Vraylar access in Pakistan: the DRAP Special Permission pathway

How adults in Pakistan living with schizophrenia, bipolar I disorder, or major depressive disorder requiring adjunctive therapy access Vraylar, the D3-preferring atypical antipsychotic, when cariprazine is not registered locally under the Vraylar brand.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page describes the DRAP Special Permission Personal Use Import pathway for Vraylar for adults in Pakistan with schizophrenia, bipolar I disorder, or major depressive disorder requiring adjunctive therapy. We use respectful psychiatric vocabulary throughout, in keeping with how families and clinicians actually speak about these conditions.

Section 1. Quick orientation

Vraylar (cariprazine) is an oral once-daily atypical antipsychotic small molecule marketed in the United States by AbbVie Inc. of North Chicago, Illinois. Cariprazine was originally discovered by Gedeon Richter Plc. of Budapest, Hungary and is marketed in the European Union as Reagila. The FDA has approved Vraylar for four indications in adults: schizophrenia (September 2015, with pediatric extension to ages 13 and older); acute manic or mixed episodes associated with bipolar I disorder (September 2015, with pediatric extension to ages 10 and older); depressive episodes associated with bipolar I disorder, also known as bipolar depression (May 2019); and adjunctive therapy to antidepressants for major depressive disorder (MDD) in adults (16 December 2022). Cariprazine is not registered with the Drug Regulatory Authority of Pakistan (DRAP) under the Vraylar brand. For adults in Pakistan whose psychiatrist has identified cariprazine as the appropriate next step, the lawful pathway is the DRAP Special Permission for Personal Use Import (also referred to as the No Objection Certificate for Personal Use Import) filed through the DRAP Online Import and Export System (OIES). Reserve Meds coordinates the US-side AbbVie-channel sourcing, the regulatory documentation, the international logistics, and a single named coordinator who stays with the family throughout the case. **Reserved for you.**

Section 2. Why patients in Pakistan need Vraylar through a named-patient pathway

Pakistan's specialty drug market gap in psychiatry is most pronounced for newer atypical antipsychotics carrying mood-spectrum indications. Cariprazine is not registered locally under the US Vraylar brand. Where cariprazine reaches the Pakistani market at all, it is typically through Indian generic manufacturers under different brand names following generic launches in India, or through limited regional commercial relationships involving Gedeon Richter and Recordati who hold rights in several MENA markets including Turkey, Algeria, and Tunisia. For patients and prescribers seeking the AbbVie-labelled Vraylar product specifically, the named-patient route is the lawful path.

The international cash-pay demand for Vraylar concentrates in three Pakistani patient buckets. The first is adults with bipolar I depression or with MDD requiring adjunctive cariprazine, where the local market has either no cariprazine product at all or where any locally available cariprazine is registered only for schizophrenia. The bipolar-depression and MDD-adjunct indications are the indications the FDA has specifically approved; the EMA Reagila label covers schizophrenia in adults only, which is a material gap for international patients seeking cariprazine for mood-disorder indications. The second is patients already responding to Vraylar during US travel or US treatment who need continuity of supply after returning home, where local substitution to a different atypical antipsychotic is not clinically acceptable to the treating psychiatrist. The third is patients seeking the branded AbbVie product specifically because of tolerability concerns with locally available alternatives or generics, where the prescriber and patient have made an informed choice to pursue brand-specific supply through a regulated import pathway. In all three cases the cash-pay-only, international-patient scope keeps Reserve Meds inside the lawful Personal Use Import pathway and outside any US reimbursement system.

Section 3. The DRAP Special Permission pathway for Vraylar

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES), with patient-level applications submitted by the patient or applicant directly on the portal and institutional applications filed by the hospital pharmacy.

The application package for a Personal Use Import of Vraylar typically includes a clinical justification letter from the treating psychiatrist, the psychiatrist's PMDC license verification (with FCPS Psychiatry or equivalent specialist registration noted), the patient identifier (CNIC for adults), the product details (Vraylar capsules in 0.5 mg, 0.75 mg, 1.5 mg, 3 mg, 4.5 mg, or 6 mg strengths as appropriate for the indication and titration plan, AbbVie NDC, requested pack size), the dispensing facility license, an AbbVie or authorised distributor letter confirming the product is genuine and was sourced through the legitimate US supply chain, and the chain-of-custody plan.

