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Stelara access in Egypt: the EDA named-patient pathway

How Egyptian patients legally obtain reference Stelara (ustekinumab) when local stocking has shifted toward biosimilars, when the IV induction presentation is missing, or when the prescribing physician has specifically named the reference brand.

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

Quick orientation

Stelara (ustekinumab) is a fully human IgG1 monoclonal antibody from Janssen Biotech (a Johnson and Johnson company) that binds the shared p40 subunit of interleukin-12 and interleukin-23. It is FDA-approved for moderate-to-severe plaque psoriasis (2009), psoriatic arthritis (2013), moderately to severely active Crohn's disease (2016), moderately to severely active ulcerative colitis (2019), and pediatric plaque psoriasis and psoriatic arthritis (ages 6 and older). Stelara is registered through EDA in Egypt, and several ustekinumab biosimilars are entering MENA and Egyptian markets. Yet Egyptian patients regularly use the EDA personal-import pathway to obtain reference Stelara specifically when local stocking has shifted toward a particular biosimilar that their treating physician has not approved switching to, or when the 130 mg IV induction vial is missing locally. Reserve Meds coordinates the US-side sourcing, the cold-chain logistics to Cairo, and the documentation packet your physician needs.

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Why Egyptian patients need Stelara 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. Stelara is not a rare drug; it is registered through EDA in Egypt and has been on the local biologic landscape since the early Janssen launch arc. Three patterns drive Egyptian patients into the named-patient pipeline despite this local registration.

First, brand and presentation alignment. A patient already on Stelara who has stabilised on the specific reference brand may need continuity of the same brand and same presentation while local stocking has shifted toward a specific biosimilar that the patient's specialist has not approved switching to. Globally, multiple ustekinumab biosimilars have launched since 2023 (Wezlana, Pyzchiva, Otulfi, Selarsdi, Yesintek, Steqeyma, Starjemza), with WAC discounts ranging from approximately 5 percent to 90 percent below reference Stelara. Egyptian and regional biosimilars are entering the MENA market on similar economics, and some Egyptian private and public formularies have begun preferential listings. The post-2022 EGP depreciation has accelerated this shift because biosimilars are markedly cheaper than reference biologics in local-currency terms.

Second, indication-specific stocking gaps. A country may carry the 90 mg subcutaneous presentation routinely for psoriasis but not maintain reliable stock of the 130 mg IV induction vial, leaving an IBD patient awaiting first dose without a local source. Egyptian gastroenterology programs at Kasr Al Ainy, Ain Shams, Dar Al Fouad, and the Cleopatra Hospitals Group network

treat moderate-to-severe Crohn's and ulcerative colitis with ustekinumab regularly; sporadic stocking gaps for the IV induction vial are a recurring driver of personal-import requests.

Third, cost-coverage gaps. Even where Stelara is registered, payer coverage in Egypt is uneven. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other private plans each assess specialty biologic claims case by case. Many will fund a biosimilar but not reference Stelara, or will fund neither for the IBD indications. Cash-pay families pursue cross-border supply rather than accept formulary substitution that their gastroenterologist or dermatologist has not approved.

The EDA named-patient pathway for Stelara

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 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 medicines, or of registered medicines where the available local stock cannot meet clinical need, for a specific patient under defined conditions. 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.

A complete application includes a clinical justification letter from the treating physician (original, stamped, on hospital letterhead, stating diagnosis, severity, prior therapies and response, and the clinical reason this specific brand or presentation is required), 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 Stelara specifically, the clinical justification angle typically rests on brand continuity. The prescriber documents that the patient has stabilised on reference Janssen Stelara, that the treating physician has not approved switching to a locally stocked biosimilar (often citing prior tolerability, response stability, or pediatric considerations), and that the named brand is therefore clinically required. For IBD induction cases, the prescriber documents the 130 mg IV vial requirement, the weight-banded induction dose (260 mg up to 55 kg, 390 mg for 55 to 85 kg, 520 mg over 85 kg), and the destination infusion-center arrangement before the consignment moves. Tuberculosis screening (interferon-gamma release assay or tuberculin skin test, plus chest imaging where clinically indicated) and treatment of any latent TB before initiation is mandatory and must be documented; Egypt's moderate TB-burden tier makes this non-negotiable in the EDA filing. Routine EDA authorisations are typically processed in 3 to 6 weeks; complex first-imports of the IV induction vial may extend to 8 to 14 weeks.

Where Stelara gets dispensed in Egypt

The Egyptian hospitals that handle named-patient biologic imports with 2 to 8 degrees Celsius cold-chain storage and infusion-center capability for the IV induction phase 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 dermatology infrastructure; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group network across multiple Cairo facilities. For pediatric plaque psoriasis or pediatric psoriatic arthritis cases (ages 6 and older), the pediatric units at Kasr Al Ainy and Ain Shams sit in the routine workflow.

For the SC maintenance phase (45 mg or 90 mg every 12 weeks for psoriasis and PsA; 90 mg every 8 weeks for IBD maintenance), the hospital outpatient pharmacy or licensed specialty importer releases the prefilled syringe or single-dose vial to the patient for self-administration after training. For the IV induction phase, the dispensing facility's infusion suite is the destination of the shipment. Physicians at smaller hospitals route through a Cairo-based licensed specialty importer with a pharmaceutical establishment licence.

