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## Stelara access in the UAE: the EDE named-patient pathway

How UAE patients legally obtain reference Stelara (ustekinumab) when the local market has shifted toward a biosimilar, the IV induction vial is not in stock, or the prescribed brand and presentation need supply continuity.

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

### Quick orientation

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Stelara (ustekinumab) is the Janssen brand name for the IL-12/23 p40-subunit blocker first approved by the US FDA in September 2009 for moderate to severe plaque psoriasis. Subsequent approvals followed for psoriatic arthritis (2013), Crohn's disease (2016), ulcerative colitis (2019), pediatric plaque psoriasis ages 6 and older (2020), and pediatric psoriatic arthritis ages 6 and older (2022). It is registered in the UAE through MOHAP, and the practical access question is rarely whether ustekinumab exists locally. Stelara cases reach the named-patient pipeline because of three precise patterns: a patient already stabilised on reference Stelara who needs continuity rather than a substitution to one of the 2025-2026 ustekinumab biosimilars now in the global market, a Crohn's or ulcerative colitis patient whose local market stocks the 90 mg SC maintenance presentation reliably but not the 130 mg IV induction vial, and a cash-pay private patient whose payer will not fund the IBD or PsA indication even where the drug is locally registered. Reserve Meds coordinates the US-side cold-chain sourcing and the documentation; the principal operational discipline is presentation-level precision.

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### Why UAE patients need Stelara through the named-patient pathway

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The UAE operates one of the most developed pharmaceutical regulatory environments in the Gulf Cooperation Council. As of 29 December 2025, under Federal Decree-Law No. 38 of 2024, the newly established Emirates Drug Establishment (EDE) assumed 44 core services from MOHAP, including marketing authorisations and personal-use import permits. The UAE MOHAP and DHA channels carry ustekinumab as a registered biologic, and patients in Dubai, Abu Dhabi, and the Northern Emirates can typically access ustekinumab through the local Janssen agent or a partner distributor.

So why does a registered biologic still drive cross-border named-patient demand? Three patterns. First, brand and presentation alignment. The 2024 to 2026 US biosimilar wave produced multiple ustekinumab products (Wezlana from Amgen, Pyzchiva from Sandoz, Otulfi from Fresenius Kabi and Formycon, Selarsdi, Yesintek, Steqeyma, Starjemza from Bio-Thera and Cipla approved May 2025 with interchangeability designation, and others), and similar dynamics are unfolding globally. A UAE patient already stabilised on reference Stelara whose specialist has documented a clinical rationale for non-substitution may pursue cross-border supply of the specific reference product when the local agent's stocking has shifted toward biosimilars. Second, indication-specific stocking gaps. A country may carry the 45 mg or 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. Third, cost-coverage gaps. Daman, Thiqa, GIG Gulf (formerly AXA Gulf), Sukoon (formerly Oman Insurance Company), ADNIC, and Orient assess specialty biologic coverage case by case. Plaque psoriasis is on the broadest formularies; the IBD and PsA indications often face restrictive prior-authorization or are denied outright. Cash-pay families fill the gap.

## **The EDE named-patient pathway for Stelara**

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The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered, not stocked locally, or where brand specification matters is the unregistered-medicine import permit, historically administered by MOHAP and, from 29 December 2025, administered through the EDE portal at [ede.gov.ae](http://ede.gov.ae). The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered option is not suitable for this patient.

A complete application includes the prescribing physician's clinical justification letter, the physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority depending on practice location), an anonymised patient identifier, full product details (brand name explicitly, generic name, manufacturer, strength, presentation, pack size, quantity, treatment duration), the destination dispensing facility name and license, the pharmacy in charge, and a chain-of-custody plan that specifies cold-chain handling end to end.

For Stelara, the clinical justification angle is brand- and presentation-specific. Where the request is for reference Stelara specifically (versus the locally stocked biosimilar), the prescribing specialist documents the patient's prior stabilisation on reference Stelara, the clinical reason against non-medical substitution, and any prior biosimilar exposure. Where the request is for the 130 mg IV induction vial unavailable locally, the prescriber documents the IBD induction regimen and the local stocking gap. Where the request is indication-driven (Crohn's, UC, or PsA payer denial), the prescriber documents prior-line therapy (corticosteroids, immunomodulators, anti-TNF) and the rationale for IL-12/23 selective blockade as the next-line choice.

