Imbruvica

India · access guide

How to access Imbruvica 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 Imbruvica (ibrutinib), where local registration or supply does not meet the need, may receive a prescription from their treating hematologist and have Imbruvica 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

Imbruvica (ibrutinib) is a first-generation Bruton tyrosine kinase (BTK) inhibitor developed by Pharmacyclics LLC (an AbbVie company) and Janssen Biotech. Imbruvica is a small-molecule, covalent, irreversible inhibitor of Bruton tyrosine kinase. By blocking BTK at the C481 binding site, it interrupts B-cell receptor signaling that drives proliferation in malignant B-cell clones, and modulates immune effector cell function in chronic graft-versus-host disease.

Imbruvica carries FDA approvals for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), Waldenstrom macroglobulinemia, mantle cell lymphoma after at least one prior therapy, marginal zone lymphoma after at least one anti-CD20-based regimen, and chronic graft-versus-host disease after failure of one or more lines of systemic therapy. EMA authorisation under Imbruvica covers an overlapping but not identical indication set.

Route and dosing. Imbruvica is administered as oral capsule or tablet. Dosing is indication-specific per the FDA label, typically 420 mg orally once daily for CLL/SLL and Waldenstrom macroglobulinemia, 560 mg once daily for mantle cell lymphoma and marginal zone lymphoma, and 420 mg once daily for chronic graft-versus-host disease.

Baseline workup. Per the FDA label, the baseline workup before initiating Imbruvica typically includes CBC with differential, hepatitis B surface antigen and core antibody (HBsAg / anti-HBc) for reactivation risk, baseline ECG with attention to QT and prior atrial fibrillation history, lipid panel, comprehensive metabolic panel, and a documented bleeding-risk review covering anticoagulant or antiplatelet use. Your hematologist will confirm suitability and document a monitoring plan before the first dose.

Important warnings. The FDA label carries warnings for hemorrhage, serious infections including opportunistic infections, cytopenias, atrial fibrillation and flutter and ventricular arrhythmias, hypertension, second primary malignancies including non-melanoma skin cancer, and tumor lysis syndrome. These are managed through CBC at regular intervals, atrial-fibrillation surveillance, infection vigilance, blood-pressure monitoring, and hepatitis B reactivation monitoring, the specifics of which your hematologist will tailor to your clinical situation.

How Imbruvica fits in the treatment landscape. Imbruvica is first-generation. Calquence (acalabrutinib) and Brukinsa (zanubrutinib) are second-generation covalent BTK inhibitors with greater target selectivity and have shown reduced cardiovascular toxicity relative to ibrutinib in head-to-head CLL data. Pirtobrutinib (Jaypirca) is a non-covalent BTK inhibitor active in BTK C481-mutated resistance settings.

Is Imbruvica 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. Imbruvica 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.

Imbruvica's regulatory status across reference jurisdictions

FDA-approved (originally 2013), EMA-authorised, listed on the WHO Essential Medicines List in 2019. India CDSCO has registered ibrutinib for select indications, but supply at the requested strength or for indications outside the local label can vary by city and specialty pharmacy.

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 Imbruvica, 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 Imbruvica. 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, hepatitis B surface antigen and core antibody (HBsAg / anti-HBc) for reactivation risk, baseline ECG with attention to QT and prior atrial fibrillation history, lipid panel, comprehensive metabolic panel, and a documented bleeding-risk review covering anticoagulant or antiplatelet use 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 Imbruvica from Pharmacyclics (AbbVie) and Janssen'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, mantle cell lymphoma, Waldenstrom macroglobulinemia), prior therapies where relevant, and Imbruvica 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 first-generation Bruton tyrosine kinase (BTK) 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 of daily dosing of Imbruvica sits in an indicative 2026 band of approximately USD 16,000 to 19,000. On an annualised basis, that equates to roughly USD 160,000 to 200,000 per year, 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 Imbruvica specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from Pharmacyclics (AbbVie) and Janssen'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 Imbruvica 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 Imbruvica, 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 Imbruvica 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 Imbruvica, 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.

