MADISON NEUROLOGY LLC

608 403 0000

Neurology Care 7 days a Week. Because Your Brain Matters.

Vyygart®

Efgartigimod alfa-fcab (IV)

COMPLETE CLINICAL PROTOCOL: PRE-TREATMENT CHECKLIST • ORDER SET • FOLLOW-UP • HOLD/DISCONTINUE CRITERIA

GENERIC NAME	efgartigimod alfa-fcab (IV)
BRAND	VYYGART®
MEDICATION CLASS	Neonatal Fc receptor (FcRn) blocker — accelerates IgG catabolism
PRESENTATION	400 mg/20 mL (20 mg/mL) single-dose vial — dilute in 0.9% NaCl to 125 mL
ROUTE	IV infusion over 1 hour
US INDICATION (FDA)	Generalized myasthenia gravis in adults who are anti-AChR antibody positive. NOTE: the CIDP-labeled formulation is efgartigimod alfa/hyaluronidase (VYVGART Hytrulo), given SUBCUTANEOUSLY — a different product, not this protocol.

Class context.
No meningococcal vaccination requirement (unlike C5 inhibitors) and no REMS — the key practical differentiator when choosing a gMG biologic. Verify the formulation on every order: IV Vyvgart vs subcutaneous Vyvgart Hytrulo are not interchangeable.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

- ☐ Confirm anti-AChR antibody positivity — the labeled population.
- ☐ Baseline MG-ADL (or equivalent) — cycles are symptom-triggered; there is no way to time the next cycle without a documented baseline and response.
- ☐ Infection review; baseline immunoglobulins reasonable (efgartigimod lowers total IgG including protective antibodies).
- ☐ Pregnancy test when relevant.

B. Vaccinations

☐ Complete age-appropriate vaccinations before initiation per immunization guidelines; evaluate any needed live vaccines BEFORE treatment (immune response may be reduced during therapy).

C. Clinical assessments & counseling

☐ Document background MG therapy (pyridostigmine, corticosteroids, steroid-sparing agents) — efgartigimod is generally ADDED to background treatment.

☐ Educate on the cyclic design: benefit wanes between cycles; agree IN ADVANCE on the score/symptom threshold that triggers the next cycle.

☐ Infection-sign counseling.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Active serious infection	Defer the cycle until resolved.
Hypersensitivity to efgartigimod products	Do not administer.
Wrong formulation on the order (Hytrulo vs IV)	Stop and clarify — different route, dose, and protocol.

Section 2 — Order Set

Premedication

☐ None required by label.

Dosing schedule

Treatment cycle	10 mg/kg IV over 1 hour once weekly × 4 consecutive weeks (maximum 1,200 mg per infusion for patients ≥120 kg).
Subsequent cycles	Initiate based on clinical evaluation when symptoms return — NOT on a fixed calendar; verify the current label's minimum interval between cycles.
Missed weekly dose	May be administered up to 3 days late; otherwise resume at the next scheduled dose and complete the 4-dose cycle.
Observation	Monitor during and for 1 hour after the infusion for hypersensitivity.

Standing orders — every infusion

☐ Infection screen before each weekly dose.

☐ Record MG-ADL at cycle start, cycle end, and between cycles — this is the trigger data for the next cycle.

☐ Verify formulation (IV) on the order before compounding.

Missed or delayed dose

A missed weekly dose may be given up to 3 days late; later than that, resume at the next scheduled day and complete the cycle.

Contraception & pregnancy

IgG-lowering therapy has fetal/neonatal implications in late pregnancy — specialist review for pregnancy planning.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Infection surveillance	Each dose and between cycles	URTI and UTI are the commonest; serious infection → hold.
MG-ADL / disease score	Baseline, during each cycle, between cycles	Defines response and next-cycle timing.
Hypersensitivity review	During and 1 hour after each infusion	Anaphylaxis is rare but labeled.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Active infection	Delay the dose or cycle until resolved.
Serious hypersensitivity during infusion	Interrupt and evaluate.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Anaphylaxis or serious hypersensitivity	Discontinue.
Recurrent serious infections attributable to therapy	Reassess mechanism with the specialist.

Section 5 — Notes & Practical Points

- ☐ Set expectations: most patients feel benefit within the first cycle and wear-off before the next — this is the drug's design, not treatment failure.
- ☐ Track cumulative IgG if recurrent infections emerge; profound or persistent hypogammaglobulinemia changes the risk-benefit.

Prepared November 2026 by Madison Neurology LLC.

This document is an educational compilation and does not reproduce the complete prescribing information. Verify every element against the current FDA label and applicable REMS requirements before clinical use.

- Current U.S. prescribing information via NIH DailyMed — https://dailymed.nlm.nih.gov/dailymed/
- FDA Drugs@FDA database — https://www.accessdata.fda.gov/scripts/cder/daf/
- FDA drug safety and availability updates — https://www.fda.gov/drugs/drug-safety-and-availability

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Questions about infusion referrals: call 608 403 0000. Neurology Care 7 days a Week. Because Your Brain Matters.