

## Dovato

Saudi Arabia · access guide

# How to access Dovato for HIV-1 from Saudi Arabia: 2026 pathway via the MOH HIV programme and the Saudi infectious-disease network

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

Saudi Arabia delivers HIV care through the Ministry of Health national HIV programme combined with the deepest infectious-disease and molecular-virology capacity in the Gulf at King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah, supported by King Saud Medical City Riyadh, King Abdulaziz Medical City NGHHA, Prince Sultan Military Medical City, and King Khalid University Hospital. NUPCO handles the supply chain for MOH and military facilities. Dovato (dolutegravir / lamivudine) is ViiV Healthcare's once-daily fixed-dose 2-drug single-tablet regimen for adult HIV-1 treatment, approved by FDA in April 2019 and by EMA in July 2019. For a Saudi-resident adult with confirmed HIV-1 infection who is starting antiretroviral therapy for the first time and meets the 2-drug-regimen eligibility criteria (HIV-1 RNA at or below 500,000 copies per millilitre, no INSTI or lamivudine resistance, HBV negative confirmed), or who is virologically suppressed on a current 3-drug regimen and considering a switch to a simplified 2-drug regimen, the operational question is which infectious-disease specialist, which procurement channel for Dovato in 2026, what the eligibility and resistance-testing workup looks like, and how the monitoring schedule and refill cycle fit into a Saudi family's life.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies, where the infectious-disease conversation happens, where the prescription is written and filled, what the realistic out-of-pocket exposure band is, what to monitor on therapy, and how the lifelong-therapy framing fits into the patient's life. It is concierge documentation written for a patient already in conversation with an infectious-disease physician who wants the operational reality laid out plainly. Reserve Meds is not the prescriber. We coordinate the documentation pack and the logistical pathway around the clinical decision your treating infectious-disease physician makes with you.

## Why Dovato, and why now

Dovato is a fixed-dose combination single tablet of dolutegravir 50 mg (a second-generation integrase strand transfer inhibitor, INSTI) and lamivudine 300 mg (a long-established nucleoside reverse transcriptase inhibitor, NRTI). One tablet, once daily, with or without food. No second NRTI. No tenofovir component, no abacavir component.

The clinical positioning of Dovato sits on four points relevant to a Saudi patient choosing among modern antiretroviral regimens:

1. **2-drug complete regimen.** Dovato is one of the first complete-regimen single-tablet 2-drug regimens (2DR-STR) for HIV-1, with a broad initial-therapy indication for treatment-naïve adults meeting eligibility criteria. Traditional standard-of-care HIV regimens use 3 drugs (typically two NRTIs plus a third agent). Dovato removes the second NRTI, simplifying the long-term toxicity surface and the drug-interaction surface. The simplification carries eligibility gates that distinguish a 2-drug-eligible patient from a 3-drug-required patient. For a Saudi patient whose viral load, resistance profile, and HBV status all fall within the eligibility window, the 2-drug approach is an option; outside that window, a 3-drug regimen is appropriate. 2. **No tenofovir, no abacavir.** The absence of tenofovir means no TDF-associated renal proximal-tubule dysfunction or bone mineral density loss signal, and no TAF-associated weight-gain or lipid signal characteristic of TAF combinations. The absence of abacavir means no HLA-B\*5701 hypersensitivity screen requirement. For patients with long-anticipated treatment duration and concern about cumulative tenofovir-related renal or bone effects, the 2-drug regimen profile is clinically attractive. 3. **Dolutegravir resistance barrier.** Dolutegravir has the highest in-vitro barrier to resistance of any INSTI to date. In the GEMINI 1 and GEMINI 2 pivotal initial-therapy trials, no patient in either arm developed treatment-emergent INSTI or NRTI resistance through 144 weeks. The high barrier is the clinical foundation for the 2-drug-regimen approach. 4. **Eligibility-gated, not universal.** Dovato is NOT a universal first-line regimen. The eligibility gates are clinically important and load-bearing: HIV-1 RNA at or below 500,000 copies per millilitre, no INSTI or lamivudine resistance, no HBV co-infection, no concurrent rifampin or strong CYP inducer. For patients outside any of these gates, a 3-drug regimen such as Biktarvy, Symtuza, Delstrigo, or Triumeq is appropriate.

Dovato is one of several modern single-tablet HIV-1 treatment regimens. Other widely used STRs in 2026 are Biktarvy (3-drug INSTI-based, widely preferred as first-line in major international guidelines), Symtuza (3-drug boosted-PI-based), Delstrigo (3-drug NNRTI-based), Triumeq (3-drug for HLA-B\*5701-negative patients), and Juluca (dolutegravir / rilpivirine, the other ViiV 2-drug regimen restricted to switch only after stable suppression). The choice among STRs is made by the treating infectious-disease physician.

