Skyrizi access in Egypt: the EDA named-patient pathway

How Egyptian patients legally obtain Skyrizi (risankizumab-rzaa) when the locally registered indication, the IV induction presentation, or payer coverage does not match the prescribing physician's plan.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Skyrizi (risankizumab-rzaa) is an interleukin-23 (p19) inhibitor approved by the US FDA across four indications: moderate-to-severe plaque psoriasis (April 2019), active psoriatic arthritis (January 2022), moderately to severely active Crohn's disease (June 2022), and moderately to severely active ulcerative colitis (June 2024). It is the first IL-23 specific inhibitor approved across both Crohn's and ulcerative colitis. Skyrizi is available through AbbVie's regional affiliate in Egypt for at least one indication, yet Egyptian patients regularly use the EDA personal-import pathway to bridge the gap between AbbVie's broad US label and uneven local registration or payer coverage for the IBD and PsA indications. Reserve Meds coordinates US-side sourcing, the cold-chain logistics into Cairo, and the documentation packet your physician needs for EDA filing.

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Why Egyptian patients need Skyrizi through the named-patient pathway

Egypt operates one of the largest pharmaceutical markets in MENA, importing roughly USD 3 billion in finished drug product annually, with a meaningful share of demand sitting in named-patient cases rather than mass-market supply. For Skyrizi specifically, demand patterns from the Egyptian patient base are driven less by the drug being unavailable and more by the gap between which indication is locally registered, which indication a patient actually has, and what local payers will fund.

Three patterns surface. First, indication mismatch. Skyrizi is broadly registered in MENA through AbbVie's regional channels for plaque psoriasis but with uneven local labels for the psoriatic arthritis, Crohn's, and (most recently) ulcerative colitis indications. An Egyptian gastroenterologist treating moderate-to-severe Crohn's disease may find Skyrizi is locally available only for the psoriasis indication, and the IBD-specific IV induction presentation is not consistently stocked. Second, payer denial. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other private plans each assess specialty biologic claims case by case. Coverage on plaque psoriasis may be partial; coverage on PsA, Crohn's, or UC is often more restrictive, particularly under the post-2022 EGP depreciation that has made imported biologics meaningfully more expensive in local-currency terms. Third, supply continuity. Patients already on Skyrizi who have stabilised at a specific dose interval may face stocking gaps for the precise pen, prefilled syringe, on-body injector cartridge, or IV induction vial the prescribing physician has specified.

In each pattern, the EDA personal-import pathway is the legal mechanism that connects an Egyptian-licensed gastroenterologist, rheumatologist, or dermatologist's clinical plan with US-sourced, FDA-labeled Skyrizi for the specific patient.

The EDA named-patient pathway for Skyrizi

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations issued by Prime Minister Decision No. 777 of 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by NODCAR, NORCB, and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The EDA Drug Registration Sector handles registration files, and the Egyptian Pharmacovigilance Center (EPVC) handles post-market safety.

EDA permits the importation of unregistered or unstocked medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally or where the available quantity of an equivalent registered product cannot meet the patient's clinical need. This pathway is commonly referred to as Personal Importation, sometimes described as Special Access or Compassionate Use in EDA correspondence. The application is filed through the dispensing institution's import pharmacy, typically a private specialty hospital, a university hospital import desk, or a licensed specialty importer.

The standard package includes a clinical justification letter from the treating physician (original, stamped, on hospital letterhead, stating diagnosis, severity, prior therapies attempted and failed, and the specific clinical reason this drug is required rather than a locally available alternative), a recent prescription specifying brand name, INN, strength, dosage form, and quantity, a patient identifier, physician licensing verification (Egyptian Medical Syndicate membership number and Ministry of Health licence reference), full product details (manufacturer, country of origin, FDA approval reference, shelf life, storage conditions), the destination dispensing facility licence, and a chain-of-custody plan covering cold-chain handling and customs clearance through Cairo International Airport.

