Skyclarys access in India through the CDSCO Rule 36 Form 12A pathway

How Indian families managing Friedreich's ataxia source Skyclarys (omaveloxolone), the first FDA-approved disease-modifying therapy, with the genetic confirmation Indian neurologists need to file the Form 12A application.

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Quick orientation

Skyclarys is the brand name for omaveloxolone, an oral Nrf2 activator. The US FDA approved Skyclarys 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 remains, as of this page date, the only disease-modifying therapy approved for FA in the United States. Skyclarys is not registered with CDSCO in India as of this page date. An Indian family with a molecularly confirmed FA diagnosis (biallelic GAA expansion in the FXN gene, or one expansion plus a pathogenic FXN point mutation) can reach Skyclarys lawfully through Rule 36 of the Drugs and Cosmetics Rules 1945, prescribed by an NMC-registered neurologist and dispensed through a hospital pharmacy or a CDSCO-licensed specialty importer. Reserve Meds coordinates the US-side sourcing and the documentation kit your Indian neurologist needs to file the Form 12A application. Reserved for you.

Why Indian families need Skyclarys through the named-patient pathway

Friedreich's ataxia is ultra-rare, affecting approximately 1 in 50,000 people. The structural access pattern in India fits the third pattern the country module describes: Skyclarys is FDA-approved, EMA-approved (centralised marketing authorisation 9 February 2024), and MHRA-approved (UK national procedure 23 April 2025), but Biogen has not pursued CDSCO marketing authorisation. The Indian patient pool is small and dispersed, and individual ataxia clinics cannot generate the volume that would prompt a local registration filing. There is no other FDA-approved or EMA-approved disease-modifying therapy for FA. Supportive care including physical therapy, occupational therapy, cardiology management for FA-associated cardiomyopathy, and endocrine management for FA-associated diabetes remains essential, but the disease-modifying option exists only through cross-border access.

Friedreich's ataxia is genetic and progressive. Symptoms typically begin in childhood or adolescence. For decades, families had no disease-modifying option. The arrival of the first such therapy in 2023 produced a sharp uptick in family-driven, cross-border demand, including from Indian families and from Indian diaspora families coordinating care for relatives in India. Reserve Meds expects inquiries to come from family members with a treating neurologist already engaged at a tertiary academic centre, frequently with the genetic confirmation report in hand from CMC Vellore, AIIMS, NIMHANS, or another centre with a medical genetics service. Rule 36 was designed for exactly this situation.

The CDSCO Rule 36 personal import pathway for Skyclarys

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. CDSCO guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete.

For Skyclarys specifically, the clinical-justification angle that anchors the Form 12A application is FA-specific genetic confirmation. Skyclarys is approved only for FA in patients aged 16 years and older, and the FXN biallelic GAA expansion (or one expansion plus a pathogenic FXN point mutation) is the molecular signature. The application is strongest when the treating neurologist's letter sets out (1) the molecular genetic confirmation of FA with the reporting laboratory named (CMC Vellore, AIIMS Delhi medical genetics, the Centre for DNA Fingerprinting and Diagnostics in Hyderabad, or other accredited lab), (2) the patient's age (16 or older to fit the FDA label), (3) the current mFARS or other ataxia rating used at the treating centre, (4) baseline ALT, AST, total bilirubin, BNP, and lipid panel to anchor the label-required monitoring, (5) cardiac status given FA-associated cardiomyopathy risk, and (6) the planned monitoring cadence per the FDA label.

A complete Form 12A application includes the clinical justification letter from the treating Registered Medical Practitioner, the prescription showing the RMP's NMC registration number and the quantity required, a patient identifier with supporting medical records including the FA genetic confirmation, product details (Skyclarys as omaveloxolone 50 mg capsules; daily dose 150 mg taken as three capsules once daily on an empty stomach; manufacturer Biogen with original development by Reata Pharmaceuticals; requested quantity not exceeding 100 average doses per application per the second proviso to Rule 36), the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy through the Indian importer to the receiving Indian pharmacy. For institutional Compassionate Use, the parallel route is a Compassionate Use application to the DCGI by a government hospital, an RMP, or the patient.