Approval timelines for routine cases are typically 5 to 15 business days. Complex cases (first import of the 130 mg IV induction vial, larger quantities for IBD induction series, brand-specification cases) can extend to 4 to 6 weeks.

## **Where Stelara gets dispensed in the UAE**

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Stelara requires a dispensing facility with 2 to 8 degrees Celsius cold-chain storage and, for IBD induction, an infusion setting capable of administering the weight-banded IV induction dose. Tertiary and major private hospitals that handle named-patient cold-chain imports as established workflow include Cleveland Clinic Abu Dhabi on Al Maryah Island (with ASHP-accredited pharmacy services and active gastroenterology, dermatology, and rheumatology programs), Sheikh Khalifa Medical City in Abu Dhabi (a SEHA-network 586-bed JCI-accredited hospital), Tawam Hospital in Al Ain (a SEHA-network referral center with pediatric services), American Hospital Dubai (a Mayo Clinic Care Network member), King's College Hospital London Dubai (with gastroenterology strength), Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare sites. For SC maintenance dispensing, the broader UAE specialty-importer network handles the bring-in and the prescribing hospital outpatient pharmacy releases

to the patient. For the 130 mg IV induction phase of Crohn's or UC cases, the dispensing facility must have the infusion-center capacity and IV admixture pharmacy.

## **Real cost picture for Stelara in the UAE**

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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 published 2025 analyses. Per single 90 mg subcutaneous dose, WAC is in the range of USD 30,000 and annualised maintenance cost commonly exceeds USD 100,000 before any rebates or assistance. The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD, so annual reference Stelara maintenance translates to roughly AED 367,000-plus on the IBD regimen at US WAC equivalents.

The biosimilar landscape has compressed this picture materially. Wezlana low-WAC launched at roughly 81 percent below Stelara; Steqeyma at approximately 85 percent discount; other entrants across a 5 percent to 90 percent discount range. For UAE patients who would accept a biosimilar, the cost picture is fundamentally different from a reference-brand request. International logistics for a cold-chain biologic shipment to the UAE typically runs USD 400 to USD 1,500 (approximately AED 1,500 to AED 5,500) depending on destination emirate and presentation. UAE customs and EDE permit fees are nominal. Reserve Meds' concierge fee is itemised separately. The Janssen CarePath program does not extend internationally.

## **Typical timeline for Stelara in the UAE**

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EDE routine processing is typically 5 to 15 business days from a complete filing. Cold-chain shipment adds 2 to 3 days versus an ambient small molecule. For plaque psoriasis or PsA cases on the standard 45 mg or 90 mg SC every-12-week regimen, end-to-end timing typically runs 3 to 5 weeks from a complete documentation set. For Crohn's or UC cases requiring the 130 mg weight-banded IV induction (approximately 260 mg, 390 mg, or 520 mg depending on weight band, rounded per the label), the destination infusion-center scheduling adds a coordination step that pushes the first-dose window to 4 to 6 weeks depending on the chosen facility's infusion calendar. The 30-day room-temperature excursion allowance on the FDA label provides operational flexibility on the SC presentations.

## **What your physician needs to provide**

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For a UAE-licensed dermatologist, rheumatologist, or gastroenterologist prescribing Stelara through the EDE pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's specific indication with severity scoring where relevant (PASI for plaque psoriasis, ACR criteria for psoriatic arthritis, Mayo or CDAI scoring for IBD), prior therapy history including topical, conventional systemic, anti-TNF, and other biologic exposure, and the clinical rationale for IL-12/23 blockade. Where the request is brand-specific, the letter records why non-medical substitution to a biosimilar is not appropriate for this patient (typically prior stabilisation on reference Stelara).

