route their named-patient cases through one of these centers or through an SFDA-licensed specialty importer. For a Enjaymo case, the dispensing facility is selected on the basis of where the treating physician practices and where the patient receives ongoing care; Reserve Meds does not select the dispensing facility on the family's behalf.

Real costs in SAR and USD

The US wholesale acquisition cost for Enjaymo is approximately USD 1,800 to USD 1,950 per 1,100 mg vial. Dosing is weight-based, and a typical adult patient receives multiple vials per infusion. Total drug cost in the maintenance phase is approximately USD 38,000 to USD 55,000 per month depending on weight, translating to roughly SAR 142,000 to SAR 206,000. Cold-chain logistics for a refrigerated biologic add approximately SAR 3,000 to SAR 5,600 per shipment. The treatment is chronic, and ongoing payer engagement is central to long-term feasibility.

Reserve Meds quotes an indicative range based on the initial intake and then a transparent firm quote with each line item shown separately. The Reserve Meds concierge fee is

published on a tiered schedule and is shown as a separate line. Nothing is bundled. Nothing is hidden.

Timing, what to expect

The SFDA Personal Importation Program processes routine cases (recognized reference-authority drug, well-documented indication, established institution) in approximately 10 to 20 business days. Complex cases (novel mechanism, off-label use within the FDA label scope, ultra-rare patient population, first-time importer) can extend to 6 to 8 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm. In parallel with the SFDA review, Reserve Meds aligns the US-side sourcing, the packaging and cold-chain validation, and the shipment plan, so the drug is ready to move on the day approval comes through. The patient experience runs through ten well-defined steps from initial physician decision through reorder coordination; the full ten-step sequence is documented in the Saudi Arabia country module and in our patient-facing operations brief.

What your physician needs to provide

The treating hematologist's clinical justification letter typically documents the confirmed cold agglutinin disease diagnosis (direct antiglobulin test positive for C3d, cold agglutinin titer, hemolysis markers including hemoglobin, LDH, indirect bilirubin, and haptoglobin), the exclusion of secondary causes, the transfusion history, the rationale for complement C1s inhibition versus rituximab-based approaches, and the proposed weight-based dosing. The SCFHS registration in hematology accompanies the letter. The mandatory meningococcal vaccination prior to initiation (per the US label) is documented in advance.

The dispensing facility's SFDA-licensed pharmacy completes the submission and accepts the chain-of-custody documentation. The institutional license is what authorizes the dispensing pharmacy to receive the imported drug, so the physician's individual SCFHS license is necessary but not sufficient on its own. Post-import pharmacovigilance commitment to report adverse events through the SFDA National Pharmacovigilance Center is part of the application and runs through the full course of therapy, not just the initial dose.

Vision 2030 and the specialty-access environment

Saudi Vision 2030's Health Sector Transformation Program (HSTP) is the operating frame for healthcare reform in the Kingdom. HSTP is restructuring the Ministry of Health from a provider-and-regulator into a regulator and strategist, with clinical delivery devolving into regional Health Clusters and Centers of Excellence. The program names tertiary cancer care, rare-disease care, organ transplantation, genomics, and digital health as priority

verticals, all of which are heavy users of specialty drugs not registered locally. The practical effect on the PIP framework is twofold. HSTP is expanding the universe of specialty drugs that get formal SFDA registration, which closes some access gaps. At the same time, HSTP is increasing diagnostic capacity in rare disease and oncology genomics, which surfaces new patients who need drugs that are FDA-approved but not yet registered in the Kingdom. The named-patient framework remains essential for the foreseeable future. Saudization (the Nitaqat workforce-nationalization program) does not change the PIP framework, but confirming the prescriber's SCFHS license status before filing is good practice in any case where the treating physician is in a renewal window.

