Hemgenix access in Egypt: certified-center coordination for AAV5 gene therapy

How Egyptian families with hemophilia B coordinate Hemgenix (etranacogene dezaparvovec-drlb) at a CSL Behring certified treatment center abroad when in-country gene therapy infrastructure is not in place.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Hemgenix (etranacogene dezaparvovec-drlb) is an adeno-associated virus serotype 5 (AAV5) based gene therapy from CSL Behring, developed in collaboration with uniQure. The therapy delivers a codon-optimised Padua variant of the human factor IX gene to hepatocytes through a single one-time intravenous infusion. The US Food and Drug Administration approved Hemgenix in November 2022 for hemophilia B in adults who currently use factor IX prophylaxis therapy, who have current or historical life-threatening hemorrhage, or who have experienced repeated serious spontaneous bleeding episodes. It is the first FDA-approved gene therapy for hemophilia and the highest-priced FDA-approved therapy at launch, with a US wholesale acquisition cost of approximately USD 3.5 million per patient. In Egypt, Hemgenix is not registered as a locally marketed product and no Egyptian institution is on the CSL Behring certified treatment center list as of this review. The practical access route for Egyptian patients is travel-to-treatment at a certified center in the United States, the European Union, the United Kingdom, or Canada.

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Why Egyptian patients need Hemgenix via certified-center coordination

Egypt has a substantial hemophilia B population concentrated at university hospital hematology services, and the Egyptian Hemophilia Association supports the wider patient community. Adult patients on lifelong factor IX prophylaxis (recombinant or plasma-derived, including extended half-life products) face the daily burden of infusion schedules, vascular access, and bleed risk that gene therapy is designed to address. The HOPE-B phase 3 trial reported a 64 percent reduction in annualised bleeding rate during months 7 through 18 versus the lead-in period, with 96 percent of participants free from continuous prophylaxis at 18 months. For patients with a documented bleed history meeting the FDA-approved indication, who are antibody-negative on AAV5 neutralising antibody testing, and who have healthy liver function, Hemgenix offers a one-time intervention that may replace years of prophylaxis.

The structural reason Egyptian patients reach for cross-border coordination is the certified-center requirement. Hemgenix cannot be shipped, stored, or administered outside a qualified infusion environment. The AAV5 vector is a regulated genetically modified organism (GMO) in many jurisdictions, the frozen biologic cold-chain class requires specific handling at each step, the mandatory pre-treatment AAV5 neutralising antibody titer test must be performed at a validated laboratory, and the post-infusion ALT monitoring with corticosteroid algorithm runs at the certified center under the prescribing hemophilia specialist's authority. Even where the

Egyptian Drug Authority could theoretically authorise importation under Law No. 151 of 2019, the certified-center capability is the operational gate.

The certified-center coordination pathway for Hemgenix

The pathway for an Egyptian hemophilia B patient to access Hemgenix consists of two distinct workstreams running in parallel rather than the standard single-jurisdiction EDA personal-import filing.

The clinical workstream sits with the destination certified treatment center. The patient's treating Egyptian hematologist prepares a referral package and contacts a CSL Behring certified center in the United States, the European Union, the United Kingdom, or Canada. The destination center performs the mandatory pre-treatment workup: baseline factor IX activity confirmation, AAV5 neutralising antibody titer testing (a mandatory pre-treatment assay per the current FDA label, with patients positive for antibodies typically not eligible), liver function tests including ALT, AST, alkaline phosphatase, and bilirubin, screening for hepatitis B and hepatitis C, and assessment for active liver disease or significant hepatic fibrosis. Patients with active or untreated viral hepatitis, advanced fibrosis, or other significant liver pathology require evaluation before consideration. If the patient is a candidate, the destination center orders the dose-pack (Hemgenix is dose-banded and patient-specific at 2 x 10^13 genome copies per kilogram of body weight), schedules the infusion, runs the infusion under monitoring, and manages the structured post-infusion follow-up including serial ALT monitoring with the label-specified corticosteroid taper triggered by elevation per protocol, serial factor IX activity to track endogenous expression, and multi-year durability follow-up.

