Vyloy access in India through the CDSCO Rule 36 Form 12A pathway

How Indian patients with CLDN18.2-positive, HER2-negative locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma source Vyloy (zolbetuximab-clzb) for first-line use with chemotherapy, including the companion diagnostic Indian oncologists need to file the Form 12A application.

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Quick orientation

Vyloy is the brand name for zolbetuximab-clzb, a chimeric IgG1 monoclonal antibody that targets Claudin 18.2 (CLDN18.2) on tumor cells and triggers antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity. 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 gastroesophageal junction (GEJ) adenocarcinoma whose tumors are CLDN18.2 positive. It is the first and only CLDN18.2-directed therapy approved globally for this indication. Vyloy is not registered with CDSCO in India as of this page date. An Indian patient with confirmed CLDN18.2-positive, HER2-negative disease can reach Vyloy lawfully through Rule 36 of the Drugs and Cosmetics Rules 1945, prescribed by an NMC-registered medical oncologist and infused at a hospital with cold-chain dispensing capability. Reserve Meds coordinates the US-side sourcing and the documentation kit your Indian oncologist needs to file the Form 12A application. Reserved for you.

Why Indian patients need Vyloy through the named-patient pathway

Gastric and GEJ adenocarcinoma is a significant disease burden across South Asia, and Indian medical-oncology referral centres see a steady volume of locally advanced and metastatic cases. The structural access pattern in India fits the third pattern the country module describes: Vyloy is FDA-approved (18 October 2024), EMA-approved (European Commission 20 September 2024), MHRA-approved (August 2024), and PMDA-approved (Japan 26 March 2024, the first country in the world to approve a CLDN18.2-directed therapy), but Astellas has not yet completed CDSCO registration, and Vyloy is not stocked by Indian hospital pharmacies or distributors as of May 2026.

Two friction points compound the standard registration gap. First, the CLDN18.2 companion diagnostic. Treatment eligibility depends on a confirmed CLDN18.2-positive result via the VENTANA CLDN18 (43-14A) RxDx assay (or a locally validated equivalent IHC assay reading at least 75 percent of tumor cells with moderate-to-strong membranous staining). Many Indian tertiary oncology centres have not yet onboarded the assay, and pathology referral workflows for CLDN18.2 testing are still being built. Patients often arrive with HER2 status documented but no CLDN18.2 status. Second, no clinical alternative for the CLDN18.2-positive subset. For a CLDN18.2-positive, HER2-negative patient, no other CLDN18.2-directed therapy is approved. The decision is Vyloy plus chemotherapy or it is not Vyloy.

The CDSCO Rule 36 personal import pathway for Vyloy

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. CDSCO guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete.

For Vyloy specifically, the clinical-justification angle that anchors the Form 12A application is the CLDN18.2 companion-diagnostic gate. The application is strongest when the treating oncologist's letter sets out (1) the diagnosis of locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma, (2) the CLDN18.2-positive result from VENTANA CLDN18 (43-14A) RxDx, or from a locally validated IHC assay with the percent-tumor-cell positivity and staining intensity reported (target threshold: at least 75 percent of tumor cells with moderate-to-strong membranous staining), (3) HER2-negative status, (4) the planned chemotherapy backbone (mFOLFOX6 paired with the SPOTLIGHT regimen, or CAPOX paired with the GLOW regimen), (5) the patient's body surface area for BSA-weighted dosing, (6) the infusion centre's premedication and infusion-reaction readiness, and (7) the planned cold-chain receipt and storage workflow at the infusion centre.

A complete Form 12A application includes the clinical justification letter from the treating Registered Medical Practitioner, the prescription showing the RMP's NMC registration number and the quantity required, a patient identifier with supporting medical records including the CLDN18.2 IHC report, product details (Vyloy as zolbetuximab-clzb 100 mg and 300 mg single-dose vials of lyophilised powder for reconstitution, manufacturer Astellas Pharma, requested quantity per the second proviso to Rule 36 mapped to the cycle plan), the dispensing facility's drug licence, and a chain-of-custody plan that captures the validated 2 to 8 degrees Celsius cold-chain from the US specialty oncology pharmacy through the importer to the receiving Indian infusion centre. For institutional Compassionate Use, the parallel route is a Compassionate Use application to the DCGI by a government hospital, an RMP, or the patient.

