Stelara access in Saudi Arabia: the SFDA Personal Importation Program

How KSA patients legally obtain reference Stelara (ustekinumab) when a specific brand, presentation, or non-substitution preference matters amid the active US and international ustekinumab biosimilar wave.

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

Quick orientation

Stelara (ustekinumab) is a fully human IgG1 monoclonal antibody manufactured by Janssen Biotech, a Johnson and Johnson subsidiary, approved by the US FDA across moderate to severe plaque psoriasis (2009), psoriatic arthritis (2013), Crohn's disease (2016), ulcerative colitis (2019), pediatric plaque psoriasis 6 and older (2020), and pediatric psoriatic arthritis 6 and older (2022). Ustekinumab binds the shared p40 subunit of IL-12 and IL-23. The Saudi Food and Drug Authority (SFDA) lists ustekinumab as a registered biologic through Janssen's regional affiliate. The KSA-specific story in 2026 is the active biosimilar wave: Wezlana, Pyzchiva, Otulfi, Selarsdi, Yesintek, Steqeyma, and Starjemza have launched in the US at WAC discounts ranging from approximately 5 percent to 90 percent below reference Stelara, and KSA biosimilar adoption is growing. KSA patients use the SFDA Personal Importation Program for Stelara when brand and presentation precision matters (continuity on reference Stelara, declined substitution to a biosimilar), when the IV induction vial is not locally stocked for IBD initiation, or when Bupa Arabia, Tawuniya, or MedGulf has declined biologic coverage.

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Why KSA patients need Stelara through the named-patient pathway

Stelara is not a rare drug. It is registered with SFDA. So why does it appear in an NPP queue at all? Three patterns drive demand, all of which surface specifically in the Saudi market in 2026.

First, brand and presentation alignment. A patient already on Stelara whose specialist has documented non-substitution may need continuity of the same brand and same presentation while the local market has shifted toward a specific biosimilar. The Drug Channels 2025 biosimilar price war analysis tracked Wezlana, Pyzchiva, Otulfi, Selarsdi, Yesintek, Steqeyma, and Starjemza in the US, and KSA hospital formularies and CCHI-regulated payers are following the global pattern of biosimilar substitution. A patient stabilized on reference Stelara for whom the prescribing specialist documents a clinical or supply-continuity rationale for non-substitution uses the SFDA PIP to maintain access.

Second, indication-specific stocking gaps. A KSA hospital may carry the 90 mg SC presentation routinely for plaque psoriasis but not maintain reliable stock of the 130 mg IV induction vial, leaving an IBD patient awaiting first dose without a local source. This is a presentation-level gap, not a registration gap. The patient does not need approval for Stelara generally; they need access to the specific IV vial format.

Third, cost-coverage gaps. Even where Stelara is registered, payer coverage in KSA is uneven for autoimmune biologics. Bupa Arabia, Tawuniya, and MedGulf Arabia each handle biologic claims case by case, with formulary moves that favor the biosimilar tier. Cash-pay patients who prefer or whose specialist has specified reference Stelara use the PIP route.

NPP coordination for Stelara in KSA is therefore less about scarcity and more about precision, getting the right brand, the right presentation (45 mg, 90 mg, or 130 mg IV vial), the right cold-chain handling, and the right import documentation into the patient's local treating clinic on a predictable schedule.

The SFDA Personal Importation Program for Stelara

The Personal Importation Program allows an SCFHS-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable for the patient. The framework covers immunology, gastroenterology, rheumatology, dermatology, and pediatric specialty therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector via the Ghad digital regulatory platform.

A complete application includes a clinical justification letter from the treating physician (diagnosis with ICD-10 coding, severity scoring, prior therapies attempted with outcomes, why a locally registered alternative is unsuitable, the specific drug, brand, presentation, dose, and duration requested), SCFHS registration verification in the relevant specialty, an anonymized patient identifier, full product details (brand name Stelara, generic name ustekinumab, manufacturer Janssen Biotech, country of origin, strength 45 mg, 90 mg, or 130 mg IV vial, dosage form, pack size, requested quantity, lot, and expiry), the destination dispensing facility license, and a chain-of-custody plan from the US release point through international transit with cold-chain validation to the receiving Saudi pharmacy.

