

Besremi

Bahrain · access guide

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

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

Bahrain has a focused adult haematology service footprint. Salmaniya Medical Complex (SMC) is the public-sector backbone with adult haematology covering myeloproliferative neoplasms (MPN) including polycythemia vera (PV). King Hamad University Hospital (KHUH), Bahrain Defence Force (BDF) Hospital, Bahrain Specialist Hospital, and the Aster network and NHRA-licensed private clinics across Manama and Riffa round out the haematology network. 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. The EMA approved Besremi in February 2019 under a slightly older label. For a Bahrain-resident adult with confirmed JAK2 V617F-positive polycythemia vera, the operational question is which cytoreductive choice fits the case (Besremi versus hydroxyurea versus ruxolitinib), whether the prescription can be dispensed in-country or requires cross-border supply, and how insurance and out-of-pocket exposure work for the multi-year treatment course.

This page explains the 2026 pathway for a Bahrain-resident patient: who qualifies, where the prescribing haematologist conversation happens, how Besremi is dispensed and stored (locally or via cross-border supply where applicable), what the dosing schedule looks like, what the realistic out-of-pocket exposure band is in BHD, what to monitor, and how the long-term treatment course fits into a Bahraini patient's life.

Why Besremi, and why now

Besremi is ropeginterferon alfa-2b-njft, a monopegylated proline-substituted recombinant interferon alfa-2b. It binds type I interferon receptors, triggers JAK/STAT-coupled signalling, and suppresses the abnormal JAK2 V617F-mutated clone in PV. The differentiating clinical claim is the potential for molecular response (declining JAK2 V617F allele burden) with sustained therapy; hydroxyurea and ruxolitinib control blood counts but do not produce molecular response.

FDA approved November 2021; EMA approved February 2019. Pivotal evidence from PROUD-PV and CONTINUATION-PV: at 36 months, Besremi was superior to hydroxyurea for complete haematologic response with normal spleen size (53% versus 38%); the molecular response advantage continues to deepen at 5-plus years.

For a Bahraini patient newly diagnosed with PV, or one switching from 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

Subcutaneous injection. After initial training, patient self-injects at home using a prefilled syringe.

Starting dose: 100 mcg subcutaneous every 2 weeks. Titrate up by 50 mcg every 2 weeks to a maximum of 500 mcg every 2 weeks based on the CBC trend. Most patients reach the effective dose within 3 to 6 months.

After sustained haematologic response (typically 6 to 12 months), transition to maintenance every 4 weeks at the same dose. Maintenance continues indefinitely so long as the patient tolerates therapy.

Injection sites: thigh, abdomen, outer upper arm; rotate. Acetaminophen pre-medication and bedtime dosing reduce flu-like symptoms in the early weeks.

Treatment is measured in years, often a decade or more.

Eligibility at a Bahrain haematologist's clinic

1. Confirmed PV by WHO 2016 or 2022 criteria: erythrocytosis, JAK2 V617F (or rarely exon 12), suppressed serum erythropoietin, characteristic bone marrow morphology where biopsy is obtained. 2. Treatment-history documentation. 3. Baseline CBC with differential, reticulocyte count, serum ferritin. 4. Baseline LFTs; severe hepatic impairment contraindicated. 5. Baseline TSH and free T4. 6. Baseline PHQ-9 depression and suicidality screen. Interferon-class warning. 7. Pregnancy testing for women of childbearing potential; contraindicated in pregnancy. 8. Autoimmune disease review. 9. Cardiovascular risk assessment.

A Bahraini patient should arrive with current diagnostic workup, JAK2 result, bone marrow biopsy report if obtained, recent CBC and LFT and TSH, prior cytoreductive therapy history, baseline PHQ-9, and insurance documentation.

The Bahrain prescribing and supply picture, plainly

Besremi availability in Bahrain depends on NHRA registration status at the point of prescription. [VERIFY: Besremi Bahrain NHRA registration and current dispensing pathway at intake.] Where Besremi is registered and commercially supplied, in-country dispensing applies. Where the indication or formulation extension has not yet been registered locally, a named-patient pathway can apply for documented physician-initiated prescriptions referencing FDA, EMA, or MHRA approved indications.

