Skyclarys

Oman · access guide

How to access Skyclarys from Oman, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Oman patient with a confirmed diagnosis of Friedreich's ataxia may receive a prescription for Skyclarys (omaveloxolone) from their treating neurologist. Skyclarys is FDA-approved as the first disease-specific therapy for Friedreich's ataxia, developed by Biogen (following Reata Pharmaceuticals). Friedreich's ataxia is a progressive autosomal-recessive neurodegenerative condition driven by GAA repeat expansion in the FXN gene, affecting coordination, cardiac function, and (in some patients) glycaemic control. In Oman, Skyclarys is not locally registered for routine dispensing, which is why your neurologist is likely guiding you toward the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient import pathway.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

The clinical situation

Skyclarys is an oral Nrf2 activator taken once daily. Eligibility is based on genetic confirmation of Friedreich's ataxia (biallelic GAA expansion in FXN) and ongoing management by a neurologist familiar with ataxia and the associated cardiomyopathy surveillance. Your neurologist will confirm diagnosis, run baseline liver function tests, review lipid panels, and coordinate cardiology input. Because Skyclarys is oral, in-country administration is straightforward once the prescribing plan is in place.

Is Skyclarys legally importable into Oman?

Yes, through the DGPADC named-patient import framework, administered in coordination with the Ministry of Health for patients treated in public tertiary centres.

The named-patient mechanism allows a Oman-licensed physician to import a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally registered alternative is available, (c) the physician takes clinical responsibility, and (d) chain of custody is documented end to end. For Friedreich's ataxia, there is no locally registered disease-specific alternative.

How the pathway works, step by step

1. **Consultation with your treating neurologist.** Genetic confirmation of Friedreich's ataxia (biallelic GAA expansion), baseline neurological status (mFARS or equivalent), cardiac assessment, and liver function tests documented.
2. **Baseline laboratory panel.** Liver function, lipid panel, BNP, and glycaemic status established.
3. **DGPADC named-patient application.** Your physician or the hospital pharmacy files the application with clinical rationale, genetic report, patient reference, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Skyclarys from authorised distribution.
5. **Shipment.** Skyclarys ships with chain-of-custody documentation to the prescribing hospital pharmacy.
6. **Arrival and dispensing.** The hospital pharmacy releases the bottle with dosing instructions; neurology and cardiology monitoring are scheduled.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming Friedreich's ataxia diagnosis, genetic report, baseline mFARS / cardiac status, and Skyclarys as the indicated treatment
- Verification of their Oman medical licence (SCFHS / MOH)
- A copy of the FXN genetic diagnostic report
- Patient identifier (anonymised reference where possible)
- An administration and monitoring plan including liver function, lipid, and cardiac surveillance

Reserve Meds provides a physician documentation kit that bundles the templates DGPADC reviewers expect to see for rare-neurology named-patient imports, including the liver-function and cardiac-surveillance plan central to Skyclarys long-term use.

Costs and timing

Skyclarys's US cash-pay annual cost sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 370,000-400,000. International logistics, DGPADC documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete DGPADC application is submitted. Refills ship on a rolling basis against the monthly dispensing schedule.

Fulfilment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

A culturally-aware note: Friedreich's ataxia, as an autosomal-recessive disease, is more common in Oman than in many Western populations because of consanguineous marriage patterns. Families often have more than one affected sibling and face long-term progressive disability together. Our concierge coordination supports multi-patient families where appropriate, and we work with caregivers, often a mother, older sibling, or spouse, as designated case contacts for refills and clinic coordination.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Skyclarys specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for DGPADC review.
- **Logistics.** Chain-of-custody shipment coordination to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact for the patient and family, managing ongoing refill logistics.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating neurologist and cardiology team.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient framework with appropriate documentation. See our trust and compliance page.

Is Skyclarys a cure? No. Skyclarys is a disease-modifying therapy shown to slow deterioration on the mFARS scale in pivotal study data. Your neurologist will discuss realistic outcome expectations.

What monitoring is required? Liver function tests at baseline and periodically, lipid panel, BNP for cardiac surveillance, and weight/glycaemic surveillance are standard. Your neurology and cardiology teams set the cadence.

Can adolescents take Skyclarys? FDA labelling covers patients aged 16 years and older. Your neurologist will confirm age-based eligibility.

Will insurance or MoH coverage apply? Cash-pay is the default. Some Oman patients may receive partial MoH or private-insurance consideration on a case-by-case basis; we supply documentation for submission but do not process claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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