Incidence of Adverse Events and Costs Among Patients Initiating Treatment for Myasthenia Gravis: A Real-World Analysis

RWD103

Lesley-Ann Miller-Wilson[1], Lincy S. Lal[1], Nicole Princic[2], Carolyn R. Lew[2], Yuriy Edwards[1], Nicholas Streicher[3]

[1]Immunovant, Inc., New York, NY, USA; [2]Merative, Ann Arbor, MI, USA; [3]Medstar Georgetown University Hospital, Washington, DC, USA

BACKGROUND

- Myasthenia gravis (MG) is an incurable autoimmune condition characterized by generalized muscle weakness that results from disruption in communication between muscles and nerves[1]
- The therapeutic landscape in MG has been rapidly expanding, to include both newly approved biologics and legacy treatments (acetylcholinesterase inhibitors [ACH], systemic immunosuppressants [SYS], and oral glucocorticoids [OG]), which are associated with various adverse events (AEs)[2,3]
- These AEs may contribute substantially to both the clinical and economic burden of MG

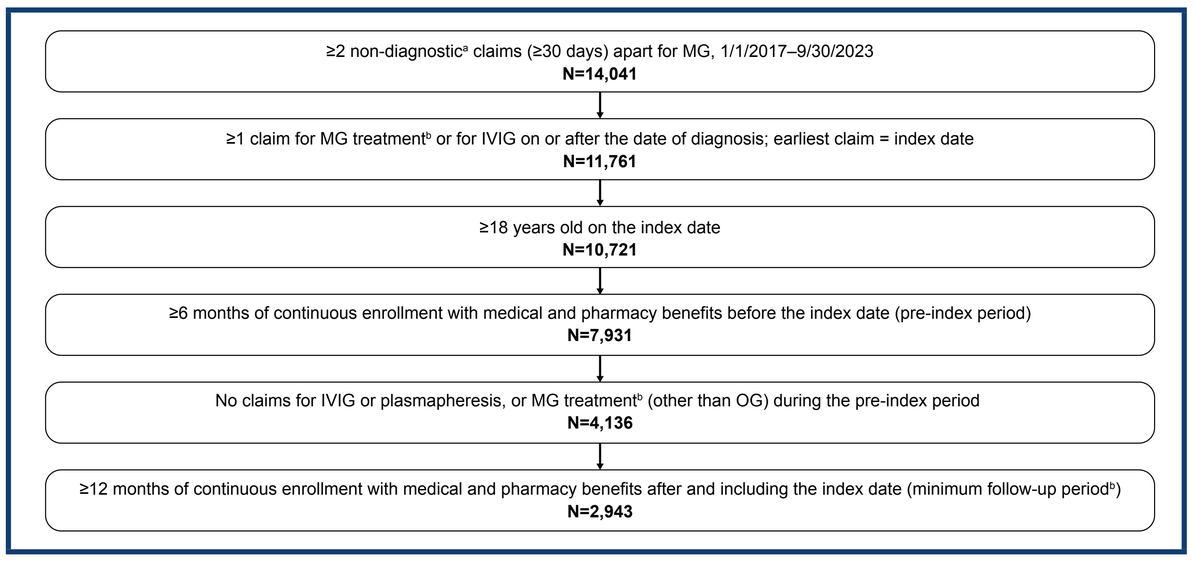
OBJECTIVE

- To examine the real-world incidence and costs associated with AEs following initiation of systemic treatment for MG

METHODS

- This retrospective cohort study used administrative claims data from the Merative™ MarketScan® Commercial and Medicare Databases between January 1, 2017 and September 30, 2024
- Eligible patients had ≥2 claims (>30 days apart) with an *International Classification of Diseases, 10th Revision* (ICD-10) diagnosis code for MG (G7000, G7001) between January 1, 2017 and September 30, 2024 and ≥1 claim for an MG systemic treatment or for IVIG on or after the earliest diagnosis
  - The date of the earliest MG treatment represents the index date
  - MG treatments included ACH (neostigmine, pyridostigmine), SYS (azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate mofetil, tacrolimus), biologics (eculizumab, efgartigimod, efgartigimod alfa and hyaluronidase-gvfc, ravulizumab, rituximab, rozanolixizumab-noli, and zilucoplan), and OG
  - Participants were required to be ≥18 years old on the index date, with ≥6 months pre- and ≥12 months post-index of enrollment with medical and pharmacy benefits
  - Those with medical or pharmacy claims for IVIG, plasmapheresis, or a systemic MG treatment (other than OG) in the pre-index period were excluded (**Figure 1**)
- The incidence of AEs and AE-related medical costs were assessed during the 12-month follow-up period
  - AEs were identified by >1 claim with a diagnosis code for conditions that are known side effects of the various treatments for MG (grouped by class into metabolic, cardiovascular, gastrointestinal [GI], neurological/psychiatric, and other categories) (**Figure 2**)
  - A diagnosis was considered an AE, associated with treatment, if the patient had no claims for that diagnosis before treatment initiation
  - The frequency of incident of AEs was determined by reporting the proportion of patients newly diagnosed with the AE during the 12-month period following initiation of systemic therapy for MG
- AE associated costs (in 2024 dollars) were derived from the amounts paid on inpatient and outpatient medical claims with a diagnosis code for the AE

