Tezspire access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Tezspire (tezepelumab-ekko), AstraZeneca's human monoclonal antibody targeting thymic stromal lymphopoietin (TSLP), through the SFDA Personal Importation Program.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the Saudi Arabia country research module with the Tezspire drug module to describe the path families actually walk.

Quick orientation

Tezspire (tezepelumab-ekko) is AstraZeneca and Amgen's first-in-class TSLP-targeted monoclonal antibody for severe asthma. It received FDA approval in December 2021 and is the first severe-asthma biologic approved without a phenotype or biomarker requirement, meaning it works across eosinophilic and non-eosinophilic disease and in patients regardless of allergic status. For Saudi Arabia patients with severe asthma whose treating pulmonologist or allergist has recommended tezepelumab, this page describes the SFDA Personal Importation Program pathway.

Why this drug is hard to source in Saudi Arabia

Severe asthma is a high-prevalence condition in KSA and the broader GCC, and the biologic prevention class is well-established. SFDA registration for the various asthma biologics (Xolair, Nucala, Cinqair, Fasenra, Dupixent, and Tezspire) varies by drug. Tezspire is the newest entrant in the class and SFDA registration uptake is still maturing. The access gap typically presents as a patient whose treating physician has chosen tezepelumab specifically (often because of non-eosinophilic phenotype, mixed phenotype, or failure on prior biologics) and where the local supply chain does not stock it. The PIP route lets the treating physician bridge the gap on a named-patient basis.

The SFDA Patient Import Permit (PIP) pathway applied to Tezspire

The Saudi Food and Drug Authority's Personal Importation Program is the federal pathway that allows an SCFHS-licensed physician to import a specific medicine for a specific named

patient when the medicine is approved by a recognized reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Tezspire (tezepelumab-ekko) holds FDA approval since 2021 for add-on maintenance treatment of severe asthma in adults and pediatric patients aged 12 years and older, which places it squarely within the framework's scope.

The application is filed through the dispensing institution's import pharmacy (or, where the institution does not hold internal import-pharmacy capability, through an SFDA-licensed specialty importer in Riyadh or Jeddah). The standard package contains the clinical justification letter from the treating physician, the SCFHS license verification, the anonymized patient identifier, the full product details for Tezspire including 210 mg per 1.91 mL subcutaneous injection (pre-filled syringe or autoinjector), every four weeks, with cold-chain handling at 2 to 8 degrees Celsius documented in the file, the destination dispensing facility license, and the chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy. The SFDA portal at sfda.gov.sa handles regulatory transactions, and named-patient activity increasingly routes through the agency's Ghad digital platform.

Where Tezspire gets dispensed in the Kingdom

The major Saudi institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network; King Saud University Medical City and the academic medical centers; King Khalid University Hospital; Dr. Sulaiman Al Habib Medical Group (HMG) across multiple Riyadh, Jeddah, and Eastern Province facilities; the Saudi German Hospital network; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. Smaller hospitals typically route their named-patient cases through one of these centers or through an SFDA-licensed specialty importer. For a Tezspire case, the dispensing facility is selected on the basis of where the treating physician practices and where the patient receives ongoing care; Reserve Meds does not select the dispensing facility on the family's behalf.

Real costs in SAR and USD

The US wholesale acquisition cost for Tezspire is approximately USD 4,400 to USD 4,800 per 210 mg pre-filled syringe. Dosing is one injection every four weeks, which produces a monthly drug cost of approximately USD 4,400 to USD 4,800 (roughly SAR 16,500 to SAR 18,000). Cold-chain logistics for a refrigerated biologic add approximately SAR 3,000 to SAR 5,600 per shipment. Bupa Arabia, Tawuniya, and MedGulf each handle severe-asthma

biologics case by case, typically with documented prior-biologic failure or non-eosinophilic phenotype as the gating criterion for tezepelumab specifically.

Reserve Meds quotes an indicative range based on the initial intake and then a transparent firm quote with each line item shown separately. The Reserve Meds concierge fee is published on a tiered schedule and is shown as a separate line. Nothing is bundled. Nothing is hidden.

Timing, what to expect

The SFDA Personal Importation Program processes routine cases (recognized reference-authority drug, well-documented indication, established institution) in approximately 10 to 20 business days. Complex cases (novel mechanism, off-label use within the FDA label scope, ultra-rare patient population, first-time importer) can extend to 6 to 8 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm. In parallel with the SFDA review, Reserve Meds aligns the US-side sourcing, the packaging and cold-chain validation, and the shipment plan, so the drug is ready to move on the day approval comes through. The patient experience runs through ten well-defined steps from initial physician decision through reorder coordination; the full ten-step sequence is documented in the Saudi Arabia country module and in our patient-facing operations brief.

What your physician needs to provide

The treating physician's clinical justification letter typically documents the severe asthma diagnosis (GINA Step 4 or Step 5, baseline FEV1, exacerbation history over 12 months, oral corticosteroid burden, asthma control questionnaire score), prior biologic trial history if any, the rationale for TSLP-targeted therapy (often the non-eosinophilic or mixed-phenotype case, or the patient who has failed prior IL-5 or IL-4/13-targeted therapy), and the proposed every-four-weeks dosing. The SCFHS registration in pulmonology, allergy and immunology, or internal medicine accompanies the letter.

