Cobenfy access in Pakistan

The first new mechanism of action for schizophrenia in more than three decades, reached through the Drug Regulatory Authority of Pakistan Special Permission pathway.

Quick orientation

Cobenfy (xanomeline and trospium chloride) is a fixed-dose oral combination approved by the US FDA on September 26, 2024 for the treatment of schizophrenia in adults. It is the first medicine in a new pharmacologic class for schizophrenia in more than thirty years. Unlike every previously approved antipsychotic, Cobenfy does not block dopamine D2 receptors; its therapeutic effect arises from selective muscarinic receptor activity in the brain. For families in Pakistan whose treating psychiatrist has cycled through multiple D2-antagonist antipsychotics with limited tolerability or inadequate response, Cobenfy offers a clinically distinct alternative that the local market does not yet stock. The lawful route into Pakistan is the Drug Regulatory Authority of Pakistan (DRAP) Special Permission for Personal Use Import (the No Objection Certificate, or NOC), filed through the DRAP Online Import and Export System (OIES). Reserve Meds coordinates the US-side specialty pharmacy sourcing, the regulatory documentation kit your psychiatrist needs, and the international logistics, while clinical decisions remain with your treating physician and your dispensing institution. We treat your family's situation with the discretion the diagnosis deserves. Reserved for you.

Why patients in Pakistan need Cobenfy via the named-patient pathway

Pakistan's specialty drug market has matured around a small number of tertiary private-sector hospitals in Karachi, Lahore, and Islamabad. Even with that maturity, the schizophrenia formulary that a treating psychiatrist actually has on hand is dominated by older and newer dopamine D2 antagonists. A subset of adult patients does not tolerate D2 blockade, often because of extrapyramidal symptoms, metabolic effects, weight gain, sedation, or prolactin elevation; another subset has tried multiple D2 antagonists across years of care and has not achieved adequate response. Until late 2024 there was no FDA-approved alternative with a different primary mechanism. Cobenfy is that alternative.

As of the module date, Cobenfy is not registered with DRAP, and the manufacturer Bristol Myers Squibb has not announced a Pakistan filing timeline. This is the "not registered locally at all" pattern that Pakistan's specialty access gap takes most often: an FDA-approved medicine that the manufacturer has not yet brought to the DRAP register, often because the addressable Pakistani patient population is small relative to the registration and commercial-launch cost. The DRAP Special Permission framework exists precisely for this scenario. The Cobenfy Cares US patient support program and BMS copay programs are US-domestic only and do not extend to international named-patient cases.

The DRAP named-patient pathway for Cobenfy

DRAP, established under the Drug Regulatory Authority of Pakistan Act 2012 and reporting to the Federal Ministry of National Health Services, Regulations and Coordination, regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific named patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed electronically through DRAP's Online Import and Export System (OIES), with patient-level personal-use applications submitted by the patient or applicant directly on the portal and institutional applications filed by the hospital pharmacy.

The application package for a Cobenfy case typically includes the clinical justification letter from the treating psychiatrist on hospital letterhead, the psychiatrist's PMDC licence verification, the patient identifier (CNIC for adult patients, or B-Form for minors although Cobenfy is approved for adults only, or passport for foreign nationals receiving treatment in Pakistan), product details (Cobenfy brand name, xanomeline-trospium INN, manufacturer of record E.R. Squibb & Sons

LLC as the BMS US subsidiary, strength 50 mg / 20 mg or 100 mg / 20 mg or 125 mg / 30 mg, oral capsule dosage form, requested quantity by titration phase), the destination dispensing facility licence, a manufacturer or authorised distributor letter confirming the product is genuine and was sourced through the legitimate US specialty pharmacy channel, and a chain-of-custody plan from the US source through international shipment to the dispensing facility.

The clinical-justification angle specific to Cobenfy is the prior-line documentation. Because Cobenfy is the only FDA-approved schizophrenia medicine that does not depend on dopamine D2 receptor antagonism, the letter typically documents the diagnosis (schizophrenia in an adult), the prior antipsychotics tried with named medicines, the tolerability or response outcomes that led to discontinuation or addition, and the clinical rationale for a muscarinic mechanism. The dosing plan reflects the FDA-approved titration: 50 mg / 20 mg twice daily on Days 1 to 2, 100 mg / 20 mg twice daily on Days 3 to 7, then 125 mg / 30 mg twice daily from Day 8 onward, with the option to step back to 100 mg / 20 mg twice daily for tolerability. Geriatric patients are capped at 100 mg / 20 mg twice daily. Cobenfy is contraindicated in moderate to severe hepatic impairment and is not recommended in mild hepatic impairment.

