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

How UAE families with a genetically confirmed Friedreich's ataxia diagnosis source Skyclarys (omaveloxolone), what the application package looks like, and where Reserve Meds fits.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Skyclarys is the brand name for omaveloxolone, an oral Nrf2 activator approved by the FDA on 28 February 2023 for the treatment of Friedreich's ataxia (FA) in adults and adolescents aged 16 years and older. It is the first and only disease-modifying therapy for Friedreich's ataxia. There is no UAE marketing authorisation on record as of this page date. A UAE family with a genetically confirmed Friedreich's ataxia diagnosis can reach Skyclarys lawfully through the unregistered-medicine import permit, administered by the Emirates Drug Establishment (EDE) since 29 December 2025 and previously by MOHAP. The medicine is dispensed by a UAE-licensed hospital or specialty import pharmacy on the prescription of the treating neurologist. Reserve Meds coordinates the US-side sourcing through the exclusive specialty channel and the documentation kit your neurologist needs. Reserved for you.

Why UAE families need Skyclarys through the named-patient pathway

Friedreich's ataxia is ultra-rare, affecting approximately 1 in 50,000 people. The patient population in the UAE is small enough that local commercial registration is uneconomic, and

Biogen (which acquired Reata Pharmaceuticals in September 2023) has not announced a UAE local-agent registration as of this page date. The disease was untreatable for decades; the arrival of the first disease-modifying therapy created a sharp uptick in family-driven, cross-border demand, including from MENA families with genetically confirmed FA cases.

The structural access gap that applies to Skyclarys in the UAE is the third pattern described in the country module: the drug is not registered in the UAE at all. There is no clinically equivalent locally registered alternative; no other FDA-approved or EMA-approved disease-modifying therapy for FA exists. Supportive care (physical therapy, occupational therapy, cardiology management for FA-associated cardiomyopathy, endocrine management for FA-associated diabetes) remains essential alongside Skyclarys, not as a substitute for it. The MOHAP and now EDE named-patient pathway is the documented route, and the Emirati Genome Programme has surfaced FA cases earlier in some UAE families through targeted variant screening, which lifts demand on the pathway.

The MOHAP and EDE named-patient pathway for Skyclarys

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. Skyclarys clears the reference-authority criterion through its FDA approval, its EMA centralised marketing authorisation granted on 9 February 2024 (held by Biogen Netherlands B.V.), and its MHRA marketing authorisation granted on 23 April 2025.

For Skyclarys specifically, the clinical-justification angle that anchors the application is the genetic confirmation of Friedreich's ataxia. The application is strongest when the treating neurologist's letter sets out (1) documentation of biallelic GAA expansion in the FXN gene, or one GAA expansion plus a pathogenic FXN point mutation, with the reporting genetic laboratory named, (2) clinical features and a baseline neurological assessment (the modified Friedreich Ataxia Rating Scale, or mFARS, is the standard reference scale even if not formally scored at every visit), (3) age of the patient (the FDA-approved indication is 16 years and older), (4) hepatic and cardiac baseline workup including ALT, AST, total bilirubin, BNP, and lipid panel, and (5) the dosing and monitoring plan.

A complete package typically includes:

- Clinical justification letter from the treating neurologist with the genetic confirmation report attached

- Treating neurologist's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority)
- Patient identifier (anonymised reference where the EDE submission allows)
- Product details: Skyclarys 50 mg oral capsules, three capsules per day at the 150 mg labelled dose; manufacturer Biogen (Cambridge, Massachusetts; Biogen Netherlands B.V. as the European authorisation holder); US distribution exclusive to Biologics by McKesson; 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. Because Skyclarys is sourced through Biogen's exclusive specialty channel at Biologics by McKesson rather than open wholesale, the US-side procurement step has its own coordination overhead that is reflected in the overall first-cycle timeline.