The dispensing facility's SFDA-licensed pharmacy completes the submission and accepts the chain-of-custody documentation. The institutional license is what authorizes the dispensing pharmacy to receive the imported drug, so the physician's individual SCFHS license is necessary but not sufficient on its own. Post-import pharmacovigilance commitment to report adverse events through the SFDA National Pharmacovigilance Center is part of the application and runs through the full course of therapy, not just the initial dose.

Vision 2030 and the specialty-access environment

Saudi Vision 2030's Health Sector Transformation Program (HSTP) is the operating frame for healthcare reform in the Kingdom. HSTP is restructuring the Ministry of Health from a provider-and-regulator into a regulator and strategist, with clinical delivery devolving into regional Health Clusters and Centers of Excellence. The program names tertiary cancer care, rare-disease care, organ transplantation, genomics, and digital health as priority verticals, all of which are heavy users of specialty drugs not registered locally. The practical effect on the PIP framework is twofold. HSTP is expanding the universe of specialty drugs that get formal SFDA registration, which closes some access gaps. At the same time, HSTP is increasing diagnostic capacity in rare disease and oncology genomics, which surfaces new patients who need drugs that are FDA-approved but not yet registered in the Kingdom. The named-patient framework remains essential for the foreseeable future. Saudization (the Nitaqat workforce-nationalization program) does not change the PIP framework, but confirming the prescriber's SCFHS license status before filing is good practice in any case where the treating physician is in a renewal window.

Pharmacovigilance and cold-chain considerations

Tezspire carries warnings for hypersensitivity reactions and live vaccine considerations. The SFDA pharmacovigilance commitment includes injection-reaction surveillance, parasitic infection screening in patients from endemic regions per the US label, and any serious adverse event reporting. Cold-chain at 2 to 8 degrees Celsius is required and the pre-filled syringe must be brought to room temperature for 30 to 60 minutes before injection.

Reserve Meds' physician documentation kit includes the SFDA adverse-event reporting reference so the treating physician has the framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician. The dispensing facility carries the chain-of-custody and storage obligations through the dispensing event, and off-label transfer of the imported supply to another patient is not permitted under the PIP framework.

Common questions about Tezspire in the Kingdom

Will Bupa Arabia, Tawuniya, or MedGulf cover this? Each insurer handles named-patient imports case by case under the Council of Cooperative Health Insurance (CCHI) framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even where the local hospital pharmacy does not stock it. Others reimburse a percentage. Many require pre-authorization with the clinical justification letter attached. Reserve Meds supplies the documentation that lets the insurer assess the case; the claim is yours or your

hospital's to file. Cash-pay is the default operating posture for cross-border access, with reimbursement sought after delivery where your plan permits.

Will my Ministry of Health-employed physician's letter be sufficient if SFDA flags the case? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license. The clinical justification letter is the cornerstone of the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must be a locally licensed pharmacy. For oral medicines, a hospital outpatient pharmacy or specialized SFDA-licensed import pharmacy dispenses to the patient. For infusion or injection products, the medicine ships to the infusion center where you will receive it. Direct-to-home delivery without a licensed dispensing facility in the chain is not the operating model.

What about pediatric patients? The PIP framework applies to pediatric patients the same way it applies to adults. The clinical justification letter typically includes weight-based dosing, pediatric-specific monitoring, and where relevant the involvement of the pediatric specialty center. KFSH&RC, KAMC, and the major HMG facilities have established pediatric specialty programs that handle named-patient imports routinely.

How does Saudization (Nitaqat) affect my case? Saudization is the workforce-nationalization program that shapes hospital staffing composition. It does not change the PIP framework. It can occasionally affect timing if a non-Saudi treating physician's license is in renewal at the moment the PIP file is being prepared. Confirming the prescriber's SCFHS license status before filing is good practice.

Is Tezspire a controlled substance? No. Tezspire is not a US DEA scheduled substance. The Saudi narcotics-section approvals do not apply. The chain-of-custody documentation, the dispensing facility's pharmaceutical establishment license, and the SFDA pharmacovigilance commitment do apply.

Where Reserve Meds fits in Tezspire cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the SFDA, the dispensing pharmacy, or the institutional import-pharmacy team. For a Tezspire case in the Kingdom, our work is to orchestrate the US-side sourcing, prepare the regulatory documentation kit your physician needs, coordinate international logistics with cold-chain validation where required, and assign a single named coordinator who stays with the case through reorders. The clinical decisions remain with the treating physician. The regulatory authority remains SFDA. The dispensing remains with the

licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US supply side and those three Saudi pillars. Reserved for you.

Next step

If a treating physician in the Kingdom is weighing Tezspire for a patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Tezspire clinical resource
- Tezspire in the United Arab Emirates
- Tezspire in Qatar
- Tezspire in Kuwait
- Kingdom of Saudi Arabia country page

Sources

1. FDA approval, Tezspire (tezepelumab-ekko), AstraZeneca in partnership with Amgen, initial FDA approval 2021.
2. Saudi Food and Drug Authority (SFDA), Personal Importation Program framework, https://www.sfda.gov.sa/en, and the Ghad digital regulatory platform at https://ghad.sfda.gov.sa/.
3. Saudi Vision 2030, Health Sector Transformation Program, https://www.vision2030.gov.sa/en/explore/programs/health-sector-transformation-program.
4. Saudi Commission for Health Specialties (SCFHS), https://scfhs.org.sa/en, for treating-physician licensing and the institutional pharmacy framework.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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 ›

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