Dovato is NOT a pre-exposure prophylaxis (PrEP) regimen. The PrEP regimens approved by FDA are Truvada and Descovy. Dovato is NOT a post-exposure prophylaxis (PEP) regimen. Dovato is exclusively for the treatment of established HIV-1 infection in adults.

## What Dovato is, in plain language

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One tablet a day. Take it at approximately the same time every day. With food or without. Storage at room temperature; no refrigeration. The infectious-disease specialist writes the prescription, the hospital pharmacy fills it through the institutional supply channel, the patient takes Dovato at home, returns for periodic lab monitoring and infectious-disease follow-up, and continues indefinitely on sustained virologic suppression.

Polyvalent cation timing is part of routine patient counselling: take Dovato either 2 hours BEFORE or 6 hours AFTER antacids, calcium supplements (apart from calcium taken with a meal alongside Dovato), iron supplements, or sucralfate. Multivitamin discipline is part of the conversation. During Ramadan, the meal-window compression makes the polyvalent-cation timing rule explicit conversation territory.

Treatment duration is lifelong. Dovato is not a cure. The clinical goal is sustained virologic suppression (HIV-1 RNA less than 50 copies per millilitre), the foundation of treatment-as-prevention (U=U).

## Eligibility at a Saudi infectious-disease clinic

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For Saudi-resident patients, the infectious-disease services apply the FDA, EMA, WHO, and IAS-USA criteria:

1. Confirmed HIV-1 infection. 2. For initial therapy, no prior ART history AND baseline HIV-1 RNA at or below 500,000 copies per millilitre. For regimen switch, virologic suppression on a stable ART regimen for at least six months, no documented resistance to dolutegravir or lamivudine. 3. Baseline genotypic resistance testing. INSTI resistance or 3TC resistance (M184V/I) excludes Dovato. 4. **HBV co-infection screen confirmed negative:** load-bearing pre-initiation gate. Dovato is INADEQUATE for HBV co-treatment; HBV-positive patients need a tenofovir-containing regimen. HCV screen at the same visit. 5. Renal function: CrCl 50 millilitres per minute or above. Alternative regimens for CrCl below 50. Dolutegravir-induced small predictable serum creatinine rise (10 to 15 percent) is benign and expected. 6. Drug interaction screen. Rifampin is CONTRAINDICATED; oxcarbazepine, phenytoin, phenobarbital, carbamazepine, and St John's wort are to be avoided. Dofetilide is contraindicated. Metformin requires close glucose monitoring. 7. Polyvalent cation counselling. 8. PHQ-9 and C-SSRS mental-health screening at baseline and periodic follow-up. Dolutegravir-specific neuropsychiatric AEs (insomnia, anxiety, depression) at 5 to 10 percent are more pronounced than with bicitegravir or raltegravir; structured screening at 4 to 6 weeks worth considering. 9. Pregnancy and lactation review. Dolutegravir-based regimens considered safe in pregnancy per WHO and US DHHS guidelines after the 2018 Tsepamo NTD signal was attenuated by subsequent data. 10. Baseline metabolic workup: CBC, comprehensive metabolic panel, fasting lipid panel, weight, BMI, blood pressure, fasting glucose. Dolutegravir weight-gain signal makes baseline metabolic profiling standard care. 11. U=U education conversation documented.

A Saudi patient should arrive at the infectious-disease consultation with prior HIV testing results, the most recent CD4 and viral load, the complete antiretroviral-treatment history (switch patients), prior genotype, HBV serology where available, current medications including supplements, and Saudi national or iqama identification.

## The Saudi prescribing and dispense picture, plainly

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HIV care in Saudi Arabia routes through Ministry of Health infectious-disease services and the major academic centres, not through community general-practice clinics or community pharmacies. The functional supply chain is:

