Vyvgart access in Pakistan: the DRAP named-patient pathway

How families and patients in Pakistan obtain Vyvgart (efgartigimod) for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy through the Drug Regulatory Authority of Pakistan Personal Use Import framework.

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Quick orientation

Vyvgart is the argenx brand name for efgartigimod alfa-fcab, a human IgG1 antibody Fc fragment engineered for high-affinity binding to the neonatal Fc receptor (FcRn). It is the first-in-class FcRn antagonist approved for human use. By blocking FcRn, Vyvgart prevents the recycling of immunoglobulin G back into circulation, accelerating the clearance of pathogenic IgG autoantibodies, including the anti-acetylcholine receptor antibodies that drive generalized myasthenia gravis. The US FDA approved Vyvgart in December 2021 for adult anti-AChR antibody positive gMG, subsequently expanded the label to cover all adults with gMG regardless of antibody serostatus, approved the subcutaneous Vyvgart Hytrulo formulation for gMG in June 2023, and added a chronic inflammatory demyelinating polyneuropathy (CIDP) indication in June 2024. For Pakistani gMG and CIDP patients losing response to chronic intravenous immunoglobulin (IVIG) or plasma exchange (PLEX), Vyvgart offers a first-in-class mechanistic alternative routed through the DRAP Special Permission pathway.

Reserved for you.

Why patients in Pakistan reach for Vyvgart through NPP

Vyvgart is a novel mechanism. Patients with gMG who are intolerant of, or losing response to, chronic IVIG or PLEX often have no equivalent FcRn-antagonist option available locally. Pakistan's neurology cohort feels this gap acutely. The country's myasthenia gravis and CIDP populations have historically relied on a chronic IVIG and steroid backbone, with PLEX available at a handful of tertiary centers, but IVIG supply in Pakistan is intermittent and the financial and time burden of repeat IVIG cycles is significant for families. Three patterns drive Vyvgart demand through the named-patient route.

First, the absence of a locally registered FcRn antagonist class. Vyvgart is not broadly registered with DRAP at the commercial level, and patients access the product through the Special Permission for Personal Use Import. Second, the documented value as an alternative to chronic IVIG or PLEX. For a gMG patient on monthly IVIG with diminishing response, or a CIDP patient cycling on alternate-week IVIG, the FcRn antagonism mechanism offers a more targeted reduction in pathogenic IgG (approximately 60 to 70 percent reduction at the nadir following a 4-week cycle) without the volume, infusion-reaction risk, or supply burden of repeat IVIG. Third, dosing modality preference. The subcutaneous Vyvgart Hytrulo formulation, after appropriate training, allows self-administration over 30 to 90 seconds and avoids the hospital-infusion

logistics that IVIG and IV Vyvgart require, which matters meaningfully for patients in Pakistani secondary cities far from a tertiary neurology infusion suite.

The DRAP Personal Use Import pathway for Vyvgart

The Drug Regulatory Authority of Pakistan (DRAP) regulates the import of medicines through its Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, commonly referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES) portal. For institutional cases, the dispensing hospital pharmacy files; for cases routed through smaller institutions, a Karachi or Lahore-based DRAP-licensed specialty importer files.

For Vyvgart the clinical justification angle is neurology-specific and emphasizes the alternative-to-IVIG-or-PLEX rationale. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating neurologist, documenting the FDA-approved on-label indication: adult generalized myasthenia gravis (regardless of antibody serostatus), or adult chronic inflammatory demyelinating polyneuropathy
- For gMG cases: documentation of diagnosis (anti-AChR antibody status where tested, electrophysiology including repetitive nerve stimulation and single-fiber EMG where available, MG-ADL and QMG baseline scores), prior therapy attempted (cholinesterase inhibitors, corticosteroids, azathioprine, mycophenolate, IVIG, PLEX), and the rationale for FcRn antagonism (loss of response, intolerability, or supply burden of IVIG or PLEX)
- For CIDP cases: documentation of diagnosis per EFNS/PNS or AAN criteria, electrophysiology evidence of demyelination, prior therapy attempted (IVIG, corticosteroids, PLEX), and the rationale for continuous weekly maintenance with subcutaneous Vyvgart Hytrulo
- A recent prescription specifying brand name (Vyvgart or Vyvgart Hytrulo), generic name (efgartigimod alfa-fcab), formulation (IV 400 mg per 20 mL single-dose vial, or subcutaneous Hytrulo 1,008 mg prefilled syringe), patient weight for the IV regimen, dosing schedule, and cycle structure
- The treating physician's PMDC license verification
- The patient identifier: CNIC for adult patients, passport for foreign nationals receiving treatment in Pakistan; Vyvgart is approved only for adults, so the B-Form pediatric identifier does not apply
- Product details: brand name, generic name (INN), manufacturer argenx SE (Netherlands-headquartered with US operations in Boston, Massachusetts), strength, dosage form, quantity, batch number where available
- The destination dispensing facility li