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

How patients in India legally obtain the US-labelled Vraylar (cariprazine) for schizophrenia, bipolar I disorder, or as adjunct therapy in major depressive disorder, when the FDA mood-disorder indications are not available on local cariprazine products.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page describes the personal-import pathway for the US-labelled AbbVie Vraylar in India for adult patients whose treating psychiatrist has selected the brand product, particularly for the bipolar I depression or MDD-adjunct indications that are not part of the EMA Reagila label.

Section 1. Quick orientation

Vraylar is the US brand name for cariprazine, an oral once-daily atypical antipsychotic small molecule that acts as a partial agonist at central dopamine D2 and D3 receptors with preferential D3 affinity and as a partial agonist at serotonin 5-HT1A receptors with antagonism at 5-HT2A. The FDA has approved Vraylar across four adult indications: schizophrenia (initial approval September 2015; pediatric extension to ages 13 and older); acute manic or mixed episodes in bipolar I disorder (approved September 2015; pediatric extension to ages 10 and older); bipolar I depression (approved May 2019); and as adjunctive therapy to antidepressants for major depressive disorder (approved 16 December 2022). Vraylar is marketed by AbbVie following the May 2020 acquisition of Allergan. In India, generic cariprazine is available through Indian manufacturers, and the EMA Reagila brand is approved for schizophrenia only. For adult patients in India whose treating psychiatrist has specifically selected the US-labelled AbbVie Vraylar product, particularly for the bipolar depression or MDD-adjunct indications, the lawful access route is the personal-importation permit under Rule 36 of the Drugs and Cosmetics Rules 1945, applied for on Form 12A and issued on Form 12B by the office of the Drugs Controller General of India. Reserve Meds coordinates the US-side sourcing, documentation kit, and international logistics under a single named coordinator. The clinical decision remains with your physician. **Reserved for you.**

Section 2. Why India patients need US-labelled Vraylar through a named-patient pathway

India's cariprazine landscape is more complex than for most matrix-deepening drugs. Generic cariprazine has launched in India through several Indian manufacturers following CDSCO approval, but the locally registered indications and the brand selection are not equivalent to the US Vraylar label. Three patient patterns drive cross-border demand for the US-labelled AbbVie product. First, patients with bipolar I depression or MDD seeking adjunctive cariprazine where the local registration is limited to schizophrenia and acute mania, leaving the FDA mood-disorder indications without a locally licensed product. Second, patients already responding to Vraylar during travel or US treatment who need continuity of supply on the same brand after returning

home, where the treating psychiatrist has determined that a switch to a different cariprazine product or a different atypical antipsychotic is not clinically acceptable. Third, patients whose prescriber has made an informed brand-specific selection, typically driven by tolerability concerns with the locally available generic or by quality-assurance expectations associated with the originator AbbVie product.

Reserve Meds approaches these cases with the respect they deserve. Psychiatric diagnosis carries social weight in many family contexts, and the patient's autonomy and the prescriber's clinical judgement are the two pillars of every Rule 36 file. The cross-border pathway exists precisely so that an Indian patient with bipolar depression or treatment-resistant MDD whose psychiatrist has chosen cariprazine for the D3-preferring partial agonist mechanism is not foreclosed by registration gaps from the medicine clinically indicated.

Section 3. The CDSCO Rule 36 named-patient pathway for Vraylar

The legal foundation for personal import of an unregistered medicine, or an unregistered brand or unregistered indication of a partially registered medicine, into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities 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 a permit to import a small quantity of a drug for personal use under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (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 registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

CDSCO's published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where documentation is complete. In practice, families and hospitals plan for a two to four week window from physician decision to dispensed medicine. A complete application includes a clinical justification letter, the treating physician's National Medical Commission (NMC) registration number with state council registration where required, a patient identifier and supporting medical records, product details (brand name, generic name, manufacturer, strength, quantity), the dispensing facility's drug licence, and a chain-of-custody plan.

The cell-specific clinical-justification angle for Vraylar is the brand-and-indication rationale. The prescriber's letter should explicitly state the indication being treated (schizophrenia, bipolar I acute mania, bipolar I depression, or MDD adjunct), the FDA-approved label support for that indication, and the reason the US-labelled AbbVie Vraylar product specifically has been selected over the locally available Indian generic cariprazine or, where relevant, the EMA Reagila brand. For mood-disorder cases (bipolar depression, MDD adjunct), the letter should note that the FDA label supports the indication while the EMA Reagila label does not, anchoring the brand selection. Prior antidepressant trials and their outcomes are documented for MDD-adjunct cases. Prior mood stabiliser and atypical antipsychotic trials and their outcomes are documented for bipolar cases. The treating psychiatrist's rationale for cariprazine over aripiprazole, brexpiprazole, lurasidone, quetiapine, or olanzapine/fluoxetine combination is stated. Two FDA boxed warnings are acknowledged in the letter: increased mortality in elderly patients with dementia-related psychosis (a class warning, with Vraylar not approved for this use), and suicidal thoughts and behaviours in pediatric and young adult patients taking antidepressants, applicable to the MDD adjunct indication.