The cell-specific clinical-justification angle for Vraylar is the indication-specific dosing rationale and, where the patient case is in the bipolar I depression, MDD-adjunct, or schizophrenia continuity-of-care space, an explicit statement of why the FDA-labelled indication is the appropriate frame. DRAP reviewers are familiar with atypical antipsychotics; the application is materially strengthened by clarity on the indication (schizophrenia, bipolar I mania, bipolar depression, or MDD adjunct), the prior antipsychotic or antidepressant trials, the planned titration schedule per the FDA label (starting 1.5 mg once daily for schizophrenia, MDD adjunct, and bipolar depression; starting 1.5 mg Day 1 and 3 mg Day 2 for bipolar I mania; with increments at intervals of no less than 14 days), and the boxed-warning acknowledgement. Vraylar carries two FDA boxed warnings that DRAP reviewers expect to see addressed in the application: 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 behaviors in pediatric and young adult patients taking antidepressants, applicable to the MDD adjunctive indication because Vraylar is added on to an antidepressant. The psychiatrist's letter confirms that the patient is not in the contraindicated dementia-psychosis population and that, for MDD-adjunct cases, suicidality screening is built into the monitoring plan. Routine personal-use cases typically clear in four to eight weeks from a complete submission.

Section 4. Where Vraylar gets dispensed in Pakistan

Vraylar is supplied as oral hard-gelatin capsules in 0.5 mg, 0.75 mg, 1.5 mg, 3 mg, 4.5 mg, and 6 mg strengths. It is room-temperature stable; the FDA label specifies storage at 20 to 25 degrees Celsius with permitted excursions to 15 to 30 degrees Celsius. No refrigeration, no freezing, no reconstitution, no diluent. The room-temperature profile makes Vraylar one of the lower-friction international logistics cases in the psychiatry category. The dispensing-facility footprint in Pakistan is therefore broad: any licensed hospital outpatient pharmacy or DRAP-licensed import pharmacy with institutional credentials to receive an unregistered medicine can serve as the dispensing point.

The major tertiary centres with established psychiatric services handle these cases. Aga Khan University Hospital (AKUH) Department of Psychiatry in Karachi, the Institute of Psychiatry at Rawalpindi Medical University, the psychiatry services at Combined Military Hospitals (CMH) Rawalpindi and CMH Lahore, the Punjab Institute of Mental Health in Lahore, the Department of Psychiatry at Liaquat National Hospital in Karachi, the Department of Psychiatry at Shifa International Hospital in Islamabad, and the Department of Psychiatry at Dow University of Health Sciences in Karachi collectively provide the institutional infrastructure for case management. For psychiatrists in private practice or at smaller institutions in Peshawar, Quetta, Multan, Faisalabad, and elsewhere, the typical route is to partner with a DRAP-licensed specialty importer based in Karachi or Lahore who handles the OIES filing, the FBR Customs clearance, and the dispensing handoff at a licensed facility.

Section 5. Real cost picture for Vraylar in Pakistan

Reserve Meds quotes in US dollars and accepts USD wire transfers from any USD-accessible source. The Pakistani Rupee has been volatile across the last several years; as of May 2026 the USD to PKR rate is in the 278 to 280 range. Quoting in USD insulates the patient from intra-case currency drift.

- **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. At a standard once-daily dosing cadence this works out to a list-price annualised figure of approximately USD 19,000 to USD 22,000 per year. At the prevailing PKR rate the monthly WAC reference corresponds to approximately PKR 445,000 before logistics, regulatory documentation, and concierge fees. Reagila list pricing in EU markets is materially lower than US WAC for the schizophrenia indication, often by a factor of three to five, but EU pricing is not directly accessible to non-EU patients without local prescriber and pharmacy involvement and is not part of any Reserve Meds quote. AbbVie's US-only access programmes (Vraylar Savings Card, AbbVie Patient Assistance Foundation) do not extend to international patients.
- **International logistics.** Standard ambient pharmaceutical air freight via DHL Medical Express or FedEx Priority Overnight International with pharma-grade packaging. The typical logistics envelope for a small-molecule consignment to Karachi or Lahore is USD 400 to USD 1,500 depending on pack volume and the carrier route.
- **Regulatory documentation handling.** DRAP OIES filing support, chain-of-custody documentation, FBR Customs coordination, and the dispensing-facility handoff

documentation. Where the family is partnering with a DRAP-licensed importer in Karachi or Lahore, the importer's documentation fee is itemised separately.

