Vyloy access in Egypt

EDA Personal Importation for CLDN18.2-positive, HER2-negative gastric and GEJ adenocarcinoma. Companion diagnostic required. Coordinated end to end.

Quick orientation

Vyloy (zolbetuximab-clzb) is the first and only FDA-approved CLDN18.2-directed monoclonal antibody for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumours are CLDN18.2 positive. It is given in combination with fluoropyrimidine and platinum-containing chemotherapy. The US Food and Drug Administration approved Vyloy on 18 October 2024. It is manufactured by Astellas Pharma. The Egyptian Drug Authority (EDA) has not registered Vyloy for the Egyptian market as of May 2026, and the access route is the EDA Personal Importation pathway under Law No. 151 of 2019. Egypt carries one of the higher regional prevalences of gastric cancer, driven in part by widespread H. pylori infection that increases gastric adenocarcinoma risk, which sharpens the relevance of a first-in-class targeted option for the CLDN18.2-positive subset of patients. Reserve Meds runs the orchestration on the US side and walks alongside your oncologist on the Egypt side. Reserved for you.

Why patients in Egypt need Vyloy via the named-patient pathway

Egypt's gastric cancer burden is shaped by the very high regional prevalence of Helicobacter pylori infection, which is a well-established driver of gastric adenocarcinoma over decades. The Egyptian oncology referral pattern at Kasr Al Ainy, Ain Shams, the National Cancer Institute affiliated to Cairo University, and the major private cancer centres reflects this elevated baseline, with locally advanced and metastatic gastric and GEJ adenocarcinoma cases as a steady fraction of the upper-GI oncology caseload. For the CLDN18.2-positive, HER2-negative subset, the FDA approval of Vyloy in October 2024 created a first-in-class targeted option where chemotherapy alone was previously the standard.

Vyloy is not yet registered with EDA, and no country-level marketing authorisation has been identified in MENA as of May 2026. This is the structural reason patients reach for the drug through the EDA Personal Importation pathway. Vyloy's named-patient candidacy is sharpened by three stacked factors. First, the recency of approval: all major approvals fall in calendar year 2024, and many MENA regulators have not yet completed local registration review. Second, the biomarker gap: treatment eligibility depends on a confirmed CLDN18.2-positive result via the VENTANA CLDN18 (43-14A) RxDx companion diagnostic, or a locally validated equivalent IHC assay reading at least 75 percent of tumour cells with moderate-to-strong membranous staining. Many tertiary oncology centres in Egypt are still building pathology referral workflows for CLDN18.2 testing. Third, the no-alternative reality for the CLDN18.2-positive, HER2-negative patient: no other CLDN18.2-directed therapy is approved.

The EDA Personal Importation pathway for Vyloy

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations under Prime Minister Decision No. 777 of 2020. EDA permits the importation of unregistered medicines for a specific patient where no equivalent registered product is available locally. The application is filed through the dispensing institution's import pharmacy at a tertiary oncology centre.

For Vyloy, the clinical justification angle is the companion diagnostic gate. Reserve Meds requires the confirmed CLDN18.2-positive pathology report in the file before coordinating supply, and EDA reviewers similarly look for the biomarker confirmation. The acceptable diagnostic is the VENTANA CLDN18 (43-14A) RxDx assay or a locally validated IHC equivalent, with the report stating the percentage of tumour cells with moderate-to-strong membranous staining at the 75 percent threshold. The pathology report also documents HER2-negative status, because Vyloy's FDA-approved

indication is restricted to HER2-negative disease. HER2-positive gastric cancer follows a separate pathway with different targeted agents.

The standard application package includes the clinical justification letter on hospital letterhead, the prescription specifying Vyloy brand name, generic name (zolbetuximab-clzb), strength (100 mg or 300 mg single-dose vial), the planned regimen (mFOLFOX6-paired or CAPOX-paired per the SPOTLIGHT or GLOW trial design), and the cycle quantity. The package also includes the pathology report confirming CLDN18.2-positive and HER2-negative status, the staging documentation, the treating oncologist's EMS membership and Ministry of Health licence reference, the infusion centre's licence, and a chain-of-custody plan with cold-chain documentation. Vyloy is refrigerated at 2 to 8 degrees Celsius and ships in validated insulated packaging with temperature loggers. Routine EDA Personal Importation authorisations for well-documented oncology cases sit inside the 3 to 6 week typical window, with complex biomarker-driven cases potentially extending. EDA reserves discretion. Reserve Meds does not file with EDA and is not an importer of record in Egypt.

Where Vyloy gets dispensed in Egypt

Vyloy is a 2-hour to 3-hour intravenous infusion administered at a certified oncology infusion centre with resuscitation equipment available, pre-infusion premedication for nausea, vomiting, and infusion reactions, and oncology nursing staff trained in infusion-reaction management. The Cairo, Giza, and Alexandria centres equipped to dispense and administer Vyloy under a routine EDA personal-import workflow include Cairo University Hospitals (Kasr Al Ainy) with its oncology and Drug Information Center infrastructure, Ain Shams University Hospitals with strong oncology services, Dar Al Fouad Hospital (JCI-accredited, part of Alameda Healthcare Group, with active oncology services), and As-Salam International Hospital. The Cleopatra Hospitals Group runs oncology services across its multiple Cairo facilities. For the CLDN18.2 companion diagnostic, the pathology laboratories at these academic and JCI-accredited centres typically run the IHC workflow or send out to validated reference laboratories. For patients whose oncologist is at a regional hospital, co-management with one of the Cairo centres is the practical path, because Vyloy infusion logistics require cold-chain capable receiving and an active oncology infusion suite.

Real cost picture for Vyloy in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. With the USD/EGP rate near 52 to 53 in May 2026, quoting in USD insulates the patient from intra-case currency drift. Three line items shape the firm quote:

- **Drug acquisition cost.** US wholesale acquisition cost is approximately USD 1,570 to 1,600 per 100 mg vial and approximately USD 4,700 per 300 mg vial. Total Vyloy drug-cost expectation per the published economic profile is approximately USD 10,000 for Cycle 1 (with the loading dose), approximately USD 7,900 per cycle for Cycles 2 through 8, and approximately USD 7,700 per cycle thereafter, on a 21-day cycle. Annualised first-year drug cost (Vyloy component only, not including chemotherapy backbone) falls in a working range of approximately USD 110,000 to USD 140,000 depending on patient BSA and treatment duration.
- **International cold-chain logistics, US to Cairo.** Because Vyloy is refrigerated at 2 to 8 degrees Celsius, the logistics surcharge sits in the validated cold-chain band of approximately USD 800 to USD 1,500 per shipment routed through Cairo International Airport, with continuous temperature monitoring and lane validation.
- **Reserve Meds concierge fee.** Itemised on the firm quote, never bundled into the drug cost.

Insurer behaviour for named-patient imports varies by carrier. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other carriers operating in Egypt assess named-patient oncology claims case by case. Pre-authorisation is typically required, and some plans reimburse a portion of cost where the indication is covered. UHIA does not currently cover most specialty imports. Cash-pay remains the dominant posture for named-pati