Section 4. Where Vraylar gets dispensed in India

India's tertiary specialty network includes the institutions that handle named-patient imports for psychiatric medicines as established workflow. The room-temperature handling profile of cariprazine means no specialised cold-chain pharmacy infrastructure is required. The National Institute of Mental Health and Neurosciences (NIMHANS) in Bangalore is the apex Indian institution for psychiatric care; NIMHANS clinicians routinely manage complex mood-disorder and schizophrenia spectrum cases and can support Rule 36 filings through institutional pharmacy infrastructure. All India Institute of Medical Sciences (AIIMS), New Delhi has a strong psychiatry department and routinely files compassionate and named-patient imports. Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute (Gurgaon) and Fortis network sites, Medanta - The Medicity (Gurgaon), Kokilaben Dhirubhai Ambani Hospital (Mumbai), Christian Medical College (CMC) Vellore, and Manipal Hospitals (Bangalore) all hold institutional drug licences and have psychiatry consultants able to support a brand-specific import filing.

For patients whose treating psychiatrist practices at a smaller hospital or a clinic without internal import infrastructure, the common pattern is to route through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that files the Rule 36 application on the prescribing physician's behalf. The importer handles customs at the port of entry, takes receipt of the shipment under chain-of-custody documentation, and delivers the medicine to the prescribing hospital's outpatient pharmacy or, where the dispensing clinic holds a drug licence, to the clinic pharmacy. Privacy is treated with care; the patient's anonymised identifier is used on submissions where the CDSCO format allows.

Section 5. Real cost picture for Vraylar 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. Reserve Meds quotes are itemised, not bundled.

- **Drug cost reference.** US wholesale acquisition cost for Vraylar is approximately USD 1,594.82 per 30-day supply at the per-capsule rate of USD 50.63, regardless of strength, as of January 2026 per AbbVie's published WAC. Annualised list price at maintenance dosing is approximately USD 19,000 to 22,000. Reagila list pricing in EU markets is materially lower than US WAC for the schizophrenia indication, often by a factor of 3 to 5, but EU pricing is not directly accessible to Indian patients without local prescriber and pharmacy involvement. The Indian generic cariprazine market prices are substantially lower than US WAC but represent different products. Reserve Meds quotes the US WAC band as the indicative reference for named-patient pricing of the AbbVie Vraylar product and issues a firm quote per case post-documentation.
- **International logistics.** Ambient room-temperature shipping for an oral small molecule, USD 400 to 1,500 (approximately INR 38,000 to 142,000) depending on destination port and urgency window. No cold chain is required for cariprazine.
- **Regulatory and concierge.** CDSCO Form 12B fees and customs handling are nominal relative to drug cost. Standard customs duty and 12 percent GST apply unless the consignment qualifies under a specific exemption confirmed at documentation stage. Reserve Meds' concierge coordination fee is itemised separately on every firm quote.

India's private insurance market is large and segmented. Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle named-patient imports case by case. None reimburses a Rule 36 personal import as a standard line item; given a locally registered generic cariprazine exists for some indications, insurer willingness to consider brand-specific reimbursement is even lower. Cash-pay is the default posture.

Section 6. Typical timeline for Vraylar in India

The room-temperature handling profile keeps Vraylar on the lower-friction side of the Reserve Meds logistics matrix. There is no cold-chain validation window and no temperature-loggers to reconcile at handoff. CDSCO Form 12B issuance for routine cases with complete documentation is typically one to two days per CDSCO published guidance, though brand-specific applications where a locally registered alternative exists can attract more careful review and may extend the regulatory window. The treating psychiatrist's documentation of why the locally available cariprazine product is not clinically acceptable is the variable that drives timeline. US-side procurement through the open AbbVie wholesaler chain (McKesson, Cardinal Health, Cencora) runs in parallel. Once the permit is issued, ambient air freight under standard pharmaceutical-grade packaging clears Indian customs within 3 to 7 business days. A reasonable end-to-end estimate from intake to first dose in hand is 3 to 5 weeks for a first import; refill cycles compress to 2 to 3 weeks. These ranges are typical, not promises.

