Elevidys

Egypt · access guide

Elevidys access in Egypt: the EDA named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Patients in Egypt access Elevidys (delandistrogene moxeparvovec) for Duchenne muscular dystrophy in eligible patients through the EDA personal-use import pathway, a federal mechanism that allows an Egyptian-licensed physician to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in EGP.

Why Egyptian families need Elevidys through the named-patient pathway

Egypt has a large pediatric population (approximately 35 million Egyptians under 18) and a documented hereditary disease profile shaped by consanguinity in Upper Egypt and the rural Delta. Duchenne muscular dystrophy prevalence sits at the global 1 in 3,500 to 1 in 5,000 male birth range; in absolute terms, the Egyptian DMD cohort is in the low thousands. The country's tertiary pediatric neurology infrastructure is concentrated in Cairo (Cairo University's Abu El Reesh Children's Hospital, Ain Shams University Children's Hospital, the National Research Centre, the 57357 Children's Cancer Hospital for hematology cases, and major private centers including Cleopatra Hospital, Dar Al Fouad, and Saudi German Hospital Cairo). Genetic confirmation of DMD has become more accessible through EDA-licensed private genomics labs and the academic medical genetics services at Cairo University and Ain Shams.

The access gap for Elevidys in Egypt has four layers. First, regulatory: Sarepta has not filed Elevidys for EDA commercial registration. Second, certified-center capability: AAV gene therapy infusion requires a pediatric institution with infusion suite, post-infusion ICU backup, and the immunomonitoring infrastructure for the post-infusion period; the count of qualified Egyptian sites is narrow and concentrated in Cairo. Third, eligibility gating: anti-AAVrh74 antibody titer must be below the FDA-labeled threshold, the patient must have a confirmed DMD mutation by next-generation sequencing or MLPA, and the family must accept the boxed-warning context for serious immune-mediated myositis. Fourth, payer reality: at USD 3.2 million list price (approximately EGP 154 million at the 2026 rate range, with rate volatility a meaningful planning variable), no Egyptian public payer reimburses, and private insurers do not cover at this list level. Cash-pay is the operating reality, most often supported by overseas family members in the GCC, North America, or Europe.

The clinical case is time-sensitive: disease-modifying benefit in DMD is greatest before substantial muscle loss has occurred, and Egyptian families who reach us are typically working against an active disease trajectory after years of corticosteroids and supportive care. Exon-skipping therapies (eteplirsen, viltolarsen, golodirsen, casimersen) are not consistently locally available in Egypt, which sharpens the case for the AAV gene therapy where the patient is eligible.

The EDA named-patient pathway for Elevidys

The legal foundation for personal import of unregistered medicines into Egypt is the Egyptian Drug Authority's framework under Law No. 151 of 2019 (which established the EDA as the unified regulatory authority, separating it from the Ministry of Health) and the Pharmacy Law No. 127 of 1955 as amended. The EDA Central Administration for Pharmaceutical Affairs handles personal-import applications for unregistered medicines required for a specific named patient, filed through the institution's import pharmacy and submitted to the EDA's Drug Inspection Department.

For Elevidys specifically, the clinical-justification angle that anchors the application is genetic confirmation plus institutional gene-therapy readiness. The strongest applications consistently document: a confirmed DMD diagnosis with the specific dystrophin gene mutation reported by a named genetics laboratory (NGS report with the deletion, duplication, or point mutation specified); the patient's age (4 years or older) and ambulatory or non-ambulatory status; the baseline North Star Ambulatory Assessment (NSAA) score for ambulatory cases, or baseline upper-limb and respiratory measures for non-ambulatory cases; the anti-AAVrh74 binding antibody titer (must be below the FDA-labeled threshold per the validated assay); the immunosuppression plan for the peri-infusion period (oral prednisone or equivalent starting one day before infusion and continuing for at least 60 days); and the receiving institution's gene therapy infusion capability, pediatric critical care backup, and laboratory infrastructure for the post-infusion creatine kinase, troponin, liver function, and platelet monitoring window.

A complete EDA application includes the clinical justification letter from the treating pediatric neurologist with active Egyptian Medical Syndicate registration, the genetic test report attached as supporting documentation, the anti-AAVrh74 titer result, the proposed dosing plan at the FDA-labeled 1.33 x 10^14 vg/kg delivered as a single intravenous infusion, the destination dispensing facility license under Pharmacy Law No. 127 of 1955, and the chain-of-custody plan describing how the medicine will move from the Sarepta manufacturing facility through the importer to the dispensing pharmacy, including the frozen cold-chain handling at minus 60 degrees Celsius or colder. Approval timelines for routine EDA personal-import cases run 3 to 6 weeks; complex first-time gene-therapy imports can extend to 8 to 12 weeks given the limited institutional precedent.

Where Elevidys gets dispensed in Egypt

The treating-center map for Elevidys in Egypt is narrow because of the AAV gene therapy infusion capability requirement. The institutions most likely to handle an Egyptian Elevidys case are Cairo University's Abu El Reesh Children's Hospital (with its long-standing pediatric neurology subspecialty), Ain Shams University Children's Hospital (Demerdash and Ain Shams Specialized Hospital), the National Research Centre's pediatric program, Cleopatra Hospital Group (notably Cairo Specialized Hospital and Cleopatra Hospital), Dar Al Fouad Hospital in 6th of October City, and Saudi German Hospital Cairo. The 57357 Children's Cancer Hospital handles pediatric hematology and oncology but participates in the broader pediatric gene-therapy conversation through its infrastructure and ICU capability.

The dispensing facility must hold validated frozen storage at minus 60 degrees Celsius or colder, gene therapy infusion suite capability, pediatric critical care backup, and laboratory turnaround for the post-infusion monitoring schedule including weekly creatine kinase, troponin, AST, ALT, total bilirubin, and platelet count for the first 90 days. The receiving institution also carries the peri-infusion corticosteroid course (oral prednisone 1 mg/kg/day or equivalent starting one day before infusion, continuing for at least 60 days, with taper based on clinical and laboratory parameters). For Egyptian families where the originating consultation is at a regional or governorate-level hospital outside Cairo, the practical pathway routes the case to one of the Cairo tertiary centers for the infusion itself, with pre- and post-infusion follow-up coordinated back to the originating center.

Real cost picture for Elevidys in Egypt

US wholesale acquisition cost for Elevidys is approximately USD 3.2 million per single-dose treatment cour

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Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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