Vyvgart access in Egypt: the EDA named-patient pathway

How patients in Egypt obtain US-sourced Vyvgart (efgartigimod alfa-fcab) for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy when chronic IVIG or PLEX is failing and a first-in-class FcRn antagonist is the next step.

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Quick orientation

Vyvgart (efgartigimod alfa-fcab) is the first-in-class neonatal Fc receptor (FcRn) antagonist approved for human use. By blocking FcRn, Vyvgart prevents the recycling of immunoglobulin G (IgG) and accelerates clearance of pathogenic IgG autoantibodies. The FDA approved Vyvgart in December 2021 for generalized myasthenia gravis (gMG), the subcutaneous Vyvgart Hytrulo presentation in June 2023 for gMG, and the same subcutaneous product in June 2024 for chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. In Egypt, Vyvgart is not on broad EDA-registered commercial stocking, and the practical access route for a neurologist whose gMG or CIDP patient needs an FcRn-antagonist option after losing response to chronic intravenous immunoglobulin (IVIG) or plasma exchange (PLEX) is EDA personal importation. Reserved for you.

Why patients in Egypt need Vyvgart via NPP

Egypt has a meaningful adult neurology population managed across the Cairo, Alexandria, and Giza tertiary-care network, and gMG and CIDP both present cohorts of patients who become dependent on chronic IVIG or PLEX cycles for symptomatic control. IVIG supply across MENA is recurrently inconsistent, and the volume, infusion-reaction, and supply-burden profile of chronic IVIG is a real clinical limitation. PLEX is operationally demanding and not universally available outside major hospital centres. The introduction of a first-in-class FcRn antagonist with a targeted IgG-reduction mechanism changes the clinical conversation: instead of repeated IVIG cycles, a defined 4-week treatment cycle with predictable IgG nadir kinetics and a clinician-led re-treatment decision.

Vyvgart sits in the country module's third structural access gap: not registered locally at all in Egypt at the time of this page, despite FDA, EMA (10 August 2022), UK MHRA, Health Canada, PMDA (January 2022), and China NMPA approvals. For a treating neurologist in Egypt to access Vyvgart on behalf of a gMG patient who is anti-AChR antibody positive (or seronegative under the expanded gMG label), or for a CIDP patient on Vyvgart Hytrulo continuous weekly maintenance, the route is EDA personal importation under the same Law No. 151 of 2019 framework that handles other unregistered specialty biologics. The clinical justification typically emphasises prior-line failure on chronic IVIG (volume tolerability, supply gaps, declining response) or PLEX (operational and access constraints), and the mechanistic difference of FcRn antagonism in targeting pathogenic IgG without the immunoglobulin loading burden.

The EDA named-patient pathway for Vyvgart

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally. Vyvgart qualifies cleanly: it is FDA-approved (December 2021 gMG, June 2024 CIDP for Hytrulo), EMA-approved (August 2022), and there is no FcRn-antagonist registered in Egypt that provides an equivalent mechanism. The application is filed through the dispensing institution's import pharmacy.

For Vyvgart specifically, the clinical justification angle in the EDA application anchors on prior-line failure documentation. For a gMG patient, the letter documents the anti-AChR antibody serostatus (positive or negative under the expanded label), the MG-ADL (Myasthenia Gravis Activities of Daily Living) and QMG (Quantitative Myasthenia Gravis) scores at baseline, the prior-therapy history (pyridostigmine, corticosteroids, azathioprine, mycophenolate, IVIG cycles with cycle count and clinical response, PLEX courses where applicable), the reason chronic IVIG or PLEX is no longer adequate (volume tolerability, supply availability, loss of response, infusion reactions), and the rationale for FcRn antagonism as the targeted next step. For a CIDP patient on continuous weekly Vyvgart Hytrulo, the letter documents the CIDP diagnosis per current diagnostic criteria, prior IVIG or corticosteroid history, electrophysiologic findings, and the rationale for continuous weekly maintenance over the relapse-remitting pattern. Vaccination status review before starting therapy is a label-noted consideration that the application captures.

A complete application includes the clinical justification letter on hospital letterhead with the physician's stamp, the prescription specifying brand name (Vyvgart for IV, or Vyvgart Hytrulo for subcutaneous), generic name (efgartigimod alfa-fcab, with hyaluronidase-qvfc for Hytrulo), strength (400 mg per 20 mL single-dose vial for IV, 1,008 mg fixed-dose for subcutaneous Hytrulo), and quantity required. The package requires a copy of the patient national ID or passport, the treating neurologist's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference, full product details including manufacturer (argenx SE, Netherlands-headquartered with US Boston operations), country of origin, FDA approval reference (BLA 761195 for Vyvgart, BLA 761304 for Hytrulo), shelf life and storage at 2 to 8 degrees Celsius, the destination dispensing facility licence, and a chain-of-custody plan for cold-chain handling through Cairo International Airport. Routine EDA personal-import authorisations for complex biologic cases like Vyvgart typically extend toward the upper end of the 3 to 6 week routine window or beyond, and can reach 8 to 14 weeks for novel-mechanism biologics requiring supplementary clarification.

