

## Duvyzat

Qatar · access guide

# Duvyzat (givinostat) for a Qatari family: what the pathway looks like in 2026

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

A Qatari family of a son with Duchenne muscular dystrophy walks into this decision with more than a treatment question. There is a clinical question, a genetic question, a regulatory question, a financial one, and a family one, and they all need answers in roughly the same week. This page is meant to be the first honest read you get on Duvyzat in Qatar, written by the team that would coordinate it for your son if you decided to go forward. We assume your paediatric neurologist has either raised it with you or you have raised it with them.

## What changed in March 2024, and why Duvyzat sits differently from the exon-skipping drugs

Duvyzat (givinostat) is the first FDA-approved oral pharmacological therapy for DMD that does not depend on a specific exon-skip-amenable mutation. The Sarepta exon-skipping family (Amondys 45, Exondys 51, Vyondys 53, Viltepso) is genotype-restricted; Elevidys gene therapy is stage-restricted. Duvyzat is approved for any patient aged 6 years and older with a genetically confirmed DMD diagnosis, regardless of which exon boundary the deletion sits on.

For families whose son's mutation has put exon-skipping out of reach, this is a meaningful change in 2026. Duvyzat does not restore dystrophin; it works at a downstream pathology level, reducing fibrosis and inflammation in dystrophin-deficient muscle. FDA approval was granted on 21 March 2024 based on the Phase 3 EPIDYS trial. EMA review is in progress as of 2026; conditional approval is anticipated but not yet granted.

## What Duvyzat actually is, in plain terms

Duvyzat is a histone deacetylase (HDAC) inhibitor, given as an oral suspension twice a day with food. The active ingredient is givinostat. HDAC inhibition in dystrophin-deficient muscle reduces fibrosis, reduces chronic inflammation, and supports the muscle's attempts at regeneration. EPIDYS data documented approximately 30 percent slower decline in four-stair-climb time over 18 months versus placebo, with consistent direction of effect on the North Star Ambulatory Assessment.

Duvyzat is not a cure. It does not address the underlying genetic defect. It is given on top of the background corticosteroid (prednisolone, deflazacort, or vamorolone) that remains the DMD standard of care. The steroid does not stop.

The oral suspension is 8.86 mg/mL, dispensed with a calibrated oral syringe. Dosing is by weight, twice daily with food, lifelong. The dose moves through bands as the child grows.

## The workup that opens the pathway

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Beyond confirmation that your son has DMD, structured baseline studies and ongoing monitoring define the protocol.

**Genetic confirmation of DMD.** Sidra Medicine paediatric neuromuscular genetics in Doha runs paediatric DMD workup in-house and is paediatric only, which fits the DMD population. Hamad Medical Corporation paediatrics handles paediatric neurology and can coordinate genetic referral. Whole-gene sequencing or MLPA confirmation. Mutation type does not gate Duvyvat eligibility.

**Baseline platelet count.** HDAC inhibitors have a class effect of thrombocytopenia. Pre-treatment platelet count, then monitoring at week 2, week 4, and every 3 months thereafter. Severe thrombocytopenia is a contraindication.

**Baseline ECG with QTc.** QT prolongation signal. Baseline ECG plus periodic monitoring. Avoid concurrent QT-prolonging drugs and strong CYP3A4 inhibitors.

**Baseline liver function** (AST, ALT, bilirubin, alkaline phosphatase). Quarterly LFT monitoring during therapy. Severe hepatic impairment is a contraindication.

**Baseline triglycerides.** Hypertriglyceridemia is a labeled warning. Baseline plus periodic monitoring.

**Baseline motor function.** Motor Function Measure (MFM) and North Star Ambulatory Assessment (NSAA).

**Weight check** at every visit (dose moves through weight bands as the child grows).

**Review of background corticosteroid regimen.** Duvyvat is added on top.

A clinical rationale letter from your paediatric neurologist documents all of the above, the rehabilitation plan, and the requested treatment.

## The Qatar regulatory pathway: how it actually works in 2026

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The Ministry of Public Health Department of Pharmacy and Drug Control (DPDC) is the federal authority. `[VERIFY: MoPH DPDC Duvyvat registration status in 2026]`. In the absence of standard registration, the named-patient mechanism is the route. The application is filed through MoPH DPDC by the dispensing hospital's pharmacy on the treating neurologist's behalf. Duvyvat sits firmly in the named-patient category in 2026 because the FDA approval is under 24 months old and the GCC standard registration lists do not yet carry it.

In our experience coordinating named-patient paediatric neuromuscular cases in Qatar, MoPH DPDC approval on a complete, well-documented file takes four to eight weeks from filing. Renewal cycles for continuous oral therapy are typically simpler than the initial approval but require advance planning. Reserve Meds maintains the renewal calendar.