Routine personal-use cases at DRAP typically clear in four to eight weeks from a complete submission. Complex cases involving novel mechanisms or recently approved drugs can extend to ten to sixteen weeks. Cobenfy sits at the novel-mechanism end of that range. Reserve Meds plans on the longer end and treats any faster turnaround as upside. DRAP reserves discretion at every step and Reserve Meds does not promise DRAP timelines.

Where Cobenfy gets dispensed in Pakistan

Cobenfy is an oral capsule stored at room temperature with no cold-chain requirement, no reconstitution, and no REMS program. The handling profile is the simplest possible for international logistics: ambient-temperature pharmaceutical cargo with standard GDP-compliant 3PL handling. What the dispensing facility actually needs is the institutional licence to receive imported medicines and the psychiatric service capability for ongoing monitoring of liver enzymes, biliary symptoms, urinary retention in male and geriatric patients, and blood pressure or heart rate changes.

The Pakistani institutions that handle DRAP named-patient imports as an established workflow with psychiatric or general medicine service capability include Aga Khan University Hospital in Karachi (the Department of Psychiatry, a 24/7 institutional pharmacy network with extensive specialty stock, and an outpatient psychiatry follow-up service), the Indus Hospital and Health Network with tertiary referral coverage across Karachi, Lahore, and Hyderabad, Liaquat National Hospital in Karachi, the Combined Military Hospitals network with tertiary capacity at CMH Rawalpindi and CMH Lahore for military families and referred civilian patients, and Shifa International Hospital in Islamabad with its established import pharmacy workflow. If the treating psychiatrist is at a smaller institution or in private practice, the practical route is to partner with a Karachi-based or Lahore-based DRAP-licensed specialty importer that handles the OIES filing and FBR Customs clearance, with dispensing through a licensed pharmacy and ongoing psychiatric care continuing with the treating physician.

Real cost picture for Cobenfy in Pakistan

Reserve Meds quotes Pakistani cases in USD and accepts USD wire transfers from any USD-accessible source, which matters because many Pakistani families fund specialty care by pooling resources across overseas relatives in Saudi Arabia, the UAE, the UK, the United States, and Canada. The transparent cost build for a Cobenfy case has three line items.

First, the underlying US drug cost. Cobenfy's US wholesale acquisition cost is approximately USD 1,887 for a 30-day supply, which BMS frames as an annual cost of therapy of approximately USD 22,500. BMS has publicly stated that the UK list price will be set equal to the US WAC at launch in 2026, so the US figure is a fair reference rather than an outlier. Because Cobenfy is dosed continuously rather than for a finite course, the family plans around a monthly cadence and an open-ended duration that the treating psychiatrist judges. Second, international logistics from a US specialty pharmacy to a Karachi, Lahore, or Islamabad dispensing facility, typically USD 200 to USD 400 per shipment for an ambient-temperature oral product (lower than cold-chain biologics). Third, regulatory documentation handling at the Pakistani end and the Reserve Meds concierge fee, itemised on the firm quote rather than bundled.

Currency context. The Pakistani Rupee traded near PKR 278 to 280 per USD in early May 2026, with annual CPI inflation at 10.9 percent in April 2026, well above the State Bank of Pakistan's 5 to 7 percent target. Because PKR has been volatile historically and inflation is again rising, quoting in USD is the family's protection. On the insurer side, Adamjee Insurance, Jubilee General and Jubilee Life, EFU General and EFU Life, State Life Insurance Corporation, IGI, and Pak-Qatar Family Takaful operate in Pakistan, and Sehat Sahulat covers up to Rs. 1,000,000 per family per year for empaneled in-hospital treatment. Most Pakistani health plans do not reimburse imported unregistered specialty drugs as a routine matter; some assess on a case-by-case basis. Reserve Meds supplies the documentation a family or hospital needs to file a claim, but the default operating posture is cash-pay.

Typical timeline for Cobenfy in Pakistan

End to end, a routine Cobenfy case at a tertiary center with established DRAP personal-import workflow typically clears in six to twelve weeks from intake to first dose in the patient's hand. The DRAP review at OIES takes four to eight weeks for routine cases or longer for the novel mechanism, the US specialty pharmacy intake adds five to ten business days, and international air freight plus FBR Customs clearance at Karachi, Lahore, or Islamabad adds three to five days. Because Cobenfy is an ambient-temperature oral product, there is no additional two-to-three-day cold-chain handling penalty. Refill cadence after the first authorised import is faster because the precedent file is established and the patient is on a stable maintenance dose; planning for monthly refills with a buffer is the operational pattern.

What your physician needs to provide

The cornerstone document is the clinical justification letter, original and stamped on hospital letterhead, signed by the treating psychiatrist under their active PMDC licence. For Cobenfy, the letter typically covers the schizophrenia diagnosis in an adult patient, the prior antipsychotics tried with named medicines and the documented tolerability or response outcomes, the clinical rationale for selective muscarinic receptor activity given the patient's specific D2-related limitations, and the dosing plan with the FDA-approved titration (50 mg / 20 mg twice daily Days 1 to 2; 100 mg / 20 mg twice daily Days 3 to 7; 125 mg / 30 mg twice daily from Day 8 onward, with step-back to 100 mg / 20 mg twice daily for tolerability and a 100 mg / 20 mg twice-daily maximum for geriatric patients).