The letter specifies the FDA-approved regimen by indication. For plaque psoriasis adult: 45 mg SC at week 0 and week 4, then every 12 weeks (90 mg for patients above 100 kg). For psoriatic arthritis: 45 mg SC at week 0 and week 4, then every 12 weeks, regardless of weight (90 mg for coexisting moderate-to-severe plaque psoriasis above 100 kg). For pediatric plaque psoriasis ages 6 and older: weight-banded dosing (0.75 mg per kg under 60 kg, 45 mg from 60 to 100 kg,

90 mg over 100 kg) at week 0 and week 4, then every 12 weeks. For Crohn's disease and ulcerative colitis adult: a single weight-banded IV induction dose (approximately 6 mg per kg, rounded to 260 mg for patients up to 55 kg, 390 mg for 55 to 85 kg, and 520 mg for over 85 kg), followed by 90 mg SC eight weeks after the IV dose, then every eight weeks for maintenance. Some specialists shorten the maintenance interval to every four weeks for inadequate response, which is a label-aligned dosing flexibility documented in the FDA prescribing information for IBD.

The monitoring plan covers baseline tuberculosis screening (interferon-gamma release assay or PPD) before initiation, with treatment of latent TB before starting therapy. Hepatitis B serology where clinically indicated, and routine follow-up for signs of infection, malignancy, or hypersensitivity. Patients should report new neurologic symptoms (the Stelara label notes posterior reversible encephalopathy syndrome, PRES, as a rare but documented event). Live vaccines should be avoided during treatment.

## Common questions about Stelara in the UAE

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**Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this?** Each insurer assesses Stelara case by case. Plaque psoriasis is on the broadest formularies; PsA, Crohn's, and UC coverage varies. Thiqa has the strongest specialty coverage for UAE nationals in Abu Dhabi. We supply documentation; the claim sits with you or your hospital. The economics shift materially if your insurer accepts a biosimilar, since some biosimilars carry deep discounts to reference Stelara.

**What is the biosimilar landscape and does it affect my case?** The US FDA has approved multiple ustekinumab biosimilars since October 2023 (Wezlana, Pyzchiva, Otulfi, Selarsdi, Yesintek, Steqeyma, Starjemza, among others). Several carry interchangeability designation. EMA and Health Canada have approved similar biosimilar slates on roughly parallel schedules. UAE local-agent stocking has begun to shift. If your specialist has specifically prescribed reference Stelara (the originator Janssen product), the named-patient route lets you obtain that specific brand even when local stocking has moved. If your specialist accepts substitution to a biosimilar, you may have lower-cost local options that do not require named-patient import.

**My gastroenterologist wants the 130 mg IV induction vial but it is not in stock locally. What now?** This is one of the most common Stelara cases in the UAE pipeline. The IV induction phase is a single weight-banded dose, and the 130 mg vial is the source. The EDE pathway is the legal mechanism. The destination infusion-center scheduling is the key timing variable.

**What is the TB screening requirement?** Stelara requires screening for latent and active tuberculosis before initiation, with treatment of latent TB before starting therapy. Your physician will order an interferon-gamma release assay or PPD as part of standard pre-biologic workup.

**What about Skyrizi (risankizumab) as a comparator?** Skyrizi is IL-23 selective (versus Stelara's IL-12/23). Some specialists prefer the IL-23-selective profile for IBD or psoriasis depending on the patient's history and comorbidities. Choice between Stelara, Skyrizi, biosimilars, and other biologics rests with the prescriber. Reserve Meds coordinates whichever medicine the physician has named.

**Can I receive Stelara at home?** Subcutaneous maintenance doses are designed for self-administration after training. The dispensing facility must be UAE-licensed; the hospital outpatient pharmacy releases the medicine to you after final verification, and you administer the injection at home. IV induction doses for Crohn's or UC are administered in a clinical infusion setting.

## Where Reserve Meds fits in Stelara cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your dermatologist, rheumatologist, or gastroenterologist, we do not replace the EDE, and we do not replace your dispensing pharmacy or infusion center. For Stelara specifically, we orchestrate the US-side sourcing through DSCSA-compliant specialty channels, build the documentation packet your physician submits including brand specification where required, coordinate validated cold-chain logistics with continuous temperature logging into the UAE, and assign a single named coordinator through the case. 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 at home, or who have IBD and face local stocking gaps for the IV induction vial. Presentation-level precision (45 mg versus 90 mg versus 130 mg IV vial) and brand specification (reference Stelara versus biosimilar) are the recurring operational fundamentals we expect.

### Next step

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If your UAE 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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