

Rystiggo

Jordan · access guide

Rystiggo access in Jordan: the JFDA named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Rystiggo (rozanolixizumab) is a neonatal Fc receptor (FcRn) antagonist (subcutaneous) developed by UCB. It is approved by the US FDA for generalised myasthenia gravis in adults who are AChR antibody-positive or MuSK antibody-positive. The standard regimen is 7 mg/kg or 10 mg/kg subcutaneous weekly for 6 weeks, repeat cycles based on clinical response. Rystiggo is available in the global pharmaceutical supply chain in subcutaneous solution prefilled syringe. The drug may or may not be locally registered in Jordan, and even when registered, a Jordan family asking for Rystiggo is often asking for a precise version of it (specific indication, specific presentation, specific schedule) that the local market has not caught up to. Reserve Meds coordinates the US-side sourcing, the validated cold-chain logistics, and the documentation packet your physician needs.

Why Jordan patients need Rystiggo through the named-patient pathway

The Jordan Food and Drug Administration (JFDA) administers the unregistered-medicine personal-import pathway. A Jordan Medical Association-licensed physician working at a JFDA-licensed facility files for the import permit when the medicine is approved by a recognised reference regulator (US FDA, EMA, MHRA, PMDA, or Health Canada) and a clinically suitable Jordan-registered alternative is not available. Jordan's regulatory framework is among the most developed in the Levant.

Several patterns drive these cases: indication lag against the FDA label; specialty biologic and oncology cases where local stock is constrained; payer denials in private cover; and patient-driven cross-border supply for the precise FDA-labeled originator product. For Rystiggo specifically, the named-patient pathway exists to handle exactly the situations the local registered route cannot: a newer FDA indication that has not yet propagated to Jordan labeling, a presentation or strength the local agent does not reliably carry, a payer denial that is uneconomic to appeal, or a biomarker-defined regimen where the prescriber's clinical judgement runs ahead of the local label's molecular language. In each pattern, the named-patient pathway is the mechanism that connects a Jordan-licensed physician's clinical decision with US-sourced, FDA-labeled Rystiggo for a specific patient.

Rystiggo (FDA June 2023) is a subcutaneous FcRn antagonist for generalised myasthenia gravis in adults who are AChR antibody-positive or MuSK antibody-positive. The MuSK-positive coverage distinguishes it from Vyvgart, which is AChR-positive only. Cycle-based subcutaneous dosing supports outpatient delivery.

The JFDA named-patient pathway for Rystiggo

A complete application typically includes a clinical justification letter from the treating physician (diagnosis, severity or stage, prior therapies, biomarker results where relevant, why Rystiggo is appropriate, why the locally available alternative is not suitable for this case); the treating physician's Jordan license verification (issued by Jordan Medical Association (JMA) and Ministry of Health); an anonymised patient identifier where the regulator submission allows; full product details (brand name Rystiggo, generic rozanolixizumab, manufacturer UCB, strength subcutaneous solution prefilled syringe, quantity requested calibrated to the planned cycles or treatment duration); the destination dispensing facility name, license number, and pharmacy in charge; and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy, including cold-chain handling at 2 to 8 degrees Celsius from the US manufacturer through to the dispensing pharmacy.

For Rystiggo, the clinical justification typically rests on documentation of AChR or MuSK antibody status for gMG where applicable, line of therapy and prior treatments, and a clear statement of why this medicine is the appropriate next step in this patient's care.

Approval timelines for routine cases are typically 10 to 25 business days from a complete filing. Complex cases (rare indication, paediatric application, larger multi-cycle quantities, gene therapy or cell therapy logistics, first-import scrutiny on a presentation new to the local route) can extend to 4 to 8 weeks. The JFDA retains discretion on timing, and we do not promise specific durations.

Where Rystiggo gets dispensed in Jordan

A small group of Jordan institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that fit this profile include King Hussein Cancer Center in Amman (JCI-accredited regional cancer referral), Jordan University Hospital, Al-Bashir Hospital, King Hussein Medical Center, Specialty Hospital, Istishari Hospital, Arab Medical Center, Khalidi Medical Center, Jordan Hospital, and the larger private hospitals in Amman.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a Amman-based specialty importer that holds a pharmaceutical establishment license and files the JFDA application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's pharmacy under chain-of-custody documentation, where the patient receives the first dose under physician supervision; subsequent doses self-administered at home after injection training.

Real cost picture for Rystiggo in Jordan

US WAC for Rystiggo is approximately USD 4,900 per dose, which translates to USD 220,000 to USD 350,000 per year (cycle-based). The Jordanian dinar is pegged to the US dollar at approximately 0.71 JOD to 1 USD, so the annual reference range converts accordingly when expressed in JOD at US WAC equivalents.

International validated cold-chain logistics typically run USD 450 to USD 1,600 (approximately JOD 320 to JOD 1,140) per shipment depending on destination city, urgency, and pack size. Jordan customs and JFDA permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each Jordan insurer assesses named-patient imports case by case. Local payer cover is administered through Jordan Insurance Company, Arab Orient Insurance, MetLife Jordan, Bupa Arabia (regional cover), and Royal Medical Services for the armed forces and dependents. We do not promise coverage from any insurer. The US manufacturer copay programmes and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage where it applies.