For Stelara specifically, the clinical justification angle has two distinguishing elements. First, brand specification. The clinical letter explicitly names reference Stelara (Janssen) rather than ustekinumab generically, because in the current biosimilar landscape a non-specified prescription may be filled with whichever ustekinumab the local agent stocks. The prescriber's documented rationale for non-substitution is part of the file. Second, the FDA label carries warnings for serious infections including tuberculosis reactivation, malignancies, hypersensitivity reactions, and posterior reversible encephalopathy syndrome (PRES). Tuberculosis screening (IGRA or PPD) is required before initiating therapy and the result is documented in the clinical letter. There is also a pediatric IBD class consideration: hepatosplenic T-cell lymphoma (HSTCL) has been reported in adolescent and young adult IBD patients receiving anti-TNF therapy, most of whom received concomitant azathioprine or 6-mercaptopurine. While this warning is most prominent on the anti-TNF labels, the class-effect awareness applies whenever a pediatric IBD patient is being initiated on any biologic.

Approval timelines for routine cases run 10 to 21 business days. Complex cases (IV induction first imports, pediatric weight-banded dosing, brand-non-substitution specification) can extend to 6 to 10 weeks.

Where Stelara gets dispensed in Saudi Arabia

For SC maintenance dosing (45 mg or 90 mg every 12 weeks for psoriasis and PsA; 90 mg every 8 weeks for IBD maintenance), any major tertiary or private center with 2 to 8 degrees Celsius

cold-chain storage and continuous monitoring qualifies. For IV induction in Crohn's and ulcerative colitis (a single weight-banded dose of approximately 6 mg per kg, rounded to 260 mg, 390 mg, or 520 mg), the dispensing facility additionally needs an infusion suite with pharmacy reconstitution capability for dilution into normal saline. The institutions that handle both modalities as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA); King Saud University Medical City (KSUMC); Dr. Sulaiman Al Habib Medical Group (HMG); Saudi German Health hospitals; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh.

For physicians at smaller hospitals without internal import infrastructure, the practical pattern is to route through an SFDA-licensed specialty importer in Riyadh or Jeddah that handles the PIP filing and the chain-of-custody documentation, with the IV vial dispensed at a partner infusion center and SC maintenance flowing through the prescribing institution's pharmacy thereafter.

Real cost picture for Stelara in Saudi Arabia

Reference Stelara 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 the annualized cost for maintenance therapy commonly exceeds USD 100,000 before any rebates or assistance. At the SAR peg of approximately 3.75 to the dollar, the 12-week plaque psoriasis supply translates to roughly SAR 49,900 and the IBD 12-week phase to roughly SAR 99,400, with annual maintenance above SAR 375,000 at US WAC equivalents.

The biosimilar wave has compressed the broader category. Wezlana low-WAC priced at roughly 81 percent below Stelara at launch. Steqeyma launched at approximately 85 percent below. Other entrants priced across a 5 percent to 90 percent discount range. For patients sourcing reference Stelara specifically, the price differential versus the biosimilar tier is part of the decision the prescriber and patient make together, and the PIP file references that decision.

International logistics for cold-chain biologic shipment into Riyadh or Jeddah typically runs USD 800 to USD 2,500 (approximately SAR 3,000 to SAR 9,400) per shipment. SFDA permit fees and customs handling are nominal relative to drug cost. The Janssen CarePath program (US benefits verification, copay assistance for commercially insured US patients, infusion site logistics for IV induction) is US-only and does not extend internationally.

Typical timeline for Stelara in Saudi Arabia

SFDA routine processing is typically 10 to 21 business days from a complete filing. Cold-chain shipment adds 2 to 3 days versus ambient because validated thermal packaging and continuous temperature logging are mandatory. The Stelara label allows excursions to room temperature up to 30 degrees Celsius for a single period of up to 30 days within the labeled shelf life, after which the product cannot be returned to refrigeration; this gives meaningful operational runway. End-to-end, most plaque psoriasis or PsA cases complete within 4 to 7 weeks from first complete documentation. IBD induction cases run longer because the IV vial dispense, the infusion center scheduling, and the subsequent SC maintenance schedule must be coordinated as a series, often extending the first-cycle window to 6 to 10 weeks.

What your physician needs to provide

For an SCFHS-licensed dermatologist, rheumatologist, gastroenterologist, or pediatric specialist prescribing Stelara through the PIP pathway, the clinical justification letter documents diagnosis with ICD-10 coding (plaque psoriasis with PASI or BSA score, psoriatic arthritis with joint count, Crohn's disease with endoscopic confirmation and CDAI score, or ulcerative colitis with endoscopic confirmation and Mayo score), prior therapy history with documented outcomes, and the clinical rationale for IL-12/23 p40 blockade.

