Rezdiffra access in UAE through the MOHAP and EDE named-patient pathway

How UAE patients with biopsy-free F2 to F3 MASH fibrosis source Rezdiffra (resmetirom), what the hepatologist's application looks like, and where Reserve Meds fits.

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Quick orientation

Rezdiffra is the brand name for resmetirom, a once-daily oral small-molecule thyroid hormone receptor-beta selective agonist. It received accelerated FDA approval on 14 March 2024 for adults with noncirrhotic nonalcoholic steatohepatitis (NASH, also referred to as MASH) with moderate to advanced liver fibrosis consistent with stages F2 to F3, used together with diet and exercise. It is the first FDA-approved therapy for this indication. There is no UAE marketing authorisation on record as of this page date. UAE hepatologists reach Rezdiffra for their F2 to F3 MASH patients through the unregistered-medicine import permit administered through the Emirates Drug Establishment (EDE) since 29 December 2025, having previously been administered by MOHAP. Reserve Meds coordinates the US-side sourcing and the documentation kit your hepatologist needs. Reserved for you.

Why UAE patients need Rezdiffra through the named-patient pathway

MASH affects an estimated 1.5 to 6.5 percent of adults in the MENA region, driven by high regional prevalence of type 2 diabetes, central obesity, and metabolic syndrome. The

treatment gap before Rezdiffra was real: there was no FDA-approved disease-directed therapy for the F2 to F3 fibrosis population. The launch of Rezdiffra in 2024 created a step change in demand from regional hepatologists, including in the UAE where the metabolic-disease burden is high and tertiary hepatology capacity is concentrated in Abu Dhabi and Dubai.

Of the three UAE structural access gaps described in the country module, the third applies directly here: Rezdiffra is FDA-approved but not on the UAE federal drug register for local commercial sale. EU approval was granted in August 2025 with a country-by-country launch beginning in Germany in Q4 2025, but EU approval does not translate to UAE availability. There is no clinically equivalent locally registered alternative for F2 to F3 MASH; GLP-1 receptor agonists are studied for MASH and may be used for comorbid metabolic disease but are not FDA-approved for the MASH histologic indication. Off-label substitution is not endorsed. The MOHAP and now EDE named-patient pathway is the documented route for UAE F2 to F3 MASH patients whose hepatologist has identified Rezdiffra as the indicated therapy.

The MOHAP and EDE named-patient pathway for Rezdiffra

The federal pathway is the unregistered-medicine import permit, filed through the EDE portal at ede.gov.ae since 29 December 2025. 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 and a clinically equivalent locally registered alternative is not suitable. Rezdiffra clears the reference-authority criterion through both its FDA accelerated approval and its EU conditional marketing authorisation granted by the European Commission on 19 August 2025.

For Rezdiffra specifically, the clinical-justification angle that anchors the application is the non-invasive diagnostic gate. The FDA-approved label does not require liver biopsy for diagnosis or treatment initiation. The hepatologist's letter is strongest when it documents (1) the non-invasive testing result that supports F2 to F3 fibrosis (transient elastography liver stiffness in kPa via FibroScan, magnetic resonance elastography result, or an ELF score, often combined with a FAST or MAST composite), (2) liver biochemistry including ALT, AST, alkaline phosphatase, and total bilirubin at baseline, (3) absence of decompensated cirrhosis on clinical assessment (use in Child-Pugh B or C is not recommended), (4) the dosing plan with weight-banded selection and any CYP2C8 or statin co-administration considerations, and (5) the monitoring plan with the predefined ALT, AST, and bilirubin thresholds for dose interruption.

A complete package typically includes:

- Clinical justification letter from the treating hepatologist with the non-invasive fibrosis testing report attached
- Treating hepatologist's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority)
- Patient identifier (anonymised reference where the EDE submission allows)
- Product details: Rezdiffra film-coated tablets, 60 mg, 80 mg, or 100 mg as indicated; 30-tablet bottle aligned to 30 days at once-daily dosing; manufacturer Madrigal Pharmaceuticals, Inc. (West Conshohocken, Pennsylvania); quantity requested per refill cycle and intended treatment duration
- Destination dispensing facility name, license number, and pharmacy in charge
- Chain-of-custody plan from the US specialty pharmacy through the importer to the UAE dispensing pharmacy

Approval timelines for routine cases are typically 5 to 15 business days. First-import cases for Rezdiffra at a facility that has not previously cleared the molecule can extend toward 4 to 6 weeks. Once the EDE dossier is on file for an established patient, refill permits typically clear at the faster end of the range.

Where Rezdiffra gets dispensed in the UAE

Rezdiffra is a room-temperature oral tablet with no cold-chain requirement and no infusion infrastructure required. The capability that matters for dispensing is a hepatology service that can prescribe, monitor, and titrate, with access to non-invasive fibrosis assessment (FibroScan or MRE) for diagnosis and follow-up. The UAE institutions with hepatology depth and established import pharmacy workflow are:

- **Cleveland Clinic Abu Dhabi** (M42 group, Al Maryah Island). Multispecialty hospital with gastroenterology and hepatology depth and ASHP-accredited pharmacy services.
- **Sheikh Khalifa Medical City (SKMC), Abu Dhabi** (SEHA network, managed by the Cleveland Clinic). 586-bed JCI-accredited acut