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Alhemo access in India: the CDSCO Rule 36 named-patient pathway

How families in India legally obtain Alhemo (concizumab-mtci) for hemophilia A or B prophylaxis (with or without inhibitors) from US-source supply through CDSCO personal importation, with validated 2 to 8 degree Celsius cold-chain and daily subcutaneous dosing logistics built into the case plan.

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

Quick orientation

Alhemo (concizumab-mtci) is a humanized IgG4 monoclonal antibody from Novo Nordisk that targets tissue factor pathway inhibitor (TFPI), restoring factor Xa generation in patients whose intrinsic coagulation cascade is broken by an absence of factor VIII or factor IX activity. It is supplied as a single-patient prefilled pen for once-daily subcutaneous injection. The US Food and Drug Administration first approved Alhemo on 20 December 2024 for routine prophylaxis in adult and pediatric patients 12 years of age and older with hemophilia A or B with inhibitors, and the label has since expanded to include hemophilia A or B without inhibitors. Alhemo is not registered with the CDSCO as of this review. Indian patients with the relevant hematology indication reach Alhemo through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with the Form 12A application and Form 12B permit issued by the office of the Drugs Controller General of India (DCGI). Reserve Meds coordinates the US-side specialty pharmacy sourcing, validated 2 to 8 degree Celsius cold-chain logistics with temperature monitoring through to handoff, and the documentation kit your treating hematologist needs to file.

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Why patients in India need Alhemo via the named-patient pathway

India has a substantial hemophilia patient population identified through state Hemophilia Society chapters and through tertiary hematology centres at AIIMS New Delhi, Christian Medical College Vellore, Tata Memorial Centre Mumbai, Apollo Hospitals, Kokilaben, Fortis, and Manipal. Within that population, the cohort of patients with high-titre factor VIII or factor IX inhibitors is small but clinically distinct: bypass therapy with recombinant factor VIIa or activated prothrombin complex concentrate manages acute bleeds but does not prevent them, and the operational burden of recurrent breakthrough bleeds on the patient and the family is heavy. The newer subcutaneous prophylactic biologics (emicizumab, concizumab) have changed the standard of care for this cohort internationally. Emicizumab is registered in India under brand name Hemlibra and is available through hematology centres, but concizumab is not registered with the CDSCO and cannot be filled at an Indian hospital pharmacy on a local prescription.

The clinical reason families pursue Alhemo specifically rather than emicizumab is the indication breadth and the treater's clinical judgment. Emicizumab is approved only for hemophilia A. Concizumab is approved for hemophilia A or hemophilia B, with or without inhibitors. For a

hemophilia B patient with inhibitors, concizumab is among the first prophylactic biologic options. The clinical decision sits with the treating hematologist; the procurement mechanism for Indian-resident patients is Rule 36. Diaspora-funded structures are common in this case profile, with an adult child working in the Gulf, the UK, or North America paying the invoice for a parent or sibling under care at AIIMS Delhi, CMC Vellore, or Apollo Chennai. The Rule 36 framework accommodates that pattern when the named patient is the Indian resident.

The NPRD 2021 INR 50 lakh financial-assistance ceiling under the Rashtriya Arogya Nidhi umbrella scheme is structured around one-time treatments for rare diseases. Hemophilia is listed under the NPRD framework but the indefinite chronic prophylactic dosing pattern of Alhemo does not fit the one-time-treatment structure, and NPRD support has not been the operating financial structure for routine Alhemo cases. Cash-pay, often through diaspora-funded channels, is the working financial posture.

The CDSCO Rule 36 named-patient pathway for Alhemo

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity 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 for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application.

For Alhemo specifically, the clinical-justification angle in a Form 12A application is the rare-bleeding-disorder rationale supported by factor and inhibitor laboratory results. The strongest applications consistently include a treating hematologist's confirmed diagnosis of hemophilia A or hemophilia B with documented factor VIII or factor IX activity level; the inhibitor titre result (Bethesda assay) where the indication is the inhibitor population, with the testing laboratory named; the bleeding history including annualised bleed rate on prior therapy; the patient's current body weight and the weight-based Alhemo dose calculation at 1 mg/kg loading followed by 0.2 mg/kg maintenance, with the planned plasma-concentration check at approximately 4 weeks of maintenance dosing and the up- or down-titration logic per label (uptitrate to 0.25 mg/kg if plasma concentration is below 200 ng/mL; downtitrate to 0.15 mg/kg if above 4,000 ng/mL); and the thrombosis risk profile assessment, given the explorer⁷ and explorer⁸ trial history of serious thromboembolic events at the higher 0.25 mg/kg maintenance dose and the resulting label guidance on concurrent bypass-agent dosing. The breakthrough-bleed plan, specifying the lowest approved dose of any concurrent procoagulant per label, is documented separately.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for an unmet medical need. Concizumab qualifies. Government institutions including AIIMS New Delhi have established workflow for this pathway. CDSCO's published guidance states Form 12B is typically issued within one to two days for routine applications where documentation is complete. Indian families and hospitals plan for a two to four week window from hematologist decision to first dose, because the bulk of elapsed time runs

through upstream documentation assembly and downstream cold-chain international logistics rather than the regulator's stamp.

