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Ravicti access in Pakistan

How families in Pakistan access Ravicti (glycerol phenylbutyrate) for chronic management of urea cycle disorders through the DRAP Special Permission Personal Use Import pathway.

1. Quick orientation

Ravicti is an oral liquid prescribed for the chronic, lifelong management of urea cycle disorders (UCDs) in pediatric and adult patients who cannot be managed on protein restriction alone. It is FDA-approved and manufactured by Horizon Therapeutics USA, Inc., now a subsidiary of Amgen. In Pakistan, Ravicti is not registered with the Drug Regulatory Authority of Pakistan (DRAP), and families with a confirmed UCD diagnosis routinely reach for the medicine through the DRAP Special Permission framework, also referred to as the No Objection Certificate for Personal Use Import. Reserve Meds coordinates the United States sourcing, the regulatory documentation kit, and the international logistics into a Karachi, Lahore, or Islamabad dispensing facility, while clinical decisions remain with your treating metabolic geneticist or pediatric specialist. Reserved for you.

2. Why Pakistan families need Ravicti through the named-patient pathway

Urea cycle disorders are ultra-rare, with a combined incidence below one in 35,000 live births. Local commercial registration of UCD therapies is uneconomic in Pakistan's small specialty market, and Ravicti is therefore not on the DRAP register. Sodium phenylbutyrate (Buphenyl), the principal pharmacologic alternative for chronic UCD management, is also rarely held in Pakistani hospital pharmacies. Carglumic acid is indicated for the NAGS-deficiency UCD subtype specifically and is not a general substitute. Pakistan's specialty pharmaceutical market is cash-pay dominant for advanced therapies, and even families with private insurance through Adamjee, Jubilee, EFU, or State Life rarely find named-patient imports covered.

The chronicity of the need is what makes the gap unusually painful for UCD families. A child diagnosed in the neonatal period or early infancy needs Ravicti continuously, year after year, for life. Without a documented import route, families end up making ad hoc decisions every refill cycle. The DRAP Special Permission pathway converts that into a repeatable workflow. Reserve Meds operates inside that workflow as the United States-side sourcing and logistics coordinator while a PMDC-licensed physician at AKUH, Children's Hospital Lahore, Shaukat Khanum, or Indus Hospital holds the clinical relationship.

3. The DRAP Special Permission pathway for Ravicti

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing Division's Import and Export Section, with Drug Registration Board oversight on new product matters. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also called the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES). For Ravicti, the pathway is the Personal Use Import sub-permission for the patient, or the institutional Special Permission for Import of Unregistered Therapeutic Goods where the hospital pharmacy files on the family's behalf.

The application package for a Ravicti case typically includes the treating physician's clinical justification letter setting out the confirmed UCD diagnosis (the specific enzyme defect, such as OTC deficiency, CPS1 deficiency, ASS1, ASL, or NAGS deficiency), the molecular genetic confirmation report, the patient's current weight, the current plasma ammonia and metabolite panel, prior phenylbutyrate experience if any, and the dosing plan against the FDA label. The PMDC license verification of the treating physician is attached. The patient identifier is the B-Form for minors (the typical Ravicti case) or the CNIC for adult UCD patients. Product details include the brand name (Ravicti), the generic name (glycerol phenylbutyrate), the manufacturer (Horizon Therapeutics USA, Inc., subsidiary of Amgen), strength (25 mL multi-dose oral

liquid bottles), and the projected three to six month supply quantity to support refill planning. A manufacturer or authorized distributor letter confirms the product is genuine and sourced through the legitimate United States DSCSA-compliant chain. The dispensing facility's institutional license accompanies the package.

Routine personal-use applications typically clear in four to eight weeks from a complete submission. Complex pediatric cases, particularly neonatal-onset UCD presentations, are usually framed clearly enough by the treating metabolic geneticist that the DRAP review is straightforward. The cell-specific clinical-justification angle for Ravicti is the documented molecular-genetic UCD diagnosis paired with the lifelong-chronicity framing, which positions the case clearly within the Personal Use Import scope rather than a one-off clinical trial supply request.