Real cost picture for Stelara in Egypt

Reference Stelara US WAC sits at approximately USD 13,300 for a 12-week supply for plaque psoriasis in a 75 kg patient and approximately USD 26,500 for a 12-week supply for Crohn's disease or ulcerative colitis where dosing intervals and induction differ. Per single 90 mg SC dose, WAC is in the range of USD 30,000 and annualised maintenance cost commonly exceeds USD 100,000 before any rebates. The global ustekinumab biosimilar wave has compressed this picture meaningfully: Wezlana low-WAC priced at roughly 81 percent below reference Stelara at launch; Steqeyma launched at approximately 85 percent discount. For an Egyptian patient seeking reference Stelara specifically (not a biosimilar), the cost reference remains near the reference WAC band rather than the discounted biosimilar band.

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 IV induction vials. 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. Many will fund a locally stocked biosimilar but not reference Stelara specifically; some require pre-authorization; some reimburse a percentage. The Janssen CarePath US patient assistance and copay support programs do not extend internationally.

Typical timeline for Stelara in Egypt

EDA routine processing for well-documented Stelara 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 (the FDA label permits a single excursion to room temperature up to 30 degrees Celsius for up to 30 days, generous compared with some peers, after which the product cannot be returned to refrigeration), and customs clearance at Cairo International Airport scheduled to avoid tarmac heat exposure are non-negotiable. For IBD induction cases, the destination infusion suite must be confirmed before the consignment moves. 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-cycle.

What your physician needs to provide

For an Egyptian-licensed dermatologist, rheumatologist, or gastroenterologist prescribing reference Stelara through the EDA pathway, the clinical justification letter is the cornerstone of the application. The letter 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, ulcerative colitis with Mayo score and endoscopic activity, or pediatric plaque psoriasis with body-surface-area involvement), prior biologic and non-biologic therapy history, and a clinical rationale for IL-12/23 (p40) blockade. The letter explicitly names reference Janssen Stelara and documents the clinical reason a biosimilar is not appropriate substitution for this patient.

The letter specifies the exact dosing plan per the FDA-approved label. For adult plaque psoriasis: 45 mg SC at week 0 and week 4, then every 12 weeks; patients over 100 kg receive 90 mg. For psoriatic arthritis: 45 mg SC at week 0 and week 4, then every 12 weeks regardless of weight (90 mg if coexisting plaque psoriasis and over 100 kg). For pediatric plaque psoriasis (ages 6 and older): weight-banded (under 60 kg, 0.75 mg per kg; 60 to 100 kg, 45 mg; over 100 kg, 90 mg) at week 0 and week 4, then every 12 weeks. For Crohn's and ulcerative colitis: weight-banded IV induction (260 mg up to 55 kg, 390 mg for 55 to 85 kg, 520 mg over 85 kg), then 90 mg SC eight weeks after the IV dose, then every 8 weeks for maintenance; some clinicians shorten maintenance to every 4 weeks for inadequate response, as documented in the prescribing information.

Pre-initiation monitoring documented in the letter: baseline TB screening (IGRA or PPD, plus chest imaging where indicated) with treatment of any latent TB; hepatitis B serology where clinically indicated; absence of contraindications to live vaccines during therapy. Posterior reversible encephalopathy syndrome (PRES), although rare, is labeled, and patients should report new neurologic symptoms or atypical infections promptly. The treating physician's EMS membership number, Ministry of Health licence reference, the dispensing facility licence, and the infusion-center identification for IBD induction complete the package.

Common questions about Stelara in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover reference Stelara? Each insurer assesses claims case by case. Many will fund a locally stocked ustekinumab biosimilar but not reference Stelara specifically, particularly under the post-2022 EGP environment where biosimilars deliver substantially lower per-claim cost. Many require pre-authorisation. We supply the documentation that allows your insurer to assess; the claim filing stays with you or the dispensing hospital.

Why not just take an ustekinumab biosimilar? That is a clinical decision your prescribing physician makes, not a Reserve Meds decision. Common reasons a treating physician documents reference Stelara specifically include prior stable response to reference brand, pediatric considerations, prior non-medical switch failure, or patient and physician preference recorded in the case notes. We coordinate whichever specific product the prescription names; we do not advocate for one over another.

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 run biologic infusion suites as routine practice. The weight-banded IV induction is followed by SC maintenance starting eight weeks later.

Is TB screening required? Yes. The Stelara FDA label warns for serious infections including tuberculosis reactivation. Baseline TB screening (IGRA or PPD, plus chest imaging where indicated) and treatment of any latent TB before initiation are mandatory. Egypt's moderate TB-burden tier makes this non-negotiable in the EDA filing. Live vaccines should not be administered during therapy.

What about HSTCL risk in pediatric IBD patients? Hepatosplenic T-cell lymphoma has been most strongly associated with anti-TNF agents (particularly when combined with azathioprine or 6-mercaptopurine) in adolescent and young adult IBD patients, not with ustekinumab. The HSTCL warning in the broader IBD biologic class is something your gastroenterologist will discuss as part of overall risk-benefit; it is not a Stelara-label boxed warning. Reserve Meds does not provide clinical risk evaluation.

What is the typical course duration? Stelara is dosed as ongoing maintenance with no fixed finite course. Continued response and tolerability are reassessed periodically by the treating physician.

Where Reserve Meds fits in Stelara 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 reference Stelara specifically, we orchestrate US-side sourcing of the named Janssen reference product through a DSCSA-compliant specialty channel, build the documentation packet your physician submits (including the brand-specification language given the live biosimilar landscape), coordinate validated cold-chain logistics with continuous temperature logging into Cairo, and assign a single named coordinator in both English and Arabic. Stelara is one of the established workhorse biologics in autoimmune NPP requests from MENA and South Asia patients seeking supply continuity at home. No prior Reserve Meds Stelara case is on file yet; standard NPP coordination under our cold-chain biologic playbook applies.

Next step

If your Egyptian physician has prescribed reference Stelara 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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