Venclexta

India · access guide

How to access Venclexta from India, the named-patient import pathway for formulary gaps, 2026

By Reserve Meds, clinical and regulatory team. Last reviewed 2026-05-17.

An Indian patient with an FDA-approved oncology indication for Venclexta (venetoclax), where local registration or supply does not meet the need, may receive a prescription from their treating hematologist and have Venclexta legally imported under the Central Drugs Standard Control Organisation (CDSCO) personal-import and named-patient framework. This guide explains the clinical context, the regulatory pathway, typical costs, indicative timing, and where Reserve Meds fits in as a US-based concierge coordinator.

The clinical situation

Venclexta (venetoclax) is a BCL-2 (B-cell lymphoma 2) inhibitor developed by AbbVie and Genentech (a member of the Roche Group). Venclexta is a selective small-molecule inhibitor of the anti-apoptotic protein BCL-2. BCL-2 overexpression is a hallmark of CLL and a feature of several acute myeloid leukemia subsets. By restoring apoptotic signaling in malignant cells that depend on BCL-2 for survival, venetoclax produces deep, often measurable-residual-disease-negative responses in CLL and synergises with hypomethylating agents in AML. The mechanism is rapid: this is why a strict ramp-up dosing schedule is mandatory to prevent tumor lysis syndrome.

Venclexta carries FDA approvals for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) in adults, and for newly diagnosed acute myeloid leukemia (AML) in adults who are 75 years or older or who have comorbidities that preclude intensive induction chemotherapy, in combination with azacitidine, decitabine, or low-dose cytarabine. EMA authorisation under the trade name Venclyxto covers a substantially overlapping indication set.

Route and dosing. Venclexta is administered as oral tablet. Dosing requires a mandatory weekly ramp-up to mitigate tumor lysis syndrome (TLS) risk. For CLL/SLL the ramp is 20 mg, 50 mg, 100 mg, 200 mg, and 400 mg daily over five weeks, after which patients are maintained at 400 mg daily. AML ramp-up is more compressed and typically completed inside the first three days of treatment with adjusted target doses depending on the partner agent. The CLL ramp must be performed under the prescribing hematologist's direct supervision with TLS-risk-stratified hospitalisation, hydration, and uric-acid prophylaxis decisions.

Baseline workup. Per the FDA label, the baseline workup before initiating Venclexta typically includes CBC with differential, comprehensive metabolic panel including uric acid and phosphate, LDH, creatinine clearance with TLS-risk stratification by tumor burden, hepatitis B serology, and review of strong CYP3A inhibitor / inducer co-medications including azole antifungals. Your hematologist will confirm suitability and document a monitoring plan before the first dose.

Important warnings. The FDA label carries warnings for tumor lysis syndrome (especially during ramp-up), neutropenia with serious infections, hepatitis B reactivation, second primary malignancies, immunisation considerations (live vaccines contraindicated during therapy), and embryo-fetal toxicity. These are managed through intensive blood-chemistry monitoring during the ramp-up phase (pre-dose, 6 to 8 hours after dose, and 24 hours after dose on the first dose of each new step for higher-risk patients), CBC at regular intervals on maintenance, and strict avoidance of grapefruit, Seville oranges, and starfruit during therapy, the specifics of which your hematologist will tailor to your clinical situation.

How Venclexta fits in the treatment landscape. Venclexta acts on a different target (BCL-2) than BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib) and is often used in fixed-duration combination regimens (with obinutuzumab in 1L CLL, or with rituximab in R/R CLL) that aim for measurable-residual-disease-negative remission. The two classes are increasingly used sequentially or in combination in trial settings.

Is Venclexta legally importable into India?

Yes. The Central Drugs Standard Control Organisation (CDSCO) operates a personal-import and named-patient import framework that allows a registered Indian medical practitioner, or an institutional importing pharmacy on the practitioner's behalf, to import a small quantity of a medicine approved by a recognised reference regulatory authority (US FDA, EMA, MHRA, PMDA, Health Canada, TGA) when the locally available channel does not meet the specific patient's clinical need.

The qualifying conditions are well-established:

- The medicine is approved by a recognised reference authority. Venclexta qualifies on the basis of its FDA approval and EMA authorisation.
- No locally available alternative meets the specific patient's indication, strength, presentation, or supply situation.
- The treating physician takes clinical responsibility for the use, in writing, with a documented prescription and monitoring plan.
- Chain of custody is documented from the US source through international transit to the named dispensing facility in India.