4. Where Ravicti gets dispensed in Pakistan

Ravicti dispensing in Pakistan concentrates at the tertiary pediatric and metabolic genetics centers with the import pharmacy infrastructure to receive an unregistered oral liquid. Aga Khan University Hospital in Karachi has a pediatric service and a 24/7 pharmacy with temperature-controlled storage and is one of the most comprehensive institutional pharmacies in Pakistan. The Children's Hospital and Institute of Child Health in Lahore is the major pediatric tertiary center for Punjab and handles named-patient imports for children routinely; pediatric oncology, hematology, and rare disease cases run through its workflow. Shaukat Khanum Memorial Cancer Hospital and Research Centre runs the pediatric oncology service in Lahore and has the institutional pharmacy experience with import permissions, though its scope is oncology-led. Indus Hospital and Health Network in Karachi has strong pediatric capability and an established dispensing model. Shifa International Hospital in Islamabad serves the federal capital region. The Combined Military Hospitals network treats military families and civilian referrals through its multi-city tertiary capacity at CMH Rawalpindi and CMH Lahore.

Because Ravicti is room-temperature stable, the dispensing facility does not need refrigerated storage for the product itself, which materially widens the institutional list relative to a cold-chain biologic. The constraint is institutional licensing and the DRAP relationship, not the cold-chain infrastructure.

5. Real cost picture for Ravicti in Pakistan

The United States wholesale acquisition cost for Ravicti is widely reported in the range of USD 65,000 to USD 120,000 per patient per year for typical weight-based doses, and substantially higher at the upper end of the dosing range for older adolescents and adults. Published price observatories have reported annual list prices reaching the USD 664,000 to USD 793,000 range at the highest weight bands, reflecting how strongly the per-patient annual cost scales with body weight and dietary protein intake. The per-bottle list price has been reported at approximately USD 5,200 to USD 5,300 per 25 mL bottle in recent disclosures.

For a Pakistan family, the cost stack is the United States acquisition cost for the projected refill period plus international air freight (typically USD 400 to USD 800 for a room-temperature liquid, lower than the cold-chain band cited at the country level because Ravicti does not require active cooling) plus the Reserve Meds coordination fee. The Pakistani Rupee has been volatile across recent years, trading in the 278 to 280 PKR per USD range in May 2026, with April 2026 CPI inflation at 10.9 percent. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source, which lets families consolidate funds across overseas relatives in Saudi Arabia, the UAE, the United Kingdom, the United States, and Canada before a refill cycle begins. The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling does not stretch to cover a year of Ravicti and is generally structured around in-network empaneled hospital treatment rather than imported drug procurement.

6. Typical timeline for Ravicti in Pakistan

Routine DRAP Personal Use Import applications clear in four to eight weeks from a complete submission. Reserve Meds plans on the longer end of this range and treats faster turnaround as upside. Because Ravicti is room-temperature stable, the physical logistics leg does not extend the timeline the way a cold-chain biologic does; standard insulated packaging without active cooling is sufficient and adds two to four days for international air freight plus Federal Board of Revenue (FBR)

Customs clearance at Karachi seaport or Karachi, Lahore, or Islamabad airports. For a confirmed UCD pediatric case with the molecular-genetic report and PMDC-licensed physician's justification in the package, the realistic end-to-end estimate from intake to dispensing is six to ten weeks for the first cycle, with subsequent refill cycles compressing as the documentation pattern is established. Refill cadence is set per patient based on dispensed pack quantity and projected daily volume; the multi-dose 25 mL glass bottle format produces large pack quantities for adolescent and adult doses, so refill scheduling typically runs every three to four months rather than monthly.

7. What your physician needs to provide

The clinical justification letter, signed by a PMDC-licensed physician, is the cornerstone of the application. For Ravicti, the letter sets out the confirmed UCD diagnosis with the specific enzyme deficiency identified by molecular genetic testing, the failure or inadequacy of dietary protein restriction alone, the patient's current weight (and body surface area where calculated), the current plasma ammonia value with reference range, the plasma glutamine and branched-chain amino acid context, and the dosing plan referenced to the FDA package insert. For phenylbutyrate-naïve patients, the FDA label provides a starting estimate of 4.5 to 11.2 mL per square metre of body surface area per day, divided three times daily with meals or feeds, with a maximum total daily dose of 17.5 mL. An alternative protein-based starting estimate is 0.6 mL per gram of dietary protein per 24 hours. For patients transitioning from sodium phenylbutyrate to Ravicti, the label provides a milligram-to-milligram conversion.

