Grafapex

Saudi Arabia · access guide

Grafapex access in Saudi Arabia: the SFDA named-patient pathway

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

Quick orientation

Grafapex (treosulfan) is alkylating agent (busulfan-like; structural dihydroxybutane derivative) approved by the US FDA in January 2025 for in combination with fludarabine, as conditioning prior to allogeneic haematopoietic stem cell transplantation (HSCT) in adult and paediatric patients 1 year of age and older with acute myeloid leukaemia or myelodysplastic syndromes. The drug is manufactured by medac and Stemline Therapeutics (US). Saudi Arabia patients use the Saudi Food and Drug Authority named-patient pathway when the locally registered indication, the stocked presentation, or the available payer coverage does not match what the prescribing physician has written. Reserve Meds coordinates the US-side sourcing through a DSCSA-compliant specialty channel, builds the documentation packet your physician needs to file, and orchestrates the logistics into Saudi Arabia with a single named coordinator carrying the case end-to-end.

Why Saudi patients need Grafapex through the named-patient pathway

Saudi Arabia operates a developed pharmaceutical regulatory environment, and Grafapex may be on the local register, may be in commercial review, or may be entirely absent depending on the stage of medac and Stemline Therapeutics (US)'s regional rollout. Several patterns drive cross-border requests. First, indication lag: newer indications, particularly the January 2025 FDA approval timeline, often reach local registration 12 to 36 months later. Second, biomarker-defined eligibility: no specific companion diagnostic; AML or MDS diagnosis with established transplant eligibility can be the diagnostic gate, and where the relevant testing infrastructure is still maturing locally, families coordinate the workup before or in parallel with sourcing. Third, payer coverage: Bupa Arabia, Tawuniya, MEDGULF, GIG Saudi, Walaa, and the Council of Health Insurance (CHI) framework each assess specialty therapies case by case, and step-therapy criteria can fail even where the drug is registered. Fourth, stocking gaps: the local agent may not carry every presentation or dose strength reliably, and named-patient import is the operational mechanism that bridges to the exact label the prescriber has written. In each pattern, the named-patient pathway is the legal mechanism that connects a Saudi-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The SFDA named-patient pathway for Grafapex

The Saudi Food and Drug Authority (SFDA) administers the Special Access Programme under Article 5 of the Drug Law, accepting personal-use and named-patient import requests through its sfda.gov.sa portal and the SFDA Ghad digital platform. Applications are filed by the prescribing physician or by a licensed pharmaceutical establishment holding the patient's authorisation. The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and either a clinically equivalent locally registered alternative is not suitable, or the patient's clinical profile does not match the locally approved label.

A complete application for Grafapex typically includes a clinical justification letter from the treating physician documenting the patient's diagnosis (conditioning prior to allogeneic haematopoietic stem cell transplantation), severity assessment, prior systemic therapy history, any relevant biomarker results (no specific companion diagnostic; AML or MDS diagnosis with established transplant eligibility), and a clinical rationale for selecting Grafapex over locally available alternatives. The Saudi physician's licensure with the Saudi Commission for Health Specialties (SCFHS) is verified through the application. The packet also specifies the dispensing facility name and license number, the pharmacy in charge of the facility, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity, intended treatment duration), and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Grafapex specifically, the clinical justification typically frames the case around Grafapex offers reduced extra-haematological toxicity versus busulfan in older or comorbid AML/MDS patients; named-patient routing addresses transplant centres where the local register has busulfan but not treosulfan. Approval timelines are typically 7 to 21 business days for routine cases, with sovereign-tied pathways (Royal Court Medical Care, Ministry of Health Higher Committee for Treatment Abroad) running in parallel where the patient qualifies. The SFDA retains discretion on timing, and we do not promise specific durations.

