Vraylar access in the UAE: the EDE named-patient pathway

How patients in the United Arab Emirates with schizophrenia, bipolar I disorder, or major depressive disorder requiring adjunctive therapy access Vraylar (cariprazine), the US-labeled atypical antipsychotic with mood-spectrum indications not part of EU or local labels.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page describes the named-patient pathway for adults whose treating psychiatrist has selected cariprazine and for whom the local cariprazine option, where one exists, does not match the prescribed indication.

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 binding affinity for D3, and as a partial agonist at serotonin 5-HT1A receptors with antagonism at 5-HT2A. Cariprazine carries four FDA-approved indications in adults: schizophrenia (September 2015), acute manic or mixed episodes associated with bipolar I disorder (September 2015), depressive episodes associated with bipolar I disorder (May 2019), and adjunctive therapy to antidepressants for major depressive disorder (December 16, 2022). The molecule was originally discovered by Gedeon Richter and is sold in the EU by Recordati under the brand name Reagila, where the local approval covers schizophrenia in adults only. For UAE patients whose treating psychiatrist has selected cariprazine for a mood-disorder indication, the US-labeled Vraylar matches the prescribed use; an EU-labeled or locally registered acute-mania-or-schizophrenia-only product does not. Reserve Meds coordinates US-side sourcing and documentation under the Emirates Drug Establishment named-patient pathway. **Reserved for you.**

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

The UAE operates one of the most developed pharmaceutical regulatory environments in the Gulf Cooperation Council. The Emirates Drug Establishment, which assumed 44 core regulatory services from MOHAP on 29 December 2025 under Federal Decree-Law No. 38 of 2024, maintains the national drug register and the unregistered-medicine personal-use import permit pathway. Three structural access gaps recur. For Vraylar, two patterns drive the typical case: registered for a different indication (where Reagila or another cariprazine brand is locally available for schizophrenia only) and not registered at all (where no local cariprazine product is on the EDE register).

AbbVie's US Vraylar carries four indications across schizophrenia and the bipolar and MDD mood spectrum. The European Commission approved Reagila in July 2017 for schizophrenia in adults only; the bipolar and MDD-adjunct indications added by the FDA in 2019 and 2022 are not part of the EMA label, and they are not part of the Reagila label in MENA markets where Reagila

reaches via Recordati. For a UAE patient whose psychiatrist has prescribed cariprazine 1.5 to 3 mg once daily as adjunctive therapy to an ongoing antidepressant for major depressive disorder, the locally available Reagila label does not cover the prescribed use. A second case profile is the patient already responding to Vraylar after US treatment who needs continuity of supply with the specific AbbVie product. The named-patient pathway is the route where the patient and prescriber elect the US-labeled product because the prescribed indication sits inside the FDA label but outside the locally approved label.

Section 3. The EDE named-patient pathway for Vraylar

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered locally, or that is registered for a different indication, is the unregistered-medicine import permit, administered through the EDE portal at ede.gov.ae from 29 December 2025. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority, in this case the US FDA, and a clinically equivalent locally registered alternative is not suitable. For a Vraylar mood-disorder case, the clinical-justification angle rests on the absence of an EDE-registered cariprazine option carrying the prescribed mood-spectrum indication.

A complete application typically includes a clinical justification letter from the treating psychiatrist documenting the diagnosis (ICD-10 F-series; schizophrenia F20, bipolar I disorder F31, major depressive disorder F32 or F33), prior pharmacotherapy and outcomes, the rationale for cariprazine specifically, and the reason a locally registered alternative is not suitable. The psychiatrist's UAE medical license is verified through the issuing authority (MOHAP, DHA, DOH, or Sharjah Health Authority). The application names the dispensing facility, the pharmacy in charge, the requested pack size (typically a 30-day supply at the prescribed strength), the intended treatment duration, and the chain-of-custody plan from the US wholesaler through the importer to the dispensing pharmacy.

