RWD78

# Burden of intravenous immunoglobulin use among adults with generalized myasthenia gravis in Japan

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## INTRODUCTION

- Generalized myasthenia gravis (gMG) is a chronic autoimmune disorder primarily mediated by autoantibodies against the neuromuscular junction, leading to fatigable skeletal muscle weakness.[1]
- In Japan, the prevalence of gMG has doubled since 2006 to 23.1 per 100,000 in 2018.[2,3]
- The current Japanese guidelines recommend early fast-acting treatments, including intravenous immunoglobulin (IVIg), to achieve prompt response while limiting oral glucocorticoid (GC) exposure.[4-6]
- In clinical practice, some patients may repeat IVIg courses as maintenance therapy. In the US, frequent IVIg users with gMG had nearly 2.5-fold higher annual medical costs compared to less frequent IVIg users.[7]
- The IVIg burden among patients with gMG in Japan may differ due to unique treatment practices, insurance coverage, and IVIg pricing. Japan-specific data on IVIg burden in gMG care are limited.

## OBJECTIVES

- To evaluate healthcare resource utilization (HCRU) and costs among adult patients with gMG in Japan receiving IVIg.

## METHODS

- A retrospective cohort study was conducted using the Japan Medical Data Vision (MDV) dataset, which includes nearly 50 million patients from over 540 hospitals. The dataset covered the period between April 1, 2008, and December 31, 2022 (**Figure 1**).

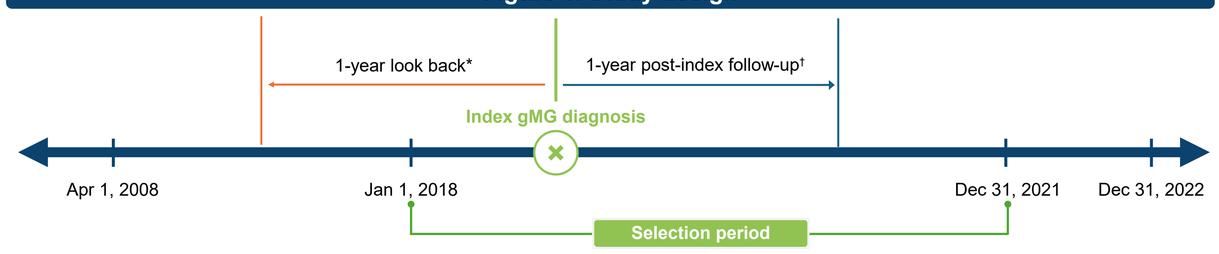
**Patients with gMG were selected based on**

- Adults (aged ≥18 years at index date) with at least 2 gMG diagnoses (excluding ocular MG) at least 30 days apart between 2008 and 2022.
- Adults with at least 1 gMG diagnosis during the selection period (Jan 2018–Dec 2021; index date).
- Adults with available data at least 1 year before and after the index date.

**IVIg user definition**

- Patients with at least 1 claim for IVIg within 1 year after the index date were considered IVIg users.
- Patients with at least 3 IVIg courses (clusters of IVIg claims ≤5 days apart) 1 year post-index were considered frequent IVIg users.
- The remaining patients were defined as intermittent IVIg users.

**Figure 1. Study design**




### Exclusion criteria

- Any claim for exclusionary conditions‡ during the 1 year pre-index and anytime during the post-index period.

### Study outcomes

- All-cause and gMG-specific HCRU.
- All-cause and gMG-specific costs.

