

Columvi

Pakistan · access guide

Columvi access in Pakistan: the DRAP named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Columvi (glofitamab) is a CD20-directed CD3 T-cell engaging bispecific antibody approved by the US Food and Drug Administration in June 2023 for adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy. The pivotal NP30179 study reported an overall response rate of 52 percent with 39 percent complete response in heavily pretreated populations, including patients who had previously received CD19 CAR-T. The product is manufactured by Roche/Genentech. Columvi is administered as a fixed-duration intravenous regimen with step-up dosing in cycle 1 to mitigate cytokine release syndrome, followed by full doses every three weeks for up to 12 cycles. Columvi is not registered with the Drug Regulatory Authority of Pakistan (DRAP), and access for a Pakistani patient runs through the personal-use Special Provision import combined with infusion at a hospital with bispecific antibody experience.

Why Pakistani patients ask about Columvi

Pakistan's tertiary oncology infrastructure includes Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore and Peshawar, Aga Khan University Hospital in Karachi, Indus Hospital and Health Network, Pakistan Atomic Energy Commission cancer hospitals, and the major private network. Families arrive at the Columvi question after the conventional aggressive B-cell lymphoma sequence has been exhausted: R-CHOP first-line, salvage with R-DHAP or R-ICE followed by autologous stem cell transplant where feasible, and where CAR-T is not operationally accessible due to cost, travel, or eligibility constraints. The bispecific antibody class is an operationally simpler option than CAR-T: the medicine ships as a vial, is administered at any qualified infusion center, and does not require autologous cell collection or specialty REMS infrastructure beyond CRS monitoring during step-up dosing.

The DRAP named-patient pathway for Columvi

Pakistan's framework for unregistered-medicine import runs through DRAP under the Drugs Act 1976 and DRAP Act 2012. The Special Provision personal-use import is available where a DRAP-licensed physician documents the clinical necessity of a medicine not registered or not available in Pakistan, and where no clinically equivalent locally registered alternative is suitable. For a bispecific antibody, the DRAP permit is operationally simpler to obtain than for CAR-T, and the dispensing infrastructure is broadly available across major tertiary centers.

A complete DRAP application includes the clinical justification letter from the treating hematologist, the physician's Pakistan Medical and Dental Council (PMDC) registration, the destination dispensing facility identification (Shaukat Khanum, AKUH, or another qualified tertiary center), and the dosing schedule. DRAP Special Provision processing for routine cases is typically 10 to 25 business days.

Where Columvi is administered in Pakistan

Columvi can be infused at any hematology-oncology-equipped tertiary center with bispecific antibody experience and CRS monitoring protocols. Shaukat Khanum Memorial Cancer Hospital (Lahore and Peshawar), Aga Khan University Hospital Karachi, Indus Hospital Karachi, Pakistan Atomic Energy Commission cancer hospitals, and the major private hematology centers are operationally equipped. The Reserve Meds operational role is the US-side sourcing and the cold-chain logistics into the patient's dispensing center.

Real cost picture for Columvi cases

US wholesale acquisition cost for Columvi is approximately USD 350,000 to USD 400,000 per full 12-cycle course, depending on the patient's response duration and whether the full course is administered. The Pakistani rupee trades at approximately 280 PKR to 1 USD, so the full-course drug acquisition cost converts to approximately PKR 98 million to PKR 112 million. International cold-chain logistics for monoclonal antibody shipment to Pakistan typically runs USD 800 to USD 2,000 per shipment cycle (approximately PKR 224,000 to PKR 560,000), with shipment cadence aligned to infusion cycles. DRAP permit fees are nominal relative to drug cost. Cash-pay is the operating assumption.

Typical timeline for Columvi in Pakistan

End-to-end, a Pakistani Columvi case typically runs 4 to 8 weeks from first complete documentation to first infusion: clinical eligibility and infusion-center confirmation (week 1); DRAP documentation and Special Provision filing (weeks 1 to 3); US-side sourcing and first cold-chain shipment to Pakistan (weeks 3 to 5); customs clearance and first dose with monitored step-up dosing for CRS (weeks 5 to 6); ongoing cycles every three weeks for up to 12 cycles. The fixed-duration regimen (rather than treat-to-progression) is a meaningful operational and financial advantage over indefinite biologic therapy.

What your physician needs to provide

For a Pakistani hematologist coordinating a Columvi case, the clinical justification letter documents the lymphoma diagnosis (DLBCL NOS or large B-cell lymphoma arising from follicular lymphoma), the prior line-of-therapy summary including at least two prior lines, current disease burden including imaging, performance status, comorbidity profile, and the step-up dosing plan with CRS monitoring protocol. The physician's PMDC registration number, the institutional affiliation, and the obinutuzumab pretreatment plan (required per the FDA label to mitigate CRS risk) complete the paperwork.

Common questions about Columvi in Pakistan

Is Columvi a CAR-T alternative? Yes for many patients. Where CAR-T is not operationally accessible due to cost, travel, or eligibility, the bispecific antibody class (Columvi, Epcinly, mosunetuzumab) offers a structurally simpler option with comparable response rates in the post-CAR-T setting.

How is CRS managed? The step-up dosing schedule (2.5 mg on cycle 1 day 8, 10 mg on cycle 1 day 15, 30 mg on cycle 1 day 22 and beyond) and obinutuzumab pretreatment 7 days before cycle 1 day 1 are designed to mitigate CRS risk. Most CRS events are Grade 1-2 and managed with supportive care; tocilizumab is available for higher-grade events.

Can my Shaukat Khanum or AKUH oncologist sign off? Yes. Hematology-oncology consultants at the major Pakistani tertiary centers have PMDC registration and signing authority for DRAP applications.

What is the alternative if Columvi is not feasible? Alternatives include Epkinly (epcoritamab), polatuzumab vedotin combinations, tafasitamab plus lenalidomide, loncastuximab tesirine, and clinical trial enrollment. Where CAR-T is operationally accessible, Yescarta, Kymriah, or Breyanzi are alternatives.

What about insurance coverage? Pakistani private insurance does not routinely reimburse bispecific antibody therapy. Cash-pay is the operating assumption.

What about supply continuity? The fixed 12-cycle regimen means the full supply chain is predictable from cycle 1, which is operationally easier than indefinite biologic supply.

Where Reserve Meds fits in Columvi cases

Reserve Meds is a US-based concierge coordinator. For Columvi cases originating in Pakistan, our role spans US-side sourcing through DSCSA-compliant specialty channels, DRAP documentation packet for your physician, validated cold-chain logistics into the dispensing facility cycle by cycle, and a single named coordinator who carries the case across the 12-cycle treatment course. No prior Reserve Meds Columvi case experience is logged yet at the Pakistan-origin profile.

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.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

reservemeds.com · hello@reservemeds.com