

Duvyzat

United Arab Emirates · access guide

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

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

A UAE 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 the UAE, from 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.

We will be specific about what Duvyzat actually changes in the DMD treatment conversation in 2026, what the workup looks like, how the UAE named-patient pathway works for a non-registered specialty oral medicine, what it costs in AED and US dollars per year for a lifelong twice-daily oral therapy, where it can be supervised in the UAE, and what life looks like once therapy is in place.

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 for exon 45, Exondys 51 for exon 51, Vyondys 53 and Viltepso for exon 53) and the Sarepta gene therapy Elevidys are all genotype-restricted or stage-restricted in different ways. 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, and for families who are not in the current Elevidys ambulatory-only window, 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 and supporting muscle function preservation. The FDA approval was granted on 21 March 2024, based on the EPIDYS Phase 3 trial.

The EMA review of givinostat is in progress as of 2026. Conditional approval is anticipated but not yet granted. We mention this because UAE families occasionally consult European clinicians and the FDA-EMA timing divergence deserves a straight answer.

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 satellite-cell-mediated regeneration that the muscle is constantly attempting against the dystrophic damage cycle. The clinical effect documented in the pivotal EPIDYS trial was approximately a 30 percent slower decline in four-stair-climb time over 18 months in givinostat-treated boys compared with placebo, with consistent direction of effect on the North Star Ambulatory Assessment and other secondary motor function endpoints.

Duvyzat is not a cure. It does not address the underlying genetic defect; the dystrophin gene remains mutated and the muscle continues to be dystrophin-deficient. What it does is slow the downstream pathological cascade, which translates into preservation of motor function over months and years.

A point that matters for families: Duvyzat is added on top of background corticosteroid therapy (prednisolone, deflazacort, or vamorolone), which remains the standard of care for DMD. Duvyzat does not replace the steroid. The steroid does not stop. If your son has been on a corticosteroid for years and you have lived with the steroid side effects, Duvyzat does not change that part of the regimen.

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

The workup that opens the pathway

Beyond confirmation that your son has DMD, several baseline studies and ongoing monitoring requirements define the Duvyzat protocol. The drug has a class effect that requires structured surveillance.

First, genetic confirmation of DMD. Whole-gene sequencing or MLPA-confirmed pathogenic variant in the DMD gene. If your son has already been genetically tested, your neurologist will pull the report. The mutation type does not gate Duvyzat eligibility (unlike the exon-skip drugs); confirmation of DMD diagnosis does. Dystrophin immunohistochemistry on muscle biopsy is acceptable supporting evidence if biopsy has been done.

Second, 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. The monitoring cadence is part of the standard Duvyzat protocol.

Third, baseline ECG with QTc. Duvyzat carries a QT prolongation signal. Baseline ECG with calculated QTc, plus periodic monitoring. Concurrent QT-prolonging medications are avoided. Strong CYP3A4 inhibitors are avoided.

Fourth, baseline liver function panel (AST, ALT, bilirubin, alkaline phosphatase). Hepatotoxicity is a labeled warning. Quarterly LFT monitoring during therapy. Severe hepatic impairment is a contraindication.

Fifth, baseline triglycerides. Hypertriglyceridemia is a labeled warning. Baseline plus periodic monitoring.

Sixth, baseline motor function assessments. Motor Function Measure (MFM) and North Star Ambulatory Assessment (NSAA) are the standard DMD functional baselines. These also serve as the metrics your neurologist will track for whether Duvyzat is doing what the EPIDYS data predict it will do in your son.

Seventh, weight and growth check. Dosing is weight-banded; weight is recorded at every visit and dose moves through the bands as your son grows.

Eighth, review of background corticosteroid regimen. Most DMD patients are on prednisolone, deflazacort, or vamorolone. Duvyzat is added on top.

A clinical rationale letter from your paediatric neurologist will document the genetic confirmation, the platelet baseline, the ECG with QTc, the LFTs, the triglycerides, the MFM and NSAA baselines, the current corticosteroid regimen, the rehabilitation plan, and the requested treatment.

The UAE regulatory pathway: how it actually works in 2026

The Emirates Drug Establishment, which absorbed 44 of the Ministry of Health and Prevention's regulatory functions by early 2026, is now the federal authority you and your treating hospital file through. `[VERIFY: EDE Duvyzat registration status in 2026]`. In the absence of EDE registration on the standard list, the named-patient mechanism is the route. It is filed via ede.gov.ae by the hospital's import pharmacy on the treating neurologist's behalf. The Department of Health Abu Dhabi or the Dubai Health Authority adds the emirate-level layer depending on where supervision is centred.

Duvyzat sits squarely in the named-patient pathway category in 2026 because the drug was FDA-approved only in March 2024, EMA conditional approval is not yet granted, and the GCC standard registration lists do not yet carry it. This is the standard pattern for an under-24-months FDA approval in this region: named-patient access mechanism, manufacturer's authorised export channel, hospital import pharmacy plus EDE filing.

In our experience coordinating named-patient paediatric neuromuscular cases in the UAE, EDE approval on a complete, well-documented file takes three to six weeks from filing. Renewal cycles thereafter (because Duvyzat is continuous oral therapy) are typically simpler than the initial approval but require advance planning so that supply continuity is never at risk. Reserve Meds maintains the renewal calendar as part of case management.

