Besremi

Saudi Arabia · access guide

How to access Besremi for polycythemia vera from Saudi Arabia: 2026 pathway via Saudi haematology and pharmacy supply

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

Saudi Arabia runs one of the deepest adult haematology service networks in the wider region. King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah operate a comprehensive adult haematology department with a dedicated myeloproliferative neoplasm (MPN) programme; King Abdulaziz Medical City (KAMC) Riyadh and Jeddah under National Guard Health Affairs, King Fahd Specialist Hospital Dammam, King Khalid University Hospital Riyadh, the Dr Sulaiman Al-Habib Medical Group (HMG) tertiary network, and the major private tertiaries (International Medical Center Jeddah, Saudi German Hospital network) all run adult haematology services that handle polycythemia vera (PV) from diagnosis through long-term cytoreductive therapy. Besremi (ropeginterferon alfa-2b-njft) was approved by the FDA in November 2021 as the first interferon explicitly approved for PV, regardless of treatment history, and the first novel PV therapy in over fourteen years. The EMA approved Besremi in February 2019 under a slightly older label. For a Saudi-resident adult with confirmed JAK2 V617F-positive polycythemia vera, the operational question is no longer whether long-acting interferon therapy is reachable: it is whether Besremi is the right cytoreductive choice over hydroxyurea or ruxolitinib, whether the patient is 1L or switching, how the prescription is dispensed under cold chain, what CCHI or commercial insurance will and will not underwrite, and how the patient handles the every-2-week self-injection routine that later spaces to every 4 weeks.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies, where the prescribing haematologist conversation happens, how Besremi is dispensed and stored, what the dosing and titration schedule looks like, what the realistic out-of-pocket exposure band is in SAR, what to monitor (depression and suicidality, liver function, and thyroid function being the headline signals), and how the long-term multi-year treatment course fits into a Saudi patient's life.

Why Besremi, and why now

Besremi is ropeginterferon alfa-2b-njft, a monopegylated proline-substituted recombinant interferon alfa-2b conjugated to a single 40 kDa methoxy-polyethylene glycol moiety. It binds to type I interferon receptors on haematopoietic cells, triggering JAK/STAT-coupled intracellular signalling. The clinical effect in polycythemia vera is to suppress the abnormal JAK2 V617F-mutated clone (the dominant driver clone in over 95% of PV cases), reduce erythrocyte and platelet production, and bring blood counts to target ranges. With sustained therapy, Besremi can drive measurable reduction in JAK2 V617F allele burden. Hydroxyurea and ruxolitinib control blood counts but do not produce molecular response. The molecular-response question is the differentiating clinical claim for Besremi.

The FDA approved Besremi in November 2021; the EMA in February 2019 under a slightly narrower label. The pivotal evidence comes from PROUD-PV and its long-term extension CONTINUATION-PV: at 36 months, Besremi was superior to hydroxyurea for complete haematologic response with normal spleen size (53% versus 38%), and the molecular response advantage continues to deepen at 5-plus years.

For a Saudi patient newly diagnosed with PV, or one who has been on hydroxyurea for years and is now asking about the molecular-response question, or one who has had inadequate haematologic control or intolerance on hydroxyurea, Besremi is the operational pathway to a long-acting interferon with a clean MPN-specific indication. Reserve Meds does not promote one PV cytoreductive over another.

What Besremi is, in plain language

Besremi is a subcutaneous injection. There is no infusion centre, no inpatient stay, no specialty-centre referral after the training session. The patient self-injects at home using a prefilled syringe.

Starting dose: 100 mcg subcutaneous every 2 weeks. The treating haematologist titrates the dose upward by 50 mcg every 2 weeks based on the CBC trend: target haematocrit below 45%, platelet count below 400,000/microL, white cell count below 10,000/microL. The maximum dose is 500 mcg every 2 weeks. Most patients reach their effective dose within 3 to 6 months.

After sustained haematologic response, typically achieved by 6 to 12 months, the haematologist transitions the patient to maintenance dosing at the same dose, every 4 weeks. Maintenance dosing continues indefinitely so long as the patient tolerates therapy and haematologic control persists.

Injection sites are the thigh, the abdomen, or the outer upper arm; sites are rotated between doses. Acetaminophen pre-medication 30 to 60 minutes before injection plus bedtime dosing reduces the flu-like symptoms typical in the early weeks.

This is not a short course. Besremi is taken for as long as it controls the disease and the patient tolerates therapy. The treatment course is measured in years, often a decade or more.

