

Keytruda

Egypt · access guide

Keytruda access in Egypt: the EDA named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Patients in Egypt access Keytruda (pembrolizumab) for multiple FDA-labelled oncology indications through the EDA personal-use import pathway, a federal mechanism that allows an Egyptian-licensed physician to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in EGP.

Why Egypt patients need Keytruda through the named-patient pathway

The Egyptian Drug Authority (EDA), established by Presidential Decree No. 777 of 2019 to carve drug regulation out of the legacy Central Administration of Pharmaceutical Affairs (CAPA), administers the personal-use importation pathway. A treating physician in Egypt licensed by the Egyptian Medical Syndicate and the Ministry of Health applies for an import permit through the EDA when the medicine is approved by the US FDA, EMA, MHRA, PMDA, or Health Canada and a clinically suitable locally registered alternative is not available.

Several patterns drive these cases: indication lag against the FDA label and EMA label; specialty biologic and oncology cases where the local route is constrained by FX availability; payer denials in the legacy HIO; and Egyptian families using cross-border supply for the precise FDA-labeled originator product. For Keytruda specifically, the named-patient pathway exists to handle exactly the situations the local registered route cannot: a newer FDA indication that has not yet propagated to Egypt labeling, a presentation or strength the local agent does not reliably carry, a payer denial that is uneconomic to appeal, or a biomarker-defined regimen where the prescriber's clinical judgement runs ahead of the local label's molecular language. In each pattern, the named-patient pathway is the mechanism that connects a Egypt-licensed physician's clinical decision with US-sourced, FDA-labeled Keytruda for a specific patient.

Newer Keytruda indications, including perioperative non-small cell lung cancer, neoadjuvant and adjuvant triple-negative breast cancer, biliary tract cancer, and high-risk muscle-invasive bladder cancer, often reach local registration 12 to 30 months after FDA approval. Many UAE patients also pursue cross-border supply for the every-six-weeks 400 mg schedule, which is not always stocked locally even when 100 mg vials are on the register.

The EDA named-patient pathway for Keytruda

A complete application typically includes a clinical justification letter from the treating physician (diagnosis, severity or stage, prior therapies, biomarker results where relevant, why Keytruda is appropriate, why the locally available alternative is not suitable for this case); the treating physician's Egypt license verification (issued by Egyptian Medical Syndicate and Ministry of Health and Population); an anonymised patient identifier where the regulator submission allows; full product details (brand name Keytruda, generic pembrolizumab, manufacturer Merck, strength 100 mg per 4 mL vial, quantity requested calibrated to the planned cycles or treatment duration); the destination dispensing facility name, license number, and pharmacy in charge; and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy, including cold-chain handling at 2 to 8 degrees Celsius from the US manufacturer through to the dispensing pharmacy.

For Keytruda, the clinical justification typically rests on documentation of PD-L1 CPS or TPS, MSI/MMR status, TMB, HER2 status for gastric where applicable, line of therapy and prior treatments, and a clear statement of why this medicine is the appropriate next step in this patient's care.

Approval timelines for routine cases are typically 10 to 30 business days from a complete filing. Complex cases (rare indication, paediatric application, larger multi-cycle quantities, gene therapy or cell therapy logistics, first-import scrutiny on a presentation new to the local route) can extend to 5 to 8 weeks. The EDA retains discretion on timing, and we do not promise specific durations.

Where Keytruda gets dispensed in Egypt

A small group of Egypt institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that fit this profile include 57357 Children's Cancer Hospital in Cairo (paediatric oncology referral), Magdi Yacoub Foundation Aswan Heart Centre, Cleopatra Hospital Group facilities in Cairo and Alexandria, As-Salam International Hospital in Maadi, Dar Al Fouad Hospital in 6th of October City, El Gouna Hospital, Ain Shams University Hospital, Cairo University Kasr Al Ainy Hospital, Mansoura University specialty centres, Alexandria University specialty centres, and the larger private hospitals in New Cairo and 6th of October.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a Cairo, Alexandria, and the new administrative capital-based specialty importer that holds a pharmaceutical establishment license and files the EDA application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's pharmacy under chain-of-custody documentation, where the patient receives the infusion under standard hospital or day-care nursing supervision.

Real cost picture for Keytruda in Egypt

US WAC for Keytruda is approximately USD 11,000 per 100 mg vial, which translates to USD 180,000 to USD 195,000 annual for 200 mg every 3 weeks. The Egyptian pound floats with material volatility against the dollar; a working reference rate of approximately 48 EGP to 1 USD applies for illustrative conversion, but live quotes track current FX, so the annual reference range converts accordingly when expressed in EGP at US WAC equivalents.

International validated cold-chain logistics typically run USD 450 to USD 1,600 (varies materially with EGP volatility) per shipment depending on destination city, urgency, and pack size. Egypt customs and EDA permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each Egypt insurer assesses named-patient imports case by case. Local payer cover is administered through the new Universal Health Insurance System (UHIS, rolling out by governorate), the legacy Health Insurance Organization (HIO) for legacy enrollees, MetLife Egypt, AXA Egypt, Allianz Egypt, Misr Insurance Holding Company, and private specialty cover for high-net-worth families. We do not promise coverage from any insurer. The US manufacturer copay programmes and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage where it applies.

