Vyloy access in UAE through the MOHAP and EDE named-patient pathway

How UAE patients with CLDN18.2-positive, HER2-negative gastric or gastroesophageal junction adenocarcinoma source Vyloy (zolbetuximab-clzb), what the oncologist's application looks like, and where Reserve Meds fits.

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Quick orientation

Vyloy is the brand name for zolbetuximab-clzb, a chimeric IgG1 monoclonal antibody targeting Claudin 18.2 (CLDN18.2). It received FDA approval on 18 October 2024 in combination with fluoropyrimidine and platinum chemotherapy 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 the first and only CLDN18.2-directed therapy approved globally. There is no UAE marketing authorisation on record as of this page date. A UAE patient with confirmed CLDN18.2-positive disease can reach Vyloy lawfully through the unregistered-medicine import permit, administered through the Emirates Drug Establishment (EDE) since 29 December 2025. The medicine is administered as an intravenous infusion at a UAE-licensed oncology infusion center. Reserve Meds coordinates the US-side cold-chain sourcing and the documentation kit your oncologist needs. Reserved for you.

Why UAE patients need Vyloy through the named-patient pathway

Vyloy reached three major regulators ahead of the FDA in 2024: Japan (PMDA, 26 March 2024, the first global approval), the European Union (EMA and European Commission, 20 September 2024), and the United Kingdom (MHRA, August 2024). The UAE is not yet on the registered-market list as of this page date. Regulatory approval is not equivalent to local commercial availability; even where the EMA approval is in force in the European Union, individual member states are negotiating price and reimbursement country by country.

The structural access gap that applies to Vyloy in the UAE is a stack of friction points rather than a single one. The drug is not on the UAE federal register, hospital pharmacies have not onboarded inventory, the CLDN18.2 companion diagnostic workflow (the VENTANA CLDN18 43-14A RxDx assay, or a locally validated IHC equivalent reading at least 75 percent of tumour cells with moderate-to-strong membranous staining) is still being built at many regional centers, and there is no clinically equivalent CLDN18.2-directed alternative to substitute. For a CLDN18.2-positive, HER2-negative patient, the clinical choice is Vyloy or it is not Vyloy; there is no second-line CLDN18.2 substitute. The MOHAP and now EDE named-patient pathway is the documented route.

The MOHAP and EDE named-patient pathway for Vyloy

The federal pathway is the unregistered-medicine import permit, filed through the EDE portal at ede.gov.ae since 29 December 2025. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable. Vyloy clears the reference-authority criterion through its FDA approval, its EMA approval, its MHRA approval, and its PMDA approval.

For Vyloy specifically, the clinical-justification angle that anchors the application is biomarker confirmation. The application is strongest when the treating oncologist's letter sets out (1) the histological diagnosis of locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma, (2) HER2-negative status from the pathology report, (3) the CLDN18.2 status report from the VENTANA RxDx companion diagnostic or a locally validated IHC equivalent meeting the at-least-75-percent threshold for moderate-to-strong membranous staining, (4) prior treatment history (Vyloy is approved first-line, so this section confirms the patient is treatment-naive in the metastatic setting), (5) the planned chemotherapy backbone (mFOLFOX6 per the SPOTLIGHT trial or CAPOX per the GLOW trial), and (6) the infusion plan and premedication protocol.

A complete package typically includes:

- Clinical justification letter from the treating oncologist with the pathology report and CLDN18.2 status documentation attached
- Treating oncologist's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority)
- Patient identifier (anonymised reference where the EDE submission allows)
- Product details: Vyloy 100 mg and 300 mg single-dose lyophilised powder vials for reconstitution; manufacturer Astellas Pharma (Tokyo, Japan; US operations through Astellas Pharma US, Inc., Northbrook, Illinois); cold-chain class 2 to 8 degrees Celsius; quantity calculated for the first cycle's loading dose plus the planned subsequent cycles
- Destination dispensing facility (oncology infusion center) name, license number, pharmacy in charge, and confirmation of refrigerated storage capability
- Chain-of-custody plan from the US specialty oncology pharmacy through the importer to the UAE infusion center, with continuous temperature monitoring through transit

Approval timelines for routine oncology cases are typically 5 to 15 business days, and Vyloy first-import cases for a UAE oncology center that has not previously cleared the molecule may extend toward 4 weeks. The EDE allows expedited review for urgent oncology and life-threatening cases at the authority's discretion, but expediting is not promised.