The most common operational forms are CDSCO Form 12A (application for a personal-import licence to import a small quantity of a new drug for personal use), Form 10 (import licence for new drugs), and the institutional no-objection certificate (NOC) pathway through the dispensing hospital's Drug Controller cell. Approval is issued on a per-patient, per-cycle basis.

Venclexta's regulatory status across reference jurisdictions

FDA-approved (initially 2016), EMA-authorised under the trade name Venclyxto. India CDSCO has registered venetoclax; specialty-pharmacy availability for the full ramp-up titration set (10 mg, 50 mg, 100 mg tablets) can be inconsistent.

The reference-authority anchor matters: CDSCO reviewers expect to see citation of at least one major reference authority's approval in the named-patient documentation package. For Venclexta, the FDA label and the EMA EPAR document together constitute that anchor.

How the pathway works, step by step

1. **Consultation with your treating hematologist.** The prescribing decision is clinical. Your hematologist documents the indication, prior therapies where relevant, and the rationale for Venclexta. If you are seeking a second opinion through Reserve Meds's medical-advisory network, we can coordinate that, but only your treating physician of record can issue the prescription.
2. **Baseline screening.** CBC with differential, comprehensive metabolic panel including uric acid and phosphate, LDH, creatinine clearance with TLS-risk stratification by tumor burden, hepatitis B serology, and review of strong CYP3A inhibitor / inducer co-medications including azole antifungals are confirmed and documented in the medical record. Findings that require management before initiation (uncontrolled hypertension, untreated hepatitis B, active untreated infection) are addressed first.
3. **CDSCO named-patient application.** Your hematologist or the importing pharmacy files the CDSCO documentation package, including the clinical rationale letter, prescription, patient identifier, product strength, requested quantity, and the chain-of-custody plan.
4. **US-side sourcing under DSCSA chain-of-custody.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Venclexta from AbbVie and Genentech's authorised distribution under the US Drug Supply Chain Security Act (DSCSA). Every transfer point is logged.
5. **International shipment.** Internationally tracked shipment to your named dispensing facility in India, with tamper-evident packaging and documented temperature handling where applicable.
6. **Arrival and first dose.** The dispensing pharmacy of record verifies the shipment against the prescription and releases the product. Your hematologist initiates therapy under your monitoring plan.
7. **Ongoing coordination.** Reserve Meds supports re-supply cadence aligned to your dosing schedule. Refills ship on a rolling basis once the pathway is established for your case.

What documentation your physician needs

Your hematologist will typically need to provide the following items as part of the CDSCO named-patient package:

- A clinical rationale letter confirming the diagnosis (chronic lymphocytic leukemia, acute myeloid leukemia), prior therapies where relevant, and Venclexta as the indicated next step
- Verification of their Indian medical registration (state medical council or National Medical Commission, formerly MCI)
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with the FDA label as summarised above
- The planned dosing regimen, indication-specific per the FDA label
- A monitoring plan covering the specific safety surveillance required for this drug class
- A formulary-gap justification explaining why the locally available channel does not meet this patient's clinical need
- The name and address of the named dispensing facility of record

Reserve Meds provides a physician documentation kit tailored for BCL-2 (B-cell lymphoma 2) inhibitor therapies, with the templates CDSCO reviewers commonly request. The kit is sent to your hematologist on request and shortens the first-time application turnaround significantly.

Typical costs and indicative timing

Reserve Meds issues a drug-only reference range at the start of intake and a transparent delivered quote once your physician's documentation is in. As an illustrative composite case, the US cash-pay reference range for a typical month at the 400 mg maintenance dose of Venclexta sits in an indicative 2026 band of approximately USD 12,000 to 14,000. On an annualised basis, that equates to roughly USD 144,000 to 168,000 per year at maintenance, with the CLL ramp-up phase costing less but requiring closer monitoring, before any indication-specific dose adjustments or ramp-up considerations.

International logistics, CDSCO documentation handling, cold-chain coordination where applicable, and Reserve Meds concierge coordination add incremental cost. The delivered quote we issue at intake itemises each line separately so your family and your physician can review the full picture before committing.

Indicative timing for the first shipment after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Re-supply is generally faster once the pathway is established. These timelines are indicative and not guarantees.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Venclexta specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from AbbVie and Genentech's authorised distribution through export.
- **Documentation.** A regulatory package tailored for your hematologist and for CDSCO review, including class-specific templates and the formulary-gap justification format reviewers expect.
- **Logistics.** Internationally tracked shipment to your named dispensing facility in India with tamper-evident packaging and documented chain of custody.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc, from intake through first dose and into re-supply.

