Luxturna

India · access guide

Luxturna access in India: the CDSCO named-patient pathway

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

Quick orientation

Luxturna (voretigene neparvovec) is a AAV2-based gene therapy developed by Spark Therapeutics (Roche). It is approved by the US FDA for confirmed biallelic RPE65 mutation-associated inherited retinal dystrophy (Leber congenital amaurosis type 2 and related dystrophies). The standard regimen is single subretinal injection per eye, administered approximately 6 days apart between eyes. Luxturna is available in the global pharmaceutical supply chain in subretinal injection, 1.5 x 10^11 vector genomes per eye. The drug may or may not be locally registered in India, and even when registered, a India family asking for Luxturna is often asking for a precise version of it (specific indication, specific presentation, specific schedule) that the local market has not caught up to. Reserve Meds coordinates the US-side sourcing, the validated cold-chain logistics, and the documentation packet your physician needs.

Why India patients need Luxturna through the named-patient pathway

The Central Drugs Standard Control Organisation (CDSCO) administers personal-import permissions under Rule 36 of the New Drugs and Clinical Trials Rules, 2019, which carve out an avenue for an Indian patient with a treating physician's prescription to import a small quantity of an unregistered medicine for personal use. Applications are filed through the SUGAM portal at cdscoonline.gov.in. The pathway applies when the medicine is approved by a recognised regulator and a clinically suitable Indian-registered alternative is not available.

Several patterns drive these cases: indication lag against the FDA label, particularly for newer biomarker-defined regimens; CDSCO-registered local generics or biosimilars for older molecules but unregistered status for newer originator brands; payer denials by private insurers on specialty indications; and patient preference for the FDA-labeled originator product where biosimilar substitution does not match the prescribing physician's view. For Luxturna specifically, the named-patient pathway exists to handle exactly the situations the local registered route cannot: a newer FDA indication that has not yet propagated to India labeling, a presentation or strength the local agent does not reliably carry, a payer denial that is uneconomic to appeal, or a biomarker-defined regimen where the prescriber's clinical judgement runs ahead of the local label's molecular language. In each pattern, the named-patient pathway is the mechanism that connects a India-licensed physician's clinical decision with US-sourced, FDA-labeled Luxturna for a specific patient.

Luxturna was the first FDA-approved directly administered gene therapy (December 2017) and remains the only gene therapy for inherited retinal dystrophy. The local register status and the genetic diagnostic infrastructure for biallelic RPE65 mutation testing vary by country, and many families pursue cross-border supply with retinal-surgery coordination at a qualified centre.

The CDSCO named-patient pathway for Luxturna

A complete application typically includes a clinical justification letter from the treating physician (diagnosis, severity or stage, prior therapies, biomarker results where relevant, why Luxturna is appropriate, why the locally available alternative is not suitable for this case); the treating physician's India license verification (issued by Medical Council of India / National Medical Commission, with state council registration); an anonymised patient identifier where the regulator submission allows; full product details (brand name Luxturna, generic voretigene neparvovec, manufacturer Spark Therapeutics (Roche), strength subretinal injection, 1.5 x 10^11 vector genomes per eye, quantity requested calibrated to the planned cycles or treatment duration); the destination dispensing facility name, license number, and pharmacy in charge; and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy, including cold-chain handling at 2 to 8 degrees Celsius from the US manufacturer through to the dispensing pharmacy.

For Luxturna, the clinical justification typically rests on documentation of biallelic RPE65 mutation confirmed by genetic testing; viable retinal cells confirmed on OCT where applicable, line of therapy and prior treatments, and a clear statement of why this medicine is the appropriate next step in this patient's care.

Approval timelines for routine cases are typically 10 to 25 business days from a complete filing. Complex cases (rare indication, paediatric application, larger multi-cycle quantities, gene therapy or cell therapy logistics, first-import scrutiny on a presentation new to the local route) can extend to 4 to 8 weeks. The CDSCO retains discretion on timing, and we do not promise specific durations.

Where Luxturna gets dispensed in India

A small group of India institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. For autologous cell therapy and gene therapy, the dispensing centre must hold the manufacturer's qualified-treatment-centre certification and operate the full apheresis, lymphodepletion, infusion, and post-infusion monitoring infrastructure. Tertiary and major private hospitals that fit this profile include Tata Memorial Centre in Mumbai (national cancer referral), Apollo Hospitals network (Chennai, Bengaluru, Hyderabad, Delhi, Kolkata), Fortis Healthcare (Gurugram, Noida, Bengaluru, Mumbai), Max Healthcare in Delhi NCR, Medanta-The Medicity in Gurugram, AIIMS Delhi, Christian Medical College Vellore, Kokilaben Dhirubhai Ambani Hospital in Mumbai, Sir Ganga Ram Hospital, Manipal Hospitals (Bengaluru), Narayana Health (Bengaluru), and the larger corporate hospitals in Mumbai, Delhi NCR, Bengaluru, Hyderabad, Chennai, and Kolkata.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a Mumbai, Delhi NCR, Bengaluru, Chennai, Hyderabad, and Kolkata-based specialty importer that holds a pharmaceutical establishment license and files the CDSCO application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's pharmacy under chain-of-custody documentation, where the patient receives the infusion under specialised oncology nursing supervision with full CRS and ICANS monitoring readiness.

Real cost picture for Luxturna in India

US WAC for Luxturna is approximately USD 425,000 per eye, which translates to USD 850,000 single-course (both eyes); total cost of care USD 1.0M-1.5M. The Indian rupee floats; a working reference rate of approximately 83 INR to 1 USD applies for illustrative conversion, so the annual reference range converts accordingly when expressed in INR at US WAC equivalents.

