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Cobenfy access in UAE: the EDE named-patient pathway

How patients in the United Arab Emirates legally obtain Cobenfy (xanomeline and trospium chloride) for adult schizophrenia, an FDA-approved medicine that is not yet locally registered.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Cobenfy is a fixed-dose oral combination of xanomeline and trospium chloride, approved by the US FDA on 26 September 2024 for the treatment of schizophrenia in adults. It is the first medicine in more than three decades for this condition that does not work by blocking dopamine D2 receptors. As of this review date, Cobenfy is not registered on the United Arab Emirates federal drug register, so a UAE-licensed psychiatrist who wants to prescribe it for a specific adult patient files an unregistered-medicine import permit through the Emirates Drug Establishment (EDE). This page walks the family and the treating physician through what that looks like in practice. Reserved for you.

Why patients in the UAE need Cobenfy via a named-patient pathway

The UAE operates one of the most developed pharmaceutical regulatory environments in the Gulf. Even so, three structural access gaps recur. A medicine may be registered but not stocked at the treating hospital. It may be registered for a different indication. Or, as with Cobenfy, it may not be registered in the UAE at all because the manufacturer has not yet filed a local marketing authorisation. Bristol Myers Squibb, which acquired the developer Karuna Therapeutics in 2024, has announced an intent to launch Cobenfy in the United Kingdom during 2026 through the MHRA International Recognition Procedure, but has not published a UAE submission timeline as of this review date.

The clinical case for Cobenfy is mechanism-driven rather than cost-driven. Every previously approved antipsychotic, first generation or second generation, depends on dopamine D2 receptor antagonism. That class produces a familiar pattern of extrapyramidal symptoms, metabolic syndrome, weight gain, prolactin elevation, and sedation. A meaningful subset of adult patients with schizophrenia have not tolerated D2 blockade, or have not responded across multiple D2-blocking trials. For those patients in the UAE, Cobenfy is not a marginal improvement on an existing class. It is the only available representative of a different class. That is why families and treating psychiatrists in Abu Dhabi, Dubai, and the Northern Emirates have begun asking how to access it.

The EDE named-patient pathway for Cobenfy

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit. The Ministry of Health and Prevention (MOHAP) historically administered this pathway, and from 29 December 2025 the newly established Emirates Drug Establishment took over the 44 core services under Federal Decree-Law No. 38 of 2024, including marketing authorisations, import and export permits, pharmacovigilance oversight, and personal-use import permits. EDE filings flow through the portal at ede.gov.ae. 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 (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable.

For a Cobenfy submission, the clinical justification letter is the heart of the package. Because Cobenfy enters the consideration set when D2 antagonism has not been tolerated or has not produced adequate response, the letter typically documents the prior antipsychotic trials by drug, dose, duration, and reason for discontinuation. The letter then sets out why the muscarinic mechanism (dual M1 and M4 receptor agonism centrally, with peripheral muscarinic blockade by trospium)

is the next clinically appropriate option, and confirms that Cobenfy is FDA-approved for the indication being treated. The treating psychiatrist also documents the planned titration schedule, the monitoring plan for liver enzymes, blood pressure, heart rate, and urinary retention, and the duration over which the request will run.

The rest of the application set is standard for the EDE pathway. The treating physician's UAE medical licence verification is filed (MOHAP for the Northern Emirates, Dubai Health Authority for Dubai, Department of Health Abu Dhabi for Abu Dhabi, Sharjah Health Authority for Sharjah). A patient identifier (anonymised where the EDE submission allows) is included, along with full product details (brand name, generic name, manufacturer Bristol Myers Squibb, strength, capsule pack size, quantity requested, intended treatment duration). The destination dispensing facility name, licence number, and pharmacy in charge are listed, together with a chain-of-custody plan describing how the medicine will move from the US specialty pharmacy channel through the importer to the dispensing pharmacy. Because Cobenfy is a small-molecule oral capsule at room temperature, the chain-of-custody documentation does not need to reference cold-chain validation, which removes one of the most common excursion points.

Approval timelines for routine cases on this pathway are typically 5 to 15 business days. Cobenfy is a first-generation novel-mechanism schizophrenia drug, so it may sit at the more complex end of the routine band on first filing for a given institution. Once a UAE hospital pharmacy or specialty importer has filed and received approval once, repeat filings for the same drug and the same patient run more quickly.

