



Skyclarys in Saudi Arabia

The SFDA named-patient coordination pathway — indicative 2026

RARE DISEASE · FRIEDREICH'S ATAXIA

The clinical situation

Skyclarys (omaveloxolone) is the first FDA-approved disease-specific therapy for Friedreich's ataxia, an oral Nrf2 activator developed by Biogen (following Reata Pharmaceuticals). Friedreich's ataxia is a progressive autosomal-recessive neurodegenerative condition driven by biallelic GAA repeat expansion in the FXN gene, affecting coordination, cardiac function, and (in some patients) glycaemic control. Once-daily oral dosing with baseline and periodic liver-function, lipid, BNP, and glycaemic monitoring. Ongoing neurology and cardiology oversight required.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Neurologist confirms Friedreich's ataxia with FXN genetic report, baseline mFARS, cardiac assessment, and LFTs.
- 2 Baseline laboratory panel.** Liver function, lipid panel, BNP, and glycaemic status established before dispensing.
- 3 SFDA named-patient application.** Physician or hospital pharmacy files clinical rationale, genetic report, patient reference, and chain-of-custody plan.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner.
- 5 Arrival & dispensing.** Hospital pharmacy releases bottle to patient; neurology and cardiology monitoring scheduled; monthly refills on rolling cadence.

Indicative economics

Reference US cash-pay range: USD 370,000–400,000 per year (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete SFDA application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody. **Documentation.** Regulatory package for your physician and SFDA review, keyed to FXN genetic diagnosis and LFT/cardiac surveillance plan. **Logistics.** Chain-of-custody shipment with monthly-refill cadence. **Concierge case lead.** Single case lead supporting multi-patient families where multiple affected siblings share the diagnosis. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating neurologist.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Skylarys × Saudi Arabia first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/skyclarys-saudi-arabia.html



SCAN TO JOIN

Reserve Meds · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.

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