Where Vyvgart gets dispensed in Egypt

Vyvgart in the IV formulation is administered as a one-hour infusion and requires hospital infusion-suite or neurology clinic infusion-centre capability. Vyvgart Hytrulo subcutaneous can be administered in clinic and, after appropriate training, by the patient at home, with a prefilled-syringe presentation supporting self-injection. Both formulations require strict 2 to 8 degree Celsius cold-chain storage, so the dispensing facility list narrows to institutions with validated refrigerated biologic pharmacy storage, neurology infusion infrastructure for the IV product, and patient training capacity for the subcutaneous product.

The practical Egypt set includes Cairo University Hospitals (Kasr Al Ainy) with its neurology service lines and Drug Information Center support, Ain Shams University Hospitals with strong

neurology and immunology programs, Dar Al Fouad Hospital (Alameda Healthcare Group, JCI-accredited, Cleveland Clinic cooperation) with active neuroscience and immunology services, As-Salam International Hospital, and the Cleopatra Hospitals Group's neurology service lines. For Children's Cancer Hospital Egypt 57357 patients with paraneoplastic gMG or CIDP-like syndromes, coordination flows through 57357's institutional import workflow with the neurology consultant signing the clinical justification. For patients outside Cairo, Giza, or Alexandria, the route is co-management with one of these centres or a Cairo-based licensed specialty importer.

Real cost picture for Vyvgart in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. US WAC for Vyvgart IV is reported in published health-economics analyses at approximately USD 63,000 to USD 95,000 per 4-week treatment cycle, with the variation driven by patient weight (the 10 mg/kg weekly dose capped at 1,200 mg for patients weighing 120 kg or more). Annualised at the typical 4 to 5 cycles per year for gMG, the reference range is approximately USD 300,000 to USD 450,000 per patient per year at US list. Vyvgart Hytrulo pricing sits at parity to the IV product on a per-cycle basis. The EGP 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 patient from intra-case currency drift.

The all-in delivered-to-Egypt cost includes the US drug acquisition at WAC plus margin, validated 2 to 8 degree Celsius cold-chain international logistics from a US specialty distributor to Cairo International Airport in the USD 800 to 2,500 range per shipment depending on volume and route, regulatory documentation handling fees on the Egyptian side, and the Reserve Meds coordination fee itemised on the firm quote. Cycle-based shipment cadence (one 4-week cycle of vials per international shipment) is the practical procurement unit for gMG cases; CIDP weekly maintenance shipments are batched to reduce cold-chain frequency.

On the insurance side, named-patient reimbursement varies meaningfully. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other Egyptian carriers each assess high-cost novel-mechanism biologics case by case. UHIA coverage under Law No. 2 of 2018 does not generally extend to specialty imports. Cash-pay remains the dominant posture, and many Egyptian families coordinate USD funds across the diaspora (UAE, Saudi Arabia, UK, US) for cases of this magnitude.

Typical timeline for Vyvgart in Egypt

From waitlist submission to first infusion or first subcutaneous injection, the typical Vyvgart case in Egypt runs as follows. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to the treating neurologist, with Arabic-language patient-facing summaries where the family requests them. The dispensing facility files the EDA personal-import application; complex novel-mechanism biologic cases typically extend toward the upper end of the 3 to 6 week routine window or beyond, sometimes reaching 8 to 14 weeks if supplementary clarification is requested. In parallel, Reserve Meds aligns US-side specialty pharmacy sourcing and the cold-chain shipment plan. Once EDA authorisation is issued, US release and validated cold-chain transit to Cairo International Airport add 5 to 10 business days. The full cycle for an initial gMG 4-week course is typically 6 to 12 weeks from waitlist to first infusion. CIDP weekly maintenance, once initiated, runs on a planned weekly cadence with multi-week shipments batching to manage cold-chain frequency.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA Vyvgart package and is more substantive than for ambient-temperature small molecules. The letter, on the prescribing institution's letterhead and signed and stamped by an EMS-registered Egyptian neurologist with an active Ministry of Health licence, typically includes: diagnosis (generalized myasthenia gravis with anti-AChR serostatus, or CIDP per current diagnostic criteria with electrophysiologic findings), severity markers (MG-ADL and QMG scores for gMG; INCAT, ONLS, or comparable disability scales for CIDP), the full prior-therapy history (pyridostigmine and other anticholinesterases, corticosteroids, azathioprine, mycophenolate, cyclosporine, rituximab where applicable, IVIG cycles with documented response and discontinuation reason, PLEX courses), the mechanistic rationale for FcRn antagonism over chronic IVIG or PLEX, the proposed dosing plan (10 mg/kg IV weekly for 4 weeks per cycle with weight-cap calculation for gMG; 1,008 mg subcutaneous Hytrulo weekly for CIDP continuous maintenance), the monitoring plan including infection surveillance and IgG levels, vaccination status review, and patient training plan for self-injection if Hytrulo is selected.