Section 7. What your physician needs to provide

The clinical justification letter is the cornerstone of the Rule 36 application. For Vraylar, the letter content should include the patient identifier, the psychiatric diagnosis with ICD-10 coding (F20 series for schizophrenia, F31 for bipolar disorder with appropriate subtype coding, F32 or F33 for major depressive disorder), the specific indication being treated, prior trial history of mood stabilisers, atypical antipsychotics, and antidepressants relevant to the current case with outcomes and reasons for discontinuation or augmentation, baseline weight and metabolic parameters (fasting glucose, lipid panel, blood pressure), baseline assessment of extrapyramidal symptoms and akathisia, the rationale for selecting cariprazine over the alternatives, and the brand-specific rationale for AbbVie Vraylar over the locally available Indian generic.

Dosing in the letter aligns with the FDA-approved label. All Vraylar dosing is once-daily oral, with or without food. Schizophrenia and bipolar I acute mania: start 1.5 mg, may increase to 3 mg on Day 2, further increases in 1.5 mg or 3 mg increments at intervals of no less than 14 days, recommended range 1.5 to 6 mg once daily (schizophrenia) or 3 to 6 mg once daily (bipolar mania), maximum 6 mg. Bipolar I depression: start 1.5 mg once daily, increase to 3 mg once daily on Day 15 if needed, maximum 3 mg. MDD adjunct: start 1.5 mg once daily, may increase to 3 mg once daily on Day 15, maximum 3 mg. Dose reduction by half is required for strong CYP3A4 inhibitors. The drug is not recommended with strong CYP3A4 inducers and is not recommended in severe renal or severe hepatic impairment. The monitoring plan covers baseline and periodic weight, fasting glucose, lipids, blood pressure, EPS and akathisia, prolactin if symptoms emerge, signs of tardive dyskinesia, and suicidality screening at every adjustment in the MDD-adjunct indication. The prescribing physician's NMC registration number with state council registration completes the package.

Section 8. Common questions about Vraylar in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each insurer assesses named-patient imports case by case. None reimburses a Rule 36 personal import as a

standard line item. Where a locally registered generic cariprazine exists for the same indication, brand-specific reimbursement is unlikely. We do not promise coverage from any insurer.

Will my CGHS or ESIC entitlement cover this? CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) case-by-case. Brand-specific imports where a locally registered alternative exists face a stricter review. ESIC's formulary is narrower.

Will my NMC-registered psychiatrist's letter be sufficient? Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Psychiatrists at NIMHANS, AIIMS, Apollo, Fortis, Medanta, Kokilaben, CMC Vellore, and Manipal routinely sign these letters as part of established institutional workflow. The brand-specific justification is the load-bearing element where a local generic exists.

What is the safety profile? Vraylar carries two FDA boxed warnings: increased mortality in elderly patients with dementia-related psychosis (a class warning for all atypical antipsychotics, with Vraylar not approved for this use), and suicidal thoughts and behaviours in pediatric and young adult patients taking antidepressants, applicable to the MDD adjunct indication because Vraylar is added to an antidepressant. Common adverse reactions include akathisia, extrapyramidal symptoms, somnolence, nausea, and headache. The metabolic and weight profile is generally more favourable than older atypicals such as olanzapine, though hyperglycemia, dyslipidemia, and weight changes remain monitorable.

How is Vraylar different from aripiprazole or brexpiprazole? Cariprazine's preferential D3 affinity and longer-acting active metabolites (active metabolites with half-lives of up to 1 to 3 weeks) are positioned as differentiators for negative symptoms in schizophrenia and for sustained adjunct effect in MDD. Clinical choice is prescriber-led, not coordinator-led.

Why a US-labelled product rather than the Indian generic? The decision is clinical and stays with the prescriber. Where the prescriber has selected the AbbVie product specifically, the Rule 36 filing carries the prescriber's rationale and the patient's decision.

Section 9. Where Reserve Meds fits in Vraylar cases

Reserve Meds is a US-based concierge coordinator. We do not replace your psychiatrist, do not replace the CDSCO, and do not replace your dispensing pharmacy or licensed importer. For Vraylar specifically, the orchestration we provide is a documentation kit your psychiatrist uses to assemble the Rule 36 application with brand-specific justification, US-side procurement through the open AbbVie wholesaler chain, ambient air-freight logistics under pharmaceutical-grade packaging, customs documentation aligned to the Form 12B permit, and a single named coordinator who stays with your case from intake through delivery. Where a locally registered cariprazine generic exists, the documentation work is heavier than for fully unregistered molecules, and the coordinator's role includes assembling the brand-specific clinical rationale alongside the prescriber. No prior Reserve Meds case experience exists for Vraylar at the date of this page. Standard NPP coordination applies.

Section 10. Next step

If your psychiatrist has selected the US-labelled Vraylar for your care and you are based in India, the next step is the waitlist. We confirm eligibility within 24 to 48 hours and send a documentation kit to your physician. **Reserved for you.**

This guide is informational, not medical or legal advice. The Rule 36 framework requires a Registered Medical Practitioner's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›
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