Rezdiffra access in India through the CDSCO Rule 36 Form 12A pathway

How Indian patients with noncirrhotic MASH (NASH) and moderate-to-advanced liver fibrosis source Rezdiffra (resmetirom) under the CDSCO Rule 36 framework, with the non-invasive diagnostic documentation Indian hepatologists need to file the Form 12A application.

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Quick orientation

Rezdiffra is the brand name for resmetirom, an oral once-daily, liver-directed thyroid hormone receptor-beta (THR-beta) selective agonist. The US FDA granted accelerated approval on 14 March 2024 for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH, now also referred to as MASH) with moderate to advanced liver fibrosis, stages F2 to F3, in combination with diet and exercise. It is the first FDA-approved therapy for this indication. Rezdiffra is not registered for commercial sale by CDSCO in India as of this page date. Patient-level access flows through Rule 36 of the Drugs and Cosmetics Rules 1945, prescribed by an NMC-registered hepatologist or gastroenterologist and dispensed through a hospital pharmacy or a CDSCO-licensed specialty importer. Reserve Meds coordinates the US-side sourcing and the documentation kit your Indian hepatologist needs to file the Form 12A application. Reserved for you.

Why Indian patients need Rezdiffra through the named-patient pathway

India sits at the centre of the global metabolic-syndrome burden. The combination of high regional prevalence of type 2 diabetes, central obesity, and metabolic syndrome has produced a population of MASH patients large enough that senior hepatologists at AIIMS, CMC Vellore, Apollo, Fortis, and Medanta have flagged the access question since the first quarter following the FDA approval. The structural gap in India fits the third pattern the country module describes: Rezdiffra is FDA-approved (and EU-approved under European Commission conditional marketing authorisation granted 19 August 2025) but Madrigal Pharmaceuticals has not pursued a CDSCO marketing authorisation, and the drug is not on any Indian hospital formulary as of May 2026.

The pre-Rezdiffra treatment gap in India was real. There was no FDA-approved or CDSCO-registered MASH-specific therapy. Hepatologists managed metabolic risk factors, used GLP-1 receptor agonists off-label for comorbid diabetes and obesity, and watched for progression to cirrhosis. The arrival of the first liver-directed disease-modifying agent for noncirrhotic MASH with F2-F3 fibrosis created a step change in demand from regional hepatology referral centres. Rule 36 is the appropriate route: an FDA-approved medicine, no locally registered or stocked alternative for the MASH F2-F3 histologic indication, and a chronic progressive condition where the treating hepatologist documents the specific reason this product is required for the named patient.

The CDSCO Rule 36 personal import pathway for Rezdiffra

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. CDSCO guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete.

For Rezdiffra specifically, the clinical-justification angle that anchors the Form 12A application is the non-invasive testing (NIT) diagnostic gate. The FDA-approved label does not require liver biopsy to start treatment, which broadens the documentation an Indian hepatologist can use to qualify a named patient. The application is strongest when the hepatologist's letter sets out (1) the diagnosis of noncirrhotic MASH with moderate to advanced liver fibrosis stages F2 to F3, (2) the non-invasive testing result that supports the fibrosis stage (transient elastography by FibroScan with the kPa value reported, or magnetic resonance elastography with the kPa value reported, or a validated blood-based panel such as Enhanced Liver Fibrosis (ELF), often combined with FAST or MAST composite scores), (3) baseline liver biochemistry (ALT, AST, alkaline phosphatase, total bilirubin), (4) absence of decompensated cirrhosis (Child-Pugh A; Child-Pugh B or C use is not recommended per the label), (5) body weight to determine the 80 mg or 100 mg once-daily dose, and (6) screening for concomitant statin and CYP2C8-inhibitor medications that may require dose modification.

A complete Form 12A application includes the clinical justification letter from the treating Registered Medical Practitioner, the prescription showing the RMP's NMC registration number and the quantity required for treatment, a patient identifier with supporting medical records and the NIT report, product details (Rezdiffra as resmetirom 80 mg or 100 mg film-coated tablets, manufacturer Madrigal Pharmaceuticals, 30-tablet bottle aligned to a 30-day course, requested quantity not exceeding 100 average doses per application per the second proviso to Rule 36), the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy through the importer to the receiving Indian pharmacy. For institutional Compassionate Use, the parallel route is a Compassionate Use application to the DCGI by a government hospital, an RMP, or the patient.

