

# A Real-World Evaluation of the Impact of One Intravenous Immunoglobulin Product on Patients With Chronic Inflammatory Demyelinating Polyneuropathy — Tolerability, Reported Outcomes, Satisfaction

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## BACKGROUND

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is an autoimmune disorder in which the body's immune system attacks the myelin sheath surrounding nerve cells throughout the peripheral nervous system, causing paresthesia, weakness, loss of reflexes, loss of balance, altered ambulation, and loss of sensation in the affected extremities.<sup>1,2</sup>
- CIDP affects men more often than women and while it is most commonly diagnosed in patients between 40 and 60 years old, it can occur at any age.<sup>1</sup>
- Intravenous immunoglobulin (IVIG) therapy is an established treatment modality for patients with CIDP.<sup>1-3</sup>
- This provider, a national infusion company and specialty pharmacy, provides home infusion services for patients with an array of chronic-care needs, including CIDP.

## PURPOSE

- The purpose of this report was to evaluate the tolerability, clinical outcomes, and patient-reported experiences among patients with CIDP during treatment with one 10% IVIG product in a real-world setting of home infusion.

## METHODS

- This analysis was based on a retrospective review of this provider's database of patients who received repeated home infusions with one specific 10% IVIG (Gammalex® 10%) over a three-year period (1/1/2021-12/31/2023).
- Female and male patients 10 years of age and older with a diagnosis of CIDP (G61.81) were included in this analysis. Data were derived from electronic records of multi-therapy skilled nurses' visits and patient-reported outcomes.
- Safety/tolerability:** adverse effects that occurred during a home-infusion visit (patient encounter) and were reported by nurses and/or patients were recorded electronically in a standardized clinical template. Patients' reports of adverse effects that occurred between 0 to 72 hours after completion of infusions were solicited by infusion nurses at each subsequent visit, as were any other reports of adverse effects.
- Infusion nurse–evaluated outcomes:** infusion nurses used three tools (Karnofsky Performance Status Scale, Inflammatory Rasch-built Overall Disability Scale [I-RODS], and Inflammatory Neuropathy Cause and Treatment [INCAT] disability score) to evaluate patients' responses to treatment during home visits. In the cohort of patients for whom complete data were available for analysis, improvement was defined as ≥10% favorable change from baseline scores.
- Patient-reported outcomes:** the 20-item patient-experience survey (via Survey Monkey) captured patients' experiences with response to therapy, energy level, activities of daily living (ADLs), disease symptoms, disease progression, adverse effects, personal/work time, financial burden of disease, duration of treatment effect after infusion, and overall satisfaction with the impact of this treatment on life and health condition.

## RESULTS

### Patient Population

- A total of 83 adult patients were identified from the database and analyzed (**Table 1**). The mean age of patients was 61.4 years and 51.8% were male. The majority of patients (n = 73, 87.9%) had body weights of 55 to 114 kg; most patients (n = 55, 66.3%) received treatment with this 10% IVIG at doses of 1.0 to 2.0 g/kg, and nearly all (n = 76, 91.2%) were on infusion cycles of 2 to 4 weeks.
- Onset of CIDP was ≤3 years in most patients (n = 44, 53.0%) and the majority of patients (n = 65, 78.3%) had not previously received IVIG treatment.
- The most common comorbidities were hypertension (42.2%) and diabetes mellitus (10.8%).

## RESULTS, CONT'D

**Table 1.** Patient Demographics and Characteristics at Baseline (N=83)

Parameter	Baseline Data
Age, mean (years)	61.4
Male, n (% of pts)	43 (51.8)
CIDP Diagnosis, n (% of pts)	83 (100)
Body Weight of 55-114 kg, n (% of pts)	73 (87.9)
Comorbidities, n (% of pts)	
Hypertension	35 (42.2)
Diabetes mellitus	9 (10.8)
Coronary artery disease	6 (7.2)
Hyperlipidemia	6 (7.2)
Migraine	6 (7.2)
Cerebral vascular access	4 (4.8)
Frequency of IVIG Infusions, n (% of pts)	
Q1 week / Q2 week / Q3 week / Q4 week	1 (1.2) / 29 (34.9) / 23 (27.7) / 24 (28.9)
Loading dose only	6 (7.2)
10% IVIG dose infused, g/visit (mean)	32.8

- Over the three-year period of study, 2652 patient home visits for IVIG infusion were documented among these 83 patients; this represents a mean of 32.0 infusions per patient, which were predominantly administered Q2W to Q4W.
- A total of 86,980 g of this 10% IVIG product were dispensed at an average of 32.8 g/visit.
- Nearly all (96%) patients received premedication (eg, acetaminophen and/or diphenhydramine) at each infusion as part of the standard order set for IVIG treatment.
- A cohort of 26 patients who participated fully and consistently with the treatment/monitoring protocol during the 3-year study period were included in the analyses of clinical outcomes; 57 patients were excluded due to incomplete clinical records, including data for the outcomes of interest.

### Safety/Tolerability

- Adverse effects occurring during infusion were reported for 2.0% of the 2652 infusion visits and those occurring 0 to 72 hours after infusion were reported for 14.9% of infusions (**Table 2**). The most prevalent adverse effects were fatigue and headache.

