Bizengri

India · access guide

Bizengri access in India: the CDSCO named-patient pathway

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

Quick orientation

Bizengri (zenocutuzumab-zbco) is HER2 x HER3 bispecific antibody approved by the US FDA in December 2024 (accelerated approval) for advanced unresectable or metastatic non-small cell lung cancer (NSCLC) and pancreatic adenocarcinoma harbouring a neuregulin 1 (NRG1) gene fusion, with disease progression on or after prior systemic therapy. The drug is manufactured by Merus. India patients use the Central Drugs Standard Control Organization named-patient pathway when the locally registered indication, the stocked presentation, or the available payer coverage does not match what the prescribing physician has written. Reserve Meds coordinates the US-side sourcing through a DSCSA-compliant specialty channel, builds the documentation packet your physician needs to file, and orchestrates the logistics into India with a single named coordinator carrying the case end-to-end.

Why Indian patients need Bizengri through the named-patient pathway

India operates a developed pharmaceutical regulatory environment, and Bizengri may be on the local register, may be in commercial review, or may be entirely absent depending on the stage of Merus's regional rollout. Several patterns drive cross-border requests. First, indication lag: newer indications, particularly the December 2024 (accelerated approval) FDA approval timeline, often reach local registration 12 to 36 months later. Second, biomarker-defined eligibility: NRG1 gene fusion confirmed by an RNA-based NGS assay (DNA-based panels miss many NRG1 fusions; the FoundationOne CDx and Tempus xR assays are commonly used regional reference options) can be the diagnostic gate, and where the relevant testing infrastructure is still maturing locally, families coordinate the workup before or in parallel with sourcing. Third, payer coverage: Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla, Tata AIG, and Manipal Cigna, alongside Ayushman Bharat for eligible beneficiaries each assess specialty therapies case by case, and step-therapy criteria can fail even where the drug is registered. Fourth, stocking gaps: the local agent may not carry every presentation or dose strength reliably, and named-patient import is the operational mechanism that bridges to the exact label the prescriber has written. In each pattern, the named-patient pathway is the legal mechanism that connects a Indian-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The CDSCO named-patient pathway for Bizengri

India's personal-import pathway sits under Rule 36 of the New Drugs and Clinical Trials Rules 2019 read with the Drugs and Cosmetics Act 1940. The CDSCO accepts applications via the SUGAM portal at cdscoonline.gov.in for a specific patient where the medicine is approved by a recognised reference authority and a locally registered equivalent is unavailable or unsuitable. Form 12A (institutional Compassionate Use) is the parallel route through a tertiary hospital ethics committee. The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and either a clinically equivalent locally registered alternative is not suitable, or the patient's clinical profile does not match the locally approved label.

A complete application for Bizengri typically includes a clinical justification letter from the treating physician documenting the patient's diagnosis (NRG1 gene fusion-positive non-small cell lung cancer and pancreatic adenocarcinoma), severity assessment, prior systemic therapy history, any relevant biomarker results (NRG1 gene fusion confirmed by an RNA-based NGS assay (DNA-based panels miss many NRG1 fusions; the FoundationOne CDx and Tempus xR assays are commonly used regional reference options)), and a clinical rationale for selecting Bizengri over locally available alternatives. The Indian physician's licensure with the Medical Council of India / National Medical Commission and the relevant State Medical Council is verified through the application. The packet also specifies the dispensing facility name and license number, the pharmacy in charge of the facility, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity, intended treatment duration), and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Bizengri specifically, the clinical justification typically frames the case around the RNA-based NGS confirmation is the critical diagnostic gate; many regional centres need to send fixed tumour blocks to a reference lab (Caris, Tempus, Foundation Medicine) for RNA sequencing rather than relying on local DNA panels. Approval timelines are typically 10 to 25 business days for routine Rule 36 cases, with institutional Compassionate Use through the Drugs Controller General of India running on a separate ethics-committee timeline. The CDSCO retains discretion on timing, and we do not promise specific durations.