Where Skyclarys gets dispensed in the UAE

Skyclarys is a room-temperature oral capsule with no cold-chain requirement and no infusion infrastructure required. The capability that matters for dispensing is a neurology service with experience in inherited and progressive ataxia, plus the cardiology and hepatology support that Friedreich's ataxia patients typically need for FA-associated cardiomyopathy and for the Skyclarys-specific transaminase monitoring. The UAE institutions with this profile and established import pharmacy workflow are:

- **Cleveland Clinic Abu Dhabi** (M42 group, Al Maryah Island). Adult neurology and complex cardiology depth, ASHP-accredited pharmacy services, and established import pharmacy infrastructure.
- **Sheikh Khalifa Medical City (SKMC), Abu Dhabi** (SEHA network, managed by the Cleveland Clinic). 586-bed JCI-accredited acute-care hospital with cardiology, neurology, and pediatric subspecialty services (the FDA approval covers patients aged 16 and older, so adolescent neurology depth matters).
- **American Hospital Dubai** (Mayo Clinic Care Network member). Multispecialty private hospital with neurology and cardiology services.
- **King's College Hospital London Dubai**. UK-affiliated private hospital with strength in neurology.

- **Mediclinic City Hospital, Dubai Healthcare City**. Multispecialty private hospital with neurology services.

For families in the Northern Emirates without a local neurologist experienced in Friedreich's ataxia, the practical pattern is co-management with a UAE-licensed neurologist at one of the Dubai or Abu Dhabi centers, with refills routed through that hospital's import pharmacy or through a specialty importer.

Real cost picture for Skyclarys in the UAE

The US wholesale acquisition cost for Skyclarys was set by Reata at the time of launch at approximately USD 370,000 per year at the labelled 150 mg daily dose. At approximately 1,095 capsules per year (three 50 mg capsules per day for 365 days), the implied per-capsule WAC is approximately USD 338. At the pegged rate of approximately 3.67 AED to 1 USD, the annual WAC translates to approximately AED 1.36M, with the per-capsule equivalent at approximately AED 1,240. The US WAC figure is the list price before payer negotiation; US patients with commercial insurance and Biogen patient support typically pay a nominal copay, but those US patient-support programs do not extend to international patients.

International logistics for a room-temperature oral capsule typically runs USD 400 to USD 800 (approximately AED 1,500 to AED 2,900) per refill, lower than refrigerated biologics. UAE customs and EDE permit fees are nominal relative to the drug cost. The Reserve Meds concierge fee is itemised separately on every firm quote. UAE insurer coverage (Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, Orient) is assessed case by case; we supply the documentation set that allows the insurer to consider the case and the claim is the patient's or the hospital's to file. Annual supply discussions are appropriate from the first case, because the drug is chronic and the family will face recurring procurement decisions.

Typical timeline for Skyclarys in the UAE

Skyclarys is room-temperature stable in oral-capsule format, which removes cold-chain handoffs. The modality-adjusted typical end-to-end timeline for a first import is 4 to 7 weeks: 5 to 15 business days for routine EDE permit review, 7 to 14 days for US-side procurement through the exclusive Biologics by McKesson specialty channel (which adds coordination overhead relative to open distribution), and 3 to 5 days for ambient air freight and UAE customs clearance. Repeat refill cycles for an established patient typically run 2 to 4 weeks because the EDE dossier and the US-side procurement path are already in place. Cardiac and hepatic baseline workup may need to be coordinated locally before shipment; Reserve Meds is not a clinical provider and does not perform this workup.

