Pluvicto access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Pluvicto (lutetium Lu 177 vipivotide tetraxetan), Novartis's radioligand therapy targeting prostate-specific membrane antigen (PSMA), 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 Pluvicto drug module to describe the path families actually walk.

Quick orientation

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) is Novartis's PSMA-targeted radioligand therapy for PSMA-positive metastatic castration-resistant prostate cancer. It received FDA approval in March 2022 for the post-taxane setting and added an earlier-line indication in March 2025. Pluvicto is a radiopharmaceutical, which means the logistics, the institutional infrastructure required to administer it, and the regulatory documentation are different in kind from conventional oncology biologics. For Saudi Arabia patients with confirmed PSMA-positive mCRPC and a treating oncologist's recommendation for Pluvicto, this page describes the SFDA Personal Importation Program pathway.

Why this drug is hard to source in Saudi Arabia

Pluvicto is a lutetium-177 radioligand therapy with a 6.6-day physical half-life. The drug must be manufactured for a specific patient on a specific calibration date, shipped under controlled radiopharmaceutical logistics, and administered at a nuclear medicine facility with the licensed infrastructure to handle therapeutic-dose unsealed radioactive sources. The institutional capability requirement is substantive. In KSA, KFSH&RC has the most established nuclear medicine therapy capability, with KAMC, MNGHA, and the larger HMG and Saudi German facilities developing or holding the capability in parallel. SFDA registration for Pluvicto has progressed but cross-border access patterns continue. The PIP route, combined with the radiopharmaceutical-specific institutional documentation, is the lawful path.

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

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. Pluvicto (lutetium Lu 177 vipivotide tetraxetan) holds FDA approval since 2022 for PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) in adult patients who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy, 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 Pluvicto including intravenous infusion, 7.4 GBq (200 mCi) per dose every six weeks for up to six doses, an ambient-temperature product, 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 Pluvicto 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 Pluvicto 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 Pluvicto is approximately USD 42,500 per dose. A full six-dose course is approximately USD 255,000, translating to roughly SAR 956,000. Radiopharmaceutical logistics are a separate cost line and are materially higher than conventional cold-chain shipping because of the calibrated isotope half-life, the licensed radioactive-materials freight forwarder, and the customs handling. Logistics for a single dose typically add USD 5,000 to USD 10,000 (roughly SAR 18,750 to SAR 37,500) per dose. Insurer coverage in KSA for radioligand therapy varies and case-by-case engagement with Bupa Arabia, Tawuniya, or MedGulf is the norm.

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 ambient-temperature shipping 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 oncologist's clinical justification letter typically documents the confirmed mCRPC diagnosis, the PSMA-PET imaging showing PSMA-positive disease (this is a labeled prerequisite), the prior treatment with androgen receptor pathway inhibition and taxane-based chemotherapy, the patient's performance status and life expectancy, the rationale for radioligand therapy now, and the planned six-dose schedule. The dispensing institution's nuclear medicine therapy license and the licensed nuclear medicine physician's identification are part of the package. The SCFHS registration in medical oncology accompanies the letter, with the receiving nuclear medicine physician's SCFHS registration as the administering practitioner.

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 shipping considerations

Pluvicto carries warnings for risk from radiation exposure, myelosuppression, renal toxicity, and embryo-fetal toxicity. The SFDA pharmacovigilance commitment includes the standard radiopharmaceutical handling documentation, post-administration radiation safety counseling for the patient and household, baseline and periodic blood count and renal function monitoring, and any serious adverse event reporting. Pluvicto does not require refrigeration; it requires shielded, licensed radioactive-materials handling end to end.

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 Pluvicto 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 Pluvicto a controlled substance? No. Pluvicto 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 Pluvicto 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 Pluvicto 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 ambient-temperature shipping 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 Pluvicto 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

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

Sources

1. FDA approval, Pluvicto (lutetium Lu 177 vipivotide tetraxetan), Novartis, initial FDA approval 2022.
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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