The letter specifies the exact dosing plan per the FDA-approved label. Plaque psoriasis (adult): 45 mg SC at week 0 and week 4, then every 12 weeks; 90 mg for patients over 100 kg. Psoriatic arthritis (adult): 45 mg SC at week 0 and week 4, then every 12 weeks regardless of weight. Pediatric plaque psoriasis (ages 6 and older): weight-banded 0.75 mg per kg below 60 kg, 45 mg at 60 to 100 kg, and 90 mg over 100 kg, at week 0 and week 4, then every 12 weeks. Crohn's disease and ulcerative colitis (adult): single IV induction dose at approximately 6 mg per kg (260 mg for up to 55 kg, 390 mg for 55 to 85 kg, 520 mg for over 85 kg), followed by 90 mg SC eight weeks after the IV dose, then every 8 weeks for maintenance. The monitoring plan documents baseline TB screening (IGRA or PPD), hepatitis B serology where clinically indicated, and follow-up for signs of infection, malignancy, or new neurologic symptoms (PRES).

For pediatric IBD patients, the prescriber's letter typically addresses the HSTCL class-awareness pattern even though this warning is most prominent on anti-TNF labels, particularly where concomitant azathioprine or 6-mercaptopurine is being used. The brand specification (reference Stelara, Janssen) is explicitly stated where non-substitution is the prescriber's intent. The treating physician's SCFHS registration, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package.

Common questions about Stelara in Saudi Arabia

The biosimilars are cheaper. Why pursue reference Stelara? The decision to stay on or initiate reference Stelara versus a biosimilar (Wezlana, Pyzchiva, Otulfi, Selarsdi, Yesintek, Steqeyma, Starjemza) is your specialist's, not Reserve Meds'. Common rationales include prior stabilization on the reference product, specific clinical judgment on non-substitution, or a documented adverse experience with biosimilar switching. We coordinate whichever specific product the prescription names.

Will Bupa Arabia, Tawuniya, or MedGulf cover reference Stelara? Each plan handles biologic claims case by case. Many KSA plans now favor the biosimilar tier on formulary, and reference Stelara may require additional prior authorization. We supply the documentation that allows the insurer to assess; the claim itself sits with you or your hospital.

The IV vial is not available locally. Is that the case I should use the PIP for? Yes. The 130 mg IV induction vial used for Crohn's and ulcerative colitis initiation is not always stocked at every KSA hospital pharmacy, even where the 45 mg or 90 mg SC presentations are routine. The PIP route exists precisely for this presentation-level gap.

What is PRES and how is it monitored? Posterior reversible encephalopathy syndrome is a rare but documented Stelara label warning. Symptoms include headache, seizures, visual disturbances, and confusion. Your specialist briefs you on what to report and when to seek urgent evaluation. This is part of the standard biologic monitoring conversation.

My child has IBD. Are there pediatric-specific considerations? Yes. Hepatosplenic T-cell lymphoma (HSTCL) has been reported in adolescent and young adult IBD patients receiving anti-TNF therapy, most of whom received concomitant azathioprine or 6-mercaptopurine. While Stelara is not the primary drug associated with HSTCL, the class-effect awareness applies to any biologic in a pediatric IBD patient. Your pediatric gastroenterologist discusses this risk with you before initiation.

Skyrizi versus Stelara, which is right for my Crohn's or psoriasis? Stelara binds the shared p40 subunit of IL-12 and IL-23; Skyrizi binds the p19 subunit of IL-23 specifically. For a patient who has failed Stelara, IL-23p19 selectivity is often the prescriber's rationale for switching to Skyrizi. The choice rests with your specialist.

Where Reserve Meds fits in Stelara cases

Reserve Meds is a US-based concierge coordinator. We do not replace your dermatologist, rheumatologist, gastroenterologist, or pediatric specialist, we do not replace SFDA, and we do not replace your dispensing pharmacy. For Stelara specifically, we orchestrate US-side sourcing of reference Stelara through a DSCSA-compliant specialty channel (distinguishing reference Stelara from the biosimilar tier in every line of the procurement), build the documentation packet your physician submits to the SFDA Personal Importation Program, coordinate validated cold-chain logistics with continuous temperature logging into Riyadh or Jeddah, and assign a single named coordinator through induction and maintenance phases. Stelara is one of the established workhorse biologics in autoimmune NPP requests, particularly from patients in the Middle East and South Asia who have been initiated on therapy abroad and need supply continuity, or who have IBD and face local stocking gaps for the IV induction presentation. No prior Reserve Meds case experience for Stelara in KSA is logged yet; standard NPP coordination under our cold-chain biologic playbook applies.

Next step

If your Saudi specialist has prescribed 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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- Saudi Arabia country page
- Skyrizi access in Saudi Arabia
- Named-patient pathway overview
- Psoriasis condition page

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