Where Vyloy gets dispensed in India

Vyloy is a refrigerated biologic. Vials must be stored at 2 to 8 degrees Celsius in the original carton, protected from light, and never frozen. Administration is a 2-hour to 3-hour intravenous infusion at a certified oncology infusion centre with resuscitation equipment available, after premedication for nausea, vomiting, and infusion reactions. The Indian institutions that fit this profile and that handle named-patient oncology imports include:

- **Tata Memorial Centre, Mumbai.** India's oldest and largest cancer institute, anchor of the National Cancer Grid, with established named-patient import workflow and the full medical-oncology and gastric-cancer multidisciplinary disease group.
- **All India Institute of Medical Sciences (AIIMS), New Delhi.** Apex public-sector institution with established compassionate and named-patient import workflow across oncology.
- **Apollo Hospitals (Chennai, Delhi, Bangalore, Hyderabad, Kolkata).** Large oncology programmes with dedicated international patient services, cold-chain dispensing capability, JCI and NABH accredited.
- **Fortis Memorial Research Institute, Gurgaon; Fortis Mulund, Mumbai; Medanta - The Medicity, Gurgaon; Kokilaben Dhirubhai Ambani Hospital, Mumbai.** Tertiary medical-oncology programmes with cold-chain pharmacy infrastructure.
- **MGM Healthcare, Chennai; Manipal Hospitals, Bangalore; Christian Medical College (CMC), Vellore.** Active medical-oncology programmes with cold-chain capability.

For patients outside the major metros, co-management with a medical oncologist at one of the centres above is the practical route, with refills routed through that hospital's import pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles cold-chain shipments.

Real cost picture for Vyloy in India

US wholesale acquisition cost for Vyloy is approximately USD 1,570 to 1,600 per 100 mg vial and approximately USD 4,700 per 300 mg vial. The published economic profile is approximately USD 10,000 for Cycle 1 (with the 800 mg/m² 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 for the Vyloy component falls in a working range of approximately USD 110,000 to USD 140,000 depending on patient BSA and treatment duration; the chemotherapy

backbone is separate. With the rupee floating against the dollar in the 94 to 95 INR per USD range in May 2026, a per-cycle Vyloy drug cost of approximately USD 7,900 converts to approximately INR 7.4 lakh per cycle.

International cold-chain logistics adds USD 800 to USD 2,000 per shipment with validated lane temperature monitoring, qualified gel-pack or PCM shippers, and a 96 to 120-hour stability envelope. The Astellas VYLOY Support Solutions copay assistance and patient-assistance programmes are US-only and do not extend to international cases. Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, Apollo Munich, and Care Health handle named-patient oncology imports case by case; none reimburse a Rule 36 personal import as a standard line item. The Union Budget 2026-27 expanded customs duty exemption on a set of named cancer medicines and the rare-disease drug list; the specific HSN code and exemption status of each shipment is confirmed at the documentation stage. CGHS provides for non-formulary anti-cancer drugs to be considered case by case by an Expert Committee under the Special DG (DGHS), with stricter constraints on drugs not approved by DCGI. Cash-pay with documented optionality to pursue reimbursement is the default operating posture.

Typical timeline for Vyloy in India

Vyloy is a cold-chain biologic, which adds 2 to 3 days versus an ambient product for transit and customs handling. The typical end-to-end timeline for a first Rule 36 import is 3 to 5 weeks: the CLDN18.2 IHC confirmation if not yet done (this can extend the upstream window if the patient's existing biopsy block needs to be re-tested), the Form 12B permit issued on a documented priority basis (often 1 to 2 days at the DCGI office once documentation is complete), 7 to 14 days for US-side procurement from an authorised specialty oncology pharmacy with cold-chain dispatch, and 4 to 7 days for cold-chain air freight and Indian customs clearance with temperature-log review at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad. Repeat cycle-aligned shipments for an established patient typically compress because the Form 12A dossier and procurement path are in place; cadence aligns with the 21-day cycle (q3w CAPOX-paired) or the 14-day chemotherapy cycle with q3w Vyloy on the mFOLFOX6-paired regimen.