- **Reserve Meds concierge fee.** Itemised separately on every firm quote, covering the single named coordinator and the case management through delivery and refill.

Pakistan's private health insurers (State Life, Adamjee, EFU, Jubilee, IGI, Pak-Qatar Family Takaful) typically do not reimburse named-patient imports of unregistered specialty psychiatric drugs as a standard formulary line. The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling does not stretch to cover a sustained Vraylar maintenance regimen at WAC. Cash-pay funded through patient and family resources, often supplemented by overseas remittances from relatives in Saudi Arabia, the UAE, the UK, the US, and Canada, is the practical funding posture for chronic atypical-antipsychotic therapy.

Section 6. Typical timeline for Vraylar in Pakistan

From the point at which Reserve Meds receives a complete documentation package (psychiatrist letter, PMDC verification, patient identifier, dispensing-facility coordination), the DRAP Special Permission for a small-molecule oral product with a clearly framed indication and dosing plan typically clears in four to eight weeks. The supply-side risk is concentrated in the international regulatory layer: countries that have not registered cariprazine require a per-patient import permit, and countries that have registered Reagila or a local brand may restrict NPP imports of the US Vraylar product on the grounds that an in-country option exists. Reserve Meds verifies the registration status per case at the country desk level before quoting. The ambient-shipping profile means logistics adds minimal additional time once the NOC is in hand; standard pharmaceutical air freight to Karachi or Lahore is a 5 to 10 business day window door-to-pharmacy. A realistic end-to-end planning horizon from first contact to in-hand dispensing for a first order is six to twelve weeks. Quarterly refill cycles follow a shorter cadence once the documentation pattern is established. These ranges are typical, not promises.

Section 7. What your physician needs to provide

The treating psychiatrist's clinical justification letter is the cornerstone of the Personal Use Import package. For Vraylar the letter ideally includes the diagnosis (schizophrenia, bipolar I disorder acute mania or mixed episode, bipolar I depression, or MDD requiring adjunctive therapy), the prior pharmacotherapy history (which antipsychotics or antidepressants have been tried, at what doses, with what response or intolerance), the rationale for cariprazine over the next-line alternatives, and the planned titration schedule per the FDA label. For schizophrenia: start 1.5 mg once daily, 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 mg to 6 mg once daily, maximum 6 mg. For bipolar I acute mania or mixed episodes: start 1.5 mg on Day 1, 3 mg on Day 2, adjust in 1.5 mg or 3 mg increments thereafter, recommended range 3 mg to 6 mg once daily, maximum 6 mg. For bipolar I depression: start 1.5 mg once daily, increase to 3 mg once daily on Day 15 if needed, maximum 3 mg. For MDD adjunctive: start 1.5 mg once daily, may increase to 3 mg once daily on Day 15, maximum 3 mg. All dosing is once-daily oral with or without food. Dose adjustment is required for strong CYP3A4 inhibitors (reduce dose by half); Vraylar is not recommended with strong CYP3A4 inducers; the drug is not recommended in severe renal or severe hepatic impairment.

The letter also acknowledges the two FDA boxed warnings: increased mortality in elderly patients with dementia-related psychosis (class warning for atypical antipsychotics, Vraylar not

approved for this use, and the application confirms the patient is not in this contraindicated population) and suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants (applicable to the MDD adjunctive indication, with suicidality screening built into the monitoring plan). Baseline and periodic monitoring of weight, fasting glucose, lipids, blood pressure, extrapyramidal symptoms and akathisia, prolactin if symptoms emerge, and signs of tardive dyskinesia is on the monitoring plan. The psychiatrist's PMDC license number and FCPS Psychiatry or equivalent specialist registration is on every document. The dispensing-facility licence sits alongside the letter in the OIES filing. Post-import pharmacovigilance reporting through the DRAP Pharmacovigilance Centre stays with the treating psychiatrist for any adverse events.