Where Cobenfy gets dispensed in the UAE

Cobenfy is an oral capsule with no infusion, no reconstitution, and no special cold-chain handling. Dispensing therefore does not require a tertiary cancer centre or a cell therapy unit. What it does require is a UAE-licensed dispensing facility with an in-house import pharmacy or a relationship with a specialty importer that holds a pharmaceutical establishment licence. In practice, that includes the established multispecialty centres named in the UAE pathway, such as Cleveland Clinic Abu Dhabi, Sheikh Khalifa Medical City, American Hospital Dubai, King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City, all of which operate behavioural health or psychiatry services and have filed unregistered-medicine permits for specialty drugs in other categories.

Patients under the care of a private psychiatric practice in Dubai or Abu Dhabi typically route the dispensing leg through a Dubai- or Abu Dhabi-based specialty importer. The importer holds the establishment licence, files the EDE permit, performs customs clearance, and delivers the medicine to a partner outpatient pharmacy under chain-of-custody documentation. Patients resident in the Northern Emirates (Ajman, Umm Al Quwain, Ras Al Khaimah, Fujairah) typically route to a Dubai or Abu Dhabi centre where their treating psychiatrist holds privileges or where the case is co-managed with a UAE-licensed specialist.

Real cost picture for Cobenfy in the UAE

Bristol Myers Squibb publishes a US wholesale acquisition cost (WAC) for Cobenfy of approximately USD 1,887 for a 30-day supply, framed as an annual cost of therapy of approximately USD 22,500. BMS has stated publicly that the United Kingdom list price will be set equal to the US WAC at launch in 2026. For named-patient orders to the UAE, the patient-facing cost picture has three layers: the underlying drug acquisition cost from a US specialty pharmacy channel, the international logistics layer, and the regulatory documentation and Reserve Meds coordination layer.

International logistics for an ambient oral capsule typically runs USD 400 to 800 to the UAE depending on the destination emirate and the urgency window. The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD, so a 30-day Cobenfy supply at WAC translates to roughly AED 6,925 for the drug itself, before logistics and coordination. EDE permit fees are nominal relative to the drug cost. UAE customs duties on personal-use pharmaceutical imports are not the dominant line item; the underlying drug acquisition cost is. Reserve Meds quotes the all-in figure as a firm itemised quote after intake documentation is received, not as a published list price, because BMS has not yet published international named-patient pricing distinct from US WAC.

On the insurance side, Daman National Health Insurance (operator of the Thiqa programme for UAE nationals), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance each assess named-patient psychiatric imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage, and many require pre-authorisation. Reserve Meds supplies the documentation set that allows the insurer to assess the case. The claim itself sits with the patient or the hospital. Cash-pay remains the default posture for a first import.

Typical timeline for Cobenfy in the UAE

End-to-end, a first Cobenfy case in the UAE typically completes in three to six weeks. The EDE permit itself runs 5 to 15 business days for routine cases. Reserve Meds confirms eligibility within 24 to 48 hours of intake and aligns US specialty pharmacy sourcing in parallel with the permit application. Because Cobenfy is ambient and oral, the international shipping leg is two to four business days under standard pharmaceutical air freight to Dubai or Abu Dhabi. UAE customs clearance under the import permit typically takes one to three business days. The dispensing pharmacy performs final verification and releases to the treating psychiatrist on receipt. Repeat fills for the same patient under continuation of therapy compress the timeline materially.

What your physician needs to provide

The treating UAE-licensed psychiatrist provides the clinical anchor of the application. The clinical justification letter typically sets out the patient's confirmed diagnosis of schizophrenia, the timeline of the illness, and the prior antipsychotic trials. For each prior agent, the letter records the drug, dose, duration, and the specific reason for discontinuation (intolerable extrapyramidal symptoms, persistent metabolic side effects, prolactin elevation, sedation that interfered with function, inadequate response, or contraindicating comorbidity). The letter then explains why Cobenfy's muscarinic mechanism is the next appropriate step and confirms it is being prescribed for the FDA-approved adult schizophrenia indication.