Clinical evidence behind Keytruda

Pembrolizumab's clinical-trial evidence spans more than 30 phase 3 readouts. Notable pivotal studies include KEYNOTE-006 (melanoma versus ipilimumab), KEYNOTE-189 and KEYNOTE-407 (NSCLC plus chemo first-line), KEYNOTE-048 (head and neck plus chemo first-line), KEYNOTE-522 (neoadjuvant TNBC), KEYNOTE-426 (renal cell with axitinib), KEYNOTE-355 (metastatic TNBC with chemo), KEYNOTE-859 (gastric with HER2 directives), and KEYNOTE-A18 (cervical with chemoradiation). Many real-world registries have replicated the pivotal-trial response signal in unselected patient cohorts.

Typical timeline for Keytruda in Egypt

EDA routine processing is typically 10 to 30 business days from a complete filing. For Keytruda specifically, cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance scheduled to avoid extreme-heat exposure are non-negotiable. End-to-end, most cases complete within 3 to 6 weeks from first complete documentation to dispensing or first dose. For longer treatment courses, we coordinate cycle-by-cycle or quarterly resupply so the patient never approaches an empty pharmacy shelf.

What your physician needs to provide

For a Egypt-licensed physician prescribing Keytruda through the EDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis with relevant staging or severity language for the indication, the prior therapy history, the rationale for Keytruda as the appropriate next step, and the precise FDA-labeled regimen (dose, route, frequency, expected duration). For Keytruda specifically, the FDA-approved regimen is 200 mg IV every 3 weeks or 400 mg IV every 6 weeks.

For Keytruda, the relevant molecular or laboratory documentation includes PD-L1 CPS or TPS, MSI/MMR status, TMB, HER2 status for gastric. The letter references the test results that establish the patient's eligibility for the FDA-labeled indication. The treating physician's Egypt license number, the dispensing facility license number, and the pharmacy in charge complete the package. Monitoring requirements relevant to Keytruda (baseline labs, imaging cadence, adverse-event surveillance) are stated in the letter and operationalised by the prescribing physician's team.

Monitoring for Keytruda: Baseline thyroid function tests, comprehensive metabolic panel, liver function tests, hepatitis B surface antigen screening, and CT imaging at 9 to 12-week intervals. **Adverse-event profile:** Immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies (thyroid dysfunction, adrenal insufficiency, type 1 diabetes), nephritis, and skin reactions can occur. The standard checkpoint-inhibitor adverse-event playbook applies.

Common questions about Keytruda in Egypt

Will my insurer cover this? Each Egypt insurer (the new Universal Health Insurance System (UHIS, rolling out by governorate), the legacy Health Insurance Organization (HIO) for legacy enrollees, MetLife Egypt, AXA Egypt, Allianz Egypt, Misr Insurance Holding Company, and private specialty cover for high-net-worth families) assesses named-patient imports case by case. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is Keytruda already locally registered in Egypt? Local registration status can shift over time; Keytruda may already be on the Egypt register for some indications but not others, or the registered presentation may not match what the prescriber needs. The EDA pathway exists precisely to bridge these gaps and is the cleanest legal route when the local supply chain does not match the prescription.

What about competitors? Alternatives in the same therapeutic class include nivolumab (Opdivo), cemiplimab (Libtayo), dostarlimab (Jemperli), atezolizumab (Tecentriq), durvalumab (Imfinzi). Choice depends on the patient's full profile, prior therapy, biomarker status, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed.

How does the cold chain work? This medicine requires cold-chain handling at 2 to 8 degrees Celsius from manufacture through to dispensing. Reserve Meds uses validated thermal packaging with continuous temperature logging. Customs clearance is scheduled to avoid prolonged tarmac exposure. The cold chain is broken only at the dispensing pharmacy.

Will my US manufacturer assistance program help? US patient assistance programs (PAP), copay cards, and bridge programs from Merck, Pfizer, AstraZeneca, Lilly, Roche, Genentech, Novartis, AbbVie, Janssen, Gilead, Biogen, BMS, and other manufacturers are generally restricted to US residents with US prescriptions filled at US pharmacies. Cross-border patients pay cash or use local payer cover.

What if treatment is multi-year? For long-running treatment, we coordinate cycle-by-cycle or quarterly resupply through the same EDA pathway, with each shipment authorised against the same physician documentation set updated for the current cycle. Patients never need to navigate the supply chain themselves.

Where is the medicine actually administered? Infusion is administered at a hospital or day-care infusion suite under nursing supervision with vital-sign monitoring. The dispensing pharmacy releases the vial only to the infusion suite on the day of administration. Home administration is not appropriate for IV infusion of this product.

What if my physician is at a smaller clinic that does not import directly? The standard pattern is to route through a Cairo, Alexandria, and the new administrative capital-based specialty importer that holds a pharmaceutical establishment license. The importer files the EDA application on behalf of the prescribing physician, takes delivery of the medicine, and transfers it under chain-of-custody to the prescribing facility's pharmacy.

Operational notes for the EDA workflow

Operationally, the EDA personal-import pathway requires the treating physician's letter routed through the Egyptian Medical Syndicate and Ministry of Health channels. Submissions go through the EDA office or its appointed agent. Common reasons for delay are FX availability (the import is a USD-denominated purchase and FX clearance through the Central Bank of Egypt is typically the rate-limiting step), incomplete diagnosis-to-FDA-label fit, or chain-of-custody plans that do not specify continuous temperature logging. The new Universal Health Insurance System is rolling out by governorate and coverage assessment is uneven across the country.

Where Reserve Meds fits in Keytruda cases

Reserve Meds is a US-based concierge coordinator. We do not replace your prescribing physician, we do not replace the EDA, and we do not replace your dispensing pharmacy. For Keytruda specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain logistics with appropriate temperature monitoring into Egypt, plan cycle-by-cycle resupply across longer treatment courses, and assign a single named coordinator through the case. Standard NPP coordination under our cold-chain biologic playbook applies.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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