

Miami Neurology & Immunology Associates

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April 7, 2026

Aetna PPO — Prior Authorization Department

Attn: Formulary Exception Review Team

P.O. Box 14462 | Lexington, KY 40512

RE: Formulary Exception Request — Medical Necessity of Privigen (Immune Globulin Intravenous [Human], 10%)

Patient: Maria Elena Vasquez | **DOB:** 03/15/1971

Member ID: AET847392018 | **Group ID:** GRP29341

Diagnosis: Common Variable Immunodeficiency (CVID) — ICD-10: D83.9

Referring Provider: James T. Harrington, MD | **NPI:** 1073541867

To Whom It May Concern,

I am writing to request a formulary exception for my patient, **Maria Elena Vasquez** (DOB: 03/15/1971), regarding the use of **Privigen (Immune Globulin Intravenous [Human], 10%)** for the treatment of her confirmed diagnosis of **Common Variable Immunodeficiency (CVID)**. Ms. Vasquez has been under my care since January 2023 and requires ongoing IVIG replacement therapy to maintain adequate immunoglobulin levels and prevent recurrent serious infections.

Clinical Background and Medical Necessity

Ms. Vasquez carries a confirmed diagnosis of CVID supported by two separate immunoglobulin panels demonstrating markedly reduced IgG levels (<400 mg/dL) and impaired vaccine responses. Prior to initiating IVIG therapy, she experienced four hospitalization-level infections over 18 months, including two episodes of community-acquired pneumonia and one episode of septic sinusitis.

Trial and Failure of Formulary Alternatives

Agent	Duration	Reason for Discontinuation
Gamunex-C (10%)	Feb – Jul 2024 (6 months)	Recurrent systemic infusion reactions (flushing, rigors, grade 2 headache); premedication required at every infusion with incomplete relief.
Octagam (10%)	Aug – Nov 2024 (4 months)	Persistent thrombotic risk concern given patient's Factor V Leiden carrier status; hematologist consultation recommended avoidance.

Rationale for Privigen

Ms. Vasquez was transitioned to Privigen (IGIV 10%) in December 2024. Since initiation, she has tolerated infusions without systemic reactions, maintained IgG trough levels within the therapeutic range of 700–900 mg/dL (most recent: 782 mg/dL on 02/14/2026), and has had no hospitalizations or serious infections in 16 months. Privigen's low IgA content (≤ 25 mg/mL) and L-proline stabilizer formulation are clinically important given her history. Switching to another agent would risk destabilizing her well-controlled clinical status.

Requested Exception

I respectfully request that Aetna grant a formulary exception authorizing coverage of **Privigen (IGIV 10%) 35 g IV every 4 weeks** for Ms. Vasquez's ongoing IVIG replacement therapy. This request is made on the basis of medical necessity, documented formulary alternative trial and failure, and established clinical stability on the current regimen. Supporting documentation including infusion records and laboratory results is available upon request.

Sincerely,

James T. Harrington, MD

Board-Certified Clinical Immunologist

NPI: 1073541867 | DEA: BH3421987

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