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Vyloy access in Pakistan

How patients in Pakistan access Vyloy (zolbetuximab-clzb) for first-line CLDN18.2-positive, HER2-negative gastric or gastroesophageal junction adenocarcinoma through the DRAP Special Permission Personal Use Import pathway.

1. Quick orientation

Vyloy is the first and only FDA-approved CLDN18.2-directed monoclonal antibody therapy for adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are CLDN18.2 positive. It is manufactured by Astellas Pharma, was FDA-approved on 18 October 2024 in combination with fluoropyrimidine- and platinum-containing chemotherapy, and was approved earlier the same year in Japan (March 2024), the United Kingdom (August 2024), and the European Union (September 2024). Vyloy is not registered with the Drug Regulatory Authority of Pakistan (DRAP), and Pakistani patients with a confirmed CLDN18.2-positive result on the VENTANA CLDN18 (43-14A) RxDx companion diagnostic (or its locally validated equivalent IHC assay) reach for the medicine through the DRAP Special Permission Personal Use Import pathway. Reserve Meds coordinates the United States sourcing, the cold-chain regulatory documentation, and the international logistics into a Pakistani oncology infusion center, while clinical decisions remain with your treating oncologist. Reserved for you.

2. Why Pakistan patients need Vyloy through the named-patient pathway

For a Pakistani patient with CLDN18.2-positive, HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma, Vyloy is the only FDA-approved targeted option, and the alternative is chemotherapy alone. The structural access gap in Pakistan is twofold. Vyloy is not on the DRAP register, and even more practically, the companion diagnostic infrastructure for CLDN18.2 testing is still being built at many Pakistani tertiary oncology services. Patients often arrive at consultation with HER2 status documented but no CLDN18.2 status, and the pathology referral workflow must be set up before a Vyloy case can move.

Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore is Pakistan's flagship cancer hospital and has historically negotiated directly with multinational manufacturers to bring modern cancer drugs to the Pakistani shelf; for unregistered drugs it continues to access medicines through DRAP import permissions. Aga Khan University Hospital in Karachi has an established Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology and bone marrow transplant capability. Indus Hospital and Health Network and Liaquat National Hospital round out the Karachi options. The DRAP Special Permission Personal Use Import framework is the documented lawful route, and Reserve Meds operates inside that framework as the United States-side coordinator while a PMDC-licensed oncologist at one of these centers holds the clinical relationship.

3. The DRAP Special Permission pathway for Vyloy

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also called the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES). For a Vyloy case, the institutional Special Permission for Import of Unregistered Therapeutic Goods filed by the hospital pharmacy is the typical route, since Vyloy is an infused biologic and must be administered at a certified oncology infusion center.

The cell-specific clinical-justification angle for Vyloy is the documented CLDN18.2-positive companion diagnostic result. The application package typically includes the treating oncologist's clinical justification letter setting out the gastric or GEJ adenocarcinoma diagnosis (stage, histology), the confirmed HER2-negative status, the confirmed CLDN18.2-positive status (the VENTANA CLDN18 RxDx assay result, or the locally validated equivalent IHC assay reading 75 percent or greater of

tumor cells with moderate-to-strong membranous staining), the planned chemotherapy backbone (mFOLFOX6 per the SPOTLIGHT regimen, or CAPOX per the GLOW regimen), the patient's body surface area (since Vyloy dosing is BSA-weighted), the planned premedication for nausea, vomiting, and infusion reactions, and the projected number of cycles for the initial supply. The PMDC license verification of the treating physician is attached. The patient identifier is the CNIC.

Product details include the brand name (Vyloy), the generic name (zolbetuximab-clzb), the manufacturer (Astellas Pharma US, Inc.), the modality (lyophilized powder for reconstitution, single-dose 100 mg and 300 mg vials), and the cold-chain requirement (storage at 2-8 degrees Celsius in the original carton, protected from light, never frozen). A manufacturer or authorized distributor letter confirms the product is genuine and sourced through the legitimate United States DSCSA-compliant chain. The dispensing facility's institutional license accompanies the package, and the institution must confirm cold-chain receiving capability and oncology infusion center certification. Routine personal-use applications typically clear in four to eight weeks from a complete submission; oncology biologics with novel mechanisms and recent approval dates can run to ten to sixteen weeks for the first case.