Where Grafapex gets dispensed in Saudi Arabia

A focused group of Saudi Arabia institutions handle named-patient specialty-medicine imports as established workflow, with in-house import pharmacy capabilities and physicians experienced with the application set. For Grafapex specifically, the dispensing facility must accommodate the administration profile: tertiary haematopoietic stem cell transplant centre; single conditioning course as part of an inpatient allogeneic HSCT admission; not a chronic outpatient therapy. Tertiary centres that meet this profile include King Faisal Specialist Hospital and Research Centre (Riyadh and Jeddah campuses), King Abdulaziz Medical City under the Ministry of National Guard Health Affairs (NGHA), Prince Sultan Military Medical City, King Fahad Medical City in Riyadh, King Abdulaziz University Hospital in Jeddah, Dr. Sulaiman Al Habib Medical Group, and Saudi German Hospitals.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment that holds the import licence and files the SFDA application on the prescribing physician's behalf. The medicine then moves under chain-of-custody documentation into the prescribing hospital's outpatient pharmacy for administration.

Real cost picture for Grafapex in Saudi Arabia

US WAC for Grafapex is approximately USD 3,100 per 1 g vial, which translates to an annual WAC in the range of USD 30,000 to USD 50,000 for a single conditioning course (one-time use, not chronic) for the standard regimen at the labelled dose. The Saudi riyal is pegged to the US dollar at approximately 3.75 SAR to 1 USD. On that basis, the drug cost alone is materially significant before logistics, the SFDA permit fees (which are nominal relative to drug cost), the destination dispensing hospital's administration fees, and Reserve Meds' concierge fee (which is itemised separately on every firm quote).

International cold-chain or ambient logistics into Saudi Arabia typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Bupa Arabia, Tawuniya, MEDGULF, GIG Saudi, Walaa, and the Council of Health Insurance (CHI) framework each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation with documented step-therapy failure. We do not promise coverage from any payer. US manufacturer patient assistance programmes do not extend internationally; cross-border patients pay cash or rely on local payer coverage where available.

Clinical evidence and where Grafapex sits in the treatment landscape

The MC-FludT.14/L pivotal trial demonstrated non-inferiority of treosulfan-fludarabine versus reduced-intensity busulfan-fludarabine conditioning in older or comorbid AML/MDS patients. The drug acts as alkylating agent (busulfan-like; structural dihydroxybutane derivative), and the dosing schedule is 10 g/m2 intravenous on conditioning days -4, -3, and -2 in combination with fludarabine 30 mg/m2 on days -6 through -2, followed by allogeneic HSCT on day 0.

Within the treatment landscape, Grafapex sits alongside busulfan (Busulfex) intravenous conditioning, fludarabine-melphalan, total body irradiation conditioning, and the various intensity and disease-specific conditioning protocols used in BMT centres globally. The choice between targeted therapies in this space depends on the patient's full clinical profile, prior therapy exposure, biomarker status, comorbidities, and the prescriber's judgment. Reserve Meds coordinates whichever therapy the physician has selected; we do not steer prescribing.

Safety surveillance for Grafapex centres on myelosuppression with neutropenia and thrombocytopenia (expected and protocol-managed), mucositis, hepatic enzyme elevations, alopecia, and the standard conditioning-regimen-related toxicities. The dispensing facility and the prescribing physician retain clinical responsibility for monitoring and adverse-event management; Reserve Meds does not provide medical care.

Typical timeline for Grafapex in Saudi Arabia

SFDA routine processing is typically 7 to 21 business days for routine cases, with sovereign-tied pathways (Royal Court Medical Care, Ministry of Health Higher Committee for Treatment Abroad) running in parallel where the patient qualifies from a complete filing. End-to-end, most cases complete within 4 to 8 weeks from first complete documentation, with first-of-kind cases and complex biomarker-dependent workups potentially extending further. Where the administration setting is tertiary haematopoietic stem cell transplant centre, hospital scheduling and infusion-chair availability are additional sequencing factors that families plan around. We do not promise specific durations; the SFDA retains discretion on timing, and shipping windows depend on lane and packaging.