### Statistical analysis

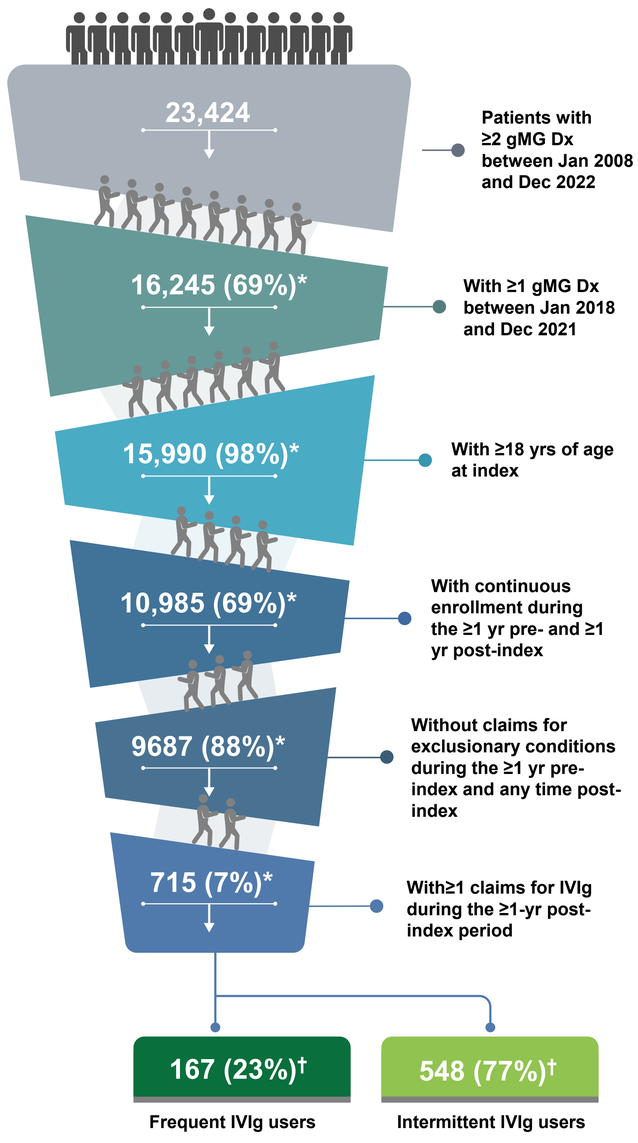
- HCRU and costs in Japanese yen (JPY or ¥) were analyzed for inpatient (IP), outpatient (OP), and drug-related visits on a per-patient per-year (PPPY) basis.

*Pre-index period (1 year pre-index) to establish baseline characteristics and prior treatment history.
†Observation period (1 year post-index and, if available data permit, up to 5 years post-index) to establish HCRU and costs.
‡The conditions include CIDP, polymyositis, multiple sclerosis, neuromyelitis optica, GBS, dermatomyositis, myelitis, Miller Fisher syndrome, encephalitis, meningoencephalitis, Fisher syndrome, sporadic inclusion body myositis, acute myelitis, acute multiple sclerosis, spinal multiple sclerosis, opticospinal multiple sclerosis, encephalomyelitis, chronic encephalitis, amyotrophic lateral sclerosis, mitochondrial encephalomyopathy, ophthalmoplegic migraine, LEMS, MMN, and limbic encephalitis.
CIDP, chronic inflammatory demyelinating polyneuropathy; GBS, Guillain–Barré syndrome; gMG, generalized myasthenia gravis; HCRU, healthcare resource utilization; LEMS, Lambert-Eaton myasthenic syndrome; MMN, multifocal motor neuropathy.

## RESULTS

- A total of 9687 patients with gMG fulfilled all criteria. Of them, 715 (7%) were IVIg users (frequent IVIg users n=167 [23%]; intermittent IVIg users n=548 [77%]) (**Figure 2**).

**Figure 2. Patient selection**




*% of patients retained from the previous step.
†% of patients out of the total IVIg users.
Dx, diagnosis; gMG, generalized myasthenia gravis; IVIg, intravenous immunoglobulin; yr, year.

- Baseline characteristics of the patients with gMG from Japan were comparable to those previously reported in real-world populations with gMG in Japan[8] (**Table 1**).
- Compared with intermittent IVIg users, frequent IVIg users had a younger mean (SD) age (57 [17.2] versus 64 [15.3] years), with a greater proportion being female.
- IVIg users exhibited a greater burden of comorbidity, as indicated by higher Charlson Comorbidity Index (CCI) scores.
- A greater proportion of IVIg users received gMG treatments during the 1-year pre-index period compared to the overall gMG cohort.