Where Vyloy gets dispensed in the UAE

Vyloy is a refrigerated lyophilised biologic that is reconstituted, diluted, and administered as a 2-hour to 3-hour intravenous infusion at a certified oncology infusion center with resuscitation equipment available. The capability that matters is oncology infusion infrastructure plus 2 to 8 degrees Celsius pharmacy storage. Subsetting the UAE specialty hospital network to centers with oncology infusion capability and refrigerated specialty oncology pharmacy:

- **Cleveland Clinic Abu Dhabi** (M42 group, Al Maryah Island). Adult oncology service line, ASHP-accredited pharmacy services, infusion infrastructure.
- **Tawam Hospital, Al Ain** (SEHA network). National referral center for oncology, established 1979, with a cancer center of excellence developed in collaboration with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. Hematology, radiation oncology, palliative care.
- **Sheikh Khalifa Medical City (SKMC), Abu Dhabi** (SEHA network, managed by the Cleveland Clinic). JCI-accredited with oncology subspecialty services.

- **American Hospital Dubai** (Mayo Clinic Care Network member). Oncology, hematology, and surgical oncology services with infusion capability.
- **Mediclinic City Hospital, Dubai Healthcare City**. Oncology service line, including urologic and gastrointestinal oncology coverage.
- **NMC Healthcare** flagship sites in Abu Dhabi and Dubai. Oncology service lines and import pharmacy infrastructure.

The CLDN18.2 companion diagnostic workflow is the limiting capability at smaller centers; some UAE tertiary oncology programmes have onboarded the VENTANA RxDx assay or a locally validated IHC equivalent, while others route pathology blocks to an outside reference laboratory. The treating oncologist's pathway team typically owns this referral.

Real cost picture for Vyloy in the UAE

US 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. Per the published economic profile, Vyloy drug cost is approximately USD 10,000 for Cycle 1 (loading dose at 800 mg/m squared), approximately USD 7,900 per cycle for Cycles 2 through 8, and approximately USD 7,700 per cycle thereafter, on the 21-day cycle. Annualised first-year drug cost for the Vyloy component alone (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. At the pegged rate of approximately 3.67 AED to 1 USD, that translates to approximately AED 404,000 to AED 514,000 for the first year of Vyloy-only drug cost.

International logistics for a refrigerated 2 to 8 degree Celsius biologic typically runs USD 800 to USD 1,500 (approximately AED 2,900 to AED 5,500) per shipment, higher than ambient because of qualified cold-chain packaging and continuous temperature monitoring. UAE customs and EDE permit fees are nominal relative to the drug cost. The Reserve Meds concierge fee is itemised separately on every firm quote. VYLOY Support Solutions (the Astellas US patient-services hub) is US-only and does not extend to international cases. UAE insurer coverage (Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, Orient) is assessed case by case; oncology biologics under named-patient import have variable insurer outcomes in the region.

Typical timeline for Vyloy in the UAE

Vyloy is a refrigerated lyophilised biologic that requires 2 to 8 degree Celsius cold-chain handling end to end. Cold-chain adds 2 to 3 days to the transit and customs window relative to an ambient shipment, because qualified shipper preparation, lane validation, and continuous temperature monitoring all add overhead. The modality-adjusted typical end-to-end timeline for a first cycle is 4 to 7 weeks: 5 to 15 business days for routine EDE permit

review (potentially expedited for urgent oncology at the authority's discretion), 7 to 10 days for US-side specialty oncology pharmacy procurement and qualified cold-chain shipper preparation, and 4 to 6 days for refrigerated air freight and UAE customs clearance. Repeat cycle shipments for an established patient typically run 2 to 3 weeks because the EDE dossier and the US-side procurement path are already in place. Cycle cadence then aligns to the chemotherapy backbone (every 2 weeks with mFOLFOX6 or every 3 weeks with CAPOX).