Where Alhemo gets dispensed in India

Alhemo is a refrigerated biologic that requires 2 to 8 degree Celsius storage in the original carton, protected from light, prior to first use. After first use, a pen can be kept at room temperature below 30 degrees Celsius or refrigerated at 2 to 8 degrees Celsius for up to 4 weeks before discarding. Pens must not be frozen. The dispensing facility must hold a valid drug licence covering refrigerated biologics and must operate a hematology pharmacy desk capable of pen training, injection-site rotation guidance, and cold-chain handoff to the family.

Indian institutions with established hemophilia treatment programmes and refrigerated-biologics dispensing infrastructure include AIIMS New Delhi (apex public-sector institution with comprehensive hematology), Christian Medical College Vellore (globally recognised for hematology with the largest hemophilia comprehensive care registry in South Asia), Tata Memorial Centre Mumbai (autonomous institution with hematology subspecialty in the National Cancer Grid model), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Kokilaben Dhirubhai Ambani Hospital Mumbai (advanced hematology and BMT capability), Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, MGM Healthcare Chennai, and Manipal Hospitals Bangalore. Many comprehensive hemophilia care centres also operate under partnerships with the state Hemophilia Society chapters that maintain inhibitor registries and bleed-rate documentation, which feed directly into the clinical justification letter.

For families identified at smaller hematology services without an in-house import pharmacy desk, the practical pattern is to route the case to one of the centres above, or to work through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating hematologist on clinical documentation. Multi-city and multi-country families (the patient and his parents in Hyderabad, the hematologist at AIIMS Delhi, an adult sibling in Bangalore handling logistics, and a son in Dubai paying the invoice) are common and Reserve Meds' single-coordinator model is built for that pattern.

Real cost picture for Alhemo in India

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Pricing in this section is expressed in USD for portability; the actual invoice converts at the prevailing rate on the day of the transaction.

Per published US pricing references, Alhemo list pricing is approximately USD 10,088 per 60 mg / 1.5 mL pen, USD 25,209 per 150 mg / 1.5 mL pen, and USD 50,411 per 300 mg / 3 mL pen. Annual cost depends on patient weight because dosing is weight-based at 0.2 mg/kg maintenance after the 1 mg/kg loading dose. For a typical adult patient at 70 kg, daily consumption is approximately 14 mg, or roughly 420 mg per month, before loading-dose effects. At list pricing the annualised cost lands well above USD 500,000 per patient per year, which is consistent with rare-disease prophylaxis pricing benchmarks for bypass and substitution biologics such as Hemlibra. Adolescent patients (12-and-older indication) at lower body weights consume proportionally fewer milligrams. The Reserve Meds quote is sized to the patient's current weight at intake and re-estimated as weight changes meaningfully through adolescence.

International validated 2 to 8 degree Celsius cold-chain shipping for the monthly-or-quarterly consolidation cadence typically runs USD 500 to 1,200 per shipment depending on city of

destination and pen count. CDSCO permit fees are nominal. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named life-saving and rare-disease drugs, and the rare-disease list now covers additional conditions; the specific HSN code and exemption status of each Alhemo shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a Rule 36 personal import of an unregistered prophylactic biologic as a standard line item. CGHS and ESIC are not structured for routine personal-import reimbursement of an unregistered concizumab supply. The NPRD INR 50 lakh ceiling is structured around one-time treatments and does not align with the indefinite chronic dosing pattern of Alhemo prophylaxis. Cash-pay through diaspora-funded structures is the working financial posture. Reserve Meds itemises the US-side procurement, the international cold-chain logistics, and the concierge coordination fee separately on every firm quote so that any reimbursement attempt the family chooses to pursue has clean documentation to work with.

Typical timeline for Alhemo in India

For a routine Indian Alhemo case, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. The cold-chain biologic class adds two to three days to international transit windows compared with ambient products. Validated 2 to 8 degree Celsius shipping is rated for 72 to 120 hours, which dictates route selection and customs-clearance timing at Delhi, Mumbai, Bengaluru, Chennai, or Hyderabad airports. Documented temperature excursions above 8 degrees Celsius or below 2 degrees Celsius during transit force a stop-the-line check before the pens are released to the family.