**Table 1. Demographics and clinical characteristics**

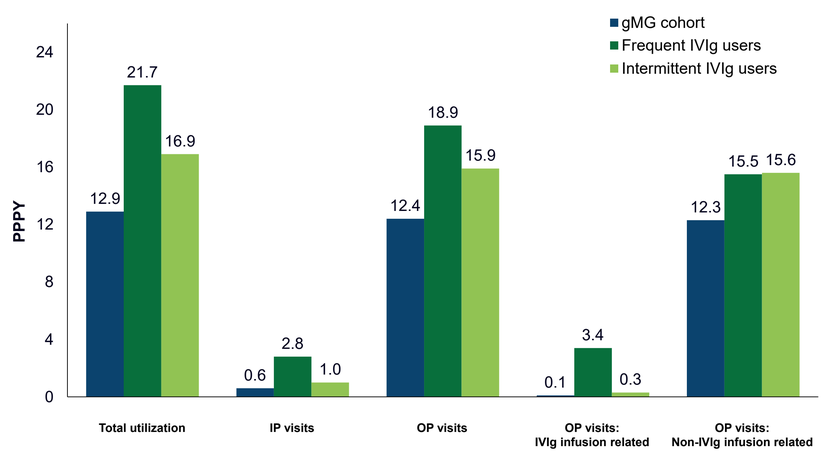
| Baseline characteristics | gMG cohort (N=9687) | Frequent IVIg (n=167) | Intermittent IVIg (n=548) |
|---|---|---|---|
| **Age** | | | |
| Mean (SD), years | 65 (15.2) | 57 (17.2) | 64 (15.3) |
| 18–40 years, n (%) | 704 (7) | 29 (17) | 45 (8) |
| 41–65 years, n (%) | 3444 (36) | 80 (48) | 216 (39) |
| 65+ years, n (%) | 5539 (57) | 58 (35) | 287 (52) |
| **Sex** | | | |
| Female, n (%) | 5466 (56) | 103 (62) | 326 (59) |
| **CCI score (excluding disease claims on index date)** | | | |
| Mean (SD) | 1.57 (1.9) | 2.21 (2.0) | 2.14 (2.3) |
| **Treatments during 1 year pre-index gMG diagnosis, n (%)†** | | | |
| AChEi | 3135 (32) | 77 (46) | 314 (57) |
| GC | 3310 (34) | 121 (72) | 388 (71) |
| Oral GC | 3258 (34) | 116 (69) | 365 (67) |
| IVMP | 271 (3) | 35 (21) | 97 (18) |
| NSISTs | 2169 (22) | 109 (65) | 289 (53) |
| IVIg | 307 (3) | 79 (47) | 51 (9) |
| PLEX | 93 (1) | 26 (16) | 60 (11) |
| Thymectomy | 68 (1) | 1 (1) | 11 (2) |
| Biologics | 13 (0) | 4 (2) | 4 (1) |

†Percentages may not add up to 100 as patients may have had multiple treatments at baseline.
AChEi, acetylcholinesterase inhibitor; CCI, Charlson Comorbidity Index; GC, glucocorticoid; gMG, generalized myasthenia gravis; IV, intravenous; IVIg, intravenous immunoglobulin; IVMP, intravenous methylprednisolone; NSIST, non-steroidal immunosuppressive therapy; PLEX, plasma exchange; SD, standard deviation.

### Healthcare resource utilization (HCRU) over a 1-year follow-up period

- The all-cause HCRU rate in the gMG cohort was 12.9 PPPY during the 1 year after index date (**Figure 3**). OP visits accounted for 96% of total HCRU.
- All-cause HCRU was higher among frequent IVIg users (21.7 PPPY) and intermittent IVIg users (16.9 PPPY) compared with the overall gMG cohort, driven primarily by OP visits (18.9 PPPY and 15.9 PPPY vs 12.4 PPPY).
- Frequent IVIg users had higher rates of IP and IVIg-infusion-related OP visits than intermittent IVIg users and the overall gMG cohort.
- gMG-specific HCRU (**Table 2**) accounted for 90% of all-cause HCRU for the overall gMG cohort, 94% for frequent IVIg users, and 97% for intermittent IVIg users.

**Figure 3. All-cause HCRU over 1-year follow-up**




An outpatient visit was considered IVIg infusion-related if an IVIg prescription claim was observed on the same date.
gMG, generalized myasthenia gravis; HCRU, healthcare resource utilization; IP, inpatient; IVIg, intravenous immunoglobulin; OP, outpatient; PPPY, per-patient per-year.