The dosing plan in the letter follows the FDA label. Days 1 to 2 at 50 mg / 20 mg orally twice daily, days 3 to 7 at 100 mg / 20 mg twice daily, day 8 and onward at 125 mg / 30 mg twice daily based on tolerability and response, with the option to step back to 100 mg / 20 mg if 125 mg / 30 mg is not tolerated. Geriatric patients are capped at 100 mg / 20 mg twice daily. The letter notes that Cobenfy is contraindicated in moderate to severe hepatic impairment, and includes the baseline and follow-up monitoring plan for liver enzymes, blood pressure, heart rate, urinary retention, and symptoms of biliary disease or pancreatitis. Capsules are taken at least one hour before a meal or at least two hours after a meal and are not opened, crushed, or chewed.

The licence verification, the dispensing facility licence, and the chain-of-custody plan complete the package. Reserve Meds supplies the dispensing-facility and chain-of-custody templates so the treating physician's time is preserved for the clinical content.

Common questions about Cobenfy in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Cobenfy? Each insurer assesses named-patient psychiatric imports case by case. Some reimburse in full when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, the government-funded programme for UAE nationals administered by Daman, has the broadest specialty coverage in Abu Dhabi. We do not promise coverage from any insurer.

Will my DHA-licensed or DOH-licensed psychiatrist's letter be sufficient? Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. A DHA-licensed psychiatrist files for a Dubai dispensing facility, a DOH-licensed psychiatrist for an Abu Dhabi facility, a MOHAP-licensed psychiatrist for a Northern Emirates facility, and a Sharjah Health Authority-licensed psychiatrist for Sharjah.

Is Cobenfy a controlled substance? No. Cobenfy is not on the DEA schedule. It is in scope for Reserve Meds named-patient coordination and does not require Federal Narcotics Department coordination on the UAE side.

Can the medicine be delivered to a home address? The dispensing facility must be UAE-licensed. A hospital outpatient pharmacy or specialty import pharmacy dispenses the capsules to the patient or the family on collection. Direct international delivery without a licensed UAE dispensing facility in the chain is not the model.

What is the safety profile we should expect? The most frequent adverse events in the EMERGENT clinical programme were gastrointestinal: nausea, dyspepsia, constipation, vomiting, abdominal pain, diarrhoea, gastroesophageal reflux. Cardiovascular signals included hypertension and tachycardia. Most gastrointestinal events were mild or moderate and generally transient. The drug avoids the extrapyramidal symptoms, tardive dyskinesia, weight gain, and prolactin signals associated with D2-blocking antipsychotics. The treating psychiatrist holds clinical responsibility for monitoring and dose adjustment.

Is there a meaningful alternative at the muscarinic level? No FDA-approved muscarinic-mechanism alternative exists at this time. Other muscarinic-acting compounds are in clinical development. All conventional alternatives in the UAE formulary are D2 antagonists.

Where Reserve Meds fits in Cobenfy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your psychiatrist, we do not replace the Emirates Drug Establishment or your emirate-level licensing authority, and we do not replace your dispensing pharmacy. What we do is orchestrate the US-side specialty pharmacy sourcing, the regulatory documentation kit your physician needs, the international logistics under chain-of-custody, and a single named coordinator through the case. For Cobenfy specifically, this means working within Bristol Myers Squibb's specialty pharmacy channel rather than a generalist wholesaler, since BMS routes US commercial dispensing through a defined network. No prior closed Reserve Meds Cobenfy case exists at this review date. Standard NPP coordination applies, with respectful psychiatric vocabulary and family-facing tone calibrated for a chronic mental health diagnosis.

Next step

If your treating psychiatrist has confirmed Cobenfy as the next clinical step, the waitlist is the first action. Reserve Meds responds within 24 to 48 hours with eligibility confirmation and a documentation kit your physician can use. Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a UAE-licensed psychiatrist's clinical judgment. Reserve Meds is the coordinator, not the prescriber.

Related

- [Cobenfy drug overview](#)
- [Cobenfy in Saudi Arabia](#)
- [United Arab Emirates: the EDE named-patient pathway](#)
- [All access pathways](#)

Sources

- [FDA approval announcement for Cobenfy \(Bristol Myers Squibb, 26 September 2024\)](#)

- Cobenfy US Prescribing Information, packageinserts.bms.com
- Emirates Drug Establishment portal, Issue of Permit to Import Medicines for Personal Use, ede.gov.ae
- MOHAP announcement of service transfer to EDE, effective 29 December 2025
- Al Tamimi and Company, Importation of Unregistered Drugs in the UAE

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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