The Egyptian workstream sits with the patient family and a Cairo-based dispensing institution. A complete travel and reintegration package typically includes:

- The destination certified center's letter of acceptance and pre-treatment-workup plan
- The treating Egyptian hematologist's clinical summary, on hospital letterhead, with original signature and stamp, stating the hemophilia B diagnosis with the documented factor IX activity baseline, the bleed history with annualised bleeding rate where available, the current prophylaxis regimen, the rationale for gene therapy, and the patient's liver health profile
- The treating Egyptian physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- Patient identifier: copy of the national ID card or passport (with destination-country travel-visa documentation prepared in parallel)
- A coordinated care-handoff plan describing how the Egyptian hematology service will resume long-term follow-up after the patient returns from the destination center, including factor IX activity monitoring across years and the multi-year durability follow-up coordinated with the certified center
- Where supplemental medicines need to ship to Egypt before or after the trip (any ongoing factor IX product, prednisone for the corticosteroid taper if transaminitis is managed locally after return), a separate EDA personal-importation filing through one of the major Egyptian dispensing institutions under Law No. 151 of 2019

The Egyptian dispensing institutions that routinely handle adult hematology coordination and could anchor the local side include Cairo University Hospitals (Kasr Al Ainy), Ain Shams

University Hospitals, Dar Al Fouad Hospital in 6th of October City (Alameda Healthcare Group, JCI-accredited since 2005), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group facilities. EDA timelines for supplemental medicine personal-import filings are typically 3 to 6 weeks. Destination-center scheduling, dose-pack manufacturing throughput, and the antibody-screening eligibility result drive the dominant timeline rather than the EDA workstream.

Where Hemgenix gets administered (and where it does not)

Hemgenix is administered only at CSL Behring certified treatment centers that have completed site qualification, staff training, and infusion-readiness validation. As of this review, no Egyptian institution is on the certified center list. The Egyptian institutions building advanced specialty infusion capability (Kasr Al Ainy, Children's Cancer Hospital Egypt 57357 for pediatric expertise, Magdi Yacoub Heart Foundation, Dar Al Fouad Hospital) may evolve into certified gene-therapy centers over time, but for 2026 cases the practical answer is travel-to-treatment.

For Egyptian patients, the destination choice typically follows a combination of family-support logistics (relatives in the destination city or region), insurance reach if any out-of-country coverage applies, and the certified center's acceptance of international self-pay patients. Pre-treatment workup steps that can be performed locally in Egypt to reduce destination-stay duration include hepatitis B and C screening, baseline ALT and AST, and factor IX activity confirmation; the AAV5 neutralising antibody titer typically must be performed at a validated laboratory the destination center accepts. The treating Egyptian hematologist and the destination center coordinate the workup-split decision.

Real cost picture for Hemgenix in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Quoting in USD insulates the family from EGP volatility during a multi-month coordination arc.

The US wholesale acquisition cost for Hemgenix is approximately USD 3.5 million per patient for the single one-time infusion, as set by CSL Behring at launch in late 2022 and reported by Fierce Pharma, MM and M, Managed Healthcare Executive, and Hemophilia News Today. CSL Behring's pricing rationale references the one-time nature of the therapy, the projected reduction in lifetime prophylaxis cost (which the company cites as exceeding USD 20 million per patient with moderate-to-severe hemophilia B), and the elimination or reduction of bleed-related morbidity. The Institute for Clinical and Economic Review (ICER) issued a cost-effectiveness assessment placing a fair price range at roughly USD 2.9 million, below the launched WAC. International list prices vary by jurisdiction and are commonly negotiated confidentially with national payers; cross-border named-patient and travel-to-treatment cases typically reference the US WAC plus international logistics and certified-center charges.

For an Egyptian self-pay patient, additional cost components include the pre-treatment workup (factor IX activity, AAV5 antibody titer, LFT panel, hepatitis screening), the certified-center infusion-and-monitoring stay, accommodation near the destination center, international flights for the patient and a companion, food and ground transport during the stay, and visa fees. Reserve Meds itemises the coordination fee separately from the destination-center pass-through costs on every firm quote.

Local payer reality is cash-dominant at this price tier. UHIA does not cover gene therapy abroad. Private insurers operating in Egypt (Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt) typically do not cover a USD 3.5 million one-time gene therapy on standard plans; international premium plans may offer partial out-of-country specialty coverage with pre-authorisation. We do not promise coverage.

Typical timeline for Hemgenix in Egypt

The dominant timeline driver is destination-center scheduling, AAV5 antibody screening turnaround, and dose-pack manufacturing throughput. The typical operational arc is 12 to 20 weeks from initial destination-center referral: 2 to 4 weeks for destination acceptance, 2 to 4 weeks for the AAV5 antibody titer and liver workup (with the result determining patient eligibility), 4 to 8 weeks for dose-pack scheduling and travel preparation, 1 to 2 weeks for travel and in-person final pre-infusion confirmation, the infusion day itself, and approximately 2 to 6 weeks at the destination for early post-infusion ALT monitoring and the initial corticosteroid-taper window if transaminitis emerges. The patient returns to Cairo or Alexandria after the early post-infusion window and the long-term factor IX activity tracking and durability follow-up continues with the Egyptian hematology service co-managing with the certified center for years.