What we do not do. We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating hematologist, and dispensing sits with the licensed Indian pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance. If Venclexta is already available to you locally for your indication and presentation, stay on the local channel.

What CDSCO actually looks at, a closer reading

Reviewers at the Central Drugs Standard Control Organisation work from a defined checklist when evaluating a personal-import or named-patient application. Understanding what the reviewer is reading from helps your hematologist prepare a package that clears on first pass:

- **Reference-authority approval.** The package must cite at least one major reference regulator's approval. For Venclexta, the FDA prescribing information and the EMA EPAR are the typical anchors. Reserve Meds provides direct links to the most recent versions of both.
- **Clinical rationale.** A free-text narrative from your treating hematologist explaining the diagnosis, prior therapies where relevant, and the specific reason Venclexta is the appropriate next step. CDSCO reviewers respond well to specificity: the indication code (ICD-11 or equivalent), the line of therapy, and the documentation that locally available alternatives are not suitable.
- **Quantity requested.** CDSCO authorises a defined quantity per application. For chronic-therapy drugs like Venclexta, a typical first authorisation covers one to three months of supply, with subsequent refill authorisations issued on the same per-patient file.
- **Chain-of-custody plan.** The package must describe how the product moves from the US source, through international transit, to the dispensing facility of record. Reserve Meds provides the standard chain-of-custody attestation that satisfies this requirement.
- **Dispensing facility of record.** A named hospital pharmacy or licensed retail pharmacy with the capability to receive, store, and dispense the product against the prescription. Most major Indian tertiary centers including Tata Memorial Centre (Mumbai), AIIMS New Delhi, AIIMS Bhubaneswar, Christian Medical College Vellore, Apollo Hospitals (Chennai, Hyderabad, Delhi, Bangalore), Fortis Memorial Research Institute (Gurugram), Max Super Speciality Hospital (Delhi), Rajiv Gandhi Cancer Institute (Delhi), HCG Cancer Hospitals (Bangalore, Ahmedabad), and the Kidwai Memorial Institute of Oncology (Bangalore) have institutional experience with named-patient supply.

The CDSCO portal accepts applications online, with physical document submission to the relevant zonal office. Average first-pass turnaround for a clean package is 10 to 21 working days, with re-supply authorisations typically faster.

BCL-2 Inhibitor-specific pitfalls Indian patients commonly encounter

Venclexta sits in the BCL-2 inhibitor class. Across BCL-2 inhibitor therapies, the most common operational and clinical issues we see in Indian named-patient cases are:

- Tumor lysis syndrome (TLS) risk during ramp-up: TLS-risk stratification by tumor burden (lymph-node size and absolute lymphocyte count) determines whether the first dose of each ramp step is given inpatient with intensive monitoring or outpatient with home hydration. Skipping this stratification is a safety failure.
- Strong CYP3A inhibitors and inducers (including azole antifungals and grapefruit, Seville oranges, and starfruit) substantially alter venetoclax levels. Either avoid co-administration or follow the FDA label's dose reduction.
- Neutropenia: dose-limiting neutropenia is common; growth-factor support and dose holds are part of standard management.
- Hepatitis B reactivation: HBsAg and anti-HBc testing is mandatory before initiation.
- Live vaccines are contraindicated during therapy and for a defined washout period after stopping.

Reserve Meds includes a class-specific operational checklist in the documentation kit we provide to your hematologist, addressing each of these items so they are handled at the start of therapy rather than discovered during a complication.

How Venclexta sits against alternatives in the same line of therapy

The following table summarises how Venclexta compares with the principal alternatives your hematologist may consider for the same or adjacent indications. The choice between agents is a clinical decision your hematologist owns; this comparison is provided for orientation, not as treatment guidance.