The monitoring plan attached to the application typically describes plasma ammonia targets (in patients aged 6 years and older, the label directs titration to maintain fasting plasma ammonia below half the upper limit of normal; in younger children, the morning ammonia is targeted to below the age-appropriate upper limit), the PAA to PAGN ratio as a decision aid where elevated, and routine liver function tests. Growth velocity, weight, and nutritional adequacy are followed in pediatric patients alongside the metabolic panel. Adverse events, if any, are reported by the treating physician through the DRAP Pharmacovigilance Centre as the post-import obligation.

8. Common questions about Ravicti in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Ravicti? Coverage for named-patient imports of unregistered specialty drugs is uncommon across Pakistani health plans. Jubilee General's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy and radiotherapy in their formularies, but ultra-rare metabolic specialty imports are typically outside formulary. Reserve Meds supplies the documentation an insurer needs to assess the claim, but the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

Does Sehat Sahulat help? The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling typically does not stretch to cover annual Ravicti cost, and the program is structured around in-network empaneled hospital treatment rather than imported drug procurement. Sehat Sahulat can still cover hospitalization, supportive care, and procedures while the Ravicti supply is procured separately on a cash-pay basis.

Can my child receive Ravicti at home rather than at a hospital? The dispensing facility must hold a Pakistani license. For an oral liquid like Ravicti, a hospital outpatient pharmacy or specialized licensed import pharmacy dispenses the product. Once dispensed, administration at home with meals or feeds is the normal pattern, since Ravicti is an outpatient chronic-management medicine.

What is the safety profile? The FDA label lists the most common adverse reactions in adult clinical studies as diarrhoea, flatulence, and headache, and in pediatric patients as upper respiratory tract infection, vomiting, diarrhoea, decreased appetite, fatigue, and rash. Neurotoxicity of phenylacetate is the principal warning, with monitoring for symptoms such as somnolence, confusion, and lethargy when plasma phenylacetic acid (PAA) is elevated.

Why Ravicti rather than sodium phenylbutyrate? The metabolic genetics literature reports better palatability and lower sodium intake with Ravicti, which can be material in young children and in patients with cardiac or fluid considerations. The clinical choice belongs to the treating physician. Reserve Meds does not endorse one product over the other.

How does diaspora-pooled funding work for Ravicti refills? Pakistan's diaspora pattern is well-established, with major remittance corridors from Saudi Arabia, the UAE, the United Kingdom, the United States, and Canada. Many UCD families fund annual Ravicti supply by pooling resources across overseas relatives. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source.

9. Where Reserve Meds fits in Ravicti cases

Reserve Meds is a United States-based concierge coordinator. We do not replace your treating metabolic geneticist, we do not replace DRAP, we do not replace your dispensing hospital pharmacy or the in-country importer. What we do for a Ravicti case is orchestrate the United States-side sourcing from the limited specialty pharmacy network that holds Horizon's Ravicti supply, the regulatory documentation kit for the DRAP Personal Use Import application, the international logistics for room-temperature oral liquid through bonded air freight, the FBR Customs coordination at the port of entry, and a single named coordinator who stays with your family across refill cycles. Because UCD therapy is lifelong, Reserve Meds plans the relationship as a multi-year coordination rather than a one-time procurement.

No prior Reserve Meds closed-case experience for Ravicti at this module date. Standard NPP coordination applies, and operational notes accumulate as cases land.

10. Next step

If your child or family member has a confirmed UCD diagnosis and your treating physician at Aga Khan University Hospital, Children's Hospital Lahore, Indus, Shaukat Khanum, Shifa, or another tertiary center is prescribing Ravicti, the next step is to join the Reserve Meds waitlist. We confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.