

Defitelio

Bahrain · access guide

How to access Defitelio for severe veno-occlusive disease after stem-cell transplant from Bahrain: 2026 pathway via KFSHRC Riyadh referral

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

Bahrain's haematology infrastructure does not include a full haematopoietic stem-cell transplant (HSCT) programme. Salmaniya Medical Complex runs general adult haematology with very limited transplant capability; King Hamad University Hospital, BDF Hospital, and Bahrain Specialist Hospital handle adult haematology referrals. Bahraini patients requiring HSCT (and therefore at potential risk for post-HSCT severe veno-occlusive disease (VOD)) are routinely referred to KFSHRC Riyadh for transplant, and any severe post-HSCT VOD that develops in a Bahraini patient is managed at KFSHRC in the inpatient setting where the transplant was performed. Defitelio (defibrotide sodium) is the only FDA-approved therapy for severe hepatic VOD with renal or pulmonary dysfunction post-HSCT, and it is stocked in the KFSHRC Riyadh HSCT pharmacy formulary. For a Bahraini patient who develops severe post-HSCT VOD, the operational question is not Defitelio acquisition in Bahrain (the drug is not registered with NHRA and no full Bahraini HSCT centre exists); it is family logistics coordination at KFSHRC Riyadh and financial pre-authorisation for what is already a cross-border inpatient episode.

This page explains how the pathway works in 2026 for a Bahraini patient who has been transplanted at KFSHRC Riyadh and is now in a severe-VOD episode requiring Defitelio: when Defitelio is indicated, who confirms the diagnosis (the KFSHRC transplant team), and what the family and Reserve Meds operational support looks like for the 21 to 60 day inpatient course.

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 in historical control data without Defitelio; the pivotal Phase 3 trial reported day-100 survival of 38.2 percent on Defitelio versus 25.0 percent on historical control.

For a Bahraini patient, this conversation almost always happens at KFSHRC Riyadh rather than in Bahrain, because Bahrain does not have a full HSCT programme and complex transplant cases route through KFSHRC. The Defitelio decision is made by the KFSHRC transplant haematologist at the bedside. The Reserve Meds role is the cross-border family logistics and the financial pre-authorisation work.

What Defitelio is, in plain language

Defibrotide is endothelium-targeted. It increases tissue plasminogen activator in the hepatic sinusoidal endothelium and reduces endothelial activation that drives post-HSCT VOD. It does not measurably prolong PT, aPTT, or INR at therapeutic doses, which is the operational distinction from heparin, warfarin, and direct oral 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 KFSHRC Riyadh (the relevant centre for Bahraini patients)

Standard FDA-aligned eligibility, applied at the KFSHRC bedside:

1. Prior HSCT within the prior 21 days. 2. VOD per Baltimore or Modified Seattle criteria: bilirubin 2 mg/dL or greater plus two or more of hepatomegaly, ascites, weight gain greater than 5 percent. 3. Severe VOD: renal or pulmonary dysfunction attributable to VOD. 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 KFSHRC bedside by the transplant team. The Bahraini patient or family is not making this eligibility determination.

The Bahrain prescribing and supply picture, plainly

Bahrain's National Health Regulatory Authority (NHRA) governs the regulatory pathway. Defitelio is not on the NHRA-registered formulary as of 2026, and Bahrain does not have a full HSCT programme that would require in-country Defitelio stocking. The operational reality is that Bahraini severe-VOD cases are managed at KFSHRC Riyadh where Defitelio is stocked.

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

- **Salmaniya Medical Complex**: general adult haematology; very limited transplant capability; not equipped for severe post-HSCT VOD management. - **King Hamad University Hospital**: adult haematology referral capability; pre-transplant workup pathway coordination. - **BDF Hospital**: adult haematology and ICU capability; military and family workup pathway. - **Bahrain Specialist Hospital**: adult haematology referral capability.

For Bahraini patients requiring HSCT, the standard pathway is referral to KFSHRC Riyadh (adult or paediatric) for transplant. Any severe post-HSCT VOD that develops is managed in the KFSHRC inpatient setting. Cross-border repatriation back to Bahrain happens only after the acute VOD episode has resolved and the patient is stable for outpatient post-transplant follow-up.

Insurance pathways: Ministry of Health public funding for Bahraini nationals; commercial cover for expatriates is case-by-case. Cross-border referral to KFSHRC requires pre-authorisation through the relevant Bahraini insurance pathway, coordinated by the Bahraini referring haematologist alongside the 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 BHD 59,000 at indicative 2026 cross rates). Full cost of care for a severe-VOD episode including the inpatient transplant unit at KFSHRC commonly USD 350,000 to USD 1.2M (approximately BHD 135,000 to BHD 455,000). Bahraini patients on referral pathway through the Ministry of Health typically have cross-border coverage; private-sector and expatriate cover varies.

What to expect on the Defitelio pathway

Day 0 (HSCT day 8 to day 21 at KFSHRC): clinical deterioration; severe VOD diagnosis confirmed by the KFSHRC transplant team. Systemic anticoagulants and fibrinolytics held. Defitelio drawn from KFSHRC 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 KFSHRC; transfusion support; renal replacement therapy and mechanical ventilation if indicated.

Day 21 onwards: continue up to 60-day maximum if VOD has not resolved. Transition to standard post-HSCT supportive care once VOD resolves. Repatriation to Bahrain only after the acute episode resolves and the patient is stable for outpatient follow-up.

When Defitelio is the wrong drug

For a Bahraini patient at KFSHRC 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 Bahraini Defitelio case the patient is at KFSHRC Riyadh in the inpatient HSCT setting; we coordinate cross-border family logistics, run financial pre-authorisation alongside clinical pre-authorisation, support the family through the KFSHRC inpatient experience, and stay with the case through the 21 to 60 day Defitelio course, the broader HSCT recovery, and the eventual repatriation to Bahrain for outpatient follow-up. Clinical decisions remain with the KFSHRC treating transplant haematologist and the HSCT centre 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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