Agent	Class and key targets	Principal indications	Distinguishing tolerability note
Venetoclax (Venclexta)	BCL-2 inhibitor	CLL/SLL (often fixed-duration with anti-CD20), AML in older or comorbid patients with HMA or LDAC	TLS risk during ramp-up, neutropenia
Ibrutinib (Imbruvica)	1st-gen covalent BTK inhibitor	CLL/SLL, WM, MCL, MZL, cGVHD	Continuous therapy; AF, bleeding
Acalabrutinib (Calquence)	2nd-gen covalent BTK inhibitor	CLL/SLL, MCL	Continuous therapy; better cardiac tolerability
Idelalisib (Zydelig)	PI3K-delta inhibitor	R/R CLL with rituximab	Hepatotoxicity, colitis, infections

Preparing for your first dose, a patient-side checklist

Patients and families coordinating cross-border supply through Reserve Meds typically have an easier first-dose experience when the following are in place before the product arrives:

- **A treating hematologist of record** in India with documented prescribing decision and a monitoring plan in writing.
- **A named dispensing facility** (hospital pharmacy or licensed retail pharmacy) that has confirmed it will accept the named-patient import and release the product against the prescription.
- **Baseline laboratory and imaging** already completed within the window the FDA label specifies for Venclexta.
- **A primary contact** in the family (typically an adult child or spouse) who can hold continuous email and phone communication with the Reserve Meds case lead across the case arc.
- **Identification and address documentation** required by the dispensing facility for the patient of record.
- **Payment readiness** for the delivered quote, with bank wire or international card payment confirmed before scheduling shipment.
- **A plan for ongoing supply** once the first authorisation is in hand. Refills require continuous communication between your hematologist, Reserve Meds, and the dispensing facility.

The Reserve Meds case lead walks each item with the family at intake. Where any item is open, we sequence the case so the open item is closed before shipment is scheduled, not discovered at customs.

Family and caregiver considerations

Cross-border specialty therapy is rarely a single-person decision. Reserve Meds is set up to communicate with a named primary contact (typically an adult family member) alongside the patient. We do not communicate with the family without the patient's documented authorisation, but in practice, families who handle logistics together tend to have smoother coordination. Topics commonly worth discussing as a family before initiation include:

- The realistic duration of therapy and the cost profile across that duration, not just the first month
- Travel and work implications for the patient if monitoring visits are frequent in the first weeks
- Who manages the dispensing-facility relationship and who manages the Reserve Meds case lead relationship
- The contingency plan if a re-supply authorisation is delayed: bridge supply through the dispensing facility, dose holds per the hematologist's instructions, and the threshold at which the family escalates
- Confidentiality preferences: how much detail about the case the family wants shared with extended relatives, employers, or community contacts

These conversations are easier before therapy starts. Reserve Meds can join the conversation on the family's invitation, and we can route to a Reserve Meds counselor for the operational decisions that do not require clinical judgement.

What insurance and corporate health plans will and will not do

The default posture for named-patient imports is cash-pay. Reserve Meds does not bill insurance and does not process claims on the family's behalf. Some Indian private insurance plans and corporate health plans do reimburse named-patient imports on a pre-authorisation, case-by-case basis when the documentation package is strong. The factors that increase the probability of reimbursement are:

- A clear formulary-gap justification documented by the treating hematologist
- Citation of FDA approval and EMA authorisation for Venclexta for the specific indication
- Cost-comparison documentation showing the cross-border total-cost-delivered against the locally available alternative (where one exists)
- A prior-authorisation submission timed before the first shipment, with the insurer's response documented

Reserve Meds supplies the documentation that family-side submissions need but does not interact with the insurer directly. Families should plan for the cash-pay path and treat insurance reimbursement as a probability-weighted bonus, not a sure thing.

Frequently asked

Is this legal in India? Yes, when executed through the Central Drugs Standard Control Organisation (CDSCO) personal-import and named-patient framework, with appropriate documentation, clinical rationale from a registered Indian medical practitioner, and a licensed dispensing pharmacy of record. The pathway is routinely used across oncology, rare disease, and immunology at Indian tertiary centers including Tata Memorial, AIIMS, and major private oncology networks.

Why does Venclexta require a ramp-up schedule? BCL-2 inhibition by venetoclax triggers rapid apoptosis in malignant cells, which can release intracellular contents fast enough to cause tumor lysis syndrome, an oncological emergency that can cause acute kidney injury, cardiac arrhythmias, and death. The weekly ramp-up from 20 mg to 400 mg over five weeks (in CLL) gives the body time to safely clear the metabolic load. Skipping or accelerating the ramp without TLS-risk stratification is a safety failure your hematologist will not permit.