In the UAE, the paediatric neurology hubs that can supervise Duvyzat include Tawam Hospital paediatric neurology in Al Ain, Sheikh Khalifa Medical City paediatric neurology in Abu Dhabi, Sheikh Shakhbout Medical City, American Hospital Dubai paediatric neurology, and Mediclinic City Hospital paediatric neurology. 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. Clinic visits handle the platelet checks, the LFTs, the triglycerides, the ECGs, and the MFM and NSAA assessments.

The cost conversation, in the form a UAE family needs

Duvyzat is lifelong, twice daily, dosed by weight. As your son grows, the dose moves through weight bands, and the annual cost moves with it.

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 AED 1.28 to 1.84 million per year. For a typical paediatric patient starting therapy at age 6 to 8, cumulative drug cost over a lifetime can reach USD 10 to 20 million plus at current pricing. That is the manufacturer's price for the drug only. The full cost of care includes the pre-treatment workup, the quarterly monitoring labs and ECGs, the MFM and NSAA assessments, the rehabilitation programme, the background corticosteroid management, and our coordination fee.

When we issue a quote at intake, we separate every line: drug per quarter, monitoring labs, ECG, MFM/NSAA assessments, paediatric neurology clinic visits, our coordination fee. Nothing is bundled. We do not put a markup on the manufacturer's drug price. The coordination fee is disclosed in writing before any funds move.

Insurance coverage of Duvyzat in the UAE is uneven and tends to be evaluated case by case under prior-authorization pathways. Because Duvyzat is a 2024 FDA-approved specialty oral DMD therapy that has not been on the UAE registration list long, private insurers are evaluating cases on a case-by-case basis with most not yet considering Duvyzat a standard covered benefit. Daman has historically supported DMD exon-skipping therapies for certain employer plans through prior authorisation; the same pathway is theoretically open for Duvyzat but is early in the operational learning curve. We supply your insurer with the documentation packet at no charge. We do not process the claim or guarantee coverage. Most UAE Duvyzat cases in 2026 are proceeding as cash-pay arrangements with partial reimbursement where available.

A direct comparison point for families weighing options: Duvyzat at roughly AED 1.28 to 1.84 million per year sits between the supportive-care-only cost picture and the Amondys 45 weekly IV exon-skip cost picture (AED 2.6 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. The financial-planning frame is genuinely different.

Life on twice-daily oral suspension

Duvyzat is a chronic oral medication integrated into mealtimes. Twice a day, with food, measured with the calibrated oral syringe Italfarmaco provides. Many families find that 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.

The most common adverse events are diarrhea, abdominal pain, nausea, and decreased weight (often related to GI tolerability). For most families these are manageable with dose adjustment, anti-diarrhoeal support, and dietary attention. Your neurologist will work with you on the practical adjustments.

The clinic visit cadence is structured around the monitoring requirements: 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 (growth, bone density, weight, blood pressure, behavior) continues as it would for any DMD child on a corticosteroid regimen.

A note on DMD beyond the muscle picture: 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 multi-disciplinary team includes neuropsychology and caregiver psychosocial support. Duvyzat itself does not add a CNS mental-health safety burden, but the MDT framework matters and we encourage families to keep the psychosocial supports active throughout the treatment journey.

Religious and ethical considerations

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. `[VERIFY: full excipient list for Duvyzat oral suspension halal status as of 2026]`. For Muslim families, the Islamic bioethics consensus on disease-modifying therapies that preserve 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

We will name the situations where Duvyzat is not the right page directly.

If your son has not had genetic confirmation of DMD, the workup begins there. The Duvyzat label requires a genetically confirmed DMD diagnosis. Suspected DMD on clinical and elevated CK grounds alone is not the eligibility standard.

If your son is younger than 6 years old, Duvyzat is not approved for him at this age. The label is age 6 and older. Your neurologist can frame what the right interim pathway looks like, which typically includes the standard supportive-care backbone, corticosteroid initiation when age-appropriate, and family preparation for the eventual disease-modifying therapy decisions.

If your son has severe hepatic impairment or severe thrombocytopenia at baseline, Duvyzat is contraindicated. The treating team will review whether the underlying issue is workable and time the therapy decision accordingly.

If your son is on a strong CYP3A4 inhibitor or a QT-prolonging medication for another indication, the treating team will review the interactions before initiating Duvyzat. Sometimes the other medication can be substituted; sometimes Duvyzat is not the right addition.

If your son's underlying diagnosis is not DMD (Becker, limb-girdle, fascioscapulohumeral, congenital muscular dystrophies, other neuromuscular conditions), Duvyzat does not apply. The label is DMD-specific.

In all of these situations, reach out anyway. We will walk through what the right pathway looks like for your son's specific picture, which often includes one of the other DMD therapy categories or a clinical-trial route.

What Reserve Meds does, and what we do not do

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For a UAE family pursuing Duvyzat, our scope is the regulatory documentation packet, the EDE filing in collaboration with your treating hospital's import pharmacy, the sourcing logistics from 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 from intake forward.

Reserve Meds is not your son's prescriber. We do not practise medicine. We do not manufacture Duvyzat. We are not your insurer. Clinical decisions stay with your paediatric neurologist and the supervising centre; we are the operational layer that turns those decisions into a coordinated case.

We work cash-pay. Our coordination fee is disclosed in writing. We will not start work without a signed engagement.

What to do if you want to start

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 and the workup-completion checklist. If not, we route through to the right paediatric genetics service first.

Most families reach us first on WhatsApp, which is the medium we hold open during UAE business hours 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.

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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