Vyloy access in Saudi Arabia through the SFDA Personal Importation Program

How Saudi patients with CLDN18.2-positive, HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma access Vyloy (zolbetuximab-clzb), what the PIP application package looks like, and where Reserve Meds fits.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Vyloy is the brand name for zolbetuximab-clzb, a chimeric IgG1 monoclonal antibody that targets Claudin 18.2 (CLDN18.2), a tight-junction protein aberrantly exposed on the surface of certain gastric and gastroesophageal junction (GEJ) adenocarcinoma cells. The US FDA approved Vyloy on 18 October 2024 in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors are CLDN18.2 positive. It is the first and only CLDN18.2-directed therapy approved globally and has not been registered with SFDA for local commercial sale as of this page date. A Saudi patient with confirmed CLDN18.2-positive HER2-negative gastric or GEJ adenocarcinoma can reach Vyloy lawfully through the SFDA Personal Importation Program (PIP), prescribed by a SCFHS-licensed oncologist and infused at an SFDA-licensed oncology infusion centre. Reserve Meds coordinates the US-side sourcing and the documentation kit your oncologist needs to file the PIP application. Reserved for you.

Why Saudi patients need Vyloy through the named-patient pathway

Vyloy reached FDA approval in October 2024, following approvals in Japan (March 2024), the UK (August 2024), and the EU (September 2024). The SFDA has not yet registered Vyloy, which fits the third of the three structural access patterns the country module describes: an FDA-approved medicine where the manufacturer (Astellas Pharma) has not yet completed local SFDA registration. Astellas's regional affiliates run country-by-country registration on a case-by-case timeline; in the interim, Saudi oncologists who have identified CLDN18.2-positive disease in eligible patients reach for the only globally approved targeted option through PIP.

The biomarker access gap is the second binding constraint. Treatment eligibility depends on a confirmed CLDN18.2-positive result via the VENTANA CLDN18 (43-14A) RxDx companion diagnostic, or a locally validated equivalent immunohistochemistry assay reading at least 75 percent of tumor cells with moderate-to-strong membranous staining. Many tertiary oncology centres in the Kingdom are still building CLDN18.2 testing workflow; pathology referral patterns for the assay are forming. Saudi Vision 2030's Health Sector Transformation Program names tertiary cancer care and precision oncology as priority verticals, and KFSH&RC and KAMC oncology pathology services have been adding CLDN18.2 IHC capacity. For confirmed-biomarker-positive patients, no other CLDN18.2-directed therapy is approved. The clinical decision is Vyloy or it is not Vyloy; there is no second-line CLDN18.2 substitute. The PIP framework is the named-patient route while local registration is pending.

The SFDA Personal Importation Program for Vyloy

The Saudi pathway for a KSA-licensed oncologist to obtain Vyloy is the SFDA Personal Importation Program. PIP allows a SCFHS-licensed physician to request the import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (the FDA, EMA, MHRA, and PMDA Japan for Vyloy) and a clinically

equivalent locally registered alternative is not suitable. Applications are filed through the dispensing institution's import pharmacy and routed through the SFDA Ghad digital platform.

For Vyloy specifically, the clinical-justification angle that anchors the application is the CLDN18.2 companion diagnostic confirmation paired with HER2-negative status. The PIP application is strongest when the oncologist's letter sets out (1) the histologic diagnosis of gastric or GEJ adenocarcinoma with stage documentation (locally advanced unresectable or metastatic), (2) the CLDN18.2 IHC report (VENTANA CLDN18 RxDx or validated equivalent, with percentage and intensity of membranous staining documented), (3) confirmed HER2-negative status by IHC or in situ hybridisation per ASCO/CAP guidance, (4) first-line setting confirmation (the patient has not received prior systemic therapy for advanced disease), (5) the planned chemotherapy backbone (mFOLFOX6 q2w paired with the SPOTLIGHT-trial Vyloy schedule, or CAPOX q3w paired with the GLOW-trial schedule), and (6) the planned infusion site and premedication regimen for nausea, vomiting, and infusion reactions.