Which CDSCO forms does my physician need? The most common forms are CDSCO Form 12A (application for a personal-import licence to import a small quantity of a new drug for personal use) and Form 10 (import licence for new drugs). For institutional named-patient supply, hospitals coordinate through their Drug Controller cell to issue the supporting NOC (no-objection certificate) and chain-of-custody plan. Reserve Meds provides physician-facing templates that match the format CDSCO reviewers expect.

Will my private health insurance cover this? Cash-pay is the default posture for named-patient imports. Some Indian private insurance plans and corporate health plans review case-by-case on a pre-authorisation basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims and do not bill insurers.

How long does CDSCO approval take? Indicative timing for the first shipment after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Re-supply is generally faster once the pathway is established for that patient. These timelines are indicative and not guarantees.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Indian tertiary centers have encountered. Our documentation kit is written for first-time applicants and tracks what CDSCO reviewers commonly ask for. We coordinate with the importing pharmacy directly so the clinical team is not the project manager.

How this guide is reviewed and kept current

Every Reserve Meds access guide is built and maintained through a defined review pipeline. The pipeline has four layers:

- **Source ingestion.** The FDA prescribing information, the EMA EPAR, the manufacturer's published label, and at least one peer-reviewed primary trial publication are pulled and pinned to a specific version for each drug.
- **Clinical-content review.** An AI-assisted clinical review layer cross-references the FDA label against the EMA EPAR and the peer-reviewed primary literature, flagging any divergence between authorities. Divergences are escalated to the Reserve Meds clinical team for adjudication before the guide publishes.
- **Regulatory-pathway review.** An AI-assisted regulatory review layer cross-references the CDSCO personal-import and named-patient framework with the current CDSCO public guidance documents, and flags any change to the framework that would alter the operational steps.
- **Editorial and accessibility review.** A final pass enforces Reserve Meds editorial standards (medical accuracy, no over-promising on outcomes, clear delineation of what Reserve Meds does and does not do) and accessibility conformance (WCAG 2.1 AA where applicable).

The publication date and the last-reviewed date are both surfaced at the top of every guide. Drug-class and country-pathway changes drive update cycles; the typical refresh cadence is every 90 days or sooner if a material regulatory or label change is published.

The Hindi-language version of this guide

This guide is also published in Hindi for patients and families who prefer to read clinical and regulatory material in Hindi. The Hindi version covers the same scope (clinical context, CDSCO named-patient pathway, costs, timing, Reserve Meds's role) and is reviewed by the Reserve Meds AI Language Team's Hindi medical linguist alongside the clinical and regulatory team. You can switch to the Hindi version at any time using the language link in the page header, or directly at the URL referenced in this guide's machine-readable hreflang metadata.

Arabic and Urdu versions are in production and will be linked from the same hreflang quartet once published. The English, Hindi, Arabic, and Urdu pages will all point to the same canonical resource so that search engines and assistive technologies treat them as a single multilingual entity.

If your situation does not fit this pathway

The named-patient import pathway suits a specific situation: an Indian patient with a clear clinical indication, a treating physician of record, and a local-supply gap. If your situation is different, other Reserve Meds resources may be more relevant:

- **If the drug is locally registered and available for your indication at acceptable cost**, stay on the local channel. We say this in every guide because it is genuinely the right answer for many patients.
- **If you do not yet have a treating physician of record**, the prescribing decision needs to come first. Reserve Meds can coordinate a second opinion through our medical-advisory network for cases that need orientation, but only your treating physician can issue the prescription.
- **If you are not in India but have family there managing the case**, that family member typically becomes the named primary contact, with the patient retaining decision-making authority on the case.
- **If you are seeking access for a child or adolescent**, pediatric considerations depend on the specific drug and indication. Our case lead reviews pediatric cases with extra documentation steps before proceeding.
- **If your situation involves an investigational or off-label use**, that sits outside the named-patient framework and typically requires either a clinical-trial pathway or an expanded-access protocol. Reserve Meds is not the right path for those situations.

Operational risks we flag at intake

Several operational risks recur in cross-border specialty cases. Reserve Meds raises each at intake and works through them with the family before scheduling shipment:

- **Documentation gaps.** Incomplete or inconsistent documentation is the single most common cause of CDSCO application delays. Our documentation kit is designed to close these gaps on first pass.
- **Dispensing-facility readiness.** The named dispensing facility must be ready to receive, store, and release the product. We confirm readiness in writing before shipment.
- **Cold-chain integrity.** Where the drug requires temperature control, every transfer point is monitored and logged. A cold-chain breach is grounds to reject the shipment.
- **Payment timing.** Payment readiness is confirmed at the start of shipment, not at arrival. International wire timing varies by sending bank; we plan around the longer timeline.
- **Communication continuity.** Case leads and family contacts can both have absences (travel, illness, religious observance). Reserve Meds maintains a backup case-lead pattern so coordination does not pause.
- **Re-supply timing.** Refills are scheduled so the patient never has a dosing gap. We work backwards from the patient's last-dose date to ensure new supply lands with a comfortable margin.