Sidra Medicine paediatric neuromuscular service in Doha is the natural setting for Duvyzat supervision. Sidra has built operational depth in paediatric advanced-therapy administration including Elevidys gene therapy and is paediatric only, which fits the DMD population. Hamad Medical Corporation paediatrics is the alternative when Sidra capacity routing or family preference favours HMC. Because Duvyzat is an oral suspension administered at home twice daily with food, the qualified-centre framework is about supervision, monitoring, and prescription continuity rather than about infusion-centre access.

National health insurance coordination for Qatari nationals runs through your consultant and the relevant MoPH framework.

## **The cost conversation, in the form a Qatari family needs**

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The Duvyzat annual drug price in 2026 sits in an indicative range of roughly USD 350,000 to 500,000 per year, depending on body weight, or approximately QAR 1.27 to 1.82 million per year. For a typical paediatric patient, cumulative drug cost over a lifetime can reach USD 10 to 20 million plus at current pricing.

The full cost of care includes pre-treatment workup, quarterly monitoring labs and ECGs, MFM and NSAA assessments, rehabilitation programme, background corticosteroid management, and our coordination fee. We separate every line. We do not put a markup on the manufacturer's drug price. The coordination fee is disclosed in writing.

For Qatari-national families, your consultant will know whether the current MoPH framework or national health insurance pathway could underwrite the case. Worth asking explicitly.

A direct comparison point: Duvyzat at roughly QAR 1.27 to 1.82 million per year sits between the supportive-care-only cost picture and the Amondys 45 weekly IV exon-skip cost picture (QAR 2.5 to 4.4 million per year). For families whose son is not eligible for any exon-skip drug, Duvyzat is the first targeted oral option available at all.

## **Life on twice-daily oral suspension**

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Duvyzat is a chronic oral medication integrated into mealtimes. Twice a day, with food, measured with the calibrated oral syringe. Anchoring the dose to breakfast and dinner is the most reliable adherence pattern; missed doses defeat the therapy's purpose because HDAC inhibition needs to be sustained.

Most common adverse events: diarrhea, abdominal pain, nausea, and decreased weight (often related to GI tolerability). Manageable with dose adjustment, anti-diarrhoeal support, and dietary attention.

Clinic visit cadence: platelets at week 2, week 4, then every 3 months; LFTs, triglycerides, and ECG every 3 months; MFM and NSAA at the assessment intervals your neurologist sets. The background corticosteroid surveillance continues as it would for any DMD child on a corticosteroid regimen.

DMD carries cognitive and behavioural comorbidities at higher prevalence than the general paediatric population, including autism-spectrum traits, ADHD, and learning differences. The standard DMD MDT includes neuropsychology and caregiver psychosocial support. Duvyzat itself does not add a CNS mental-health safety burden, but the MDT framework matters.

## Religious and ethical considerations

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Givinostat is a small-molecule synthetic chemistry. The active ingredient itself is not derived from animal sources. Standard halal acceptability hinges on the full excipient list of the oral suspension; this is the question to put to your religious advisor with the dispensing pharmacist's full label disclosure in hand. The Islamic bioethics consensus on disease-modifying therapy that preserves life and function is broadly permissive, and families typically consult with their religious advisors before committing to a lifelong therapy.

## When Duvyzat is not the right option

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If your son has not had genetic confirmation of DMD, the workup begins there. If your son is younger than 6 years old, Duvyzat is not approved for him at this age. If your son has severe hepatic impairment or severe thrombocytopenia at baseline, Duvyzat is contraindicated. If your son is on a strong CYP3A4 inhibitor or a QT-prolonging medication, the treating team will review interactions before initiating Duvyzat. If your son's underlying diagnosis is not DMD, Duvyzat does not apply.

In all of these situations, reach out anyway.

## What Reserve Meds does for a Qatari family

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. Our scope is the regulatory documentation packet, the MoPH DPDC named-patient filing in collaboration with the dispensing hospital pharmacy, sourcing logistics through the manufacturer's authorised US distribution channel, cold-chain shipment where the formulation requires it, the renewal-cycle calendar so supply continuity is never at risk, and named case-lead coordination.

Reserve Meds is not your son's prescriber. We do not practise medicine. We do not manufacture Duvyzat. Clinical decisions stay with your paediatric neurologist and the supervising centre.

We work cash-pay. Our coordination fee is disclosed in writing.

## What to do if you want to start

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The first concrete step is a call with our case-lead so we can confirm whether Duvyzat is the right consideration for your son. If genetic confirmation of DMD is already in hand, we move directly into documentation work. If not, we route to Sidra Medicine paediatric neuromuscular genetics first.

Most families reach us first on WhatsApp, which is the medium we hold open during Qatar business hours (Sunday-Thursday) and on weekends for active cases.

Start your son's case on the portal, or open a WhatsApp conversation with the case-lead and we will take it from there.

### *Reserve Meds's role*

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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**Reserve Meds**

*reserved for you.*

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

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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