Where Skyclarys gets dispensed in India

Skyclarys is a room-temperature stable oral capsule (storage 20-25 degrees Celsius, with excursions permitted 15-30 degrees Celsius). Cold-chain capability is not required; what matters is access to neurology and medical genetics depth, and a hospital pharmacy or CDSCO-licensed importer able to carry the Rule 36 paperwork. The Indian institutions that fit this profile for FA include:

- **All India Institute of Medical Sciences (AIIMS), New Delhi.** Apex public-sector institution, designated Centre of Excellence under the National Policy for Rare Diseases, with established medical genetics and neurology programmes and named-patient import workflow.
- **Christian Medical College (CMC), Vellore.** Globally recognised for medical genetics and rare-disease neurology; long-standing FA genetic testing capability.
- **Apollo Hospitals (Chennai, Delhi, Bangalore, Hyderabad, Kolkata).** Large neurology and medical-genetics network with dedicated international patient services, JCI and NABH accredited.
- **Fortis Memorial Research Institute, Gurgaon; Fortis Mulund, Mumbai; Medanta - The Medicity, Gurgaon; Kokilaben Dhirubhai Ambani Hospital, Mumbai; MGM Healthcare, Chennai; Manipal Hospitals, Bangalore.** Tertiary neurology programmes with rare-disease workflow.
- **National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore.** Anchor neurology institution with active ataxia and movement-disorders clinic.

For families outside the major metros, co-management with a neurologist at one of the centres above is the practical route, with refills routed through that hospital's import pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore. The 30-capsule monthly pack format supports a monthly or quarterly refill cadence.

Real cost picture for Skyclarys in India

The US wholesale acquisition cost for Skyclarys was set by Reata at launch at approximately USD 370,000 per year at the labelled 150 mg daily dose. The implied per-capsule WAC at approximately 1,095 capsules per year is approximately USD 338. With the rupee floating against the dollar in the 94 to 95 INR per USD range in May 2026, an annual drug cost of approximately USD 370,000 converts to approximately INR 3.5 crore per year, with monthly drug cost in the working range of approximately USD 30,000 to USD 31,000 (approximately INR 28 lakh to INR 29 lakh per month). International

logistics for an ambient-shipped oral capsule typically runs USD 300 to USD 550 per refill (approximately INR 28,000 to INR 52,000). Standard tamper-evident specialty pharmacy packaging is retained through the international leg.

The Biogen US patient assistance and copay support programmes are US-only and do not extend to international cases. Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, Apollo Munich, and Care Health handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item, and CGHS or ESIC routes face stricter Expert Committee review for DCGI-unapproved drugs. The National Policy for Rare Diseases 2021 provides up to INR 50 lakh one-time financial assistance per patient for rare diseases through Centres of Excellence under the Rashtriya Arogya Nidhi umbrella scheme; the ceiling and one-time framing fall well short of the lifetime cost of indefinite Skyclarys therapy but can be relevant in the first year of care for eligible patients. Cash-pay with documented optionality to pursue NPRD or insurer reimbursement is the default operating posture. GST on most life-saving medicines is 5 percent; the specific HSN code is confirmed at the documentation stage.

Typical timeline for Skyclarys in India

Skyclarys is room-temperature stable, which keeps the modality-adjusted timeline at the simpler end of the country module range. The typical end-to-end timeline for a first Rule 36 import is 3 to 5 weeks: the Form 12B permit is issued on a documented priority basis (often 1 to 2 days at the DCGI office once documentation is complete), 7 to 14 days for US-side procurement through Biologics by McKesson (the sole exclusive specialty pharmacy for Skyclarys in the US), and 3 to 5 days for ambient air freight and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad. The exclusive specialty pharmacy channel adds documentation steps relative to a standard wholesale-distributed product. Repeat monthly refill cycles for an established patient typically compress to 2 to 3 weeks because the Form 12A dossier and the procurement path are already in place. Annual supply discussions are appropriate from the first case, because the drug is chronic and the family will face recurring procurement decisions.