4. Where Vyloy gets dispensed in Pakistan

Vyloy dispensing in Pakistan concentrates at the tertiary oncology services with cold-chain receiving infrastructure and certified oncology infusion centers. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore operates outpatient and inpatient pharmacy services and has the most extensive oncology infusion experience in the country. Aga Khan University Hospital in Karachi has an established Department of Oncology since 2012 with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, bone marrow transplant capability, and a 24/7 pharmacy with temperature-controlled storage. Indus Hospital and Health Network in Karachi has strong oncology, hematology, and pediatric capability. Liaquat National Hospital in Karachi has oncology, cardiology, and transplant programs. Shifa International Hospital in Islamabad serves the federal capital region with oncology infusion services. The Combined Military Hospitals network at CMH Rawalpindi and CMH Lahore treats military families and civilian referrals.

The cell-specific institutional filter for Vyloy is twofold: 2-8 degrees Celsius cold-chain receiving capability with continuous temperature monitoring, and the institutional pathology service that can validate CLDN18.2 status. Centers without on-site CLDN18.2 testing typically refer the pathology block to a partner laboratory before the oncology decision is finalized.

5. Real cost picture for Vyloy in Pakistan

The United States wholesale acquisition cost for Vyloy is approximately USD 1,570 to USD 1,600 per 100 mg vial and approximately USD 4,700 per 300 mg vial. Total Vyloy drug-cost expectation is approximately USD 10,000 for Cycle 1 (the 800 mg per square metre 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 (CAPOX backbone). Annualized first-year drug cost (Vyloy component only, not including the chemotherapy backbone) falls in a working range of approximately USD 110,000 to USD 140,000 depending on patient body surface area and treatment duration.

For a Pakistan patient, the cost stack is the United States acquisition cost for the projected cycles in the supply window, plus international air freight with validated cold-chain shipper (typically USD 1,000 to USD 1,500 per shipment for a 2-8 degrees Celsius oncology biologic) plus the Reserve Meds coordination fee. The Pakistani Rupee has been volatile, trading in the 278 to 280 PKR per USD range in May 2026. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. Sehat Sahulat's Rs. 1,000,000 annual ceiling and in-network empaneled-hospital structure do not typically stretch to cover Vyloy plus the chemotherapy backbone; private insurance through Jubilee General's Personal HealthCare and Adamjee Health Insurance covers in-hospital chemotherapy and radiotherapy in their formularies but specialty imports of recently approved targeted biologics are typically outside formulary.

6. Typical timeline for Vyloy in Pakistan

Routine DRAP Personal Use Import applications clear in four to eight weeks from a complete submission. Reserve Meds plans on the longer end of this range and the complex-case range (ten to sixteen weeks) for first Vyloy cases given the recency of FDA approval and the novel CLDN18.2 mechanism. Cold-chain biologics add two to three days to the international logistics leg versus an ambient shipment, since the validated 2-8 degrees Celsius shipper requires careful lane planning. The realistic end-to-end estimate from intake to first infusion is eight to fourteen weeks for the first cycle, with subsequent cycles compressing as the documentation and logistics pattern are established. Treatment continues until disease progression, unacceptable toxicity, or a physician and patient decision to stop; oxaliplatin within the chemotherapy backbone is typically capped at 6 to 8 cycles before transitioning to fluoropyrimidine plus Vyloy maintenance.

7. What your physician needs to provide

The clinical justification letter, signed by a PMDC-licensed medical oncologist, is the cornerstone of the application. For Vyloy, the letter sets out the gastric or GEJ adenocarcinoma diagnosis (with stage and histology), the confirmed HER2-negative status, the confirmed CLDN18.2-positive status (the VENTANA CLDN18 RxDx report, or the locally validated equivalent IHC assay reading 75 percent or greater of tumor cells with moderate-to-strong membranous staining), the patient's body surface area, the planned chemotherapy backbone with rationale (mFOLFOX6 q2w paired with the SPOTLIGHT regimen, or CAPOX q3w paired with the GLOW regimen), the dosing plan (Vyloy 800 mg per square metre IV on Day 1 of Cycle 1 as loading dose, then 600 mg per square metre IV every 3 weeks on the CAPOX cadence, or 600 mg per square metre on the mFOLFOX6 q3w shifted cadence), and the premedication plan for nausea, vomiting, and infusion reactions. The treating oncologist confirms infusion-reaction readiness at the certified infusion center.