What your physician needs to provide

The treating oncologist's clinical justification letter is the cornerstone of the Form 12A package. For Vyloy specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Zolbetuximab-clzb is a chimeric IgG1 monoclonal antibody targeting CLDN18.2, a tight-junction protein aberrantly exposed on gastric and GEJ adenocarcinoma cells. Binding triggers ADCC and CDC. FDA approval 18 October 2024 in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors are CLDN18.2 positive.
- **Companion diagnostic confirmation.** CLDN18.2-positive result via VENTANA CLDN18 (43-14A) RxDx, or a locally validated equivalent IHC assay, with at least 75 percent of tumor cells showing moderate-to-strong membranous staining. The pathology report names the assay, the percentage, the staining intensity, and the laboratory.
- **HER2-negative status.** Documented HER2-negative result on the index tumor. The FDA-approved indication is restricted to HER2-negative disease; HER2-positive gastric cancer follows a separate targeted-therapy pathway.
- **Regimen plan.** Vyloy 800 mg/m² IV on Day 1 of Cycle 1 (loading dose); Vyloy 600 mg/m² IV on Day 22 (Cycle 2 Day 1) and every 3 weeks thereafter, paired with mFOLFOX6 on its own q2w cadence (SPOTLIGHT regimen); or Vyloy 800 mg/m² IV on Day 1 of Cycle 1 and 600 mg/m² IV on Day 1 of each subsequent 21-day cycle with CAPOX (GLOW regimen). Oxaliplatin typically capped at 6 to 8 cycles per chemotherapy backbone convention, with fluoropyrimidine plus Vyloy maintenance thereafter until progression or unacceptable toxicity.

- **Premedication and infusion-readiness plan.** Premedication for nausea, vomiting, and infusion reactions required prior to each infusion per the FDA label. Resuscitation equipment available at the infusion centre. The first-cycle loading dose carries the highest infusion-reaction risk.
- **Cold-chain reception protocol.** Receiving infusion centre confirms 2 to 8 degrees Celsius integrity on arrival via temperature-log review before vial acceptance.
- **Physician registration.** Active NMC registration in medical oncology, with state-council registration where required.
- **Pharmacovigilance acknowledgement.** The Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission is referenced; adverse event reporting through PvPI stays with the prescribing physician.

Common questions about Vyloy in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this?

Each plan handles named-patient oncology imports case by case. None reimburse a Rule 36 personal import as a standard line item, and Vyloy is not on any Indian formulary as of this page date. Some plans have reimbursed full or partial drug cost when the underlying medicine was on their formulary and the import was a stocking workaround; that does not apply here. We supply the documentation that lets your insurer evaluate; the claim itself is filed by you or your hospital. Cash-pay is the default operating posture.

Does my pathology already have CLDN18.2 status, or does the biopsy need re-testing?

This is the most common question and the most common reason a Vyloy case timeline extends. CLDN18.2 IHC is a relatively new assay; many Indian pathology departments have not yet onboarded the VENTANA CLDN18 (43-14A) RxDx assay or a validated locally equivalent IHC. If your existing biopsy block has not been tested, your oncologist routes the block to a pathology service that runs the assay (Tata Memorial, Apollo, and several reference labs offer this), or the assay is run at a US reference laboratory if Indian capacity is unavailable. Reserve Meds confirms the result is in hand before product ships.

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. Your oncologist confirms both HER2 status and CLDN18.2 status before Vyloy is the appropriate option.

Is there a competitor or alternative?

For the CLDN18.2-positive subset, Vyloy is the only FDA-approved targeted option as of this page date. The comparator in both registrational trials (SPOTLIGHT and GLOW) was chemotherapy plus placebo. Other CLDN18.2-directed agents (other monoclonals, bispecifics, ADCs, CAR-T) are in clinical development but not approved. The decision is made by your treating oncologist on a per-patient basis.

What is the safety profile?

The most common adverse reactions 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) are the safety signals that drive monitoring. The treating oncologist owns the safety plan and the premedication regimen.

How long does treatment continue?

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.

Where Reserve Meds fits in Vyloy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, CDSCO, your dispensing pharmacy, or your infusion centre. For Vyloy specifically, we orchestrate the US-side sourcing exclusively through DSCSA-authorised specialty oncology pharmacies and wholesalers, with full chain-of-custody documentation and validated cold-chain dispatch, prepare the documentation kit your Indian oncologist needs to file the Form 12A application (with the CLDN18.2 companion-diagnostic template, SPOTLIGHT and GLOW regimen references, premedication checklist, and PvPI acknowledgement pre-built), align the validated 2 to 8 degrees Celsius cold-chain shipment plan with the Indian importer and the receiving infusion centre, and assign a single named coordinator who carries the case from CLDN18.2 confirmation through Cycle 1 loading and the ongoing cycle cadence. No prior Reserve Meds closed-case experience for Vyloy as of this page date; standard Rule 36 coordination with the CLDN18.2 diagnostic gate applies. Operational notes will be added as cases land.

Next step

If you have a diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma with confirmed CLDN18.2-positive, HER2-negative status, and your Indian medical oncologist has identified Vyloy plus chemotherapy as the right first-line regimen, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

This guide is informational, not medical or legal advice. The CDSCO Rule 36 pathway requires an NMC-registered 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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