

Defitelio

Kuwait · access guide

How to access Defitelio for severe veno-occlusive disease after stem-cell transplant from Kuwait: 2026 pathway via KFSHRC Riyadh referral and limited Kuwait adult HSCT capability

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

Kuwait's haematology infrastructure spans the Kuwait Cancer Control Centre (KCCC), Sheikh Jaber Al-Ahmad Al-Sabah Hospital, and Mubarak Al-Kabeer Hospital for adult haematology, with limited adult bone marrow transplant capability for selected cases. NBK Children's Hospital handles paediatric haematology and oncology with no full paediatric HSCT programme. Complex adult and paediatric Kuwaiti HSCT cases routinely route to KFSHRC Riyadh, Sidra Medicine Doha for paediatrics, or King Hussein Cancer Center Amman. Defitelio (defibrotide sodium) is the only FDA-approved therapy for severe hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction post-HSCT, and the Kuwait MoH Drug and Food Control Administration (DFC) has not registered Defitelio on the standard formulary as of 2026. For a Kuwaiti patient who develops severe post-HSCT VOD, the operational reality is that the patient is most commonly already at the referral HSCT centre (KFSHRC Riyadh, Sidra Doha, or KHCC Amman) where the transplant was performed, and Defitelio is administered in that inpatient setting.

This page explains how the pathway works in 2026 for a Kuwaiti adult or paediatric patient who is in a post-HSCT severe-VOD episode at the referral HSCT centre: when Defitelio is indicated, who confirms the diagnosis, and what the family and Reserve Meds operational support looks like during the 21 to 60 day inpatient course and the subsequent repatriation to Kuwait.

Why Defitelio, and when

Defitelio is defibrotide sodium, a purified mixture of single-stranded oligodeoxyribonucleotides from porcine intestinal mucosa. FDA-approved March 2016 for adult and paediatric patients aged 1 month and older with hepatic VOD with renal or pulmonary dysfunction post-HSCT. Severe post-HSCT VOD has day-100 mortality approaching 75 percent without Defitelio; pivotal data show day-100 survival of 38.2 percent on Defitelio versus 25.0 percent on historical control.

For a Kuwaiti patient the Defitelio decision is made by the referral-centre transplant haematologist at the bedside (KFSHRC Riyadh for adult, Sidra Doha for paediatric, KHCC Amman for either depending on the original referral pathway). The Reserve Meds role is the cross-border family logistics, the financial pre-authorisation work with the Kuwaiti payer, and the eventual repatriation logistics.

What Defitelio is, in plain language

Defibrotide is endothelium-targeted. It increases tissue plasminogen activator in the hepatic sinusoidal endothelium and reduces endothelial activation. It does not measurably prolong PT, aPTT, or INR at therapeutic doses, which is the operational distinction from systemic anticoagulants (all contraindicated in severe post-HSCT VOD).

The drug is given as 6.25 mg/kg IV every 6 hours over 2 hours each, for a minimum of 21 days and a maximum of 60 days. Given through a central line, in a transplant unit or ICU setting.

Eligibility for Defitelio at the referral HSCT centre

Standard FDA-aligned eligibility, applied at the referral-centre bedside:

1. Prior HSCT within the prior 21 days. 2. VOD per Baltimore or Modified Seattle criteria. 3. Severe VOD: renal or pulmonary dysfunction. 4. Age 1 month or older. 5. No active uncontrolled bleeding. 6. No concurrent systemic anticoagulant or fibrinolytic that cannot be held. 7. Adequate central venous access.

The diagnosis is made at the referral-centre bedside by the transplant team. The Kuwaiti patient or family is not making this eligibility determination.

The Kuwait prescribing and supply picture, plainly

The Kuwait MoH Drug and Food Control Administration (DFC) governs the regulatory pathway. Defitelio is not on the DFC-registered formulary as of 2026, and Kuwait does not have a full HSCT programme that would require in-country Defitelio stocking. The operational pathway routes Kuwaiti HSCT cases out of country.

The Kuwait haematology centres that handle adult workup, pre-transplant referral coordination, and post-transplant outpatient care:

- **Kuwait Cancer Control Centre (KCCC)**: the principal adult haematology and oncology centre; coordinates HSCT referral to KFSHRC Riyadh or KHCC Amman. - **Sheikh Jaber Al-Ahmad Al-Sabah Hospital**: adult haematology with limited adult BMT capability for selected cases; complex severe-VOD cases referred to KFSHRC Riyadh. - **Mubarak Al-Kabeer Hospital**: adult haematology referral capability. - **Amiri Hospital, Al-Sabah Hospital**: adult haematology and ICU capability supporting pre-transplant and post-transplant care. - **NBK Children's Hospital**: paediatric haematology and oncology; complex paediatric HSCT cases referred to KFSHRC Riyadh or Sidra Medicine Doha.

For Kuwaiti patients requiring HSCT, the standard pathway is referral to KFSHRC Riyadh for adult or paediatric, Sidra Medicine Doha for paediatric, or KHCC Amman. Any severe post-HSCT VOD that develops is managed at the referral centre where Defitelio is stocked. Cross-border repatriation to Kuwait happens only after the acute VOD episode resolves and the patient is stable for outpatient follow-up.

Insurance pathways: Kuwait MoH public funding covers nationals for cross-border referral with pre-authorisation; commercial cover for expatriates is case-by-case. Cross-border referral pre-authorisation is coordinated by the Kuwaiti referring haematologist with Reserve Meds concierge support.

Cost band

US list price approximately USD 825 per 200 mg vial; 21-day adult drug-only course approximately USD 156,000 (approximately KWD 48,000 at indicative 2026 cross rates). Full cost of care for a severe-VOD episode including the inpatient transplant unit at the referral centre commonly USD 350,000 to USD 1.2M (approximately KWD 110,000 to KWD 370,000). Kuwaiti national patients on cross-border referral typically have MoH coverage; private-sector and expatriate cover varies.

What to expect on the Defitelio pathway

Day 0 (HSCT day 8 to day 21 at the referral centre): clinical deterioration; severe VOD diagnosis confirmed by the referral-centre transplant team. Systemic anticoagulants and fibrinolytics held. Defitelio drawn from referral-centre HSCT pharmacy stock.

Day 0 to day 21: minimum course of 6.25 mg/kg IV q6h over 2 hours each. Daily inpatient monitoring at the referral centre; transfusion support; renal replacement therapy and mechanical ventilation if indicated.

Day 21 onwards: continue up to 60-day maximum if VOD has not resolved. Repatriation to Kuwait only after the acute episode resolves and the patient is stable for outpatient follow-up.

When Defitelio is the wrong drug

For a Kuwaiti patient at the referral centre who does not meet severe-VOD criteria, who has active uncontrolled bleeding, who has a porcine-product hypersensitivity, or who is on a systemic anticoagulant that cannot be held, the operational alternative is supportive care alone. The porcine-derived sourcing is a documented religious-ethical consideration; the published Islamic jurisprudence consensus for porcine-derived medicines used in life-threatening conditions follows the principle of dharura.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Kuwaiti Defitelio case the patient is at the referral HSCT centre (KFSHRC Riyadh, Sidra Doha, or KHCC Amman) in the inpatient setting; we coordinate cross-border family logistics, run financial pre-authorisation alongside clinical pre-authorisation with the Kuwait MoH or commercial payer, support the family through the inpatient experience, and stay with the case through the 21 to 60 day Defitelio course, the broader HSCT recovery, and the eventual repatriation to Kuwait. Clinical decisions remain with the treating transplant haematologist and the referral-centre HSCT care team.

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.

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