International validated cold-chain logistics typically run USD 350 to USD 1,400 (approximately INR 29,000 to INR 116,000) per shipment depending on destination city, urgency, and pack size. India customs and CDSCO permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each India insurer assesses named-patient imports case by case. Local payer cover is administered through Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla Health, Tata AIG, Manipal Cigna, and the public Ayushman Bharat / PM-JAY scheme for eligible families; corporate group health is administered through the same private carriers. We do not promise coverage from any insurer. The US manufacturer copay programmes and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage where it applies.

Clinical evidence behind Luxturna

Luxturna's pivotal phase 3 trial demonstrated improvement in functional vision via the multi-luminance mobility test in patients with biallelic RPE65 mutation. Long-term follow-up continues to support durability of treatment effect.

Typical timeline for Luxturna in India

CDSCO routine processing is typically 10 to 25 business days from a complete filing. For Luxturna specifically, cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance scheduled to avoid extreme-heat exposure are non-negotiable. End-to-end, most cases complete within 3 to 6 weeks from first complete documentation to dispensing or first dose. For longer treatment courses, we coordinate cycle-by-cycle or quarterly resupply so the patient never approaches an empty pharmacy shelf.

What your physician needs to provide

For a India-licensed physician prescribing Luxturna through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis with relevant staging or severity language for the indication, the prior therapy history, the rationale for Luxturna as the appropriate next step, and the precise FDA-labeled regimen (dose, route, frequency, expected duration). For Luxturna specifically, the FDA-approved regimen is single subretinal injection per eye, administered approximately 6 days apart between eyes.

For Luxturna, the relevant molecular or laboratory documentation includes biallelic RPE65 mutation confirmed by genetic testing; viable retinal cells confirmed on OCT. The letter references the test results that establish the patient's eligibility for the FDA-labeled indication. The treating physician's India license number, the dispensing facility license number, and the pharmacy in charge complete the package. Monitoring requirements relevant to Luxturna (baseline labs, imaging cadence, adverse-event surveillance) are stated in the letter and operationalised by the prescribing physician's team.

Monitoring for Luxturna: Pre-procedure ophthalmic workup including OCT, electroretinography, dark-adapted full-field stimulus testing, visual field testing, and genetic confirmation of biallelic RPE65 mutation; post-procedure ophthalmic follow-up. **Adverse-event profile:** Conjunctival hyperaemia, cataract, increased intraocular pressure, retinal tear, eye inflammation, eye irritation, and eye pain. Two-stage administration with approximately 6 days between eyes.

Common questions about Luxturna in India

Will my insurer cover this? Each India insurer (Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla Health, Tata AIG, Manipal Cigna, and the public Ayushman Bharat / PM-JAY scheme for eligible families; corporate group health is administered through the same private carriers) assesses named-patient imports case by case. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is Luxturna already locally registered in India? Local registration status can shift over time; Luxturna may already be on the India register for some indications but not others, or the registered presentation may not match what the prescriber needs. The CDSCO pathway exists precisely to bridge these gaps and is the cleanest legal route when the local supply chain does not match the prescription.

What about competitors? Alternatives in the same therapeutic class include no approved alternative gene therapy for RPE65 dystrophy; vitamin A supplementation is supportive only. Choice depends on the patient's full profile, prior therapy, biomarker status, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed.

How does the cold chain work? This medicine requires cold-chain handling at 2 to 8 degrees Celsius from manufacture through to dispensing. Reserve Meds uses validated thermal packaging with continuous temperature logging. Customs clearance is scheduled to avoid prolonged tarmac exposure. The cold chain is broken only at the dispensing pharmacy.

Will my US manufacturer assistance program help? US patient assistance programs (PAP), copay cards, and bridge programs from Merck, Pfizer, AstraZeneca, Lilly, Roche, Genentech, Novartis, AbbVie, Janssen, Gilead, Biogen, BMS, and other manufacturers are generally restricted to US residents with US prescriptions filled at US pharmacies. Cross-border patients pay cash or use local payer cover.

What if treatment is multi-year? For long-running treatment, we coordinate cycle-by-cycle or quarterly resupply through the same CDSCO pathway, with each shipment authorised against the same physician documentation set updated for the current cycle. Patients never need to navigate the supply chain themselves.

Where is the medicine actually administered? Autologous cell therapy and gene therapy infusions are administered at certified qualified treatment centres only. The patient typically commits to a 4-week local stay following infusion for adverse-event monitoring. Home administration is not appropriate for this product.

What if my physician is at a smaller clinic that does not import directly? The standard pattern is to route through a Mumbai, Delhi NCR, Bengaluru, Chennai, Hyderabad, and Kolkata-based specialty importer that holds a pharmaceutical establishment license. The importer files the CDSCO application on behalf of the prescribing physician, takes delivery of the medicine, and transfers it under chain-of-custody to the prescribing facility's pharmacy.

Operational notes for the CDSCO workflow

Operationally, the CDSCO Rule 36 personal-import permission is filed through the SUGAM portal at cdscoonline.gov.in. The applicant is typically the patient or the patient's treating physician with hospital pharmacy support; common patterns include filings under the personal-use category for quantities consistent with the planned treatment duration. Common reasons for delay are missing import quantity justification against the dosing schedule, incomplete documentation of the unmet need versus locally registered alternatives, or chain-of-custody plans for cold-chain product that do not specify continuous temperature logging.

Where Reserve Meds fits in Luxturna cases

Reserve Meds is a US-based concierge coordinator. We do not replace your prescribing physician, we do not replace the CDSCO, and we do not replace your dispensing pharmacy. For Luxturna specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain logistics with appropriate temperature monitoring into India, plan cycle-by-cycle resupply across longer treatment courses, and assign a single named coordinator through the case. Standard NPP coordination under our cell and gene therapy playbook applies.

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