Authoritative sources cited on this page

This guide is built on primary regulatory and peer-reviewed sources. Key citations:

1. U.S. FDA - VENCLEXTA prescribing information (U.S. Food and Drug Administration)
2. AbbVie - Venclexta product page (AbbVie Inc.)
3. European Medicines Agency - Venclyxto EPAR (European Medicines Agency)
4. DiNardo CD et al, Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia (VIALE-A), NEJM 2020 (New England Journal of Medicine)
5. Central Drugs Standard Control Organisation (India) (Central Drugs Standard Control Organisation)

The full machine-readable citation block is in the JSON-LD CreativeWork node above. Methodology and limitations of the review process are documented at Trust and Compliance.

Mechanism of action, deeper reading

For patients and family members who want to understand more about how this drug works at the molecular level, the following points expand on the high-level mechanism summary above:

- Venclexta is an orally bioavailable BH3 mimetic that binds with high affinity to the BCL-2 protein, displacing pro-apoptotic factors (BIM, BID, BAX, BAK) sequestered by BCL-2.
- Once released, the pro-apoptotic factors converge on the mitochondrial outer membrane, triggering MOMP (mitochondrial outer-membrane permeabilisation), cytochrome-c release, and caspase activation.
- BCL-2 overexpression is a defining feature of CLL biology (driven by deletion of microRNAs miR-15a and miR-16-1) and is also present in subsets of AML, multiple myeloma, and other hematologic malignancies.
- The rapidity of apoptosis on BCL-2 inhibition is the mechanistic basis for tumor lysis syndrome risk. The five-week weekly ramp-up in CLL is engineered to titrate tumor cell killing gradually.
- Resistance mechanisms include BCL-2 G101V mutation, upregulation of MCL-1 or BCL-xL (alternative anti-apoptotic proteins), and microenvironmental survival signals.

Key trials that built the evidence base

The clinical evidence supporting the use of this drug across its approved indications comes from a defined set of randomised trials. The principal trials are summarised below; your treating physician will know the trial design and patient-population details relevant to your specific situation:

Trial	Design	Headline finding
MURANO	Venetoclax + rituximab vs bendamustine + rituximab in R/R CLL	Phase 3, fixed-duration VR superior on PFS and OS
CLL14	Venetoclax + obinutuzumab vs chlorambucil + obinutuzumab in 1L CLL	Phase 3, fixed-duration VO superior on PFS, MRD-negativity
VIALE-A	Venetoclax + azacitidine vs azacitidine alone in 1L AML in older or comorbid patients	Phase 3, combination superior on CR rate and OS
VIALE-C	Venetoclax + LDAC vs LDAC alone in 1L AML in older or comorbid patients	Phase 3, combination superior on OS

Glossary

CDSCO
: Central Drugs Standard Control Organisation, India's national drug regulatory authority.

Named-patient import
: A regulatory pathway that allows import of an unregistered or locally unavailable medicine for an individual patient under their physician's responsibility.

DSCSA
: Drug Supply Chain Security Act, the US law that requires chain-of-custody tracking from manufacturer through dispensing pharmacy.

Reference authority
: A major regulatory authority whose approval CDSCO will recognise as evidence of safety and efficacy. US FDA, EMA, MHRA, PMDA, Health Canada, and TGA are the principal reference authorities.

Formulary gap
: A documented mismatch between what is available in the local market and what the patient's clinical situation requires. The formulary-gap justification is a core element of the CDSCO named-patient application.

Concierge coordinator
: A non-prescribing, non-dispensing service that coordinates sourcing, documentation, and logistics for cross-border specialty medicine, while clinical decisions remain with the treating physician and dispensing remains with the licensed pharmacy.

Related pages on Reserve Meds

- Venclexta in India - drug overview and matrix cell
- Chronic lymphocytic leukemia
- Acute myeloid leukemia
- Named-patient program pathway
- Compassionate use pathway
- Cross-border prescription pathway
- All access guides
- India country guide

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

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