

## Vyvgart

Bahrain · access guide

# How to access Vyvgart from Bahrain, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

An Bahraini patient living with generalised myasthenia gravis (gMG) may receive a prescription for Vyvgart (efgartigimod alfa-fcab) from their treating neurologist or neuromuscular specialist. Vyvgart is FDA-approved for gMG in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, and it is manufactured by argenx. It is the first neonatal Fc receptor (FcRn) antagonist approved for gMG, reducing pathogenic IgG autoantibodies without the broad immunosuppression of corticosteroids. The Bahrain has a significant gMG patient population, and while conventional therapy (pyridostigmine, steroids, azathioprine, mycophenolate, rituximab, IVIG, plasma exchange) remains the backbone of care, Vyvgart is increasingly sought by patients with refractory or steroid-dependent disease. In Bahrain, Vyvgart is not yet broadly registered, which is why your neurologist may be navigating a named-patient import pathway with you.

This guide explains the legal pathway, what your physician needs to provide, typical timelines, and where Reserve Meds fits in.

## The clinical situation

Vyvgart (IV formulation) is administered as a one-hour IV infusion of 10 mg/kg once weekly for four weeks, with additional treatment cycles initiated based on clinical evaluation. A subcutaneous formulation (Vyvgart Hytrulo) is also available. Eligibility typically requires confirmed AChR-antibody seropositivity, an MGFA clinical classification, and pre-treatment screening (vaccinations, infection screen). Your treating neurologist confirms diagnosis and supervises the cycle schedule per FDA labeling.

## Is Vyvgart legally importable into Bahrain?

Yes, through the Central Drugs Standard Control Organization (NHRA) named-patient / personal-use import framework. The pathway allows an Bahraini-licensed physician (or the patient directly, with physician prescription) to request import of a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent registered alternative fits, (c) the physician takes clinical responsibility, and (d) the imported quantity is proportionate to a defined treatment period.

For Vyvgart specifically, the application integrates the infusion-facility plan; Bahrain has well-established infusion infrastructure at tertiary-care centres across metropolitan cities capable of administering biologics.

## How the pathway works, step by step

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1. **Consultation with your treating neurologist.** AChR antibody confirmation, gMG clinical diagnosis, MGFA classification, and pre-treatment screening.
2. **Infusion facility identification.** The administering facility must be equipped to manage infusion reactions.
3. **NHRA named-patient / personal-use application.** Your physician files the application.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner.
5. **Cold-chain shipment.** Vyvgart ships at 2-8°C with continuous temperature monitoring.
6. **Arrival and cycle administration.** The licensed facility administers the four-weekly cycle; additional cycles per clinical response.

## What documentation your physician needs

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Your physician will typically need to provide:

- Clinical rationale letter confirming gMG diagnosis, AChR antibody positivity, MGFA class, and prior therapy history (pyridostigmine, steroids, immunosuppressants, IVIG/PLEX as relevant)
- Verification of Bahrainn medical licence
- Identification of the administering infusion facility
- Patient identifier
- Pre-treatment screening results and vaccination record
- Planned cycle schedule

Reserve Meds provides a physician documentation kit that bundles the templates NHRA reviewers expect to see for FcRn-antagonist therapy.

## Costs and timing

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Vyvgart's US cash-pay drug-only reference price sits in a broad indicative range, the annualised treatment cost varies with dosing frequency but falls in the USD 400,000-600,000 range in US list pricing. International cold-chain logistics, NHRA documentation, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for the first infusion after cohort intake opens is 7-14 days from the moment a complete application is submitted.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

## Reserve Meds's role

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Vyvgart specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for NHRA review.
- **Logistics.** Cold-chain, temperature-monitored shipment.
- **Concierge case lead.** A named point of contact.

**What we do not do:** We are not the prescriber. We do not practise medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating neurologist.

## Frequently asked

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**Is this legal in Bahrain?** Yes, when executed through the NHRA named-patient / personal-use framework with appropriate documentation. The Bahrain's named-patient pathway is well-established and routinely used for specialty biologics not yet locally registered.

**How does Vyvgart compare with IVIG or plasma exchange?** IVIG and plasma exchange are acute-rescue therapies used for myasthenic crisis or short-term stabilisation. Vyvgart is a maintenance therapy delivered in cycles; it works by reducing pathogenic IgG at the FcRn level rather than replacing or removing IgG directly. Many neurologists position Vyvgart as a steroid-sparing maintenance option rather than a rescue therapy.

**Can I continue pyridostigmine and other conventional therapies?** Yes, Vyvgart is typically added on top of ongoing symptomatic therapy (pyridostigmine) and may allow dose reduction of chronic immunosuppressants or steroids under your neurologist's supervision.

**Will private insurance cover this?** Cash-pay is the default. Some Bahrainn private insurers reimburse named-patient biologic imports on escalated review; we supply documentation but do not process claims directly.

### *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.

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### **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.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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