Camzyos

India · access guide

Camzyos access in India: the CDSCO Rule 36 pathway

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

Quick orientation

Camzyos (mavacamten) is the first-in-class oral selective allosteric cardiac myosin inhibitor approved by the US Food and Drug Administration in April 2022 for adults with symptomatic New York Heart Association (NYHA) class II to III obstructive hypertrophic cardiomyopathy. Manufactured by Bristol-Myers Squibb, the medicine works by reducing actin-myosin cross-bridge formation, lowering excessive cardiac contractility, reducing left ventricular outflow tract obstruction, and improving exercise capacity and symptoms. The EXPLORER-HCM and VALOR-HCM pivotal trials demonstrated significant improvements in peak VO2, NYHA class, and a substantial reduction in the proportion of patients meeting criteria for invasive septal reduction therapy (surgical myectomy or alcohol septal ablation). The medicine is dispensed only through the Camzyos REMS program in the US due to the risk of heart failure from systolic dysfunction. Camzyos is not registered with India's CDSCO, and access for Indian patients runs through Rule 36 personal-import combined with rigorous local cardiology follow-up.

Why Indian patients ask about Camzyos

India has a substantial obstructive HCM patient population given the country's overall scale. Tertiary cardiology programs at AIIMS Delhi, AIIMS Rishikesh, Sree Chitra Tirunal Institute Trivandrum, PGIMER Chandigarh, Madras Medical Mission Chennai, Narayana Health Bangalore, Asian Heart Institute Mumbai, Fortis Escorts Heart Institute Delhi, Medanta Heart Institute Gurgaon, Apollo Hospitals, Kokilaben, and other major private cardiac centers actively manage these patients. The conventional Indian pathway for symptomatic oHCM is beta-blocker monotherapy, escalation to combined beta-blocker plus disopyramide, calcium channel blocker substitution in beta-blocker intolerance, and septal reduction therapy (surgical myectomy at high-volume centers like AIIMS, SCTIMST, or Asian Heart Institute, or alcohol septal ablation) for refractory cases. Camzyos offers a pharmacologic alternative to septal reduction therapy for many patients, with the pivotal trials showing that approximately 75 percent of patients who would otherwise have been candidates for invasive intervention no longer met procedural criteria after 16 weeks of mavacamten.

The CDSCO Rule 36 pathway for Camzyos

The legal foundation for import is Rule 36 of the Drugs and Cosmetics Rules 1945, which permits import of a small quantity of a drug whose import would otherwise be prohibited, for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit issued by the Drugs Controller General of India. The application requires a prescription from a Registered Medical Practitioner with NMC registration. For Camzyos, the Form 12A justification rests on the FDA approval, the documented failure or intolerance of conventional therapy, and the documented LVOT gradient with symptomatic oHCM.

A complete application includes the clinical justification letter from the treating cardiologist documenting the oHCM diagnosis with echocardiographic LVOT gradient measurement, NYHA class, prior therapy course, and the planned REMS-equivalent monitoring schedule (baseline and serial echocardiograms, LVEF tracking, CYP2C19 genotype where available); the physician's NMC registration; the patient identifier; the product details; and the receiving Importer of Record.

Where Camzyos is dispensed in India

Tertiary cardiology centers handling oHCM cases include AIIMS Delhi, SCTIMST Trivandrum, PGIMER Chandigarh, Madras Medical Mission, Narayana Health Bangalore, Asian Heart Institute Mumbai, Fortis Escorts Delhi, Medanta Gurgaon, Apollo Hospitals across major cities, and Kokilaben Mumbai. Camzyos is an oral capsule and does not require cold-chain handling. The dispensing pharmacy is the prescribing hospital's outpatient pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, or Chennai.

Real cost picture for Camzyos in India

US wholesale acquisition cost for Camzyos is approximately USD 89,500 per year. The Indian rupee trades at approximately 83 to 95 INR to 1 USD, so the annual reference range converts to roughly INR 74 lakh to INR 85 lakh at current rates. International logistics for oral medicines runs USD 200 to USD 500 per shipment quarter. CDSCO permit fees are nominal.

Typical timeline for Camzyos in India

End-to-end, most Indian Camzyos cases complete within 2 to 4 weeks from physician decision to dispensed product. Form 12B priority issuance runs 1 to 2 business days. Documentation assembly takes 3 to 5 business days. US-side sourcing and shipment runs 7 to 14 days. Refill cadence aligns to a quarterly reorder rhythm with serial echocardiographic monitoring between refills.

What your physician needs to provide

For an Indian cardiologist prescribing Camzyos, the clinical justification letter documents the oHCM diagnosis with echocardiographic confirmation of LVOT gradient (resting or provocable), NYHA class II to III symptoms, the prior therapy course (beta-blocker, calcium channel blocker, disopyramide), the patient's LVEF baseline (must be 55 percent or greater per FDA label), the planned monitoring schedule (echocardiogram at baseline, 4, 8, 12, then every 12 weeks; LVEF monitoring; CYP2C19 genotyping where available to guide dosing), and the contingency plan for dose adjustment or discontinuation if LVEF drops below 50 percent. The physician's National Medical Commission registration completes the package.

Common questions about Camzyos in India

Will Indian private insurance cover this? Indian private insurers (Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa) do not routinely reimburse Rule 36 personal imports. Some assess case by case where the medicine is on their formulary even if not stocked.

What about CGHS or ESIC? CGHS provides for medicines not in standard formulary case by case through Expert Committee review. Camzyos as a relatively new specialty cardiology medicine would require committee review.

How is the LVEF monitored? Serial echocardiograms at baseline, 4, 8, 12 weeks, and then every 12 weeks. Dose adjustments are based on LVOT gradient and LVEF. Treatment is held if LVEF drops below 50 percent.

What about CYP2C19 genotyping? Mavacamten is metabolised primarily by CYP2C19. Poor metabolisers have higher exposure and lower starting doses are used. CYP2C19 genotype testing is available at several Indian molecular pathology labs.

What if my LVEF drops? The FDA label requires treatment interruption if LVEF drops below 50 percent. After interruption and recovery, treatment can be resumed at a lower dose under close monitoring.

What about alternative therapy? Beta-blockers (metoprolol, propranolol) and disopyramide remain the conventional first- and second-line options. Septal reduction therapy (surgical myectomy at AIIMS, SCTIMST, Asian Heart Institute; alcohol septal ablation at experienced centers) is the invasive alternative for medically refractory cases.

Where Reserve Meds fits in Camzyos cases

Reserve Meds is a US-based concierge coordinator. For Camzyos cases originating in India, we orchestrate US-side sourcing through DSCSA-compliant channels, build the Form 12A documentation packet your cardiologist submits, coordinate shipment to the receiving Indian importer, and assign a single named coordinator. We work with your local cardiology team to ensure the REMS-equivalent monitoring schedule is maintained. No prior Reserve Meds Camzyos case experience is logged yet at the India-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.

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