What your physician needs to provide

The treating neurologist's clinical justification letter is the cornerstone of the EDE package. For Skyclarys specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Omaveloxolone is an Nrf2 activator FDA-approved on 28 February 2023 for Friedreich's ataxia in patients aged 16 years and older. It is the first and only disease-modifying therapy for the condition.
- **Genetic confirmation.** Documented biallelic GAA expansion in the FXN gene, or one GAA expansion plus a pathogenic FXN point mutation, with the reporting genetic laboratory named. Reserve Meds requires this confirmation in the patient record before coordinating supply; clinical suspicion alone is not sufficient.
- **Age and clinical features.** Confirmation that the patient is 16 years or older and a brief neurological assessment summary.
- **Dosing plan.** 150 mg orally once daily as three 50 mg capsules, on an empty stomach at least one hour before or two hours after eating, with no loading dose. The label also provides for sprinkle administration on approximately two tablespoons of applesauce when capsule swallowing is difficult.
- **Hepatic dose-adjustment plan.** Moderate hepatic impairment (Child-Pugh B) is dosed at 100 mg once daily with further reduction to 50 mg if adverse reactions emerge. Severe hepatic impairment (Child-Pugh C) is a contraindication.
- **Monitoring plan.** Baseline ALT, AST, total bilirubin prior to initiation, then monthly for the first three months and periodically thereafter, with treatment discontinuation thresholds at ALT or AST above 5 times the upper limit of normal or above 3 times ULN with evidence of liver dysfunction. Baseline BNP with cardiac evaluation if elevated, baseline and periodic lipid panel, and clinical monitoring for fluid overload and heart failure given underlying FA cardiomyopathy risk.
- **Physician license.** Verification of MOHAP, DHA, DOH, or Sharjah Health Authority licensing in active standing, matching the emirate of the dispensing facility.

Common questions about Skyclarys in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this?

Each insurer assesses named-patient imports case by case. Rare-disease and ultra-rare-disease coverage decisions are case-specific, and Skyclarys is recent enough that few UAE

insurer formularies have formally considered it. We do not promise coverage. We supply the documentation set that lets your insurer assess the case; the claim sits with you or your hospital.

Will my DHA-licensed or DOH-licensed neurologist's letter be sufficient?

Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority. For Friedreich's ataxia the EDE expects a neurologist with experience in inherited or progressive ataxia. The credential is institutional rather than a separate EDE registration.

Is genetic confirmation required?

Yes. Reserve Meds requires documentation of biallelic GAA expansion in the FXN gene, or one GAA expansion plus a pathogenic FXN point mutation, before coordinating supply. Clinical suspicion of Friedreich's ataxia without genetic confirmation is not sufficient. Genetic confirmation documentation arrives in varied formats and foreign-language reports are common; translation can be coordinated as part of intake.

What is the safety profile?

The most common adverse reactions reported in the MOXIe pivotal trial were elevated liver transaminases, headache, nausea, abdominal pain, fatigue, diarrhoea, and musculoskeletal pain. Elevations of ALT or AST above 5 times ULN occurred in 16 percent of treated patients, and elevations above 3 times ULN occurred in 31 percent; these elevations were generally reversible on dose reduction or discontinuation.

Is there a competitor or alternative?

No. There is no other FDA-approved or EMA-approved disease-modifying therapy for Friedreich's ataxia. Supportive care remains essential alongside Skyclarys.

What is the typical course duration?

Treatment is chronic and indefinite for as long as the patient tolerates the drug and the prescribing physician judges that clinical benefit is reasonable. Friedreich's ataxia is a progressive lifelong genetic disease and Skyclarys does not cure it; the MOXIe trial demonstrated a 2.41-point placebo-corrected improvement on the mFARS at 48 weeks, interpreted as slowing of measured decline rather than restoration of function.

Where Reserve Meds fits in Skyclarys cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist, the EDE, or your dispensing pharmacy. For Skyclarys specifically, we orchestrate the US-side sourcing through a partner with procurement access to the Biologics by McKesson exclusive specialty channel and a defensible export pathway compliant with US DSCSA, prepare the documentation kit your UAE neurologist needs to file the EDE permit (with the genetic confirmation summary, hepatic dose-adjustment plan, and cardiac and hepatic monitoring template pre-built for FA cases), align the ambient air-freight shipment plan with the UAE importer, and assign a single named coordinator who carries the family through the first cycle and the recurring refill cadence. No prior Reserve Meds closed-case experience for Skyclarys as of this page date; standard NPP coordination applies.

Next step

If you have genetically confirmed Friedreich's ataxia and your UAE neurologist has identified Skyclarys 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.

Add my Skyclarys UAE case to the waitlist

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a UAE-licensed 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 ›
Last medically reviewed: 2026-05-12.