Section 8. Common questions about Vraylar in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover this? Coverage for named-patient imports of unregistered branded specialty psychiatric drugs is uncommon across Pakistani health plans. Some assess case by case. We supply the documentation an insurer needs to assess a claim; the claim is yours or your hospital's to file. The realistic default is cash-pay.

How does Sehat Sahulat interact with named-patient imports? The Rs. 1,000,000 per family per year ceiling is structured around in-network empaneled hospital treatment, not imported drug procurement, and does not cover a sustained Vraylar maintenance regimen at WAC pricing.

Will my PMDC-licensed psychiatrist's letter be sufficient if DRAP queries the case? Yes. PMDC-licensed psychiatrists with FCPS Psychiatry or equivalent specialist registration at the major tertiary centres have signing authority on Personal Use Import applications. DRAP may request additional clarification on the indication, on the boxed-warning acknowledgement, or on the local-availability comparison with cariprazine generics or with Reagila where regionally available; the treating psychiatrist answers those queries directly.

What is the safety profile? Vraylar carries two FDA boxed warnings: increased mortality in elderly patients with dementia-related psychosis (class warning for all atypical antipsychotics, with Vraylar not approved for this use), and suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants, applicable to the MDD adjunctive indication. Common adverse reactions across indications include akathisia, extrapyramidal symptoms, somnolence, nausea, and headache. The metabolic and weight profile is generally more favorable than older atypicals such as olanzapine, though the label still flags hyperglycemia, dyslipidemia, and weight changes as monitorable. Both boxed warnings are flagged in every patient-facing communication and confirmed acknowledged by the treating psychiatrist in the Reserve Meds case file.

What is the monitoring requirement? Baseline and periodic monitoring of weight, fasting glucose, lipids, blood pressure, extrapyramidal symptoms and akathisia, prolactin if symptoms emerge, and signs of tardive dyskinesia. Suicidality screening at every adjustment in the MDD adjunct indication.

Why Vraylar versus aripiprazole or another atypical? Cariprazine's preferential D3 affinity and longer-acting active metabolites are positioned as differentiators for negative symptoms in schizophrenia and for sustained adjunct effect in MDD. Other atypical antipsychotics with mood-spectrum labels include aripiprazole, brexpiprazole, lurasidone, quetiapine, and olanzapine/fluoxetine combination, none of which has the same D3-preferring partial agonist profile. Clinical choice is prescriber-led, not coordinator-led.

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 DRAP, and do not replace your dispensing hospital pharmacy or the in-country importer. For Vraylar specifically, the orchestration we provide is US-side sourcing through AbbVie's open distribution channel via McKesson, Cardinal Health, or AmerisourceBergen (no specialty-pharmacy enrolment is required for cariprazine), the regulatory documentation kit your psychiatrist and the dispensing hospital pharmacy need for the DRAP Personal Use Import filing through OIES, the AbbVie authenticity attestation tying the consignment back to the legitimate US supply chain, the international ambient air-freight logistics, and a single named coordinator who stays with the family across the first order and the monthly or quarterly refill cycles that maintenance therapy generates. Both FDA boxed warnings are flagged in patient-facing materials and confirmed acknowledged by the treating psychiatrist before the case proceeds. Reserve Meds verifies cariprazine registration status per case at the country desk level before quoting, including any regional availability of Reagila or local cariprazine generics that may bear on the documentation framing. No prior Reserve Meds case experience exists for Vraylar at the date of this page; standard NPP coordination applies with the room-temperature handling profile making this one of the lower-complexity drugs in the Reserve Meds matrix to coordinate.

Section 10. Next step

If your psychiatrist has identified Vraylar as the appropriate next step for schizophrenia, bipolar I disorder, or major depressive disorder requiring adjunctive therapy, and you are based in Pakistan, the next step is the waitlist. We confirm eligibility within 24 to 48 hours, route the conversation to a structured documentation work-up, and align with your dispensing hospital pharmacy or the DRAP-licensed importer on the OIES filing. **Reserved for you.**

This guide is informational, not medical or legal advice. The DRAP Personal Use Import framework requires licensed clinical judgment; Reserve Meds is the coordinator, not the prescriber or the dispensing facility.

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 ›
Last medically reviewed: 2026-05-12.