A complete PIP package typically includes:

- Clinical justification letter from the treating oncologist (gastric or GEJ adenocarcinoma diagnosis, stage, CLDN18.2-positive and HER2-negative status with attached lab reports, first-line setting, chemotherapy backbone, why Vyloy, why a locally registered alternative is not suitable)
- CLDN18.2 IHC report and HER2 report attached as supporting documents
- Treating oncologist SCFHS license verification in medical oncology
- Patient identifier in SFDA-required format
- Product details: Vyloy lyophilised powder for reconstitution, 100 mg and 300 mg single-dose vials, manufacturer Astellas Pharma US, Inc., country of origin USA, requested quantity per cycle, lot, and expiry
- Destination infusion facility license (certified oncology infusion centre with resuscitation equipment)
- Cold-chain validated chain-of-custody plan (2 to 8 degrees Celsius, qualified gel-pack or PCM shippers, continuous temperature monitoring) from the US specialty oncology pharmacy through the importer to the receiving Saudi infusion centre
- Post-import pharmacovigilance acknowledgement through the SFDA National Pharmacovigilance Center

Approval timelines for routine PIP cases run 10 to 21 business days. Because Vyloy is a recently approved drug under multiple reference authorities with a clear biomarker gating criterion, complex first-imports at a smaller facility can extend to 6 to 10 weeks. Established cancer centres with companion-diagnostic infrastructure typically process Vyloy PIP applications on the routine track.

Where Vyloy gets dispensed in Saudi Arabia

Vyloy is a refrigerated lyophilised biologic that requires reconstitution and a 2-hour to 3-hour intravenous infusion at a certified oncology infusion centre, with premedication and infusion-reaction readiness. The capability requirements subset the country module institutional list to centres with (a) CLDN18.2 companion diagnostic capacity or established pathology referral for it, (b) cold-chain 2 to 8 degrees Celsius pharmacy receiving and storage, and (c) a certified infusion centre with resuscitation equipment. The Saudi institutions with this profile are:

- **King Faisal Specialist Hospital and Research Centre (KFSH&RC).** Tertiary and quaternary referral centre with deep oncology, oncology pathology, and infusion capability across Riyadh, Jeddah, and Madinah. CLDN18.2 IHC is on the assay menu or available via internal pathology referral.
- **King Abdulaziz Medical City (KAMC) and the MNGHA network.** Major tertiary oncology services in Riyadh and Jeddah with full infusion infrastructure.
- **King Saud University Medical City (KSUMC) and KSAU-HS affiliated centres.** Academic medical centres with oncology and pathology research programs.

- **Dr. Sulaiman Al Habib Medical Group (HMG).** Large private hospital network with oncology centres in Riyadh, Jeddah, and the Eastern Province, with cold-chain pharmacy infrastructure and routine PIP activity.
- **Saudi German Health and Dr. Soliman Fakeeh Hospital (Jeddah).** Private referral centres with oncology services and infusion capability.

Smaller community oncology practices without on-site CLDN18.2 IHC and cold-chain infusion infrastructure typically route Vyloy cases through one of these centres. Direct-to-home infusion is not the model.

Real cost picture for Vyloy in Saudi Arabia

The US wholesale acquisition cost (WAC) for Vyloy is approximately USD 1,570 to USD 1,600 per 100 mg vial and approximately USD 4,700 per 300 mg vial. Per the published economic profile, total Vyloy drug-cost expectation is approximately USD 10,000 for Cycle 1 (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 Vyloy drug cost (excluding the chemotherapy backbone) falls in a working range of approximately USD 110,000 to USD 140,000 depending on body surface area and treatment duration, equivalent to approximately SAR 413,000 to SAR 525,000 at the pegged rate of approximately 3.75 SAR to 1 USD.

International logistics for a cold-chain biologic in qualified shippers typically runs USD 800 to USD 2,500 per shipment (approximately SAR 3,000 to SAR 9,400), the upper end of the country module logistics range because of validated gel-pack or PCM packaging and continuous temperature monitoring. SFDA permit and importer handling fees are itemised separately. The Reserve Meds concierge fee appears as its own line on every firm quote. Astellas patient assistance through VYLOY Support Solutions is US-only and does not extend to Saudi cases. Bupa Arabia, Tawuniya, and MedGulf handle named-patient oncology imports case by case; oncology budgets are managed centrally at the dispensing facility, and reimbursement (where available) typically follows the patient's or hospital's after-the-fact claim.

Typical timeline for Vyloy in Saudi Arabia

Vyloy is a cold-chain biologic, which adds 2 to 3 days to ambient-shipping baselines for the validated 2 to 8 degrees Celsius packaging and shipment. The typical end-to-end timeline for a first PIP import is 6 to 10 weeks: 10 to 21 business days for routine SFDA review at an established cancer centre (longer if the institution is a first-time Vyloy importer, with the CLDN18.2 diagnostic confirmation being a parallel-path workstream), 5 to 7 days for US-side specialty oncology pharmacy procurement of the vial quantities for the cycle, and 4 to 7 days for refrigerated air freight, Saudi customs clearance with cold-chain inspection, and reception at the infusion centre. The first cycle is timed against the chemotherapy backbone (mFOLFOX6 q2w or CAPOX q3w), with the Cycle 1 Day 1 loading dose at 800 mg per square metre being the largest single drug-volume event. Subsequent cycles at 600 mg per square metre compress shipment quantities and Saudi customs handling time, and the typical refill cycle reaches 2 to 4 weeks at steady state.