End-to-end, most families plan for two to four weeks from hematologist decision to first injection, with the elapsed time dominated by upstream documentation assembly (factor activity result, inhibitor titre, bleed history, weight-based dose calculation, thrombosis risk assessment) and downstream cold-chain logistics rather than the permit stamp. Because Alhemo is dosed daily on an indefinite chronic basis, Reserve Meds plans repeat-shipment cadence at case acceptance, with the plasma-concentration check at approximately 4 weeks of maintenance dosing scheduled as a fixed milestone. The dose-titration result from that 4-week assay can shift maintenance to 0.25 mg/kg or 0.15 mg/kg, which adjusts the pens-per-month consumption rate and therefore the subsequent shipping cadence. Daily dosing leaves no buffer for prolonged customs delays, and Reserve Meds maintains a small safety-stock margin on each cycle to absorb routine logistics variance.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Alhemo, the strongest letters consistently include: a treating hematologist's confirmed diagnosis of hemophilia A or hemophilia B with documented factor VIII or factor IX activity level; the inhibitor titre result (Bethesda assay) with the testing laboratory named, where the indication is the inhibitor population; the bleeding history with annualised bleed rate on prior therapy; the patient's current weight and the weight-based Alhemo dose calculation (1 mg/kg loading on Day 1, then 0.2 mg/kg subcutaneous once daily from Day 2); the planned plasma-concentration check at approximately 4 weeks of maintenance dosing and the titration logic (up-titrate to 0.25 mg/kg if below 200 ng/mL, down-titrate to 0.15 mg/kg if above 4,000 ng/mL); the breakthrough-bleed plan specifying the lowest approved dose of any concurrent bypass agent per label; and the

thrombosis risk-factor assessment (active cancer, severe atherosclerosis, recent thromboembolic events). The prescribing hematologist's NMC registration number, the dispensing facility's drug licence covering refrigerated biologics, and a chain-of-custody plan from the US specialty pharmacy to the Indian dispensing pharmacy complete the file.

The treating hematologist retains the clinical decision (including the concizumab-versus-emicizumab decision, which Reserve Meds does not advise on) and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation through the Indian Pharmacopoeia Commission for any imported product. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician, with particular attention to thrombosis surveillance throughout therapy.

Common questions about Alhemo in India

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

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered prophylactic biologic as a standard line item. Reserve Meds provides the itemised documentation that lets the insurer evaluate. The claim itself is filed by the patient or the hospital. Cash-pay is the working posture.

What is the thrombosis safety profile we should be aware of?

The Alhemo mechanism of action carries a thrombosis risk and this is the central safety consideration. In the explorer⁷ and explorer⁸ trials, three serious thromboembolic events occurred, including a renal infarction, which prompted a clinical-hold pause, a dose reduction from 0.25 mg/kg to 0.20 mg/kg maintenance, and explicit risk-mitigation guidance on concurrent bypass-agent dosing. Patients with risk factors for thrombosis (active cancer, severe atherosclerosis, recent thromboembolic events) require careful assessment by the treating hematologist before initiation. The most common adverse reactions reported in clinical trials are injection-site reactions and urticaria.

Why concizumab versus emicizumab (Hemlibra)?

The clinical case for concizumab is indication breadth (hemophilia A and hemophilia B, with or without inhibitors) versus emicizumab's narrower hemophilia A approval. Emicizumab is dosed less frequently (weekly to monthly subcutaneously). Concizumab is daily. The treating hematologist makes the comparator decision. Reserve Meds does not advise on which prophylactic biologic to choose; once the prescriber has set the plan, our role is procurement, logistics, and documentation.

What about pediatric patients (12 and older indication)?

The framework applies the same way. The clinical justification letter typically includes weight-adjusted dosing, the planned 4-week plasma-concentration check, and pediatric-specific monitoring. AIIMS, Christian Medical College Vellore, Apollo, Kokilaben, and Manipal handle pediatric and adolescent named-patient hemophilia imports routinely.

What happens if there is a customs delay on a cold-chain shipment?

Reserve Meds maintains a small safety-stock margin on each cycle to absorb routine logistics variance. Documented temperature excursions above 8 degrees Celsius or below 2 degrees Celsius during transit force a stop-the-line check before the pens are released to the family, and

the case coordinator works with the treating hematologist on bridging guidance through the breakthrough-bleed bypass-agent plan if administration must be paused. The daily-dosing cadence is the operational constraint that drives this cycle planning.

Does FCRA affect a diaspora-funded Alhemo case?

The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, including an adult sibling or parent overseas paying for an Indian-resident patient's treatment, FCRA is generally not engaged. Where a foreign foundation or hemophilia-focused diaspora group is funding the treatment, FCRA registration of the recipient organisation and the donation route can become relevant. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

Where Reserve Meds fits in Alhemo cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate the US-side specialty pharmacy sourcing under DSCSA serialization with full pedigree, validated 2 to 8 degree Celsius cold-chain logistics with temperature monitoring through to handoff, and the documentation kit your treating hematologist needs for the Form 12A filing. No prior Reserve Meds case experience exists for Alhemo as of this review, so standard NPP coordination applies with particular attention to the once-daily subcutaneous cadence (which leaves no buffer for prolonged customs delays), the thrombosis risk surveillance the prescribing hematologist holds, the 4-week plasma-concentration milestone that drives the dose-titration decision, and family training on the prefilled pen and injection-site rotation. A single named coordinator carries the case from intake through indefinite chronic prophylaxis dosing.

Next step

If an Indian patient with hemophilia A or B has a treating hematologist considering Alhemo prophylaxis, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your hematologist and an indicative cost range scaled to the patient's current weight.

Reserved for you.

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