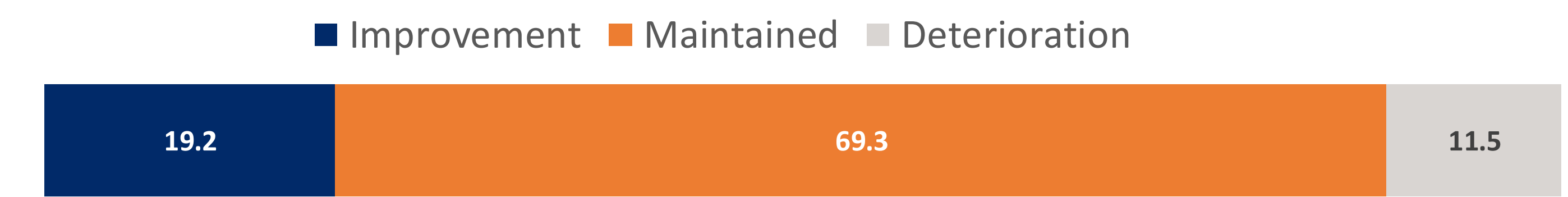
**Table 2.** Incidence of Adverse Effects Through 2652 Infusions; n (% of infusions)

Adverse Effect	During Infusion	0 to 72 Hours After Infusion
Any	52 (2.0)	396 (14.9)
Fatigue	27 (1.0)	182 (6.9)
Headache	13 (0.5)	117 (4.4)
Rash/pruritus	4 (0.2)	14 (0.5)
Fever	0	12 (0.5)
Nausea/vomiting	2 (0.07)	10 (0.4)
Shortness of breath	0	10 (0.4)
Dysphagia	0	9 (0.3)
Migraine	1 (0.04)	4 (0.2)
Chest tightness	1 (0.04)	4 (0.2)
Other	4 (0.2)	34 (1.3)

### Infusion Nurse–Evaluated Outcomes

- During treatment with this 10% IVIG, most patients were observed to have either improved by ≥10% on all three outcome measures (5 patients, 19.2%) or maintained their same level of wellness from baseline (18 patients, 69.3%); a minority (3 patients, 11.5%) were reported to have experienced deterioration (**Figure 1**).

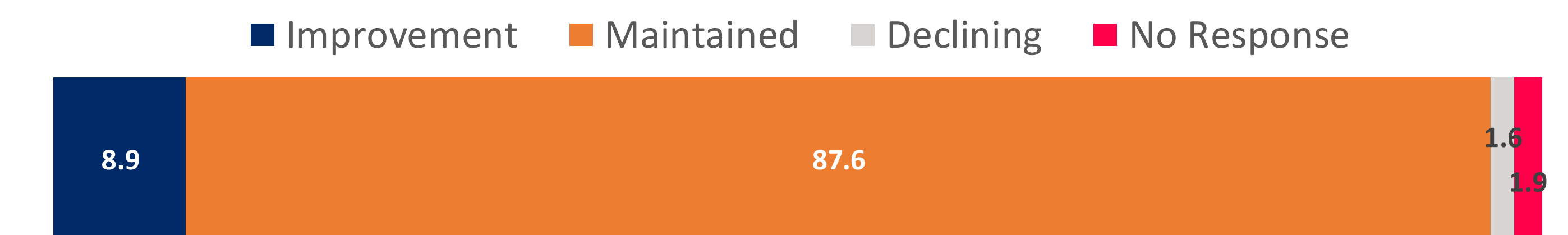
**Figure 1.** Infusion-Nurse–Evaluated Outcomes: Percentage of Patients Experiencing ≥10% Improvement on All Three Outcome Measures (Karnofsky Performance Status Scale, I-RODS, and INCAT) During Treatment With This 10% IVIG (n=26)



### Patient-Reported Outcomes

- The positive impact reported by patients receiving this 10% IVIG included increased energy, improved ability to participate in ADLs, overall improvement in disease symptoms, and decreased disease progression.
- Patients reported improvement in symptoms at 8.9% of visit encounters, maintenance of symptoms at 87.6%, and decline at 1.6% (**Figure 2**); for 1.9% of encounters, no response was provided on this metric (**Figure 2**).

**Figure 2.** Patient-Reported Outcomes: Percentage of Patients Who Reported Improvement, Maintenance, or Decline in Symptoms or Showed No Response During Treatment With This 10% IVIG (n=26)



Most patients had been receiving this 10% IVIG product for more than 3 to 4 infusion cycles before the start of the study period.

- Negative effects of IVIG therapy included loss of personal and work time, inability to participate fully in ADLs, and financial impact.
- Duration of treatment effect: 50% of patients (n=18) who responded to this survey question reported wearing-off of treatment effect within one week of their next infusion and 50% reported that the benefits lasted through to the next infusion.

## CONCLUSIONS

- The 10% IVIG product evaluated in this real-world experience appears to be well tolerated, with minimal adverse effects.
- Three-year results of our study show that this 10% IVIG product often resulted in improvement or prevention of further disease progression in patients with CIDP receiving ongoing IVIG infusions. Outcomes evaluated by infusion nurses and by patients were consistent with respect to improvement versus deterioration.

<sup>1</sup> Gammalex® 10% Immune Globulin Intravenous [Human], 10% Liquid is not approved for the treatment of CIDP in the US.  
<sup>2</sup> Adverse effects were defined as any undesired effect of a drug or other type of treatment, which can range from mild to severe, and can be life-threatening.

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