**Table 2. gMG-specific* HCRU over 1-year follow-up**

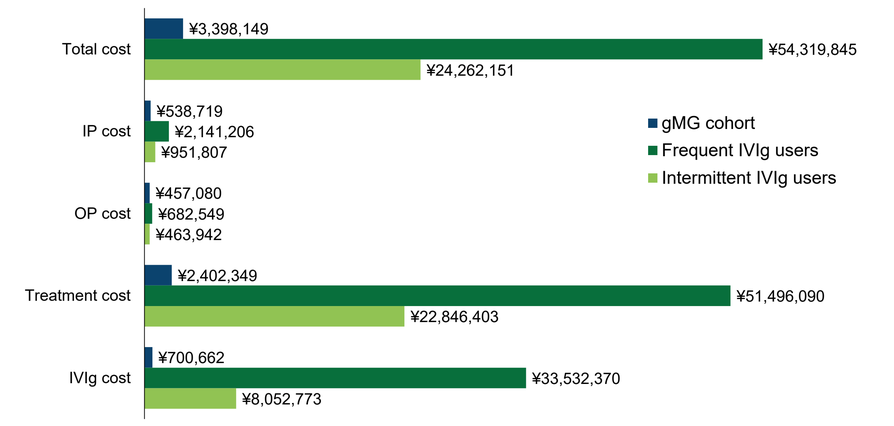
| HCRU categories | gMG cohort (N=9687) | Frequent IVIg (n=167) | Intermittent IVIg (n=548) |
|---|---|---|---|
| **Person-years†** | 8981 | 159 | 487 |
| **Total utilization rate, PPPY** | 11.6 | 20.4 | 16.3 |
| **IP visit rate, PPPY** | 0.1 | 2.3 | 0.6 |
| Average LoS per hospitalization, days | 19.8 | 15.2 | 29.6 |
| Median LoS per hospitalization (IQR), days | 12 (6–22) | 7 (4–14) | 10 (5–20) |
| **OP visit rate, PPPY** | 11.5 | 18.1 | 15.7 |
| IVIg infusion related | 0.1 | 3.2 | 0.3 |
| Non-IVIg infusion related | 11.4 | 14.9 | 15.4 |

*Visits were considered gMG-related if the patient had a gMG diagnosis claim in the same month as the claim.
†Person-years for the relevant observation periods.
gMG, generalized myasthenia gravis; HCRU, healthcare resource utilization; IP, inpatient; IVIg, intravenous immunoglobulin; IQR, interquartile range; LoS, length of stay; OP, outpatient; PPPY, per-patient per-year.

### Costs over 1-year follow-up

- The mean all-cause total cost PPPY for the overall gMG cohort was ¥3,398,149 (**Figure 4**), with treatment as the primary cost driver (71%).
- Mean all-cause total costs PPPY were ~16x higher for frequent IVIg users (¥54,319,845) and ~7x higher for intermittent IVIg users (¥24,262,152) versus the overall gMG cohort.
- The majority of costs were attributed to treatments among frequent (95%) and intermittent (94%) IVIg users. Specifically, IVIg cost accounted for 62% of the all-cause total cost in the frequent IVIg cohort (¥33,532,370).
- gMG-specific costs (**Table 3**) accounted for the majority of all-cause costs (87% in the overall gMG cohort; 98% among frequent and intermittent IVIg users).

**Figure 4. All-cause costs PPPY (¥) over 1-year follow-up**




gMG, generalized myasthenia gravis; IP, inpatient; IVIg, intravenous immunoglobulin; OP, outpatient; PPPY, per-patient per-year.

**Table 3. gMG-specific* costs PPPY (¥) over 1-year follow-up**

| | gMG cohort (N=9687) | Frequent IVIg (n=167) | Intermittent IVIg (n=548) |
|---|---|---|---|
| **Person-years†** | 8981 | 159 | 487 |
| **Total cost PPPY** | ¥2,945,378 | ¥53,219,791 | ¥23,831,637 |
| **Average IP cost PPPY (%)** | ¥126,435 (4) | ¥1,114,774 (2) | ¥533,412 (2) |
| **Average OP cost PPPY (%)** | ¥417,865 (14) | ¥631,919 (1) | ¥458,349 (2) |
| **Average treatment cost PPPY (%)** | ¥2,401,078 (82) | ¥51,473,099 (97) | ¥22,839,876 (96) |
| IVIg (%) | ¥700,257 (24) | ¥33,512,416 (63) | ¥8,050,136 (34) |

*Visits were considered gMG related if the patient had a gMG diagnosis claim in the same month as the claim.
†Person-years for the relevant observation periods.
gMG, generalized myasthenia gravis; IP, inpatient; IVIg, intravenous immunoglobulin; OP, outpatient; PPPY, per-patient per-year.

## CONCLUSIONS

**In Japan, substantial economic burden was observed among adults with gMG, particularly among frequent IVIg users.**

**Among frequent IVIg users, higher HCRU was partially driven by higher rates of inpatient visits, suggesting unmet clinical needs.**

**Frequent and intermittent IVIg users incurred total all-cause healthcare costs that were approximately 16-fold and 7-fold higher, respectively, compared to the overall gMG cohort.**

**With multiple novel gMG therapy options becoming available in Japan, considering the treatment burden and economic impact on patients reflected by HCRU/costs is important for decision-making.**

### Limitations

- This study captures only the direct economic burden of gMG using administrative claims data and does not account for indirect impacts due to loss of productivity, employment, and quality of life.
- Findings may not fully represent the global gMG population due to variations in healthcare systems and treatment practices.

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