For Skyrizi, the clinical justification angle typically rests on prior-line failure documentation. For a Crohn's case, the prescriber documents prior anti-TNF response or intolerance, prior anti-IL-12/23 (ustekinumab) experience where applicable, and the specific clinical rationale for IL-23p19 selective blockade as the next-line step. For a UC case, the prescriber documents the 2024 FDA approval, the 1200 mg IV induction dosing that differs from the Crohn's regimen, and the destination infusion-center arrangement before the consignment moves. For a PsA case, the prescriber documents joint involvement, prior conventional DMARD or biologic experience, and the SC dosing schedule. A standing-order Egypt clinical note: tuberculosis screening before initiation is mandatory. Egypt sits in the moderate TB-burden tier per WHO classification, and EDA reviewers expect a documented baseline TB workup (interferon-gamma release assay or tuberculin skin test, plus chest imaging where clinically indicated) and treatment of any latent TB before starting Skyrizi.

Routine EDA personal-import authorisations for well-documented cases are typically processed in 3 to 6 weeks once a complete package is submitted. Complex biologic cases involving cold-chain sensitivity, first imports of the IV induction vial, or large maintenance quantities can extend to 8 to 14 weeks. EDA reserves discretion at every step.

Where Skyrizi gets dispensed in Egypt

The Egyptian hospitals that handle named-patient biologic imports with cold-chain 2 to 8 degrees Celsius storage and infusion-center capability (for the Crohn's 600 mg and UC 1200 mg IV induction doses) include Cairo University Hospitals (Kasr Al Ainy) with its Drug Information Center and dedicated gastroenterology, rheumatology, and dermatology services; Ain Shams University Hospitals with strong gastroenterology and hepatology programs; Dar Al Fouad Hospital (6th of October City, Giza), a JCI-accredited private super-specialty hospital with active gastroenterology and rheumatology infrastructure; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group network across multiple Cairo facilities.

For the IV induction phase, the dispensing facility's infusion suite is the destination of the shipment. For SC maintenance presentations (the prefilled pen, prefilled syringe, or on-body injector), the hospital outpatient pharmacy or a licensed specialty importer's pharmacy releases the device to the patient for self-administration after training. Physicians at smaller hospitals or outpatient clinics typically route through a Cairo-based licensed specialty importer that holds a pharmaceutical establishment licence and files the EDA application on the prescribing physician's behalf.

Real cost picture for Skyrizi in Egypt

US WAC for Skyrizi is approximately USD 23,838 per single dose as of early 2026 per AbbVie disclosures, with annual gross cost at WAC running in the USD 90,000 to USD 100,000-plus range per patient-year for the plaque psoriasis 150 mg every-12-weeks maintenance regimen after induction. For Crohn's disease and ulcerative colitis, the IV induction phase (600 mg for Crohn's, 1200 mg for UC at weeks 0, 4, and 8) plus SC maintenance produces a first-year gross cost that is materially higher than the psoriasis steady state. Reserve Meds quotes in USD and accepts USD wire transfers. The EGP/USD rate is near 52 to 53 in May 2026 per IMF Article IV consultation reference, and quoting in USD insulates the patient from intra-case EGP drift.

International cold-chain logistics from a US source to Cairo typically runs USD 400 to USD 1,500 depending on volume, route, and whether the consignment includes the IV induction vials (which add temperature-class and quantity considerations). Regulatory documentation handling fees on the Egyptian side vary by dispensing facility. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each Egyptian insurer assesses named-patient imports case by case. Bupa Egypt, AXA Egypt, and Allianz Egypt commonly require pre-authorisation; some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary. UHIA does not currently cover most specialty biologic imports. The Skyrizi Complete savings card and myAbbVie Assist patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

Typical timeline for Skyrizi in Egypt

EDA routine processing for well-documented Skyrizi cases is typically 3 to 6 weeks from a complete filing. Cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance at Cairo International Airport scheduled to avoid tarmac heat exposure are non-negotiable. For Crohn's and UC cases requiring the IV induction phase, the timeline lengthens because the destination infusion suite must be confirmed before the consignment moves, and the first SC

maintenance dose at week 12 ships separately. End-to-end, most psoriasis or PsA SC-only cases complete within 5 to 9 weeks from first complete documentation; IBD cases with full induction-and-maintenance choreography may run 8 to 14 weeks for the full first-year cycle.

What your physician needs to provide

For an Egyptian-licensed dermatologist, rheumatologist, or gastroenterologist prescribing Skyrizi through the EDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (plaque psoriasis with PASI score, psoriatic arthritis with joint count and prior DMARD response, Crohn's disease with endoscopic findings and CDAI or Harvey-Bradshaw index, or ulcerative colitis with Mayo score and endoscopic activity), prior biologic and non-biologic therapy history, and a clinical rationale for IL-23p19 selective blockade.