What your physician needs to provide

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

- **Mechanism and FDA indication.** Zolbetuximab-clzb is a CLDN18.2-directed monoclonal antibody approved by the FDA on 18 October 2024 in combination with fluoropyrimidine and platinum chemotherapy for first-line treatment of CLDN18.2-positive, HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma.
- **Histological diagnosis.** Pathology confirming gastric or GEJ adenocarcinoma; HER2-negative status from the pathology report.
- **CLDN18.2 biomarker confirmation.** VENTANA CLDN18 (43-14A) RxDx assay result or a locally validated IHC equivalent, with the at-least-75-percent-of-tumour-cells, moderate-to-strong, membranous-staining threshold explicitly addressed.
- **Prior-line documentation.** Confirmation that the patient is treatment-naive in the metastatic setting (Vyloy is first-line).
- **Dosing plan.** Either Regimen 1 (mFOLFOX6 backbone, every 2 weeks): Vyloy 800 mg/m squared on Cycle 1 Day 1 (loading dose), then 600 mg/m squared on Day 22 (Cycle 2 Day 1), then 600 mg/m squared every 3 weeks thereafter with mFOLFOX6 continuing on its q2w cadence; or Regimen 2 (CAPOX backbone, every 3 weeks): Vyloy 800 mg/m squared on Cycle 1 Day 1 (loading dose), then 600 mg/m squared on Day 1 of each subsequent 21-day cycle with CAPOX (capecitabine plus oxaliplatin) on the standard q3w schedule. Oxaliplatin typically capped at 6 to 8 cycles after which fluoropyrimidine plus Vyloy continues as maintenance.
- **Premedication and monitoring plan.** Premedication for nausea, vomiting, and infusion reactions prior to each infusion, with resuscitation readiness for the first-cycle loading dose where infusion reactions are most common. Standard oncology labs between cycles.
- **Infusion-center capability.** Confirmation that the dispensing infusion center has 2 to 8 degree Celsius refrigerated specialty pharmacy storage and resuscitation infrastructure.

- **Physician license.** Verification of MOHAP, DHA, DOH, or Sharjah Health Authority licensing in active standing, matching the emirate of the dispensing facility.

Common questions about Vyloy in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this?

Each insurer assesses named-patient imports case by case. Oncology biologics are recent additions to many UAE insurer formularies and Vyloy is a 2024-approved molecule, so few formularies have formally considered it. We do not promise coverage. We supply the documentation set that lets your insurer assess the case; the claim sits with you or your hospital.

Will my DHA-licensed or DOH-licensed medical oncologist's letter be sufficient?

Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority. For first-line metastatic gastric or GEJ adenocarcinoma the EDE expects a medical oncologist or gastrointestinal oncologist. The credential is institutional rather than a separate EDE registration.

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 treatment pathway with different targeted agents.

Is there a competitor or alternative for the CLDN18.2-positive subset?

For the CLDN18.2-positive subset, Vyloy is the only FDA-approved targeted option. The comparator is chemotherapy alone, which is the placebo arm in both the SPOTLIGHT and GLOW registrational trials. Other CLDN18.2-directed agents are in clinical development but are not approved as of this page date.

What is the safety profile?

The most common adverse reactions reported in SPOTLIGHT and GLOW 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) drive the monitoring requirements. The first cycle, including the 800 mg/m squared loading dose, is the highest-risk infusion.

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 fluoropyrimidine plus Vyloy maintenance.

Where Reserve Meds fits in Vyloy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, the EDE, or your dispensing pharmacy. For Vyloy specifically, we orchestrate the US-side sourcing through a DSCSA-authorised specialty oncology pharmacy that holds Vyloy inventory under 2 to 8 degree Celsius conditions, prepare the documentation kit your UAE oncologist needs to file the EDE permit (with the CLDN18.2 biomarker summary, the SPOTLIGHT or GLOW regimen template, and the cold-chain handling annex), align the qualified cold-chain shipper plan and lane validation with the UAE importer and the receiving infusion center, and assign a single named coordinator who carries the case through the first cycle's loading dose and the subsequent maintenance cycles. Vyloy sits in the Reserve Meds drug index at the named-patient launch tier; standard NPP coordination applies and no prior closed-case experience for the UAE Vyloy combination exists as of this page date.

Next step

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

Add my Vyloy UAE case to the waitlist

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a UAE-licensed physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

Review and oversight. Content on this page is reviewed by Reserve Meds's 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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