Where Rezdiffra gets dispensed in India

Rezdiffra is a room-temperature stable oral tablet (storage 20-25 degrees Celsius, with excursions permitted 15-30 degrees Celsius). Cold-chain capability is not required; what matters is hepatology depth, access to NIT (FibroScan or MRE) for diagnosis confirmation, and a hospital pharmacy or CDSCO-licensed importer able to carry the Rule 36 paperwork. The Indian institutions that fit this profile include:

- **All India Institute of Medical Sciences (AIIMS), New Delhi.** Apex hepatology and gastroenterology programme, with FibroScan and MRE capability and established named-patient import workflow.
- **Christian Medical College (CMC), Vellore.** Globally recognised hepatology programme with strong NIT infrastructure.
- **Apollo Hospitals (Chennai, Delhi, Bangalore, Hyderabad, Kolkata).** Large hepatology and liver-transplant centres with dedicated international patient services, JCI and NABH accredited.
- **Fortis Memorial Research Institute, Gurgaon, and Fortis Mulund, Mumbai.** Active hepatology and liver-transplant programmes.
- **Medanta - The Medicity, Gurgaon.** Multi-superspecialty institution with major Institute of Liver Transplantation and Regenerative Medicine.
- **Kokilaben Dhirubhai Ambani Hospital, Mumbai; MGM Healthcare, Chennai; Manipal Hospitals, Bangalore.** Tertiary hepatology programmes with NIT access.

For patients outside the major metros, co-management with a hepatologist at one of the centres above is the practical route, with refills routed through that hospital's import pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore.

Real cost picture for Rezdiffra in India

The US wholesale acquisition cost for Rezdiffra is approximately USD 47,400 per year, with a per-bottle WAC of approximately USD 4,115 to USD 4,200 for a 30-tablet bottle (the same per-bottle figure applies to both the 80 mg and 100 mg strengths), corresponding to approximately USD 49,000 per year at twelve refills before any discount or assistance. With the rupee floating against the dollar in the 94 to 95 INR per USD range in May 2026, a monthly drug cost of

approximately USD 4,115 converts to approximately INR 3.9 lakh per month, or roughly INR 46 lakh per year before logistics and coordination.

International logistics for an ambient-shipped oral tablet typically runs USD 300 to USD 550 per refill (approximately INR 28,000 to INR 52,000). Standard tamper-evident specialty pharmacy packaging is retained through the international leg. GST on most life-saving medicines is 5 percent; the specific HSN code and any Union Budget 2026-27 customs duty exemption status is confirmed at the documentation stage. Rezdiffra Cares (Madrigal's US-only patient support programme, including copay assistance for commercially insured US patients) does not extend to international cases. Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, Apollo Munich, and Care Health handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item, and CGHS or ESIC routes face stricter Expert Committee review for DCGI-unapproved drugs. Cash-pay with optionality to pursue reimbursement after the fact is the default operating posture.

Typical timeline for Rezdiffra in India

Rezdiffra is room-temperature stable, which keeps the modality-adjusted timeline at the simpler end of the country module range. The typical end-to-end timeline for a first Rule 36 import is 2 to 4 weeks: the Form 12B permit is issued on a documented priority basis (often 1 to 2 days at the DCGI office once documentation is complete), 5 to 10 days for US-side procurement through the Madrigal specialty pharmacy network, and 3 to 5 days for ambient air freight and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad. NIT confirmation (FibroScan or MRE result with reported kPa value) sometimes adds upstream time if a baseline study has not already been done. Repeat monthly refill cycles for an established patient typically compress to 2 to 3 weeks because the Form 12A dossier and the procurement path are already in place. A quarterly or semi-annual cadence is feasible once the hepatologist confirms supply alignment with monitoring visits.