The cell-specific clinical-justification angle for Vraylar is the indication framing. For an MDD-adjunct case, the letter explicitly identifies the December 16, 2022 FDA approval, names the ongoing antidepressant on which cariprazine is being added, and documents prior antidepressant response (partial response, residual symptoms, or treatment-resistant features). For a bipolar I depression case, the letter references the May 2019 FDA approval and documents the bipolar I diagnosis, recent depressive episode, and prior therapies. For a schizophrenia continuity-of-care case, the letter documents the prior US Vraylar regimen and the clinical reason for not substituting to a locally registered alternative. Approval timelines for routine cases are typically 5 to 15 business days; mood-disorder-indication framing may extend review to 3 to 4 weeks at the authority's discretion.

Section 4. Where Vraylar gets dispensed in the UAE

The relevant capability for Vraylar is psychiatry, supported by a hospital outpatient pharmacy able to dispense an oral medicine. The room-temperature handling profile means no specialised cold-chain pharmacy infrastructure is required. Cleveland Clinic Abu Dhabi (M42 group, Al Maryah Island) and Sheikh Khalifa Medical City (SEHA network, Abu Dhabi) carry strong psychiatric service lines and routinely file unregistered-medicine permits. American Hospital Dubai (Mayo Clinic Care Network member), King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City similarly hold pharmaceutical establishment licenses. NMC Healthcare's flagship Dubai and Abu Dhabi sites also handle these cases. Dubai-

based outpatient psychiatry practices that hold institutional admitting privileges can co-manage with a hospital outpatient pharmacy for the dispensing leg.

For patients whose treating psychiatrist practices at a smaller clinic without internal import infrastructure, the common pattern is to route through a Dubai- or Abu Dhabi-based specialty importer that holds a pharmaceutical establishment license and files the EDE application on the prescribing physician's behalf. Patients resident in the Northern Emirates typically route to a Dubai or Abu Dhabi centre where their treating physician holds joint privileges. Continuity of care, single-prescriber follow-up, and stable dispensing-pharmacy relationships are particularly important for chronic psychiatric therapy; Reserve Meds aligns the supply rhythm to the prescriber's follow-up cadence.

Section 5. Real cost picture for Vraylar in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. 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. At once-daily dosing this works out to a list-price annualised figure of approximately USD 19,000 to USD 22,000 per year. Reagila list pricing in EU markets is materially lower than US WAC for the schizophrenia indication, often by a factor of 3-5x, but EU pricing is not directly accessible to non-EU patients without local prescriber and pharmacy involvement. International cash-pay procurement against US WAC is the indicative reference for the named-patient pathway.
- **International logistics.** Ambient room-temperature shipping for an oral capsule, USD 400 to 1,500 (approximately AED 1,500 to 5,500) depending on destination emirate and urgency. No cold chain is required.
- **Regulatory and concierge.** EDE permit fees and customs handling are nominal relative to the drug cost. Reserve Meds' concierge coordination fee is itemised separately on every firm quote.

Daman National Health Insurance (operator of the Thiqa programme for UAE nationals), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance each handle named-patient imports case by case. Coverage of chronic psychiatric therapy varies. Reserve Meds supplies the documentation that allows your insurer to assess; the claim sits with you or your hospital. Cash-pay is the default posture. AbbVie's US-only Vraylar Savings Card and Patient Assistance Foundation do not extend to international patients and Reserve Meds does not represent them as available outside the United States.

Section 6. Typical timeline for Vraylar in the UAE

The room-temperature handling profile keeps logistics straightforward. End-to-end timing is governed by the regulatory layer. EDE permit issuance for a routine schizophrenia case is typically 5 to 15 business days. Mood-disorder-indication framing (bipolar I depression, MDD adjunct), where the locally available cariprazine product is registered for schizophrenia only, can extend review to 3 to 4 weeks at the authority's discretion. US-side procurement runs in parallel through the open AbbVie wholesaler chain (McKesson, Cardinal Health, Cencora). Once the permit is issued, ambient air freight clears UAE customs within 2 to 5 business days. Hospital