Pharmacovigilance and cold-chain considerations

Enjaymo carries a warning for serious infections including meningococcal disease (the C1s inhibition increases susceptibility to encapsulated organism infections). Meningococcal vaccination prior to initiation is mandatory per the US label and the SFDA pharmacovigilance commitment includes vaccination documentation, infusion reaction monitoring, and serious infection surveillance through the full course. Cold-chain at 2 to 8 degrees Celsius is required end to end.

Reserve Meds' physician documentation kit includes the SFDA adverse-event reporting reference so the treating physician has the framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician. The dispensing facility carries the chain-of-custody and storage obligations through the dispensing event, and off-label transfer of the imported supply to another patient is not permitted under the PIP framework.

Common questions about Enjaymo in the Kingdom

Will Bupa Arabia, Tawuniya, or MedGulf cover this? Each insurer handles named-patient imports case by case under the Council of Cooperative Health Insurance (CCHI) framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even where the local hospital pharmacy does not stock it. Others reimburse a percentage. Many require pre-authorization with the clinical justification letter attached. Reserve Meds supplies the documentation that lets the insurer assess the case; the claim is yours or your hospital's to file. Cash-pay is the default operating posture for cross-border access, with reimbursement sought after delivery where your plan permits.

Will my Ministry of Health-employed physician's letter be sufficient if SFDA flags the case? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license. The clinical justification letter is the cornerstone of

the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must be a locally licensed pharmacy. For oral medicines, a hospital outpatient pharmacy or specialized SFDA-licensed import pharmacy dispenses to the patient. For infusion or injection products, the medicine ships to the infusion center where you will receive it. Direct-to-home delivery without a licensed dispensing facility in the chain is not the operating model.

What about pediatric patients? The PIP framework applies to pediatric patients the same way it applies to adults. The clinical justification letter typically includes weight-based dosing, pediatric-specific monitoring, and where relevant the involvement of the pediatric specialty center. KFSH&RC, KAMC, and the major HMG facilities have established pediatric specialty programs that handle named-patient imports routinely.

How does Saudization (Nitaqat) affect my case? Saudization is the workforce-nationalization program that shapes hospital staffing composition. It does not change the PIP framework. It can occasionally affect timing if a non-Saudi treating physician's license is in renewal at the moment the PIP file is being prepared. Confirming the prescriber's SCFHS license status before filing is good practice.

Is Enjaymo a controlled substance? No. Enjaymo is not a US DEA scheduled substance. The Saudi narcotics-section approvals do not apply. The chain-of-custody documentation, the dispensing facility's pharmaceutical establishment license, and the SFDA pharmacovigilance commitment do apply.

Where Reserve Meds fits in Enjaymo cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the SFDA, the dispensing pharmacy, or the institutional import-pharmacy team. For a Enjaymo case in the Kingdom, our work is to orchestrate the US-side sourcing, prepare the regulatory documentation kit your physician needs, coordinate international logistics with cold-chain validation where required, and assign a single named coordinator who stays with the case through reorders. The clinical decisions remain with the treating physician. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US supply side and those three Saudi pillars. Reserved for you.

Next step

If a treating physician in the Kingdom is weighing Enjaymo for a patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Enjaymo clinical resource
- Enjaymo in the United Arab Emirates
- Enjaymo in Qatar
- Enjaymo in Kuwait
- Kingdom of Saudi Arabia country page

Sources

1. FDA approval, Enjaymo (sutimlimab-jome), Sanofi, initial FDA approval 2022.
2. Saudi Food and Drug Authority (SFDA), Personal Importation Program framework, https://www.sfda.gov.sa/en, and the Ghad digital regulatory platform at https://ghad.sfda.gov.sa/.
3. Saudi Vision 2030, Health Sector Transformation Program, https://www.vision2030.gov.sa/en/explore/programs/health-sector-transformation-program.
4. Saudi Commission for Health Specialties (SCFHS), https://scfhs.org.sa/en, for treating-physician licensing and the institutional pharmacy framework.