Eligibility at a Saudi haematologist's clinic

For Saudi-resident patients, adult haematology services apply the WHO 2016 or 2022 PV diagnostic criteria with local insurance and CCHI adaptation:

1. Confirmed diagnosis of polycythemia vera by a haematologist applying WHO 2016 or 2022 criteria: persistent erythrocytosis, JAK2 V617F mutation (or rarely JAK2 exon 12 mutation), suppressed serum erythropoietin, and characteristic bone marrow morphology where biopsy is obtained. 2. Treatment-history documentation. 1L for newly diagnosed PV, or switch from hydroxyurea, anagrelide, ruxolitinib, or peginterferon alfa-2a, with documented reason for switch. 3. Baseline CBC with differential, reticulocyte count, and serum ferritin. 4. Baseline comprehensive metabolic panel including liver function tests. Severe hepatic impairment is a contraindication; mild-moderate hepatic impairment may require dose adjustment. 5. Baseline thyroid function (TSH, free T4). Interferon-class therapy can trigger or unmask autoimmune thyroid disease. 6. Baseline depression and suicidality screen using PHQ-9 or equivalent. Interferon-class therapy carries a class-wide warning for depression and suicidality. Active untreated major depression, recent suicide attempt, or severe unstable psychiatric history makes the patient an inappropriate candidate. 7. Pregnancy testing for women of childbearing potential. Besremi is contraindicated in pregnancy. Effective contraception for both partners during therapy and washout. 8. Autoimmune disease review. 9. Cardiovascular risk assessment.

A Saudi patient should arrive at the Besremi conversation with the most recent haematology documentation: full diagnostic workup confirming PV, JAK2 V617F result with allele burden if available, bone marrow biopsy report if obtained, recent CBC and LFT and TSH results, any prior cytoreductive therapy history with reasons for switch, baseline PHQ-9 result, and the insurance pre-authorisation paperwork the haematologist's office initiates.

The Saudi prescribing and supply picture, plainly

Besremi's MENA registration status is younger than the established interferon products. [VERIFY: Besremi Saudi SFDA registration and current dispensing pathway at intake.] Where Besremi is registered and commercially supplied, in-country dispensing applies. Where it is not yet locally registered, a named-patient pathway can apply for documented physician-initiated prescriptions referencing FDA, EMA, or MHRA approved indications. The pathway is:

1. **Prescribing haematologist with myeloproliferative neoplasm expertise**: any board-certified Saudi adult haematologist treating PV. MPN expertise concentrates at KFSHRC Riyadh and Jeddah (Department of Adult Haematology and the MPN programme), King Abdulaziz Medical City Riyadh and Jeddah (National Guard Health Affairs), King Fahd Specialist Hospital Dammam, King Khalid University Hospital Riyadh, Dr Sulaiman Al-Habib Medical Group hospitals, International Medical Center Jeddah, and the Saudi German Hospital network. Public sector haematology at MoH tertiary centres handles the same role for Saudi nationals. 2. **Pharmacy dispensing**: hospital pharmacy if prescribed in the inpatient or specialty outpatient setting; community or specialty pharmacy with cold-chain refrigeration for ongoing every-2-week or every-4-week dispensing. Storage at 2 to 8 degrees Celsius. Do not freeze. 3. **Insurance pre-authorisation**: CCHI coverage rules apply for public-sector employees and many private-sector employees through CCHI-compliant plans. Bupa Arabia, Tawuniya, MedGulf, AlRajhi Takaful, and Allianz Saudi Fransi require documented diagnosis, treatment history, and clinical rationale. The pre-authorisation conversation centres on Besremi versus hydroxyurea, particularly for 1L use; documented intolerance or inadequate control on hydroxyurea typically simplifies approval. For public-sector employees at MoH tertiary centres, internal formulary procedures apply with similar documentation. 4. **NUPCO context**: the National Unified Procurement Company is the centralised procurement entity for MoH and other government hospitals. Besremi at public hospitals is procured through NUPCO channels where listed; the dispensing point will be the hospital pharmacy. 5. **Self-injection training**: a single supervised session at the prescribing haematologist's clinic or a clinical nurse educator visit. 6. **Ongoing monitoring**: monthly CBC and LFT during titration; TSH every 3 months; PHQ-9 at each clinic visit. After maintenance transition, CBC and LFT every 3 months; TSH every 3 to 6 months; PHQ-9 continues at each visit. JAK2 V617F allele burden measured annually where the assay is available.

The 2026 pathway, step by step

Week 0 to 1: Documentation pack built with the treating haematologist's office. Full PV diagnostic workup, JAK2 result, bone marrow biopsy report if obtained, recent CBC and LFT and TSH, prior cytoreductive therapy history, baseline PHQ-9, insurance card details. Insurance pre-authorisation submitted.

Week 1 to 4: Insurance pre-authorisation review. Most Saudi commercial insurers turn this around within 2 to 4 weeks. Public-sector formulary review timelines vary.

Week 4 to 6: First dispensing at the haematologist's clinic or partner pharmacy. First dose 100 mcg with self-injection training. Acetaminophen pre-medication and bedtime injection timing coached at this visit.

Month 1 to 6: Titration phase. Patient self-injects every 2 weeks at home. Cold-chain delivery coordinated for each scheduled dose. Monthly CBC and LFT, TSH every 3 months, PHQ-9 at each visit. Dose increases by 50 mcg every 2 weeks until target counts achieved.

Month 6 to 12: Stabilisation phase at the effective dose. Monitoring continues. Haematologic response formally assessed at 12 months.

Month 12 onwards: Maintenance phase. Sustained responders transition to every-4-week dosing at the same dose. CBC and LFT every 3 months; TSH every 3 to 6 months; PHQ-9 at each visit. JAK2 V617F allele burden measured annually where available.