Where Bizengri gets dispensed in India

A focused group of India institutions handle named-patient specialty-medicine imports as established workflow, with in-house import pharmacy capabilities and physicians experienced with the application set. For Bizengri specifically, the dispensing facility must accommodate the administration profile: tertiary oncology day-care infusion centre; the 4-hour cycle 1 infusion plus 1-hour observation period drives the operational schedule. Tertiary centres that meet this profile include Tata Memorial Centre in Mumbai, Apollo Hospitals (Chennai, Hyderabad, Delhi), Fortis Healthcare network, Max Healthcare network in Delhi NCR, Medanta The Medicity in Gurugram, AIIMS Delhi, CMC Vellore, Kokilaben Dhirubhai Ambani Hospital in Mumbai, Sir Ganga Ram Hospital in Delhi, Manipal Hospitals, and Narayana Health.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment that holds the import licence and files the CDSCO application on the prescribing physician's behalf. The medicine then moves under chain-of-custody documentation into the prescribing hospital's outpatient pharmacy for administration.

Real cost picture for Bizengri in India

US WAC for Bizengri is approximately USD 22,000 per 750 mg vial, which translates to an annual WAC in the range of USD 180,000 to USD 200,000 per year for the standard regimen at the labelled dose. The Indian rupee floats; 1 USD is approximately 83 INR as of May 2026. On that basis, the drug cost alone is materially significant before logistics, the CDSCO permit fees (which are nominal relative to drug cost), the destination dispensing hospital's administration fees, and Reserve Meds' concierge fee (which is itemised separately on every firm quote).

International cold-chain or ambient logistics into India typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla, Tata AIG, and Manipal Cigna, alongside Ayushman Bharat for eligible beneficiaries each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation with documented step-therapy failure. We do not promise coverage from any payer. US manufacturer patient assistance programmes do not extend internationally; cross-border patients pay cash or rely on local payer coverage where available.

Clinical evidence and where Bizengri sits in the treatment landscape

eNRGy (NCT02912949) phase 2 trial showed an overall response rate of 33 percent in NRG1-positive NSCLC and 40 percent in pancreatic adenocarcinoma, with durable responses in a tumour-agnostic biomarker-selected population. The drug acts as HER2 x HER3 bispecific antibody, and the dosing schedule is 750 mg IV every 2 weeks, with the first infusion delivered over 4 hours and subsequent infusions over 2 hours if no infusion reaction.

Within the treatment landscape, Bizengri sits alongside chemotherapy alone in NRG1-positive disease (the historical SOC before Bizengri), investigational HER3-targeted ADCs (patritumab deruxtecan), and broader tumour-agnostic targeted therapy (larotrectinib for NTRK, selpercatinib for RET). The choice between targeted therapies in this space depends on the patient's full clinical profile, prior therapy exposure, biomarker status, comorbidities, and the prescriber's judgment. Reserve Meds coordinates whichever therapy the physician has selected; we do not steer prescribing.

Safety surveillance for Bizengri centres on infusion-related reactions (most common in cycle 1; premedication with antihistamine, antipyretic, and corticosteroid is recommended for the first 2 infusions), diarrhoea, asthenia, and embryo-fetal toxicity. The dispensing facility and the prescribing physician retain clinical responsibility for monitoring and adverse-event management; Reserve Meds does not provide medical care.

Typical timeline for Bizengri in India

CDSCO routine processing is typically 10 to 25 business days for routine Rule 36 cases, with institutional Compassionate Use through the Drugs Controller General of India running on a separate ethics-committee timeline from a complete filing. End-to-end, most cases complete within 4 to 8 weeks from first complete documentation, with first-of-kind cases and complex biomarker-dependent workups potentially extending further. Where the administration setting is tertiary oncology day-care infusion centre, hospital scheduling and infusion-chair availability are additional sequencing factors that families plan around. We do not promise specific durations; the CDSCO retains discretion on timing, and shipping windows depend on lane and packaging.

