Skyclarys access in Egypt

EDA Personal Importation for Friedreich's ataxia in adults and adolescents aged 16 and older. Genetic confirmation required. Coordinated end to end.

Quick orientation

Skyclarys (omaveloxolone) is an oral capsule and the first and only disease-modifying therapy approved for Friedreich's ataxia (FA) in adults and adolescents aged 16 years and older. The US Food and Drug Administration approved Skyclarys on 28 February 2023. It was developed by Reata Pharmaceuticals and is now commercialised globally by Biogen following the 2023 acquisition. The Egyptian Drug Authority (EDA) has not registered Skyclarys for the Egyptian market, which means Egyptian families with a genetically confirmed Friedreich's ataxia diagnosis reach for the drug through the EDA Personal Importation pathway under Law No. 151 of 2019. Friedreich's ataxia is ultra-rare, the disease is progressive, the genetics are well-characterised, and the arrival of the first disease-modifying option created a sharp uptick in family-driven cross-border demand worldwide. Reserve Meds runs the orchestration on the US side and walks alongside your neurologist on the Egypt side. Reserved for you.

Why patients in Egypt need Skyclarys via the named-patient pathway

Friedreich's ataxia affects approximately 1 in 50,000 people globally. National payers in non-approved jurisdictions have no incentive to expedite a local registration for a small patient pool, and individual ataxia clinics in those countries cannot generate the volume that would attract distributor interest. The structural result in Egypt is that Skyclarys is not registered locally at all, alongside large segments of the orphan neurology and rare-disease catalogue. The EDA Personal Importation framework exists for exactly this pattern.

The disease itself reinforces the named-patient candidacy. Friedreich's ataxia is genetic, with biallelic GAA repeat expansion in the FXN gene as the molecular signature. It is progressive and was untreatable in a disease-modifying sense for decades. The MOXIe pivotal trial demonstrated a placebo-corrected improvement of 2.41 points on the modified Friedreich Ataxia Rating Scale at 48 weeks, interpreted as slowing of measured neurological decline rather than restoration of function. The drug does not reverse damage, and that framing matters in family conversations. Egyptian neurologists at tertiary academic centres routinely face this gap when a patient or sibling pair receives a confirmed FA diagnosis through molecular genetic testing. The named-patient pathway is the practical, lawful route.

The EDA Personal Importation pathway for Skyclarys

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations under Prime Minister Decision No. 777 of 2020. EDA permits the importation of unregistered medicines for a specific patient where no equivalent registered product is available locally. The pathway is commonly referred to as Personal Importation, and the application is filed through the dispensing institution's import pharmacy at a tertiary academic centre or private specialty hospital.

For Skyclarys, the clinical justification angle is the genetic confirmation gate. Reserve Meds requires documented confirmation of biallelic GAA expansion in the FXN gene, or one GAA expansion plus a pathogenic FXN point mutation, before coordinating supply. EDA reviewers similarly expect the molecular genetic confirmation in the file, not clinical suspicion alone. The genetic report may originate from an Egyptian molecular pathology laboratory, from an international reference laboratory (where the family pursued a confirmatory test abroad), or from research-grade testing at one of the academic centres. Where reports are in a non-Arabic, non-English language, translation accompanies the file.

The standard application package includes the clinical justification letter on hospital letterhead, the prescription specifying Skyclarys brand name, generic name (omaveloxolone), strength (50 mg capsule), the 150 mg daily dose taken as three capsules once daily on an empty stomach, and the dispensed quantity sufficient for a defined refill cycle. The package also includes the genetic confirmation report, the baseline neurological assessment, the baseline cardiac and hepatic workup (ALT, AST, total bilirubin, BNP, lipid panel) per the FDA label monitoring requirements, the treating physician's EMS membership and Ministry of Health licence reference, the destination dispensing facility's licence, and a chain-of-custody plan. Skyclarys is room-temperature stable (20 to 25 degrees Celsius with permitted excursions to 15 to 30) and does not require cold-chain logistics. Routine EDA Personal Importation authorisations for well-documented rare-disease cases are typically processed in a 3 to 6 week window once a complete package is filed. EDA reserves discretion at every step. Reserve Meds does not file with EDA and is not an importer of record in Egypt.

Where Skyclarys gets dispensed in Egypt

The institutions equipped to run a Skyclarys import workflow are the neurology-strong tertiary centres in Cairo, Giza, and Alexandria with import pharmacy infrastructure. Cairo University Hospitals (Kasr Al Ainy) operates a large neurology service, a Drug Information Center, and an institutional import workflow. Ain Shams University Hospitals carry strong neurology services and routine experience with imported specialty medicines. Dar Al Fouad Hospital in 6th of October City is JCI-accredited and part of the Alameda Healthcare Group, with established import pharmacy capacity and an active neurology referral base. As-Salam International Hospital and the Cleopatra Hospitals Group also handle named-patient cases as routine practice. Where Friedreich's ataxia cases involve concurrent cardiomyopathy evaluation, the Magdi Yacoub Heart Foundation is a relevant referral partner for the cardiology workup that the FDA label monitoring requires. For families whose neurologist is at a regional hospital, co-management with one of the Cairo centres or routing through a licensed specialty importer is the practical path.

