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Rezdiffra access in Pakistan

How patients in Pakistan access Rezdiffra (resmetirom) for noncirrhotic MASH with moderate to advanced fibrosis through the DRAP Special Permission Personal Use Import pathway.

1. Quick orientation

Rezdiffra is the first FDA-approved therapy for noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), also referred to as NASH, with moderate to advanced liver fibrosis at stages F2 to F3. It is an oral once-daily small molecule developed by Madrigal Pharmaceuticals, received accelerated FDA approval on 14 March 2024, and is intended for use in combination with diet and exercise. Rezdiffra is not registered with the Drug Regulatory Authority of Pakistan (DRAP), and adult Pakistani patients with FibroScan-confirmed or MRE-confirmed F2 or F3 fibrosis whose hepatologist has identified Rezdiffra as the next step reach for the medicine through the DRAP Special Permission Personal Use Import pathway. Reserve Meds coordinates the United States sourcing, the regulatory documentation kit, and the international logistics into a Pakistani dispensing facility, while clinical decisions remain with your treating hepatologist. Reserved for you.

2. Why Pakistan patients need Rezdiffra through the named-patient pathway

MASH prevalence is rising in Pakistan in parallel with the growth of type 2 diabetes, central obesity, and metabolic syndrome. Hepatology services at the major tertiary centers in Karachi, Lahore, and Islamabad routinely identify patients with FibroScan kilopascal values placing them in the F2 to F3 fibrosis range, and before March 2024 there was no FDA-approved therapy specifically for noncirrhotic MASH. The arrival of the first targeted treatment created a step change in demand, but Pakistan has no DRAP registration for Rezdiffra and no local stocking through hospital pharmacies.

Two patterns of access gap apply in Pakistan. Rezdiffra is not on the DRAP register at all (the structural gap), and even where a hepatologist wants to start treatment, the local distributor network does not carry it. Insurance coverage through Adamjee, Jubilee, EFU, State Life, IGI, or Pak-Qatar Family Takaful is unlikely to apply to a recently approved United States specialty drug without local registration, so the default is cash-pay. The DRAP Special Permission Personal Use Import framework is the documented lawful route, and Reserve Meds operates inside that framework as the United States-side coordinator while a PMDC-licensed hepatologist at AKUH, PKLI Lahore, Shifa International, or Shaukat Khanum holds the clinical relationship.

3. The DRAP Special Permission pathway for Rezdiffra

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 called the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES). For Rezdiffra, the cell-specific clinical-justification angle is the non-invasive testing (NIT) diagnostic gate, since the FDA-approved label does not require liver biopsy and the registrational MAESTRO-NASH trial cohort can be reproduced in Pakistan through FibroScan, magnetic resonance elastography (MRE), or validated blood-based panels.

The application package typically includes the treating hepatologist's clinical justification letter setting out the MASH diagnosis, the NIT result documenting F2 or F3 fibrosis (the FibroScan kilopascal value or the MRE result, combined with a FAST or MAST composite score where used), the liver biochemistry panel including ALT, AST, alkaline phosphatase, and total bilirubin baselines, the patient's body weight (which determines whether the dose is 80 mg or 100 mg once daily), the documented absence of decompensated cirrhosis (Child-Pugh A status), and confirmation that the patient is committed to diet and exercise alongside therapy. The PMDC license verification of the treating physician is attached. The patient identifier is the CNIC. Product details include the brand name (Rezdiffra), the generic name (resmetirom), the manufacturer (Madrigal Pharmaceuticals, Inc.), strengths (60 mg, 80 mg, or 100 mg film-coated tablets in 30-tablet bottles), and the

projected three to six month supply quantity. 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. Because Rezdiffra is a recently approved drug with a novel mechanism (liver-directed THR-beta agonism), DRAP may request clarification on dosing rationale, prior therapy, or the patient's clinical course. The treating hepatologist answers those queries directly. Reserve Meds plans on the longer end of the routine range for first cases and tightens as the documentation pattern is established.

4. Where Rezdiffra gets dispensed in Pakistan

Rezdiffra dispensing in Pakistan concentrates at the tertiary hepatology and gastroenterology services at the major Karachi, Lahore, and Islamabad centers. Pakistan Kidney and Liver Institute (PKLI) in Lahore is a public-sector specialty institute with kidney, liver, and bone marrow transplant programs and the natural hepatology home for Punjab-region MASH cases. Aga Khan University Hospital in Karachi has a tertiary gastroenterology and hepatology service and a 24/7 pharmacy with temperature-controlled storage. Shaukat Khanum Memorial Cancer Hospital and Research Centre operates institutional pharmacy services in Lahore with established import-permission experience. Indus Hospital and Health Network in Karachi has the institutional infrastructure for ongoing specialty dispensing. Shifa International Hospital in Islamabad serves the federal capital region. Liaquat National Hospital in Karachi has a large adult tertiary service. The Combined Military Hospitals network treats military families and civilian referrals at CMH Rawalpindi and CMH Lahore.

Because Rezdiffra is a room-temperature oral tablet with no cold-chain requirement, the dispensing facility constraint is the institutional license and the import-pharmacy workflow rather than refrigerated storage. The monthly 30-tablet bottle format aligns with monitoring visits and supports a quarterly shipment rhythm if the hepatologist confirms supply alignment with lab follow-up cadence.

5. Real cost picture for Rezdiffra in Pakistan

The United States wholesale acquisition cost for Rezdiffra is approximately USD 47,400 per year as published by Madrigal Pharmaceuticals at launch. State price transparency filings in January 2025 reflected a per-bottle WAC of approximately USD 4,115.90 for a 30-tablet bottle, which corresponds to roughly USD 49,000 per year at twelve refills before any discount, rebate, or copay assistance. The same per-bottle price applies to the 80 mg and 100 mg strengths used in adult treatment.

For a Pakistan patient, 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 tablet) plus the Reserve Meds coordination fee. The Pakistani Rupee has been volatile, 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. Sehat Sahulat's Rs. 1,000,000 annual ceiling and in-network empaneled-hospital structure do not typically cover imported MASH therapy.

6. Typical timeline for Rezdiffra 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 for first Rezdiffra cases given the recency of FDA approval and the relatively novel mechanism. Because Rezdiffra is a room-temperature oral tablet with no cold-chain requirement, the physical logistics leg adds two to four days for international air freight plus FBR Customs