1. **Prescribing infectious-disease physician:** a board-certified infectious-disease specialist at a Saudi tertiary centre with established HIV-treatment capacity. Primary prescribing centres include King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah infectious disease (deepest molecular-virology capacity in the region), King Saud Medical City Riyadh, King Abdulaziz Medical City NGHHA, Prince Sultan Military Medical City, King Khalid University Hospital, KFSH Dammam, and the Dr Sulaiman Al Habib hospital network. MOH HIV programme coordinates national procurement; NUPCO handles MOH and military supply. 2. **Diagnostic and resistance-testing workup:** HIV-1 RNA quantification, CD4 count, and genotypic resistance testing run at the diagnosing centre's reference laboratory (KFSHRC molecular virology is a regional reference) or sent to a partnered laboratory. HBV serology is part of the same lab panel. 3. **Procurement pathway:** Dovato procurement in Saudi Arabia depends on SFDA registration and on MOH HIV programme formulary status. For Saudi nationals managed through the MOH HIV programme, the procurement channel is institutional and the patient-facing cost is typically zero or nominal. For patients managed through private infectious-disease services, the operational reality depends on whether Dovato is commercially available through local pharmacies or whether named-patient European-import supply applies. 4. **Insurance pre-authorisation:** Saudi private insurers (Bupa Arabia, Tawuniya, MedGulf, AXA Cooperative, and others under the CCHI regulatory framework) typically cover antiretroviral therapy for HIV under the standard pharmacy benefit in most plans. Some employer-sponsored plans exclude HIV-related care; the patient's specific plan needs to be checked. Where named-patient import applies and where insurance coverage is partial or absent, cash-pay supply is the operational pathway. 5. **Refill cycle:** monthly or quarterly thereafter, tied to infectious-disease follow-up visits.

## The 2026 pathway, step by step

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Week 0 to 2: Reserve Meds builds the documentation pack with the patient. Prior testing, prior CD4 and viral load, prior ART history (switch patients), prior genotype, HBV serology, current medications including supplements, Saudi national or iqama identification. We coordinate first-visit booking with the chosen Saudi infectious-disease service.

Week 2 to 4: Infectious-disease first visit. Diagnosis confirmation or review, CD4 and viral load, baseline genotype or review, renal function, HBV / HCV screening, lipid panel, fasting glucose, weight / BMI / BP, mental-health screen (PHQ-9 / C-SSRS), pregnancy review where relevant, drug-interaction screen, polyvalent cation counselling.

Week 4 to 6: Regimen-selection conversation. Where Dovato is the appropriate choice (HBV negative, viral load at or below 500,000 for initial therapy, no INSTI / 3TC resistance, CrCl 50 or above, no contraindicated inducers, weight and metabolic baseline acceptable), prescription is written. MOH HIV programme channel activated for nationals; CCHI commercial pre-authorisation submitted where required.

Week 6 to 8: First dispense. Dovato started one tablet once daily. Mental-health screening repeated at 4 to 6 weeks for the dolutegravir-specific neuropsychiatric window.

Week 12: First on-treatment viral load.

Week 24: Confirmation of virologic suppression. CD4, renal function, lipid panel, weight / BP / fasting glucose.

Ongoing: One tablet once daily, monthly or quarterly pharmacy refill, infectious-disease follow-up every 3 to 6 months in stable suppression. Quarterly viral load in the first year, then every 6 months. Annual fasting lipid panel and metabolic surveillance, annual renal function, periodic CD4. Annual mental-health re-screen minimum.

## Cost expectation in SAR

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US WAC list price for Dovato in 2026 is approximately USD 2,950 to USD 3,250 per 30-day supply, with annual list-price cost approximately USD 36,000 to USD 40,000 per patient.

For Saudi patients managed through the MOH HIV programme, end-user cost to nationals is typically zero or nominal.

For patients on the named-patient European-import pathway, the indicative cash-pay band is USD 24,000 to USD 32,000 per year. At indicative 2026 cross rates, the annual cost at USD 28,000 is approximately SAR 105,000.

For commercial covers under the CCHI regulatory framework, ART coverage is the norm in most plans. Out-of-pocket exposure for a covered patient is generally a co-payment band in the SAR 50 to 500 per month range, not the full list price.

## Monitoring on therapy

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- **HIV-1 RNA viral load:** baseline, 2 to 4 weeks, 12 weeks, 24 weeks, then every 3 to 6 months in stable suppression. Above-200 copy result triggers adherence, polyvalent-cation timing review, resistance review, regimen-revisit conversation. - **CD4 count:** baseline and at 3 to 6 month intervals in the first one to two years; less frequently in sustained suppression. - **Renal function:** serum creatinine, calculated CrCl at baseline, 3 to 6 months in first year, then annually. Expected dolutegravir-induced creatinine rise (10 to 15 percent) is benign. - **Liver function tests:** baseline and periodically; more frequent in the first three months. - **Fasting lipid panel:** baseline and at 3 to 6 month intervals in the first year, then annually. - **Weight, blood pressure, fasting glucose:** baseline and at 3 to 6 month intervals in first year. INSTI weight-gain signal makes structured surveillance standard. Dietary and physical-activity counselling at baseline. - **Mental health:** PHQ-9 and C-SSRS baseline, 4 to 6 weeks (dolutegravir-specific window), 3 months, at least annually. - **Adherence:** self-report, refill history, viral load suppression as three operational anchors. - **Drug-interaction re-screen:** each follow-up and any new medication or supplement. Polyvalent cation timing rules apply continuously.