What your physician needs to provide

The Egyptian treating hematologist's referral letter is the cornerstone of the destination certified center's acceptance review. The strongest letters consistently include the hemophilia B diagnosis with the documented factor IX activity baseline, the bleed history meeting the FDA-approved indication (current factor IX prophylaxis, current or historical life-threatening hemorrhage, or repeated serious spontaneous bleeding episodes), the current prophylaxis regimen with response and adherence data, the patient's liver health profile (baseline ALT and AST, hepatitis B and C status, any history of liver disease), and the rationale for gene therapy over continued lifelong factor IX prophylaxis. The destination center's hemophilia specialist owns the AAV5 antibody titer interpretation, the eligibility decision, the dose-pack request, the infusion, and the post-infusion corticosteroid algorithm. Reserve Meds is the coordinator, not the clinician, and does not weigh in on the gene-therapy-versus-prophylaxis choice or the Hemgenix-versus-Beqvez choice (Beqvez is fidanacogene elaparvovec, an alternative hemophilia B gene therapy approved by FDA in April 2024 by Pfizer; selection is the treating specialist's call).

Common questions about Hemgenix in Egypt

Can Hemgenix be infused at Kasr Al Ainy or another Egyptian center?

Not as of this review. Hemgenix is shipped only to CSL Behring certified treatment centers that have completed site qualification. Egyptian institutions are not on the certified center list. The Egyptian institutions building advanced specialty infusion capability may evolve into certified centers over time, but for 2026 cases the practical answer is travel-to-treatment at a US, EU, UK, or Canada destination center.

What if my AAV5 antibody titer is positive?

Patients with detectable AAV5 neutralising antibodies are typically not eligible for Hemgenix because pre-existing antibodies can neutralise the vector and prevent transduction. The screening test is mandatory per the current FDA label. If positive, continued factor IX

prophylaxis or, where appropriate, alternative gene therapy programs with different AAV serotypes may be discussed by the treating specialist.

What is the safety profile we should be aware of?

The most common adverse reactions reported in clinical development include hepatic transaminase elevations, headache, flu-like symptoms, infusion-related reactions, creatine kinase elevation, malaise, and fatigue. Transaminase rises are expected in a meaningful fraction of patients and are managed with the label-specified corticosteroid algorithm at the certified center. Long-term follow-up through 5 years has not identified AAV-related oncogenicity or chronic hepatotoxicity in reported data.

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover Hemgenix abroad?

Each insurer assesses out-of-country specialty cases case by case. International or premium plans may include partial out-of-country specialty coverage with pre-authorisation; standard plans typically do not at this price tier. We supply the documentation set; we do not promise coverage. Cash-pay is the default posture.

Is Hemgenix a controlled substance?

No. Hemgenix is a gene therapy biologic and is not on any DEA schedule. The control is the certified-center requirement and the GMO regulatory status of the AAV5 vector in many jurisdictions, not a DEA schedule.

Our family is split between Cairo and the Gulf. Can you coordinate?

Yes. Reserve Meds runs patient-side coordination in Arabic where requested and family-side coordination in English in parallel, with a single named coordinator running the case end to end across the Egyptian diaspora.

Where Reserve Meds fits in Hemgenix cases

Reserve Meds is a US-based concierge coordinator. We do not administer Hemgenix, do not infuse Hemgenix, do not perform the AAV5 antibody titer, and do not act as a clinical decision-maker. What we do for Egyptian Hemgenix cases is orchestrate the destination certified-center referral package preparation in coordination with the treating Egyptian hematologist, support pre-treatment workup logistics where parts of the workup can be done locally in Egypt to reduce destination-stay duration, support family travel and accommodation logistics around the post-infusion monitoring window, prepare any supplemental EDA personal-importation filings for medicines that need to ship to Egypt, and run a single named concierge throughout the case in Arabic and English. Hemgenix has no prior Reserve Meds case experience as of this review, so the operating posture is standard certified-center coordination with particular attention to the AAV5 antibody screening result (which determines eligibility), the dose-pack lead time, the corticosteroid algorithm for transaminitis, and the multi-year durability follow-up coordination back to Egyptian hematology services.

Next step

If you or a family member has hemophilia B meeting the FDA-approved indication and your treating Egyptian hematologist is discussing gene therapy, add the case to the waitlist. We will respond within 24 to 48 hours to scope certified-center options, the AAV5 antibody screening

logistics, the operational timeline, and an indicative USD cost envelope for the full travel-to-treatment course.

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This guide is informational, not medical or legal advice. Hemgenix is administered only at CSL Behring certified treatment centers under the treating hemophilia specialist's authority; Reserve Meds is the coordinator, not the clinician.