Figure 1. Selection of patients with MG newly initiating systemic treatment



[a]Non-diagnostic claims are claims that are not for diagnostic tests and therefore indicate a confirmed diagnosis. [b]MG treatments included ACH, OG, SYS, and biologics therapies. [b]Patients' follow-up periods were variable in length, beginning with the index date and ending with the earliest of either the end of continuous database enrollment or the end of the study period (September 30, 2024).

ACH, acetylcholinesterase inhibitors; ICD-10, international classification of diseases 10th modification, IVIG, intravenous immunoglobin; MG, myasthenia gravis; OG, oral corticosteroids; SYS, systemic non-steroid immunosuppressants.

RESULTS

- The analysis included 2,943 individuals who newly initiated systemic treatment for MG (**Table 1**)
  - Patients had a mean [SD] age of 58.1 [15.7] years at the time of systemic treatment start, 52.4% were female, and 67.3% were covered by commercial insurance
  - More than half of patients (56.4%) had evidence of ocular involvement and common comorbid diagnoses assessed in the pre-index period included hypertension (42.8%), dyslipidemia (34.7%), obesity (19.9%), and type 2 diabetes (19.6%)
- Most patients (99.8%) initiated systemic treatment on traditional (ACH, SYS, or OG) therapies despite availability of newer biologics therapy options, and 76.2% of the study population initiated treatment within six months of MG diagnosis (**Table 2**)

Table 1. Characteristics of patients with MG newly initiating systemic treatment

	All Newly Treated MG Patients N=2,943
Demographic Characteristics on index date	
Age, mean (SD)	58.1 (15.7)
Female, n (%)	1,543 (52.4%)
Commercial insurance, n (%)	1,982 (67.3%)
Months of follow-up, mean (SD)	37.2 (21.4)
Clinical Characteristics during the pre-index period	
Patients with ocular involvement, n (%)[a]	1,660 (56.4%)
Charlson Comorbidity Index, mean (SD)	1.2 (1.8)
Other diagnoses, n (%)	
Anxiety	423 (14.4%)
Autoimmune condition	288 (9.8%)
Chronic obstructive pulmonary disease	170 (5.8%)
Depression	334 (11.3%)
Dyslipidemia	1,021 (34.7%)
Hypertension	1,261 (42.8%)
Obesity	586 (19.9%)
Osteoporosis	70 (2.4%)
Systemic infection[b]	52 (1.8%)
Type 2 diabetes	578 (19.6%)

[a]Defined by the presence of >1 non-diagnostic inpatient or outpatient claim with an ICD-10 diagnosis code for facial muscle weakness (R29810) or eye muscle weakness (H0582) or a visit to an ophthalmologist. [b]Systemic infections include bacteremia, septicemia, and systemic inflammatory response syndrome.

MG, Myasthenia Gravis; SD, standard deviation.