1. **Prescribing haematologist with myeloproliferative neoplasm expertise:** any board-certified Bahraini adult haematologist. Salmaniya Medical Complex (SMC), King Hamad University Hospital (KHUH), Bahrain Defence Force (BDF) Hospital, Bahrain Specialist Hospital, and the Aster network plus NHRA-licensed private clinics across Manama and Riffa cover adult haematology. Sidra Medicine is paediatric-only (Qatar) and is not the venue for adult PV. 2. **Pharmacy dispensing:** hospital pharmacy for inpatient or specialty outpatient prescriptions; community or specialty pharmacy with cold-chain refrigeration for ongoing dispensing. Storage 2 to 8 degrees Celsius; do not freeze. For named-patient supply, cross-border procurement from KSA or UAE distributors may apply. 3. **Insurance pre-authorisation:** Bahraini nationals on MoH cover for advanced therapies on a case-by-case basis. Commercial cover (AXA Gulf, Bahrain National Insurance, GIG Bahrain, the regional Bupa product) varies. Documented diagnosis, treatment history, and clinical rationale are the standard pre-authorisation requirements. 4. **Self-injection training:** a single supervised session at the prescribing haematologist's clinic or clinical nurse educator visit. 5. **Ongoing monitoring:** monthly CBC and LFT during titration; TSH every 3 months; PHQ-9 at each visit. Maintenance phase: CBC and LFT every 3 months; TSH every 3 to 6 months; PHQ-9 at each visit. JAK2 V617F allele burden annually where the assay is available.

The 2026 pathway, step by step

Week 0 to 1: Documentation pack with the treating haematologist's office, including NHRA registration confirmation for Besremi at the point of prescription.

Week 1 to 4: Insurance pre-authorisation review.

Week 4 to 6: First dispensing (in-country if registered, or via named-patient cross-border supply). First dose 100 mcg with self-injection training.

Month 1 to 6: Titration phase; every-2-week dosing at home. Cold-chain delivery coordinated.

Month 6 to 12: Stabilisation at effective dose. Response formally assessed at 12 months.

Month 12 onwards: Maintenance every 4 weeks. JAK2 V617F allele burden measured annually where available.

Cost expectation in BHD

US list price (WAC) approximately USD 12,000 to 14,000 per month, 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 2026 indicative cross rates, the BHD-equivalent annual cost band is approximately BHD 36,000 to 54,500 at cash-pay retail. For Bahraini nationals, MoH cover for advanced therapies has historically extended on a case-by-case basis. Commercial cover varies. Cross-border named-patient supply, where applicable, adds modest overhead for cold-chain procurement. PharmaEssentia and AOP Health patient-support programmes may apply. [VERIFY: PharmaEssentia/AOP MENA patient-support programme reach at intake.]

What to monitor

Depression and suicidality. Interferon-class warning. Baseline PHQ-9 plus ongoing PHQ-9 at each clinic visit. New depression on therapy is managed by dose reduction, interruption, or discontinuation alongside psychiatric referral and antidepressant therapy where indicated.

Liver function abnormality. Monthly LFTs during titration; significant elevations trigger dose reduction or interruption.

Thyroid dysfunction. TSH every 3 months. Levothyroxine for hypothyroidism alongside continued Besremi.

Autoimmune flare. 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*, chemically conjugated to a synthetic mPEG polymer. No animal-source material, no donor element. The classical analogy to vaccines and recombinant biologics holds in Bahraini Islamic medical ethics.

The self-injection element is operationally simple for most patients given the every-2-week and eventual every-4-week cadence.

The chronic-treatment nature means a years-long, often decade-plus routine. Plan for cold-chain pharmacy access (in-country or cross-border named-patient supply), travel-friendly storage, and haematology follow-up cadence.

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

When Besremi is not the right call

For a Bahraini patient where the diagnosis is not clearly PV, where conventional cytoreductive therapy controls the disease and no molecular-response question is being raised, where untreated severe depression or recent suicide attempt makes interferon unsafe, where pregnancy applies, 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**. - **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.

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 Besremi case we build the documentation pack with the treating haematologist's office, confirm NHRA registration status and the appropriate dispensing pathway (in-country versus cross-border named-patient), run the insurance pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the cold-chain supply logistics, organise self-injection training, and stay with the case through the first year of dosing. 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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