What your physician needs to provide

The treating oncologist's clinical justification letter is the cornerstone of the SFDA PIP package. For Vyloy specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Zolbetuximab-clzb is a chimeric IgG1 monoclonal antibody that binds CLDN18.2 on gastric or GEJ adenocarcinoma cells and triggers ADCC and CDC, leading to tumor cell death. FDA-approved 18 October 2024 in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of CLDN18.2-positive HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma.

- **CLDN18.2 companion diagnostic.** VENTANA CLDN18 (43-14A) RxDx assay (or locally validated equivalent IHC) showing at least 75 percent of tumor cells with moderate-to-strong membranous staining. The reporting laboratory is named.
- **HER2-negative status.** Confirmed by IHC or in situ hybridisation per ASCO/CAP guidance.
- **First-line setting.** Confirmation that the patient has not received prior systemic therapy for advanced disease.
- **Dosing plan.** Regimen 1 (SPOTLIGHT, mFOLFOX6 backbone, q2w): Vyloy 800 mg per square metre IV on Day 1 Cycle 1 loading dose, 600 mg per square metre on Day 22, and 600 mg per square metre every 3 weeks thereafter, with mFOLFOX6 continuing on its own q2w cadence. Regimen 2 (GLOW, CAPOX backbone, q3w): Vyloy 800 mg per square metre IV Cycle 1 Day 1, 600 mg per square metre on Day 1 of each subsequent 21-day cycle, with CAPOX on the standard q3w schedule. Oxaliplatin typically capped at 6 to 8 cycles.
- **Premedication and infusion site.** Premedication for nausea, vomiting, and infusion reactions before each infusion per the FDA label. Infusion at a certified oncology infusion centre with resuscitation equipment, with extra attention to the first-cycle loading dose where infusion reactions are most common.
- **Physician license.** Active SCFHS registration in medical oncology.

Common questions about Vyloy in Saudi Arabia

Does the CLDN18.2 test get done in Saudi Arabia?

CLDN18.2 IHC capacity is expanding at Saudi tertiary cancer centres. KFSH&RC, KAMC, and KSUMC pathology services can run the assay or refer to a pathology partner. If your patient is at a community oncology practice, the practice typically sends the tumor block to one of these centres for CLDN18.2 testing before initiating Vyloy.

Will Bupa Arabia, Tawuniya, or MedGulf cover this?

Each insurer assesses named-patient oncology imports case by case. Some plans reimburse partially when the medicine appears on the insurer's formulary review and clinical justification is documented. Many require pre-authorisation with the CLDN18.2 IHC report and the oncologist's clinical justification attached. Cash-pay is the default operating posture for the first cycle, with reimbursement sought after the fact where applicable.

What is the safety profile?

The most common adverse reactions reported in the SPOTLIGHT and GLOW trials were nausea, vomiting, decreased appetite, diarrhoea, 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 and premedication requirements.

Why Vyloy 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.

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.

How long does treatment continue?

There is no fixed course length. Treatment continues until disease progression, unacceptable toxicity, or a physician or patient decision to stop. Oxaliplatin within the chemo backbone is typically limited to 6 to 8 cycles before transitioning to maintenance with fluoropyrimidine plus Vyloy.

Where Reserve Meds fits in Vyloy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, SFDA, or your dispensing infusion centre. For Vyloy specifically, we orchestrate the US-side sourcing exclusively through DSCSA-authorised specialty oncology pharmacies, prepare the documentation kit your Saudi oncologist needs to file the PIP application (with the CLDN18.2 companion diagnostic, HER2-negative confirmation, chemotherapy-backbone regimen, and premedication and pharmacovigilance templates pre-built), validate the cold-chain shipping lane with continuous temperature monitoring, align the refrigerated air-freight shipment plan with the Saudi importer and the infusion centre's cycle calendar, and assign a single named coordinator who carries the patient through Cycle 1 and the recurring cycle cadence. No prior Reserve Meds closed-case experience for Vyloy as of this page date; standard NPP coordination applies. Cold-chain integrity is treated as load-bearing on every shipment.

Next step

If you have a CLDN18.2-positive HER2-negative gastric or GEJ adenocarcinoma diagnosis in the first-line setting and your Saudi oncologist has identified Vyloy as the right addition to the chemotherapy backbone, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your oncologist.

Reserved for you.

This guide is informational, not medical or legal advice. The SFDA Personal Importation Program requires a SCFHS-licensed physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

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