What your physician needs to provide

The treating hepatologist's clinical justification letter is the cornerstone of the Form 12A package. For Rezdiffra specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Resmetirom is an oral, liver-directed THR-beta selective agonist that activates THR-beta in hepatocytes to reduce hepatic triglyceride accumulation, hepatocellular injury, and downstream fibrogenesis without meaningful THR-alpha activity. FDA accelerated approval 14 March 2024 for adults with noncirrhotic MASH and moderate to advanced liver fibrosis (F2-F3) in combination with diet and exercise.
- **Diagnostic confirmation.** Non-invasive testing is the gate. FibroScan kPa value (transient elastography), MRE kPa value (magnetic resonance elastography), or a validated blood-based panel such as ELF, often combined with FAST or MAST composite scores. The pivotal MAESTRO-NASH trial enrolled by biopsy, but the FDA label does not require biopsy for diagnosis or treatment initiation.
- **Dosing plan.** Once daily, taken orally with or without food, swallowed whole. Body weight less than 100 kg: 80 mg once daily. Body weight 100 kg or greater: 100 mg once daily. The 60 mg strength supports dose-modification scenarios per the prescribing information.
- **Concomitant medication review.** Statins and CYP2C8 inhibitor co-administration require dose-adjustment review per the label.
- **Exclusion of decompensated cirrhosis.** Use is not recommended in patients with decompensated cirrhosis (Child-Pugh B or C). The clinical letter confirms Child-Pugh A status.
- **Monitoring plan.** Baseline and periodic monitoring of ALT, AST, alkaline phosphatase, and total bilirubin with defined thresholds for dose interruption. Pregnancy is avoided during treatment per the label.

- **Physician registration.** Active NMC registration in hepatology, gastroenterology, or internal medicine, with state-council registration where required.
- **Pharmacovigilance acknowledgement.** The Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission is referenced; adverse event reporting through PvPI stays with the prescribing physician.

Common questions about Rezdiffra in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this?

Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item, and Rezdiffra is not on any Indian formulary as of this page date. We supply the documentation that lets your insurer evaluate; the claim itself is filed by you or your hospital. Cash-pay is the default operating posture.

Does liver biopsy need to be done first?

No. The FDA-approved label does not require liver biopsy for diagnosis or treatment initiation. Diagnosis of MASH with F2 to F3 fibrosis can be supported by non-invasive testing including FibroScan, MRE, or validated blood-based panels such as ELF, often combined with FAST or MAST composite scores. This NIT diagnostic gate is the meaningful practical change versus the biopsy-based enrolment criteria of the MAESTRO-NASH pivotal trial. Your hepatologist documents the NIT result in the Form 12A package.

Are GLP-1 agonists like semaglutide a substitute?

GLP-1 receptor agonists are studied for MASH and are widely used by Indian clinicians for the comorbid metabolic disease (type 2 diabetes, central obesity) that drives MASH. They are not FDA-approved for the MASH histologic indication, and Reserve Meds does not endorse off-label substitution. The choice between adding a MASH-directed agent and managing metabolic risk factors alone is a clinical decision your hepatologist makes.

How long does treatment continue?

Therapy is chronic and ongoing per the FDA label. There is no defined stop date. Continuation is based on the treating hepatologist's longitudinal assessment, including tolerability, monitoring labs, and longitudinal NIT to track fibrosis. Treatment may be paused or discontinued if predefined ALT, AST, or bilirubin thresholds are crossed, or if the patient progresses to decompensated cirrhosis.

What is the safety profile?

The most commonly reported adverse events in the MAESTRO-NASH trial were diarrhoea and nausea, both more frequent on resmetirom than placebo and generally occurring early in therapy. The FDA label includes warnings around drug-induced liver injury, hepatic decompensation in unrecognised cirrhosis, and gallbladder-related adverse reactions. The prescribing hepatologist owns the safety assessment and the periodic-monitoring plan.

Does CGHS or ESIC cover Rezdiffra?

CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under the Special DG (DGHS), case by case. Drugs not approved by the DCGI for use in India (including Rezdiffra as of this page date) face stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement; check eligibility with your CGHS Wellness Centre or ESIC dispensary before assuming coverage.

Where Reserve Meds fits in Rezdiffra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hepatologist, CDSCO, or your dispensing pharmacy. For Rezdiffra specifically, we orchestrate the US-side sourcing through Madrigal's specialty pharmacy network with full DSCSA chain-of-custody documentation, prepare the documentation kit your Indian hepatologist needs to file the Form 12A application (with the NIT diagnostic-gate template, weight-banded dosing reference, and PvPI acknowledgement pre-built for MASH cases), align the ambient air-freight shipment plan with the Indian importer or hospital pharmacy, and assign a single named coordinator who carries the case from first contact through the monthly refill cadence. No prior Reserve Meds closed-case experience for Rezdiffra as of this page date; standard Rule 36 coordination applies. Operational notes will be added as cases land.

Next step

If you have a diagnosis of noncirrhotic MASH with F2 to F3 fibrosis on non-invasive testing and your Indian hepatologist has identified Rezdiffra as the right next step, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

This guide is informational, not medical or legal advice. The CDSCO Rule 36 pathway requires an NMC-registered physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

Review and 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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