pharmacy receipt and release to the treating psychiatrist completes the cycle. A reasonable end-to-end estimate from intake to first dose in hand is 3 to 6 weeks for a first import; established 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 EDE application. For Vraylar, the letter should contain the patient identifier, the psychiatric diagnosis with ICD-10 coding, a documented episode and treatment history, the specific FDA-approved indication being treated (schizophrenia, bipolar I mania or mixed episodes, bipolar I depression, or MDD adjunct), prior therapies and their outcomes (other atypical antipsychotics, mood stabilisers, antidepressants), the reason a locally registered alternative does not match the prescribed indication or is otherwise unsuitable, and the rationale for cariprazine selection (D3-preferring partial agonism, long-acting active metabolites for sustained adjunct effect in MDD, prior US response and continuity of care).

Dosing in the letter aligns with the FDA-approved label. All Vraylar dosing is once-daily oral, with or without food. For schizophrenia in adults and adolescents 13 and older: 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, maximum 6 mg. For bipolar I acute mania or mixed episodes in adults and pediatric patients 10 and older: start 1.5 mg on Day 1, 3 mg on Day 2, recommended range 3 mg to 6 mg, maximum 6 mg. For bipolar I depression and for MDD adjunct in adults: start 1.5 mg once daily, may increase to 3 mg once daily on Day 15, maximum 3 mg. Dose adjustment is required for strong CYP3A4 inhibitors (reduce dose by half); cariprazine is not recommended with strong CYP3A4 inducers and not recommended in severe renal or severe hepatic impairment. The letter references both FDA boxed warnings: increased mortality in elderly patients with dementia-related psychosis (class warning, not approved for this use), and suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants (applicable in the MDD-adjunct setting). Baseline and periodic monitoring of weight, fasting glucose, lipids, blood pressure, EPS and akathisia, prolactin if symptoms emerge, and signs of tardive dyskinesia is documented as the plan. The treating physician's UAE medical license number, issuing authority, and the dispensing facility's pharmaceutical establishment license complete the package.

Section 8. Common questions about Vraylar in the UAE

If Reagila is available locally, why import Vraylar? Reagila in EU and MENA markets is registered for schizophrenia in adults only. The bipolar I mania, bipolar I depression, and MDD-adjunct indications that the US Vraylar carries are not part of the Reagila label. For a patient whose psychiatrist has prescribed cariprazine for a mood-disorder indication, the US product matches the prescribed indication; the local Reagila label does not.

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this? Each insurer assesses named-patient imports case by case. We do not promise coverage. Coverage for chronic psychiatric therapy varies. Reserve Meds supplies the documentation that allows your insurer to assess; the claim sits with you or your hospital.

Will my DHA-licensed or DOH-licensed psychiatrist's letter be sufficient? Yes. Any UAE-licensed psychiatrist practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. Continuity with a single prescriber is encouraged for chronic psychiatric therapy.

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; Vraylar is not approved for this use) and suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants (applicable to the MDD-adjunct indication because Vraylar is added on to an antidepressant). Common adverse reactions 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.

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

How is Vraylar different from aripiprazole? Both are partial agonists at dopamine receptors. 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. The 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 physician, do not replace the Emirates Drug Establishment, and do not replace your dispensing pharmacy. For Vraylar specifically, the orchestration we provide is a documentation kit your treating psychiatrist uses to assemble the EDE application with indication-appropriate framing (schizophrenia, bipolar I mania, bipolar I depression, or MDD adjunct), US-side procurement through the open AbbVie wholesaler chain, ambient air-freight logistics under pharmaceutical-grade packaging, customs documentation aligned to the permit, and a single named coordinator who stays with your case from intake through delivery. For chronic psychiatric therapy, supply continuity matters as much as the first import; refill cadence is aligned to the prescriber's follow-up cycle. 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 treating psychiatrist has selected Vraylar and you are based in the UAE, 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 named-patient framework requires a licensed UAE physician'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 ›

Last medically reviewed: 2026-05-12.