What your physician needs to provide

The treating neurologist's clinical justification letter is the cornerstone of the Form 12A package. For Skyclarys specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Omaveloxolone is an oral Nrf2 (nuclear factor erythroid 2-related factor 2) activator that upregulates the cellular antioxidant response and supports mitochondrial function in cells affected by frataxin deficiency. FDA approval 28 February 2023 for FA in adults and adolescents aged 16 years and older. The drug does not reverse existing neurological damage; the MOXIe pivotal trial demonstrated a placebo-corrected 2.41-point improvement on the mFARS at 48 weeks, interpreted as slowing of measured decline.
- **FA genetic confirmation.** Documented biallelic GAA expansion in the FXN gene, or one GAA expansion plus a pathogenic FXN point mutation, with the reporting laboratory and date named. Clinical suspicion of FA without genetic confirmation is not sufficient.
- **Dosing plan.** 150 mg once daily, taken as three 50 mg capsules on an empty stomach (at least one hour before or two hours after eating). No loading dose. Capsules swallowed whole; if unable to swallow, contents may be sprinkled on approximately two tablespoons of applesauce per the prescribing information and consumed immediately.
- **Hepatic dose adjustment.** Moderate hepatic impairment (Child-Pugh B): 100 mg once daily, with reduction to 50 mg once daily if adverse reactions emerge. Severe hepatic impairment (Child-Pugh C): avoid use.
- **Monitoring plan.** ALT, AST, and total bilirubin prior to initiation, monthly for the first 3 months, then periodically. BNP prior to initiation, with cardiac evaluation if elevated. Lipid panel prior to initiation and periodically. Monitor for clinical signs of fluid overload and heart failure given FA-associated cardiomyopathy risk. Permanent

discontinuation if ALT or AST exceeds 5 times the upper limit of normal, or 3 times ULN with evidence of liver dysfunction.

- **Physician registration.** Active NMC registration in neurology or medical genetics, with state-council registration where required.
- **Pharmacovigilance acknowledgement.** The Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission is referenced; adverse event reporting through PvPI stays with the prescribing physician.

Common questions about Skyclarys in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this?

Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item, and Skyclarys is not on any Indian formulary as of this page date. We supply the documentation that lets your insurer evaluate; the claim itself is filed by you or your hospital. Cash-pay is the default operating posture.

Does the National Policy for Rare Diseases cover Skyclarys?

NPRD 2021 provides up to INR 50 lakh one-time financial assistance per patient for rare diseases, administered through Centres of Excellence under the Rashtriya Arogya Nidhi umbrella scheme. FA fits the rare-disease framework, and AIIMS is among the designated Centres of Excellence. The ceiling and one-time framing fall well short of the lifetime cost of indefinite Skyclarys therapy at approximately USD 370,000 per year, but can be relevant in the first year of care. Eligibility and access route through your treating CoE.

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 FA on examination is not sufficient. CMC Vellore, AIIMS medical genetics, the Centre for DNA Fingerprinting and Diagnostics, and several private accredited labs offer FXN testing. Reports in regional languages or foreign languages may require translation; Reserve Meds intake supports translation review.

Is Skyclarys approved for children younger than 16?

No. The FDA approval covers adults and adolescents aged 16 years and older. Use in younger children is off-label, and Reserve Meds does not endorse off-label use. Treating neurologists who wish to discuss timing of initiation around the 16-year threshold should align with their institutional ethics review where applicable.

Is there a competitor or alternative?

No. There is no other FDA-approved or EMA-approved disease-modifying therapy for Friedreich's ataxia as of this page date. Supportive care (physical therapy, occupational therapy, cardiology management, endocrine management) remains essential and is not displaced by Skyclarys. The clinical decision to initiate is made by the treating neurologist case by case.

How long does treatment continue?

Treatment is intended for chronic, indefinite use. There is no finite course. Continuation is based on tolerability and the prescribing neurologist's longitudinal assessment. The cost of indefinite therapy is the primary factor in international access conversations, and we recommend planning annual supply discussions from the first case.

Where Reserve Meds fits in Skyclarys cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist, CDSCO, or your dispensing pharmacy. For Skyclarys specifically, we orchestrate the US-side sourcing through Biologics by McKesson (the exclusive US specialty pharmacy for Skyclarys) with full DSCSA chain-of-custody documentation, prepare the documentation kit your Indian neurologist needs to file the Form 12A application (with the FA genetic-confirmation template, hepatic-dose-adjustment reference, and PvPI acknowledgement pre-built), align the ambient air-freight shipment plan with the Indian importer or hospital pharmacy, and assign a single named coordinator who carries the case from first contact through the monthly refill cadence and the annual cardiac and hepatic monitoring discussions. No prior Reserve Meds closed-case experience for Skyclarys as of this page date; standard Rule 36 coordination applies. Operational notes will be added as cases land.

Next step

If you have a genetically confirmed FA diagnosis (biallelic GAA expansion in FXN, or one expansion plus a pathogenic point mutation) and your Indian neurologist has identified Skyclarys as the right disease-modifying therapy, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

This guide is informational, not medical or legal advice. The CDSCO Rule 36 pathway requires an NMC-registered 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 ›
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