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Real World Use of IVIG in US Regional Healthcare Plans

T.D. Williams¹, M. Polson¹, M.C. Runken²

Background

- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a neuromuscular disease characterized by inflammation of peripheral nerves with progressive pain, weakness, or sensory deficit
- Treatment focuses on improving functional mobility and decreasing symptoms
- The results of the ICE study lead to a level-A first-line treatment recommendation for intravenous immunoglobulin (Ig)¹
- Few studies have assessed the correlation between these recommendations and real world practice

Objective

 Analyze real-world health plan claims data to understand current utilization of Ig therapy in patients with CIDP and assess correlation with best practice treatment recommendations of the ICE study

Methods

- This study retrospectively analyzed real-world pharmacy and medical administrative claims data from multiple regional health plans consisting of commercial and Medicare lives between January 1, 2012, and July 31, 2017 and Prior Authorization (PA) data from June 24, 2013 to July 31, 2017
- Index date was the first claim with a diagnosis of CIDP
- Inclusion criteria include:
 - At least two medical claims with an ICD-9/10-diagnosis for CIDP (357.81/G61.81)
 occurring at least 90 days apart
 - 18 years of age or older on the index date
 - Continuously enrolled for at least 6 months prior (baseline period) and at least 18 months post index date (follow up period)
 - At least one Ig claim during the follow up period, and no Ig claims during the baseline period
- Discrete data were represented by counts and percentages
- Continuous results were presented as means, medians, and standard deviations, minima, and maxima

Results

- The study population included 157 patients with CIDP receiving Ig therapy, 59% male, mean age of 56.3 years, and a mean baseline Charlson Comorbidity Index of 2.59 (SD 2.13) Patients were 93.0% commercial and 7.0% Medicare (Table 1)
- 69.4% of patients had height and weight data, with a mean BMI of 27.4 (SD=17.5) (Table 1)
- Gamunex®-C/Gammaked™ was initiated most often (46%), followed by Gammagard® (25%) and Privigen® (9%) (Table 2)
- 35% of CIDP patients had a loading dose within 10% of the ICE-recommended 2g/kg. The mean loading dose was 1.5g/kg (Figure 1)
- 54.1% of patients had dose adjustment (i.e. 5 gram) during the follow up period
- 67.5% of patients discontinued Ig therapy during the follow up period
- Product switching was uncommon (22%), with the products most frequently switched to being Gamunex-C®/Gammaked™ (26.5%), Gammagard Liquid ™ (23.5%), and Octagam® (14.7%) (Figure 2)

| | | 4 |
|----------------------------------|-----------------|---------------------------------------|
| Total Enrolled | Members | 157 |
| Gender | F | 64 (40.76%) |
| | M | 93 (59.24%) |
| Age | Age, Continuous | 56.25 (57)[13.38 ; 24 - 91] |
| | 21-30 | 7 (4.46%) |
| | 31-40 | 10 (6.37%) |
| | 41-50 | 34 (21.66%) |
| | 51-60 | 45 (28.66%) |
| | 61-64 | 26 (16.56%) |
| | 65+ | 35 (22.29%) |
| Charlson Comorbidity Index | CCI, Continuous | 2.59 (2.0) [2.13; 1-10] |
| | 0 | 101 (64.33%) |
| | 1 | 22 (14.01%) |
| | 2 | 14 (8.92%) |
| | 3+ | 20 (12.74%) |
| BMI | | 27.38 (27.93) [5.49 ; 9.8- 48.01] |
| Weight by Gender (kg) | F | 73.0 (72.1) [16.5; 45-118] |
| | M | 90.1 (91.0)[14.5; 30-125] |