What your Indian physician needs to provide

For a Indian-licensed specialist prescribing Bizengri through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (NRG1 gene fusion-positive non-small cell lung cancer and pancreatic adenocarcinoma), the relevant biomarker work (NRG1 gene fusion confirmed by an RNA-based NGS assay (DNA-based panels miss many NRG1 fusions; the FoundationOne CDx and Tempus xR assays are commonly used regional reference options)), prior systemic therapy history, the FDA-approved indication being invoked, and the clinical rationale for Bizengri as the appropriate next step.

The letter also specifies the exact dosing plan per the FDA-approved label: 750 mg IV every 2 weeks, with the first infusion delivered over 4 hours and subsequent infusions over 2 hours if no infusion reaction. The monitoring plan references infusion-related reactions (most common in cycle 1; premedication with antihistamine, antipyretic, and corticosteroid is recommended for the first 2 infusions), diarrhoea, asthenia, and embryo-fetal toxicity. The treating physician's licence number with the Medical Council of India / National Medical Commission and the relevant State Medical Council, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Where biomarker testing requires reference-lab coordination, the physician documents the assay used and the report; Reserve Meds can route this through a US-side reference laboratory where the regional pathway is unavailable.

Common questions about Bizengri in India

Will Star Health or other major Indian insurers cover Bizengri? Each insurer assesses named-patient imports case by case. Some reimburse fully when Bizengri is on their formulary even if not currently stocked; others assess based on step-therapy criteria and biomarker documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you, your physician, or your hospital. We do not promise coverage from any payer.

Is Bizengri registered locally in India? Local registration status changes as Merus pursues regional rollout; even where the drug is registered, the specific indication, presentation, or dosing strength your prescriber has written may not align with what is currently stocked. The CDSCO named-patient pathway exists precisely to bridge these gaps for individually identified patients.

What about competitor therapies? The treatment landscape includes chemotherapy alone in NRG1-positive disease (the historical SOC before Bizengri), investigational HER3-targeted ADCs (patritumab deruxtecan), and broader tumour-agnostic targeted therapy (larotrectinib for NTRK, selpercatinib for RET). The choice depends on the patient's full clinical profile and prescriber judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not steer prescribing decisions and we do not have a financial relationship with any specific manufacturer.

How is the cold chain or storage managed? Bizengri ships in validated thermal packaging with continuous temperature logging through the lane. The cold-chain handoff or temperature-controlled handoff ends at the dispensing pharmacy; home storage instructions, where the patient takes the medicine home for self-administration, are part of the patient onboarding kit.

Do US manufacturer patient assistance programmes (such as Merus co-pay or PAP programmes) extend to India patients? No. US-resident patient assistance programmes are limited to US-resident patients with US prescription coverage by programme design. Cross-border patients pay cash for the drug and the coordination fee, with local payer reimbursement assessed separately.

Can the case be resupplied year over year if the patient responds? Yes. Reserve Meds maintains the case file and re-files CDSCO permits at the relevant intervals (or coordinates with the dispensing hospital's pharmacy if they hold the permit). Patients on long-term therapy typically settle into a quarterly or biannual resupply cadence after the first cycle.

What is the administration setting? Tertiary oncology day-care infusion centre; the 4-hour cycle 1 infusion plus 1-hour observation period drives the operational schedule.

My physician is at a smaller hospital without an internal import pharmacy. Can the case still proceed? Yes. The common pattern is to route through a Dubai, Riyadh, Mumbai, Cairo, Karachi, or other regional licensed pharmaceutical establishment that holds the import licence and files the CDSCO application on the prescribing physician's behalf. The medicine moves into the prescribing hospital's outpatient pharmacy under chain-of-custody documentation.

Where Reserve Meds fits in Bizengri cases

Reserve Meds is a US-based concierge coordinator. We do not replace your Indian specialist, we do not replace the CDSCO, and we do not replace your dispensing pharmacy. For Bizengri specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate logistics into India, and assign a single named coordinator through the case. The pharmacist-of-record review, prescription validation, biomarker confirmation, and physician sign-off are the recurring operational fundamentals for this drug.

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.

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