Duvyzat

Saudi Arabia · access guide

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

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

A Saudi 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 Kingdom of Saudi Arabia, 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.

We will be specific about what Duvyzat actually changes in the DMD treatment conversation in 2026, what the workup decides, how the SFDA named-patient pathway works for this drug, what it costs in SAR and US dollars per year for a lifelong twice-daily oral therapy, where supervision can be centred in the kingdom, 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. KFSHRC Riyadh and KAMC Riyadh have run the Saudi DMD reference cohort across all mutation subsets; the mutation-agnostic Duvyzat label opens the targeted-therapy conversation for a broader share of those families than the exon-skip drugs ever could.

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 Saudi 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. 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.

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. KFSHRC molecular genetics in Riyadh has run the Saudi DMD reference cohort and is the natural setting for whole-gene sequencing or MLPA testing if your son has not yet been tested. KAMC Riyadh's rare-disease genetics service runs the same workup. KFSHRC Jeddah covers the western region. The mutation type does not gate Duvyzat eligibility (unlike the exon-skip drugs); confirmation of DMD diagnosis does.

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.

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.

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.

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 consultant documents 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 Saudi regulatory pathway: how it actually works in 2026

The Saudi Food and Drug Authority published its Gene Therapy Products Registration Guidelines in 2023 and has built operational depth in advanced-therapy regulatory review since. The same procedural depth supports named-patient access for non-gene-therapy specialty medicines like Duvyzat. `[VERIFY: SFDA Duvyzat registration status in 2026]`. As of 2026 the named-patient mechanism is the working assumption for Saudi paediatric neurology services seeking Duvyzat access. The application is filed through SFDA's drug.sfda.gov.sa portal by the dispensing hospital's licensed pharmacist on the consultant's behalf, with the clinical rationale letter, genetic report, monitoring baselines, qualified-centre plan, and requested supply quantity attached.

NUPCO sits in the procurement loop for public-sector hospitals. For named-patient cases at NUPCO-contracted public hospitals, NUPCO coordinates the procurement once SFDA approval is in hand. For private-sector cases, the dispensing hospital's pharmacy handles procurement directly through the manufacturer's authorised export channel.

Typical SFDA approval timing on a complete, well-documented file is four to eight weeks. 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 kingdom, the paediatric neurology hubs that can supervise Duvyzat are clustered in the tertiary research hospitals. King Faisal Specialist Hospital and Research Centre, Riyadh, has the deepest demonstrated DMD clinical and research base in the country, with a paediatric neuromuscular service that has authored Saudi DMD management consensus statements. King Abdulaziz Medical City under National Guard Health Affairs has comparable infrastructure and runs an active rare-disease genetics service. King Fahad Medical City paediatric neurology covers complex paediatric neuromuscular cases. KFSHRC Jeddah serves the western region with the same standards. Dr Sulaiman Al-Habib Medical Group's flagship Riyadh facilities can coordinate Duvyzat cases in conjunction with a Saudi consultant who holds privileges there.

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. This is operationally lighter on the family than a weekly infusion routine.

The cost conversation, in the form a Saudi 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 SAR 1.31 to 1.88 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, quarterly monitoring labs and ECGs, MFM and NSAA assessments, rehabilitation programme, background corticosteroid management, and our coordination fee.

When we issue a quote at intake, we separate every line. 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 Saudi Arabia is uneven. Because Duvyzat is unlikely to be on the CCHI list, reimbursement under standard CCHI-regulated plans is not currently expected. Private insurers (Bupa Arabia, Tawuniya, MedGulf, Walaa) handle specialty DMD therapies on case-by-case prior-authorisation basis, with approval uncommon outside flagship-hospital Vision 2030 pilot frameworks. We supply the prior-authorisation documentation packet to your insurer at no charge. We do not process claims directly. Most Saudi DMD specialty-therapy cases to date have proceeded as cash-pay arrangements with partial reimbursement where available.

For Saudi-national families being treated at KFSHRC or KAMC, your consultant will know whether any current MoH or Vision 2030 pilot framework could underwrite the case in full or in part. Worth asking explicitly.

A direct comparison point: Duvyzat at roughly SAR 1.31 to 1.88 million per year sits between the supportive-care-only cost picture and the Amondys 45 weekly IV exon-skip cost picture (SAR 2.6 to 4.5 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

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.

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 consultant 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]`. The Islamic bioethics consensus across the schools 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

If your son has not had genetic confirmation of DMD, the workup begins there. Suspected DMD on clinical and elevated CK grounds alone is not the eligibility standard for Duvyzat.

If your son is younger than 6 years old, Duvyzat is not approved for him at this age. Your consultant 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.

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.

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.

What Reserve Meds does for a Saudi family

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For a Saudi family pursuing Duvyzat, our scope is the regulatory documentation packet, the SFDA named-patient filing in collaboration with your consultant and the dispensing hospital's pharmacist, 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. Clinical decisions stay with your paediatric neurologist and the supervising centre.

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. If not, we route through to the right paediatric genetics service at KFSHRC or KAMC first.

Most families reach us first on WhatsApp, which is the medium we hold open during Saudi 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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