The letter specifies the exact dosing plan per the FDA-approved label. For plaque psoriasis and psoriatic arthritis: 150 mg SC at week 0 and week 4, then every 12 weeks. For Crohn's disease: 600 mg IV induction at weeks 0, 4, and 8, then 360 mg SC at week 12 and every 8 weeks thereafter. For ulcerative colitis: 1200 mg IV induction at weeks 0, 4, and 8 (the UC induction dose is unique to UC and not interchangeable with the Crohn's regimen), then 180 mg or 360 mg SC at week 12 and every 8 weeks thereafter per clinical response.

Pre-initiation monitoring requirements that must be documented: baseline tuberculosis screening (IGRA or tuberculin skin test, plus chest imaging where indicated) with treatment of any latent TB before starting therapy. Baseline hepatitis B and C serology. Live vaccines should not be administered during treatment. The treating physician's EMS membership number, Ministry of Health licence reference, the dispensing facility licence and pharmacy in charge, and the infusion-center identification for IBD induction complete the package. Pharmacovigilance reporting through EPVC during therapy stays with the treating physician.

Common questions about Skyrizi in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover this? Each insurer assesses named-patient biologic imports case by case. Many require pre-authorisation. Coverage is more reliable on plaque psoriasis than on PsA, Crohn's, or UC indications in the typical Egyptian private-insurance plan. We supply the documentation set that allows your insurer to assess. The claim filing remains with you or the dispensing hospital. Many Egyptian families reimburse themselves later where coverage applies.

Is TB screening required before starting Skyrizi? Yes. The FDA label requires baseline tuberculosis screening (latent and active) before initiating Skyrizi, with treatment of latent TB before starting therapy. Egypt sits in the moderate TB-burden tier, and EDA reviewers expect this workup to be documented in the clinical justification letter. Ongoing monitoring for signs and symptoms of active TB continues throughout treatment.

Can the IV induction be administered in Egypt? Yes. The dispensing facility for the IV induction phase must hold a valid hospital licence with infusion-center capability. Major Cairo academic and private hospitals routinely run biologic infusion suites. The 600 mg Crohn's induction or 1200 mg UC induction is diluted in saline and administered at weeks 0, 4, and 8, then the patient transitions to the SC maintenance schedule at week 12.

What about Stelara, Humira, or other competitors? Ustekinumab (Stelara) sits in the broader IL-12/23 class and is a long-established alternative across the same indications.

Guselkumab (Tremfya) and tildrakizumab (Ilumya) are direct IL-23p19 competitors. Anti-TNF agents (infliximab, adalimumab) and vedolizumab sit in adjacent treatment algorithms for IBD. Choice rests with the prescribing physician based on prior therapy history, comorbidity, and patient preference. Reserve Meds coordinates whichever medicine the prescription names.

What is the typical course duration? Skyrizi is a chronic therapy in all four indications. There is no defined finite course. Treatment continues while clinical benefit is sustained and tolerability remains acceptable, with periodic specialist review.

Can I receive the SC maintenance dose at home? The dispensing facility must hold a valid Egyptian pharmacy or hospital licence. After the pharmacy releases the SC presentation, the patient self-administers at home after training. Cold-chain handoff ends at the dispensing pharmacy; home refrigeration and proper handling are part of patient onboarding.

Where Reserve Meds fits in Skyrizi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your dermatologist, rheumatologist, or gastroenterologist, we do not replace EDA, we do not replace your dispensing pharmacy or infusion center, and we do not act as an importer of record in Egypt. For Skyrizi 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 continuous temperature logging into Cairo, and assign a single named coordinator in both English and Arabic through the case. No prior Reserve Meds Skyrizi case is on file yet; standard NPP coordination under our cold-chain biologic playbook applies. The recurring operational fundamentals for this drug are TB screening alignment, infusion-center arrangement for IBD induction, presentation-level precision across pen, syringe, on-body injector, and IV vial, and tarmac-time minimisation through Cairo International Airport.

Next step

If your Egyptian physician has prescribed Skyrizi and you are weighing the cross-border route, the next step is a short waitlist request. We confirm eligibility within 24 to 48 hours and send a documentation kit to your physician.

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Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

Last medically reviewed: 2026-05-12.