What your Saudi physician needs to provide

For a Saudi-licensed specialist prescribing Grafapex through the SFDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (conditioning prior to allogeneic haematopoietic stem cell transplantation), the relevant biomarker work (no specific companion diagnostic; AML or MDS diagnosis with established transplant eligibility), prior systemic therapy history, the FDA-approved indication being invoked, and the clinical rationale for Grafapex as the appropriate next step.

The letter also specifies the exact dosing plan per the FDA-approved label: 10 g/m2 intravenous on conditioning days -4, -3, and -2 in combination with fludarabine 30 mg/m2 on days -6 through -2, followed by allogeneic HSCT on day 0. The monitoring plan references myelosuppression with neutropenia and thrombocytopenia (expected and protocol-managed), mucositis, hepatic enzyme elevations, alopecia, and the standard conditioning-regimen-related toxicities. The treating physician's licence number with the Saudi Commission for Health Specialties (SCFHS), the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Where biomarker testing requires reference-lab coordination, the physician documents the assay used and the report; Reserve Meds can route this through a US-side reference laboratory where the regional pathway is unavailable.

Common questions about Grafapex in Saudi Arabia

Will Bupa Arabia or other major Saudi insurers cover Grafapex? Each insurer assesses named-patient imports case by case. Some reimburse fully when Grafapex is on their formulary even if not currently stocked; others assess based on step-therapy criteria and biomarker documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you, your physician, or your hospital. We do not promise coverage from any payer.

Is Grafapex registered locally in Saudi Arabia? Local registration status changes as medac and Stemline Therapeutics (US) pursues regional rollout; even where the drug is registered, the specific indication, presentation, or dosing strength your prescriber has written may not align with what is currently stocked. The SFDA named-patient pathway exists precisely to bridge these gaps for individually identified patients.

What about competitor therapies? The treatment landscape includes busulfan (Busulfex) intravenous conditioning, fludarabine-melphalan, total body irradiation conditioning, and the various intensity and disease-specific conditioning protocols used in BMT centres globally. The choice depends on the patient's full clinical profile and prescriber judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not steer prescribing decisions and we do not have a financial relationship with any specific manufacturer.

How is the cold chain or storage managed? Grafapex ships in validated packaging with continuous temperature logging through the lane where cold-chain handling applies. The handoff ends at the dispensing pharmacy; home storage instructions, where the patient takes the medicine home for self-administration, are part of the patient onboarding kit.

Do US manufacturer patient assistance programmes (such as medac and Stemline Therapeutics (US) co-pay or PAP programmes) extend to Saudi Arabia patients? No. US-resident patient assistance programmes are limited to US-resident patients with US prescription coverage by programme design. Cross-border patients pay cash for the drug and the coordination fee, with local payer reimbursement assessed separately.

Can the case be resupplied year over year if the patient responds? Yes. Reserve Meds maintains the case file and re-files SFDA permits at the relevant intervals (or coordinates with the dispensing hospital's pharmacy if they hold the permit). Patients on long-term therapy typically settle into a quarterly or biannual resupply cadence after the first cycle.

What is the administration setting? Tertiary haematopoietic stem cell transplant centre; single conditioning course as part of an inpatient allogeneic hsct admission; not a chronic outpatient therapy.

My physician is at a smaller hospital without an internal import pharmacy. Can the case still proceed? Yes. The common pattern is to route through a Dubai, Riyadh, Mumbai, Cairo, Karachi, or other regional licensed pharmaceutical establishment that holds the import licence and files the SFDA application on the prescribing physician's behalf. The medicine moves into the prescribing hospital's outpatient pharmacy under chain-of-custody documentation.

Where Reserve Meds fits in Grafapex cases

Reserve Meds is a US-based concierge coordinator. We do not replace your Saudi specialist, we do not replace the SFDA, and we do not replace your dispensing pharmacy. For Grafapex specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate logistics into Saudi Arabia, and assign a single named coordinator through the case. The pharmacist-of-record review, prescription validation, biomarker confirmation, and physician sign-off are the recurring operational fundamentals for this drug.

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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reserved for you.

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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