The monitoring plan attached to the application typically describes pre-infusion premedication, standard oncology labs between cycles, attention to gastrointestinal toxicity (particularly during the loading dose), and the chemotherapy-backbone monitoring (CBC, renal function, hepatic function, neuropathy assessment). Adverse events are reported through the DRAP Pharmacovigilance Centre.

8. Common questions about Vyloy in Pakistan

Is CLDN18.2 testing required before Vyloy? Yes. 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 75 percent or greater of tumor cells with moderate-to-strong membranous staining. Many Pakistani tertiary oncology centers do not yet run this assay routinely; the typical workflow is pathology block referral to a partner laboratory before the oncology decision is finalized.

Does Vyloy treat HER2-positive gastric cancer? No. The FDA-approved indication is restricted to HER2-negative, CLDN18.2-positive disease. HER2-positive gastric cancer follows a separate pathway with different targeted agents.

What is the safety profile? The most common adverse reactions reported in the SPOTLIGHT and GLOW trials were nausea, vomiting, decreased appetite, diarrhea, peripheral sensory neuropathy, fatigue, neutropenia, decreased weight, abdominal pain, and constipation. Infusion-related reactions and gastrointestinal toxicity (particularly during the loading dose) are the safety signals that drive monitoring requirements. The first cycle is the highest-risk infusion.

Will Adamjee, Jubilee, or other insurers cover Vyloy? Coverage for named-patient imports of recently approved targeted biologics is uncommon. Jubilee General's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy and radiotherapy in their formularies, but Vyloy as an unregistered specialty import is typically outside formulary. Reserve Meds supplies the documentation an insurer needs to assess the claim. The realistic default is cash-pay.

Why this drug versus chemotherapy alone? In SPOTLIGHT (mFOLFOX6 backbone), Vyloy plus mFOLFOX6 produced a 25 percent reduction in the risk of disease progression or death versus placebo plus mFOLFOX6. In GLOW (CAPOX backbone), median progression-free survival was 8.2 months with Vyloy plus CAPOX versus 6.8 months with placebo plus

CAPOX, and median overall survival was 14.4 months versus 12.2 months. The decision is made by the treating oncologist on a per-patient basis.

What is the typical course duration? There is no fixed course length. Treatment continues until disease progression, unacceptable toxicity, or a physician and patient decision to stop. Oxaliplatin within the chemotherapy backbone is typically limited to 6 to 8 cycles before transitioning to maintenance.

9. Where Reserve Meds fits in Vyloy cases

Reserve Meds is a United States-based concierge coordinator. We do not replace your treating oncologist, we do not replace DRAP, we do not replace your dispensing hospital pharmacy or infusion center. What we do for a Vyloy case is orchestrate the United States-side sourcing exclusively through DSCSA-authorized specialty oncology pharmacies, the regulatory documentation kit for the DRAP institutional Special Permission application, the validated 2-8 degrees Celsius cold-chain logistics through bonded air freight with continuous temperature monitoring, the FBR Customs coordination at the port of entry, and a single named coordinator who stays with the case across infusion cycles. Reserve Meds enforces a CLDN18.2 status confirmation before any shipment, to avoid sending product the destination physician cannot prescribe.

Vyloy sits in the Reserve Meds drug index at the named-patient launch tier. Case experience with CLDN18.2-positive gastric oncology is at the inquiry-pattern stage rather than the closed-case stage; standard NPP coordination applies.

10. Next step

If you or a family member has CLDN18.2-positive, HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma and your treating oncologist at Shaukat Khanum, AKUH, Indus, Liaquat National, Shifa, or CMH is considering Vyloy, the next step is to join the Reserve Meds waitlist. We confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.