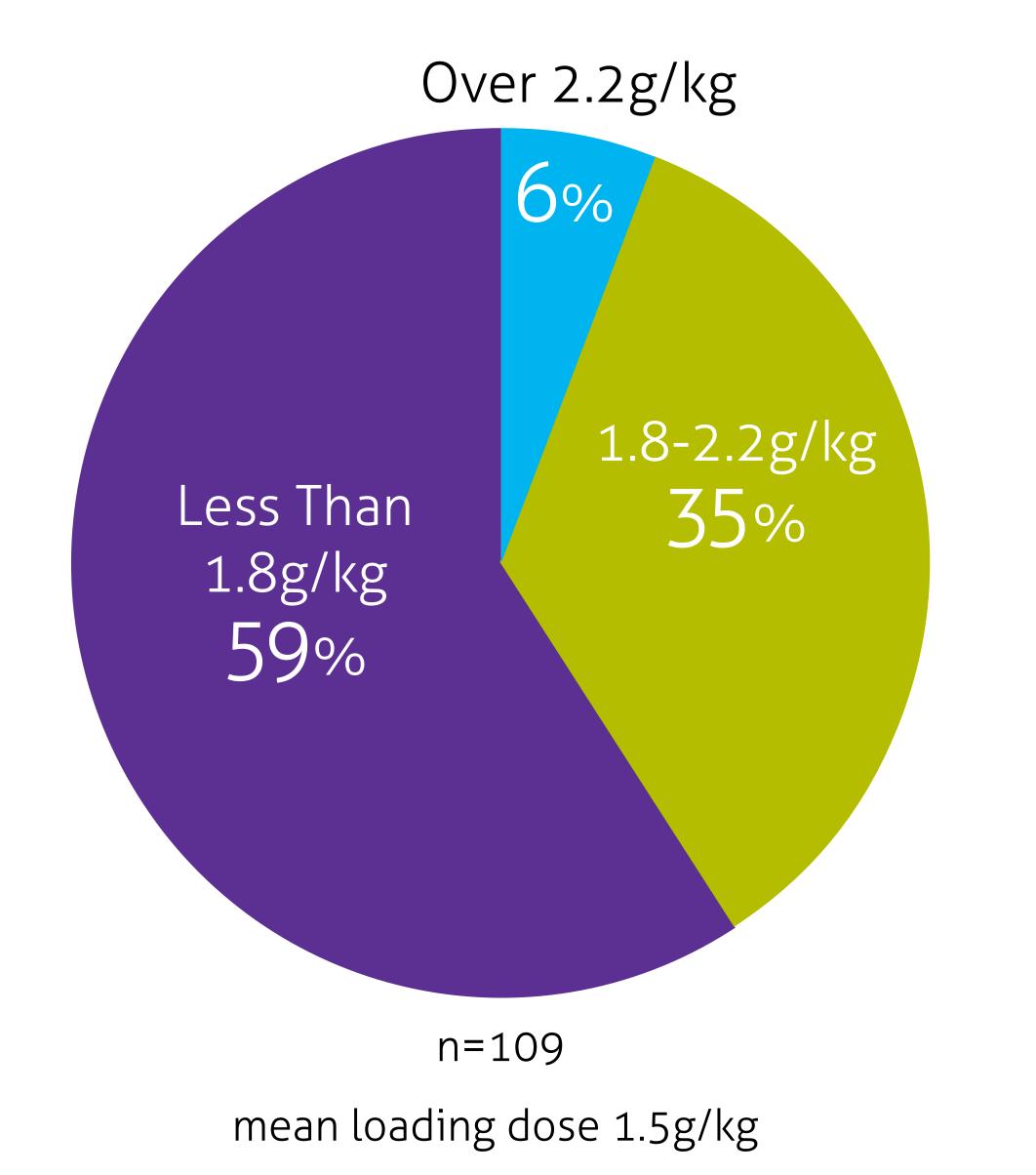
| Mean(Median)[SD; Min-Max] |
|---------------------------|
|---------------------------|

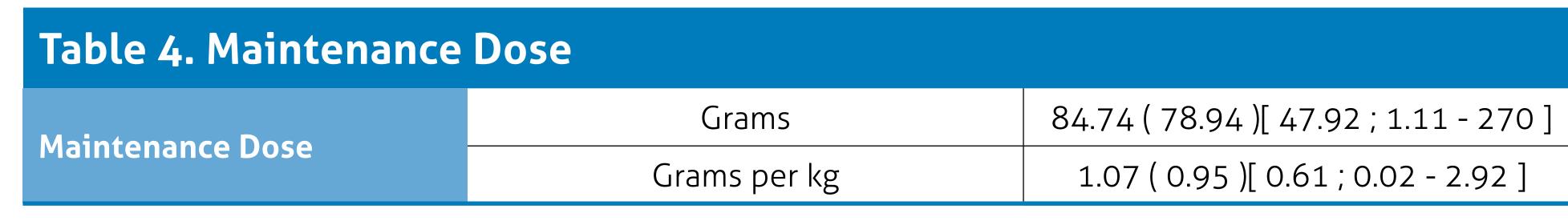
| Table 2. Initial Ig Product | | |
|---------------------------------|-------------|--|
| Flebogamma® (J1572) | 7 (4.46%) | |
| Gammagard Liquid ™ (J1569) | 39 (24.84%) | |
| Gammaplex® (J1557) | 2 (1.27%) | |
| Gamunex-C®/Gammaked™ (J1561) | 72 (45.86%) | |
| Immune globulin, powder (J1566) | 13 (8.28%) | |
| Octagam® (J1568) | 10 (6.37%) | |
| Privigen® (J1459) | 14 (8.92%) | |