BTK Inhibitor-specific pitfalls Indian patients commonly encounter

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

- Anticoagulation interaction: warfarin, direct oral anticoagulants, and dual antiplatelet therapy substantially raise bleeding risk. Surgical pauses are typically 3 to 7 days before and after procedures.
- Atrial-fibrillation surveillance: a baseline ECG and prior-history review are non-negotiable. New-onset AF on therapy frequently triggers dose reduction or switch to a second-generation BTK inhibitor.
- Hepatitis B reactivation: HBsAg and anti-HBc testing is mandatory before initiation. Patients with prior exposure may require prophylactic entecavir or tenofovir during therapy and beyond.
- Strong CYP3A inhibitor and inducer interactions: azole antifungals, certain HIV protease inhibitors, and rifampin require dose adjustment or substitution.

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 Imbruvica sits against alternatives in the same line of therapy

The following table summarises how Imbruvica 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
Ibrutinib (Imbruvica)	1st-gen covalent BTK inhibitor	CLL/SLL, WM, MCL, MZL, cGVHD	Higher AF, hypertension, bleeding
Acalabrutinib (Calquence)	2nd-gen covalent BTK inhibitor	CLL/SLL, MCL (accelerated)	Lower AF, lower bleeding vs ibrutinib
Zanubrutinib (Brukinsa)	2nd-gen covalent BTK inhibitor	CLL/SLL, WM, MCL, MZL, FL	Lower AF, lower bleeding
Pirtobrutinib (Jaypirca)	Non-covalent BTK inhibitor	CLL/SLL and MCL after BTKi failure	Active in C481-mutated resistance

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 Imbruvica.
- **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 Imbruvica 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.

How does Imbruvica compare to Calquence and Brukinsa? Imbruvica is first-generation. Calquence (acalabrutinib) and Brukinsa (zanubrutinib) are second-generation covalent BTK inhibitors with greater target selectivity and have shown reduced cardiovascular toxicity relative to ibrutinib in head-to-head CLL data. Choice between them is a clinical decision your hematologist will make based on cardiac history, drug interactions, age, and indication.

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 - IMBRUVICA prescribing information (U.S. Food and Drug Administration)
2. AbbVie - Imbruvica product page (AbbVie Inc.)
3. European Medicines Agency - Imbruvica EPAR (European Medicines Agency)
4. WHO Model List of Essential Medicines, 22nd edition (World Health Organization)
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:

- Imbruvica binds covalently to cysteine-481 in the ATP-binding pocket of Bruton tyrosine kinase, irreversibly inactivating the enzyme.
- BTK is a non-receptor tyrosine kinase essential for B-cell receptor (BCR) signaling. In B-cell malignancies (CLL, MCL, WM, MZL), constitutive BCR signaling drives proliferation and survival.
- By irreversibly inactivating BTK, ibrutinib blocks downstream PLC-gamma2, PKC-beta, and NF-kB pathways, removing the survival signal that the malignant clone depends on.
- Resistance most commonly emerges through C481S mutation, which prevents the covalent bond from forming. Non-covalent BTK inhibitors like pirtobrutinib retain activity against C481-mutated disease.
- In chronic graft-versus-host disease, ibrutinib modulates both B-cell and T-cell effector function, dampening the alloreactive response.

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
RESONATE	Ibrutinib vs ofatumumab in previously treated CLL	Phase 3, ibrutinib superior on PFS and OS
RESONATE-2	Ibrutinib vs chlorambucil in treatment-naive CLL aged >=65	Phase 3, ibrutinib superior on PFS and OS
iLLUMINATE	Ibrutinib + obinutuzumab vs chlorambucil + obinutuzumab in 1L CLL	Phase 3, combination superior on PFS
ELEVATE-RR	Ibrutinib vs acalabrutinib in previously treated high-risk CLL	Phase 3, acalabrutinib non-inferior on PFS with lower cardiovascular toxicity

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

- Imbruvica in India - drug overview and matrix cell
- Chronic lymphocytic leukemia
- Leukemia overview
- 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

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