



# Skyclarys in India

The CDSCO named-patient coordination pathway — indicative 2026

RARE DISEASE · FRIEDREICH'S ATAXIA

## The clinical situation

Skyclarys (omaveloxolone) is an FDA-approved oral Nrf2 activator indicated for patients aged 16+ with Friedreich's ataxia, the first and only disease-modifying therapy for this progressive neurodegenerative disorder. Manufactured by Biogen (Reata). Dosed 150 mg once daily, with baseline and periodic monitoring of liver enzymes, lipids, and BNP. Capsules are stored ambient, simplifying cross-border logistics compared with biologics.

### The pathway, 5 steps

- 1 Consultation & genetic confirmation.** Treating neurologist confirms FXN mutation, baseline LFTs, lipid panel, and BNP; documents clinical rationale and no-alternatives status.
- 2 Treating centre & prescription confirmed.** An Indian tertiary neurology centre (Delhi, Mumbai, Bengaluru, Chennai) issues the prescription and commits to ongoing monitoring.
- 3 CDSCO named-patient application.** Form 12A / personal-import documentation is filed: clinical rationale, prescription, patient reference, and product details for CDSCO review.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner; ambient courier shipment booked.
- 5 Dispensing & monitoring.** Capsules delivered to the patient or treating centre; LFTs, lipids, and BNP checked per label; refills coordinated on a 30-day cycle.

### Indicative economics

**Reference US cash-pay range:** USD 30,000–33,000 per 30-day supply drug-only. Ambient logistics, CDSCO documentation, and concierge coordination are incremental. Full transparent quote at intake.

### Indicative first-fill timing

**7–14 days** from a complete CDSCO application to first-fill delivery, once cohort intake opens. Indicative — not guaranteed.

## Reserve Meds's role

**Sourcing.** US-licensed specialty wholesale partner, DSCSA chain-of-custody. **Documentation.** CDSCO named-patient / Form 12A package for your physician's review. **Logistics.** Ambient, tracked courier shipment coordination. **Concierge case lead.** Named point of contact for family and physician through the full process. **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 × India first-cohort waitlist.** *Our concierge reaches out as we open intake.*

[reservemed.com/access-guides/skyclarys-india.html](https://reservemed.com/access-guides/skyclarys-india.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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