## Religious, ethical, and family-logistics framing

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Dovato is a small-molecule oral tablet. The ViiV Dovato formulation does not list animal-derived gelatin in the tablet coating; patients with specific halal-certification requirements may ask the dispensing pharmacy to confirm excipient sourcing for the current lot.

The lifelong-therapy framing is compatible with classical Islamic jurisprudence on the use of medicine to preserve life. Ramadan dosing: suhoor or iftar timing per the treating physician, with explicit polyvalent-cation timing conversation given the compressed meal window.

For pregnancy planning, dolutegravir-based regimens are now considered safe in pregnancy per WHO and US DHHS guidelines. The 2018 NTD signal was attenuated by subsequent data through 2020 and beyond. Vertical-transmission prevention with maternal ART and infant prophylaxis is the standard-of-care framework.

## **Stigma, dignity, disclosure, and the residency conversation**

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HIV is a chronic, manageable, transmissible viral infection. People living with HIV on effective ART have life expectancy approaching the general population. Treatment is personal health, public health, and partner protection.

The U=U principle (undetectable equals untransmittable) is endorsed by WHO, IAS-USA, BHIVA, and US DHHS treatment guidelines.

Disclosure to partners, family, or employers is a personal decision with medical, social, and legal dimensions. Reserve Meds does not give disclosure advice. The recommended pathway is the conversation with the treating infectious-disease physician and, where indicated, with a social worker, counsellor, or local lawyer. The medical record is confidential within the treating institution.

Residency and employment considerations are real and vary by patient circumstance. Saudi Arabia operates visa medical-screening protocols at visa issuance and renewal that have historically included HIV testing in most cases. Reserve Meds does not provide legal advice. The recommended language for the patient conversation is: consult your treating infectious-disease physician about the social, employment, and residency considerations specific to your situation. Where indicated, the treating institution can refer to local legal counsel.

The clinical relevance of HIV is the same regardless of how the patient was infected. The Reserve Meds page set does not assume any particular sexual orientation, transmission route, or behavioural context.

## **When Dovato is not the right call**

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- PrEP. Use Truvada or Descovy in a PrEP-specific pathway. - PEP after potential HIV exposure within the last 72 hours. Use a PEP-specific triple-drug regimen. - Treatment-naïve patients with HIV-1 RNA above 500,000 copies per millilitre. Use a 3-drug regimen. - HBV co-infection. Use a tenofovir-containing regimen (Biktarvy, Symtuza, Delstrigo, Genvoya). - Documented INSTI resistance or 3TC resistance (M184V/I). - CrCl below 50 millilitres per minute. - Concurrent rifampin (contraindicated) or rifabutin without regimen adjustment, strong anticonvulsants, St John's wort, dofetilide. - Significant hepatic impairment (Child-Pugh C); data are limited. - HIV-2 or dual HIV-1 / HIV-2 infection. - Paediatric patients.

Alternatives in 2026: Biktarvy, Symtuza, Delstrigo, Triumeq, Juluca, Genvoya, Cabenuva. The choice belongs to the treating infectious-disease physician.

Reserve Meds does not push a default. If the conversation with the treating physician points toward a 3-drug regimen, the operational pathway shifts accordingly.

## What Reserve Meds does on this case

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We are a US-based concierge coordinator. We are not the prescriber, not the dispensing pharmacy, and not a legal or immigration adviser. On a Saudi Dovato case we build the documentation pack (prior HIV testing, prior CD4 and viral load, prior ART history for switch patients, prior genotype, HBV serology, current medications and supplements, Saudi national or iqama identification), submit first-visit booking requests to the chosen Saudi infectious-disease service, coordinate the MOH HIV programme channel activation or CCHI commercial pre-authorisation as applicable, set up the first 30-day dispense through the appropriate procurement channel, organise the baseline-plus-week-12-plus-week-24 monitoring schedule, and stay with the case through the first year of dosing with handoff to the local infectious-disease specialist for ongoing surveillance. Clinical decisions remain with your treating infectious-disease physician. Disclosure, residency, and employment considerations are conversations with your treating physician and, where indicated, with a local lawyer.

### *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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