The physician confirms their EMS membership and MoH licence are in active standing at the time of filing. Egyptian Health Council (EHC) examination status and continuing professional development standing are not blockers but active licence status at the moment of submission is. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) runs through the course of therapy on Vyvgart, not just the initial dose.

Common questions about Vyvgart in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, Allianz, or Misr Insurance cover Vyvgart?

Each insurer assesses high-cost novel-mechanism biologic named-patient imports case by case. Some plans reimburse a percentage when the underlying condition is covered even if the specific product is not on a local formulary; many require detailed pre-authorisation with prior-line failure documentation. We do not promise coverage. We supply the documentation set; the claim sits with you or your hospital.

Can Vyvgart be considered as an alternative to chronic IVIG or PLEX?

The clinical decision rests with the treating neurologist. Vyvgart offers targeted IgG reduction with a defined cycle structure rather than the volume-loading and supply considerations of IVIG and the operational demands of PLEX. The ADAPT phase 3 trial (Howard et al., Lancet Neurology 2021) reported clinically meaningful improvement in MG-ADL and QMG scores versus placebo. Other approved FcRn antagonists (rozanolixizumab) and complement inhibitors (eculizumab, ravulizumab) address different nodes in the same pathway. Reserve Meds does not direct the choice and procures only against a prescriber-issued direction.

What is the safety profile?

The ADAPT phase 3 trial reported a safety profile comparable to placebo across the treatment period. The most common adverse reactions in labeling include upper respiratory tract infections, urinary tract infections, and headache. Infusion-related reactions and injection-site reactions (for Hytrulo) are documented. Because FcRn antagonism reduces total circulating IgG by approximately 60 to 70 percent at the nadir following a 4-week cycle, infection risk is a class consideration; treating clinicians monitor for signs of infection during and between cycles.

Can the subcutaneous Hytrulo formulation be self-administered at home?

Yes, after appropriate training. A prefilled-syringe presentation supports self-injection. The dispensing facility must still be Egyptian-licensed, and training typically occurs at the prescribing hospital or clinic before self-administration begins.

What is the typical course duration?

For gMG, treatment is open-ended with cycles re-administered on clinical evaluation, typically with the next cycle initiated no sooner than 50 days from the start of the previous cycle. Over a year this averages 4 to 5 cycles depending on individual clinical response and IgG rebound kinetics. For CIDP, Hytrulo is given as continuous weekly maintenance rather than discrete cycles.

What pharmacovigilance reporting applies?

The treating physician and dispensing pharmacy report adverse events to the Egyptian Pharmacovigilance Center (EPVC) per Yellow Card or CIOMS reporting standards, with the obligation running through the full course of therapy. Reserve Meds supplies EPVC reference contacts in the physician documentation kit.

Where Reserve Meds fits in Vyvgart cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating neurologist, do not replace EDA, do not replace the Egyptian dispensing pharmacy, and do not act as an importer of record in Egypt. What we do is orchestrate US-side specialty distribution sourcing of argenx-manufactured Vyvgart or Vyvgart Hytrulo with DSCSA chain-of-custody documentation, prepare the regulatory documentation kit the treating neurologist needs for the EDA filing, coordinate validated 2 to 8 degree Celsius cold-chain international logistics to Cairo International Airport, and run a single named coordinator throughout your case in both English and Arabic. The local EDA filing, customs clearance, and final dispensing all remain with the licensed Egyptian dispensing facility. No prior Reserve Meds case experience with Vyvgart specifically at the time of this page; standard NPP coordination applies, with the cycle-based gMG cadence and the weekly CIDP cadence each anchored to a planned cold-chain shipment schedule.

Next step

If the neurologist has recommended Vyvgart or Vyvgart Hytrulo for a gMG or CIDP patient who needs an FcRn-antagonist option, the waitlist is the first step. We confirm eligibility within 24 to 48 hours and send the physician documentation kit, with Arabic-language patient summaries where the family requests them.

Reserved for you.

This guide is informational, not medical or legal advice. The EDA personal-importation framework requires a licensed Egyptian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.