Clinical evidence behind Rystiggo

Rystiggo's pivotal MycarinG-1 demonstrated MG-ADL responder benefit in both AChR-positive and MuSK-positive gMG patients. The MuSK-positive coverage distinguishes the agent.

Typical timeline for Rystiggo in Jordan

JFDA routine processing is typically 10 to 25 business days from a complete filing. For Rystiggo specifically, cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance scheduled to avoid extreme-heat exposure are non-negotiable. End-to-end, most cases complete within 3 to 6 weeks from first complete documentation to dispensing or first dose. For longer treatment courses, we coordinate cycle-by-cycle or quarterly resupply so the patient never approaches an empty pharmacy shelf.

What your physician needs to provide

For a Jordan-licensed physician prescribing Rystiggo through the JFDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis with relevant staging or severity language for the indication, the prior therapy history, the rationale for Rystiggo as the appropriate next step, and the precise FDA-labeled regimen (dose, route, frequency, expected duration). For Rystiggo specifically, the FDA-approved regimen is 7 mg/kg or 10 mg/kg subcutaneous weekly for 6 weeks, repeat cycles based on clinical response.

For Rystiggo, the relevant molecular or laboratory documentation includes AChR or MuSK antibody status for gMG. The letter references the test results that establish the patient's eligibility for the FDA-labeled indication. The treating physician's Jordan license number, the dispensing facility license number, and the pharmacy in charge complete the package. Monitoring requirements relevant to Rystiggo (baseline labs, imaging cadence, adverse-event surveillance) are stated in the letter and operationalised by the prescribing physician's team.

Monitoring for Rystiggo: Anti-AChR or anti-MuSK antibody status confirmation, IgG levels during cycle therapy, infection surveillance, and ongoing clinical assessment by neurology. **Adverse-event profile:** Headache, infections, diarrhoea, pyrexia, hypersensitivity reactions, injection-site reactions. IgG reduction can predispose to infection.

Common questions about Rystiggo in Jordan

Will my insurer cover this? Each Jordan insurer (Jordan Insurance Company, Arab Orient Insurance, MetLife Jordan, Bupa Arabia (regional cover), and Royal Medical Services for the armed forces and dependents) assesses named-patient imports case by case. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is Rystiggo already locally registered in Jordan? Local registration status can shift over time; Rystiggo may already be on the Jordan register for some indications but not others, or the registered presentation may not match what the prescriber needs. The JFDA pathway exists precisely to bridge these gaps and is the cleanest legal route when the local supply chain does not match the prescription.

What about competitors? Alternatives in the same therapeutic class include efgartigimod (Vyvgart), eculizumab (Soliris), ravulizumab (Ultomiris), zilucoplan (Zilbrysq), IVIG, plasma exchange. Choice depends on the patient's full profile, prior therapy, biomarker status, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed.

How does the cold chain work? This medicine requires cold-chain handling at 2 to 8 degrees Celsius from manufacture through to dispensing. Reserve Meds uses validated thermal packaging with continuous temperature logging. Customs clearance is scheduled to avoid prolonged tarmac exposure. The cold chain is broken only at the dispensing pharmacy.

Will my US manufacturer assistance program help? US patient assistance programs (PAP), copay cards, and bridge programs from Merck, Pfizer, AstraZeneca, Lilly, Roche, Genentech, Novartis, AbbVie, Janssen, Gilead, Biogen, BMS, and other manufacturers are generally restricted to US residents with US prescriptions filled at US pharmacies. Cross-border patients pay cash or use local payer cover.

What if treatment is multi-year? For long-running treatment, we coordinate cycle-by-cycle or quarterly resupply through the same JFDA pathway, with each shipment authorised against the same physician documentation set updated for the current cycle. Patients never need to navigate the supply chain themselves.

Where is the medicine actually administered? After the first physician-supervised dose, most patients self-administer at home using the prefilled syringe or autoinjector pen after a brief injection-technique training. Home refrigeration is required; we provide a patient onboarding kit.

What if my physician is at a smaller clinic that does not import directly? The standard pattern is to route through a Amman-based specialty importer that holds a pharmaceutical establishment license. The importer files the JFDA application on behalf of the prescribing physician, takes delivery of the medicine, and transfers it under chain-of-custody to the prescribing facility's pharmacy.

Operational notes for the JFDA workflow

Operationally, the JFDA personal-import workflow is concentrated at King Hussein Cancer Center, Jordan University Hospital, and the larger Amman private hospitals. The Jordan Medical Association license verification, hospital pharmacy license, and the chain-of-custody plan are the core attachments. Jordan's regulatory infrastructure is among the most developed in the Levant, which often produces shorter turnaround than other regional markets for routine cases.

Where Reserve Meds fits in Rystiggo cases

Reserve Meds is a US-based concierge coordinator. We do not replace your prescribing physician, we do not replace the JFDA, and we do not replace your dispensing pharmacy. For Rystiggo specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain logistics with appropriate temperature monitoring into Jordan, plan cycle-by-cycle resupply across longer treatment courses, and assign a single named coordinator through the case. Standard NPP coordination under our cold-chain biologic playbook applies.

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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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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