Real cost picture for Skyclarys in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. With the USD/EGP rate near 52 to 53 in May 2026, quoting in USD insulates the family from intra-case currency drift. Three line items shape the firm quote:

- **Drug acquisition cost.** 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. This is the manufacturer-stated US list price and is widely cited in pricing analyses. At approximately 1,095 capsules per year, the implied per-capsule list price is approximately USD 338. The annual figure is the US list price before US payer negotiation, not the patient out-of-pocket figure that a US-insured patient typically faces. For Egyptian named-patient cases, the relevant anchor is the unsubsidised list-equivalent, because Biogen's US patient support programmes do not extend internationally.
- **International ambient logistics, US to Cairo.** Because Skyclarys is a room-temperature oral capsule, the logistics surcharge sits at the lower end of the Egypt corridor range, typically USD 400 to USD 1,000 per shipment routed through Cairo International Airport.
- **Reserve Meds concierge fee.** Itemised on the firm quote, never bundled into the drug cost.

Insurer behaviour for named-patient imports varies by carrier. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other carriers operating in Egypt assess named-patient claims case by case. Pre-authorisation is typically required. UHIA does not currently cover most specialty imports in most governorates. The cost of indefinite therapy at the Skyclarys list anchor is the primary factor in international access conversations, and many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or the US.

Typical timeline for Skyclarys in Egypt

Routine EDA Personal Importation authorisations for well-documented ultra-rare neurology cases with genetic confirmation in the file sit inside the 3 to 6 week typical window once a complete package is filed. Because Skyclarys is room-temperature stable, the post-authorisation logistics leg is simple. End to end, a first Skyclarys shipment to a Cairo or

Alexandria dispensing pharmacy is typically achievable within a 5 to 9 week window from intake to in-hand at the hospital pharmacy for cases with complete documentation, with the document-collection step on the front end (genetic report translation where required, baseline cardiac and hepatic workup) being the most variable timeline element. Refill cadence runs on a 4 to 8 week cycle depending on the dispensed pack quantity, and Reserve Meds plans the refill rhythm with the family from the first shipment, because Skyclarys is chronic and lifelong. Timelines vary case by case and EDA reserves discretion.

What your physician needs to provide

Your treating neurologist, with EMS membership and an active Ministry of Health licence, prepares the clinical justification letter on hospital letterhead. The letter sets out the Friedreich's ataxia diagnosis with the genetic confirmation reference (biallelic GAA expansion in FXN, or one expansion plus a pathogenic point mutation), the current modified FARS score or equivalent neurological assessment, the baseline cardiomyopathy and endocrine assessment characteristic of FA, the prior management trajectory, and the clinical rationale for Skyclarys initiation.

The prescription specifies brand name (Skyclarys), generic name (omaveloxolone), strength (50 mg capsule), and the standard 150 mg daily dose taken as three 50 mg capsules once daily, on an empty stomach, at least one hour before or two hours after eating, with capsules swallowed whole or sprinkled on approximately two tablespoons of applesauce per the prescribing information. The letter includes the FDA-label monitoring plan: ALT, AST, 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 during treatment; and clinical monitoring for fluid overload and heart failure given the underlying FA cardiomyopathy risk. The EPVC reporting framework runs through the full course of therapy, and the documentation kit includes EPVC reference contacts.

Common questions about Skyclarys in Egypt

Do I need genetic confirmation to start? Yes. Reserve Meds requires documented 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 molecular confirmation is not sufficient. EDA reviewers similarly expect the genetic report in the file.

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover this? Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary, and many require pre-authorisation. Reserve Meds supplies the documentation an insurer needs to assess. Claim filing remains with the family or hospital.

Does UHIA cover Skyclarys? Not as a general rule, and not consistently across governorates yet. The UHI rollout is phased through to 2032. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path; cash-pay or private insurance reimbursement is.

What does the drug actually do? The MOXIe pivotal trial demonstrated a 2.41-point placebo-corrected improvement on the modified FARS at 48 weeks, interpreted as slowing of measured neurological decline rather than restoration of function. Long-term extension data have suggested persistent slowing of decline. The decision to initiate is your neurologist's, not ours.

What about side effects? The most common adverse reactions reported in MOXIe were elevated liver transaminases, headache, nausea, abdominal pain, fatigue, diarrhoea, and musculoskeletal pain. Elevations of ALT or AST above 5 times the upper limit of normal occurred in 16 percent of treated patients and were generally reversible on dose reduction or discontinuation. Your neurologist owns the monitoring decisions.

Is the drug for children? The FDA-approved indication is adults and adolescents aged 16 years and older. Use in younger pediatric patients is outside the FDA label.

Where Reserve Meds fits in Skyclarys cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist, we do not replace EDA, we do not replace the licensed dispensing pharmacy, and we do not act as an importer of record in Egypt. For a Skyclarys case the orchestration is concrete. We confirm eligibility within 24 to 48 hours, we send a documentation kit to the treating physician with Arabic-language patient-facing summaries where the family requests them, we anticipate translation needs on the genetic confirmation report, we source through a DSCSA-compliant US specialty pharmacy channel into the Biologics by McKesson exclusive distribution channel, we coordinate the ambient-temperature international shipment to Cairo International Airport, and we run a single named coordinator throughout the case. Annual supply planning is appropriate from the first case, because therapy is chronic and the family will face recurring procurement decisions.

Next step

If you have a genetically confirmed Friedreich's ataxia diagnosis and your neurologist has indicated Skyclarys is the right next step, the practical move is to start the intake. We confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

About Skyclarys

Rare neurology (Friedreich's ataxia)
Manufacturer: Biogen (originally Reata)
Modality: Oral capsule, room temperature
Full drug page

About Egypt

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