The monitoring plan covers baseline liver function with re-assessment as clinically indicated through treatment and discontinuation criteria per label (jaundice, pruritus, ALT greater than five times the upper limit of normal or five times baseline), surveillance for symptoms of biliary disease or pancreatitis given the labeled risk of bile duct obstruction, gallstones, pancreatitis, and liver enzyme elevation, urinary retention monitoring particularly in male and geriatric patients, and blood pressure and heart rate surveillance given the cardiovascular adverse event profile. Administration counseling notes that capsules are taken at least one hour before a meal or at least two hours after a meal and are not to be opened, crushed, or chewed. Patient-counseling points cover the gastrointestinal adverse events most frequently observed in the EMERGENT program (nausea, dyspepsia, constipation, vomiting, abdominal pain, diarrhea, gastroesophageal reflux), most mild or moderate and generally transient. PMDC-licensed psychiatrists at the major tertiary centers, military medical services, and provincial public-sector institutions all have signing authority on Pakistan Personal Use Import applications.

Common questions about Cobenfy in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Cobenfy?
Coverage of named-patient imports for unregistered specialty psychiatric medicines is uncommon across Pakistani health plans. Jubilee and Adamjee assess on a case-by-case basis. Reserve Meds supplies the documentation a family or hospital needs to file a claim; the realistic default is cash-pay.

How does Sehat Sahulat interact with this?
The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling is generally structured around in-hospital empaneled treatment rather than imported outpatient psychiatric medicines. Families who qualify can use Sehat Sahulat for hospitalisation and procedural care while the named-patient Cobenfy procurement runs on a cash-pay parallel.

Will my PMDC-licensed psychiatrist's letter be sufficient if DRAP queries the case?
Yes. PMDC-licensed psychiatrists at the major tertiary centers and military medical services have signing authority on Personal Use Import applications. DRAP may request additional clarification on dosing rationale, prior antipsychotics, or the patient's clinical course; the treating psychiatrist answers those queries directly.

What is the side effect profile we should know about?
The most frequent adverse events in the EMERGENT clinical program were gastrointestinal: nausea, dyspepsia, constipation, vomiting, abdominal pain, diarrhea, and 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 elevation associated with D2-blocking antipsychotics, which is a meaningful part of why a family may consider this option after multiple unsuccessful trials.

Is Cobenfy a controlled substance?
No. Cobenfy is not on a DEA schedule, and it does not require additional Anti-Narcotics Force coordination at the Pakistan end. It is in scope for Reserve Meds named-patient coordination.

Is there a comparable alternative we should consider first?
At the muscarinic mechanism level there is no FDA-approved alternative. All conventional alternatives are dopamine D2 antagonists. Selection between Cobenfy and an existing D2 antagonist is a treating-psychiatrist decision based on prior tolerability, response, and the patient's clinical context. Reserve Meds does not make that selection.

Where Reserve Meds fits in Cobenfy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating psychiatrist, we do not replace DRAP, we do not replace your dispensing institution or the in-country importer where one is involved. For a Cobenfy case in Pakistan, we orchestrate the US specialty pharmacy procurement through a DSCSA-compliant channel with full chain-of-custody documentation back to E.R. Squibb & Sons LLC, prepare the documentation kit your psychiatrist needs for the DRAP Special Permission filing through the OIES portal, coordinate ambient-temperature international shipping and the FBR Customs interface at Karachi, Lahore, or Islamabad, and stay with the case through monthly refills under a single named coordinator who speaks English and Urdu and can communicate with relatives in the Gulf, the UK, or North America who are pooling funds. No prior Reserve Meds Cobenfy case is on file at this date; standard NPP coordination applies, and the operational profile (small molecule, oral, room temperature, no REMS) is among the simplest in our catalog. Clinical decisions remain with your psychiatrist. Regulatory authority remains DRAP. Dispensing remains with the licensed Pakistani institution.

Next step

If your family is exploring Cobenfy for an adult relative whose psychiatrist has documented a schizophrenia diagnosis and prior trials of D2-antagonist antipsychotics, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating psychiatrist in English with Urdu-language family-facing summaries where requested, and align with your dispensing institution or a Karachi or Lahore-based DRAP-licensed importer on the OIES filing.

Reserved for you.

Related

- Cobenfy drug overview
- Pakistan country guide
- DRAP Personal Use Import pathway
- Cobenfy in Saudi Arabia
- Cobenfy in the UAE
- Cobenfy in India

- Schizophrenia condition page

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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