Table 3. Ig Infusion Interval

| Infusion Frequency (days) | 22.45 (22.65)[10.07 ; 3.00 - 56.00] |
|---------------------------|---|
| Mean(Median)[SD; Min-Max] | |

Figure 1. Average Loading Doses



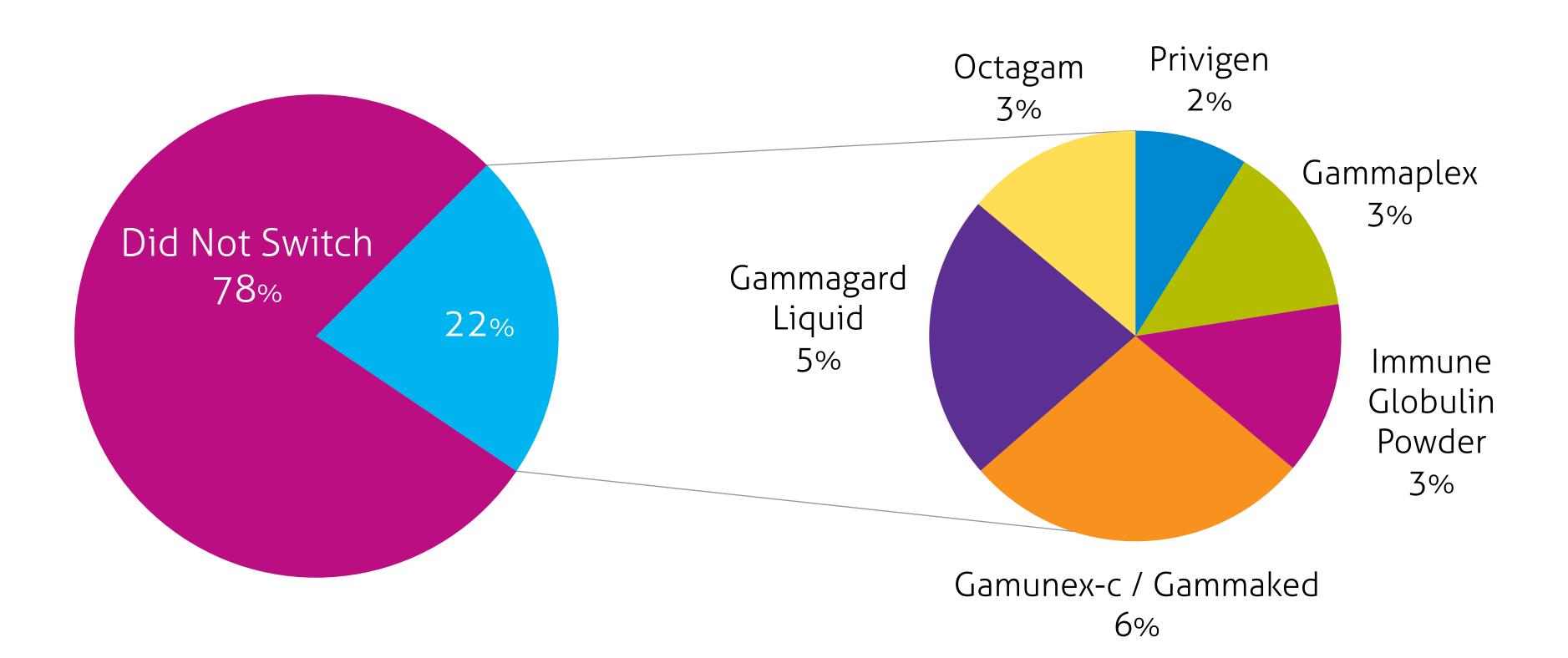


Mean(Median)[SD; Min-Max]

Dose (Grams) calculated for all included members (n=157)

Dose (Grams per kg) only calculated for members with weights from PA approvals (n=109)

Figure 2. Product Switching



Conclusion

- Discontinuation rates for chronic Ig therapy were high (68%)
- Loading doses in accordance with ICE trial (2g/kg) were uncommon (35%)
- Opportunities may exist to improve the management of CIDP, including administration of indicationappropriate dosing, assessments of response to therapy, and modification of treatment regimen

References

1. Hughes R., Donofrio P., Bril V., Dalakas M., Deng C., Hanna K., et al. for the ICE Study Group (2008) Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. Lancet Neurol 7: 136–44

Disclosures

• This study was conducted by Magellan Rx Management, Scottsdale, AZ, and sponsored by Grifols.