Cost expectation in SAR

US list price (WAC) for Besremi is approximately USD 12,000 to 14,000 per month at typical maintenance dosing, which translates to roughly USD 140,000 to 170,000 per year. MENA cash-pay retail in regional specialty pharmacies could realistically sit in the USD 8,000 to 12,000 per month range, giving an annual cash-pay band of roughly USD 96,000 to 144,000.

At the SAR-USD peg of 3.75, the SAR-equivalent annual cost band is approximately SAR 360,000 to 540,000 at cash-pay retail. Insurance or CCHI pre-authorisation reduces out-of-pocket exposure substantially for covered patients. For public-sector employees and Saudi nationals at MoH tertiary centres, formulary cover applies once the case is approved.

PharmaEssentia and AOP Health patient-support programmes may apply to specific cohorts. [VERIFY: PharmaEssentia/AOP MENA patient-support programme reach at intake.]

What to monitor

The headline adverse-event signals for Besremi are depression and suicidality, liver function abnormality, thyroid dysfunction, and autoimmune flare.

Depression and suicidality. Interferon-class therapy carries a class-wide warning. Baseline PHQ-9 plus ongoing PHQ-9 at each clinic visit is the standard. Patients and families should be coached to report mood changes, sleep changes, withdrawal, irritability, hopelessness, or thoughts of self-harm immediately. New depression on therapy is managed by dose reduction, dose interruption, or discontinuation alongside psychiatric referral and antidepressant therapy where indicated.

Liver function abnormality. Monthly LFTs during titration catch most cases of transaminase elevation. Significant elevations trigger dose reduction or interruption.

Thyroid dysfunction. TSH every 3 months catches new-onset hypothyroidism (most common) or hyperthyroidism. Levothyroxine for hypothyroidism alongside continued Besremi is the usual approach.

Autoimmune flare. Patients with pre-existing autoimmune disease can flare; new autoimmune phenomena can rarely emerge. Clinical vigilance at each visit.

Flu-like symptoms in the first 2 to 3 months; acetaminophen pre-medication and bedtime dosing mitigate.

Injection-site reactions are common and typically resolve.

Mild reversible alopecia and skin changes affect some patients.

Pregnancy is contraindicated.

Religious, ethical, and family-logistics framing

Besremi is a recombinant interferon produced in E. coli, then chemically conjugated to a synthetic mPEG polymer. There is no animal-source material, no donor element, no foreign genetic content in the patient. The classical analogy to vaccines and recombinant biologics holds in Saudi Islamic medical ethics, where recombinant biologics are generally treated as permissive with the standard expectation that the patient and family decide in consultation with the treating physician.

The self-injection element is operationally simple for most Saudi patients, particularly given the every-2-week cadence and the eventual every-4-week maintenance. Patients uncomfortable with home injection can request clinic-administered dispensing.

The chronic-treatment nature means a years-long, often decade-plus routine. Saudi patient logistics should plan for cold-chain pharmacy access, travel-friendly storage planning, and haematology follow-up cadence.

The depression and suicidality signal deserves a separate cultural note. In some Saudi family contexts mental-health symptoms are under-reported. The interferon-class warning is real and the PHQ-9 monitoring is non-negotiable. Families should treat mood changes, withdrawal, sleep changes, or any thought of self-harm as urgent medical signals and report them to the haematologist immediately rather than tolerate silently.

When Besremi is not the right call

For a Saudi patient where the diagnosis is not clearly polycythemia vera, where well-controlled blood counts on hydroxyurea over years are not raising a molecular-response question, where untreated severe depression or recent suicide attempt makes interferon-class therapy unsafe, where the patient is pregnant or planning pregnancy in the near term, where severe hepatic impairment exists, or where unstable autoimmune disease exists:

- **Hydroxyurea (Hydrea)**: oral cytoreductive, conventional first-line in high-risk PV. - **Ruxolitinib (Jakafi)**: oral JAK1/2 inhibitor for PV after hydroxyurea failure or intolerance. - **Peginterferon alfa-2a (Pegasys)**: older long-acting interferon; weekly SC dosing. - **Anagrelide**: oral platelet-lowering agent. - **Phlebotomy and low-dose aspirin alone**: foundational therapy in low-risk PV. - **Allogeneic stem cell transplantation**: reserved for transformation to myelofibrosis or AML.

Reserve Meds does not push a default. We do not promote one PV cytoreductive over another. If the conversation with the treating haematologist points toward continued hydroxyurea, a switch to ruxolitinib, or continued phlebotomy alone, the operational pathway shifts accordingly.

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 Saudi Besremi case we build the documentation pack with the treating haematologist's office, confirm SFDA registration status and the appropriate dispensing pathway, run the insurance or CCHI pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the cold-chain supply logistics for ongoing every-2-week or every-4-week dispensing, organise self-injection training, and stay with the case through the first year of dosing with handoff to the local haematologist for ongoing surveillance. Clinical decisions remain with your treating haematologist.

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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reservemeds.com · hello@reservemeds.com