Skyclarys access in Saudi Arabia through the SFDA Personal Importation Program

How Saudi families with a genetically confirmed Friedreich's ataxia diagnosis source Skyclarys (omaveloxolone), the first disease-modifying therapy for FA, what the PIP application package looks like, and where Reserve Meds fits.

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Quick orientation

Skyclarys is the brand name for omaveloxolone, an oral once-daily small-molecule Nrf2 activator approved by the US FDA 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 the only disease-modifying therapy approved for Friedreich's ataxia. The European Medicines Agency granted centralised marketing authorisation on 9 February 2024 and the UK MHRA approved Skyclarys on 23 April 2025. The SFDA has not registered Skyclarys for local commercial sale in the Kingdom of Saudi Arabia as of this page date. A Saudi family with a genetically confirmed FA diagnosis can reach Skyclarys lawfully through the SFDA Personal Importation Program (PIP), prescribed by a SCFHS-licensed neurologist and dispensed by an SFDA-licensed hospital or specialty import pharmacy. Reserve Meds coordinates the US-side sourcing and the documentation kit your neurologist needs to file the PIP application. Reserved for you.

Why Saudi families need Skyclarys through the named-patient pathway

Friedreich's ataxia is ultra-rare, affecting approximately 1 in 50,000 people worldwide. National payers in non-approved jurisdictions have no incentive to expedite a local registration for a small patient pool, and individual ataxia clinics cannot generate the volume that attracts distributor interest. The structural access pattern in Saudi Arabia is the third of the three the country module describes: the drug is FDA-approved (and EMA-approved, and MHRA-approved) but the manufacturer Biogen has not sought SFDA registration. Saudi families with an FA-affected child often have a confirmed genetic diagnosis through KFSH&RC's medical genetics service or another tertiary genomics programme, with no locally registered disease-modifying option to offer.

Friedreich's ataxia is genetic, progressive, and was for decades untreatable. The arrival of the first disease-modifying therapy created a sharp uptick in family-driven cross-border demand globally. Patient advocacy networks (Friedreich's Ataxia Research Alliance, Ataxia UK) actively educate families about the drug's existence. Saudi Vision 2030's Health Sector Transformation Program names genomics and rare-disease care as priority verticals, and pediatric and adolescent FA cases are being identified earlier through expanded genetic confirmation capability. The PIP framework was designed for exactly this situation: an FDA-approved medicine, no clinically equivalent locally registered alternative (no other disease-modifying FA therapy exists), and a serious progressive condition where the treating physician documents why this specific drug is appropriate for this specific genetically confirmed patient.

The SFDA Personal Importation Program for Skyclarys

The Saudi pathway for a KSA-licensed neurologist to obtain Skyclarys is the SFDA Personal Importation Program. PIP allows a SCFHS-licensed physician to request the import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (the US FDA, the EMA, and the UK MHRA for Skyclarys) and a clinically equivalent locally registered alternative is not suitable. Applications are filed through the dispensing institution's import pharmacy and increasingly routed through the SFDA Ghad digital platform.

For Skyclarys specifically, the clinical-justification angle that anchors the application is GAA genetic confirmation. Skyclarys is approved only for Friedreich's ataxia, and FA is defined molecularly by biallelic GAA trinucleotide repeat expansion in intron 1 of the FXN gene (or one GAA expansion in trans with a pathogenic FXN point mutation). Clinical suspicion alone is not sufficient. The PIP application is strongest when the neurologist's letter sets out (1) the molecular genetic confirmation of FA with the reporting laboratory named (specifically the GAA expansion size or the compound heterozygous mutation profile), (2) the clinical phenotype including age at onset and disease trajectory using a validated scale such as mFARS (modified Friedreich Ataxia Rating Scale), (3) confirmed age 16 years or older (the FDA-label age threshold), (4) baseline hepatic function (ALT, AST, total bilirubin) and the planned monitoring schedule, (5) cardiac baseline (BNP, echocardiogram where indicated, given FA-associated cardiomyopathy risk), and (6) lipid baseline.

A complete PIP package typically includes:

- Clinical justification letter from the treating neurologist (FA diagnosis with GAA genetic confirmation, severity assessment via mFARS or equivalent, prior therapies, why Skyclarys, why a locally registered alternative is not suitable)
- Genetic test report attached as a supporting document, with the reporting laboratory named
- Treating neurologist SCFHS license verification (neurology, pediatric neurology, or movement disorders subspecialty)
- Patient identifier in SFDA-required format
- Product details: Skyclarys 50 mg oral capsules in bottle format, manufacturer Biogen (originally Reata Pharmaceuticals, acquired September 2023), country of origin USA, requested quantity (typically a 30-day or 90-day supply at 3 capsules daily), lot and expiry
- Destination dispensing facility license
- Chain-of-custody plan from the US specialty pharmacy (Biologics by McKesson is the sole exclusive US channel) through the importer to the receiving Saudi pharmacy
- Post-import pharm