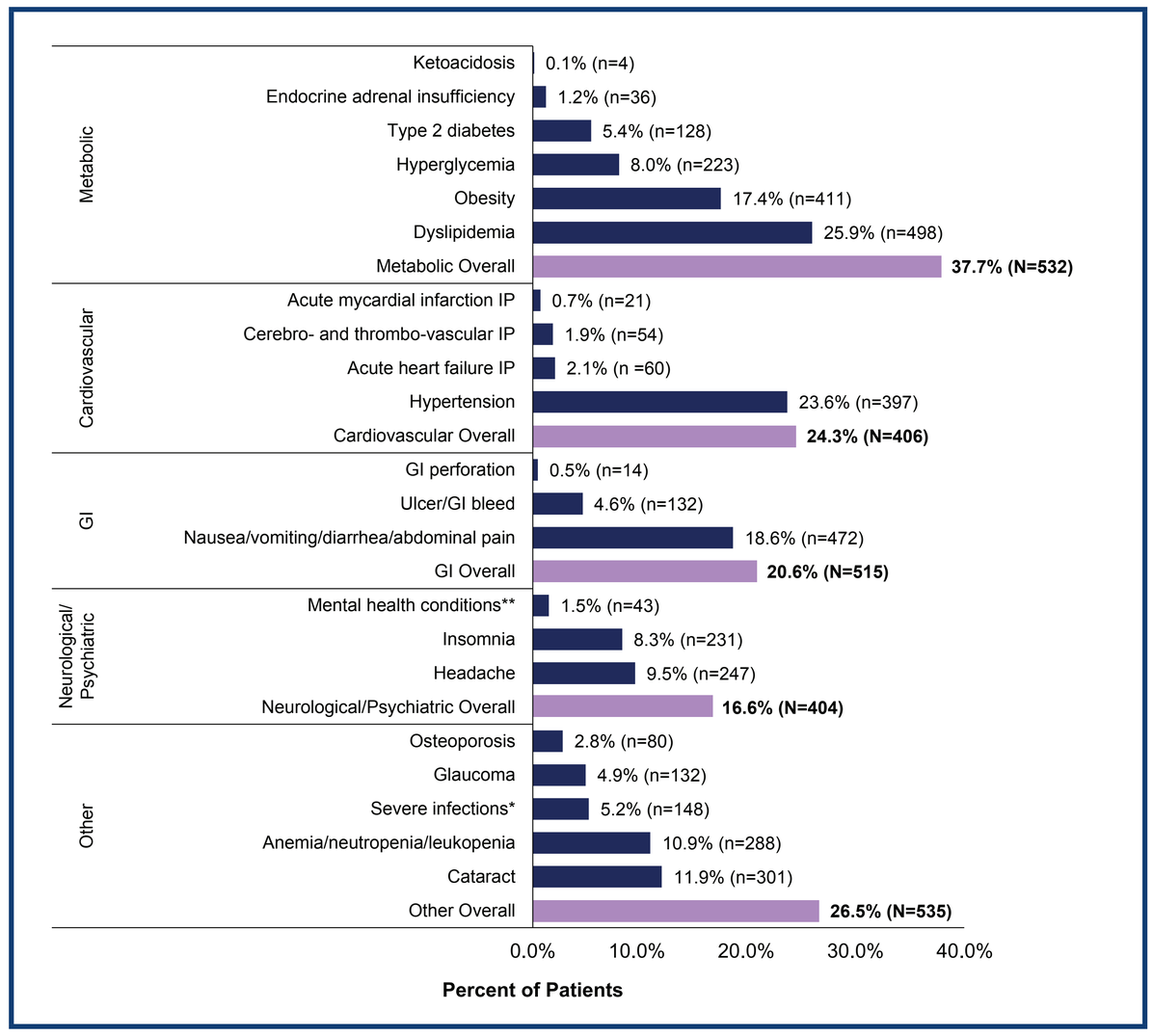
Table 2. Index treatment characteristics

	All Newly Treated MG Patients N=2,943
Months from MG diagnosis date to index date, n (%)	
<6 months	2,243 (76.2%)
6-12 months	313 (10.6%)
12-24 months	227 (7.7%)
24+ months	160 (5.4%)
Initiated treatment on monotherapy regimen[a], n (%)	2,324 (79.0%)
Index regimen drug type(s)[a,b], n (%)	
Acetylcholinesterase (ACH) inhibitors, +/- IVIG	1,321 (44.9%)
Oral corticosteroids (OG) +/- IVIG	959 (32.6%)
ACH + OG +/- IVIG	451 (15.3%)
Systemic immunosuppressants (SYS) or biologics +/- all others	212 (7.2%)

[a]Index treatment regimens defined by all MG treatments observed during the 30 days after and including the index date (i.e., index date + the next 29 days). [b]Groups include acetylcholinesterase inhibitors (ACH), oral corticosteroids (OG), systemic non-steroid immunosuppressants (SYS), and biologics therapies with or without IVIG.

IVIG, intravenous immunoglobulin; MG, Myasthenia Gravis.

Figure 2. Incidence of adverse events during 12 months of follow-up after initiation of systemic treatment for MG

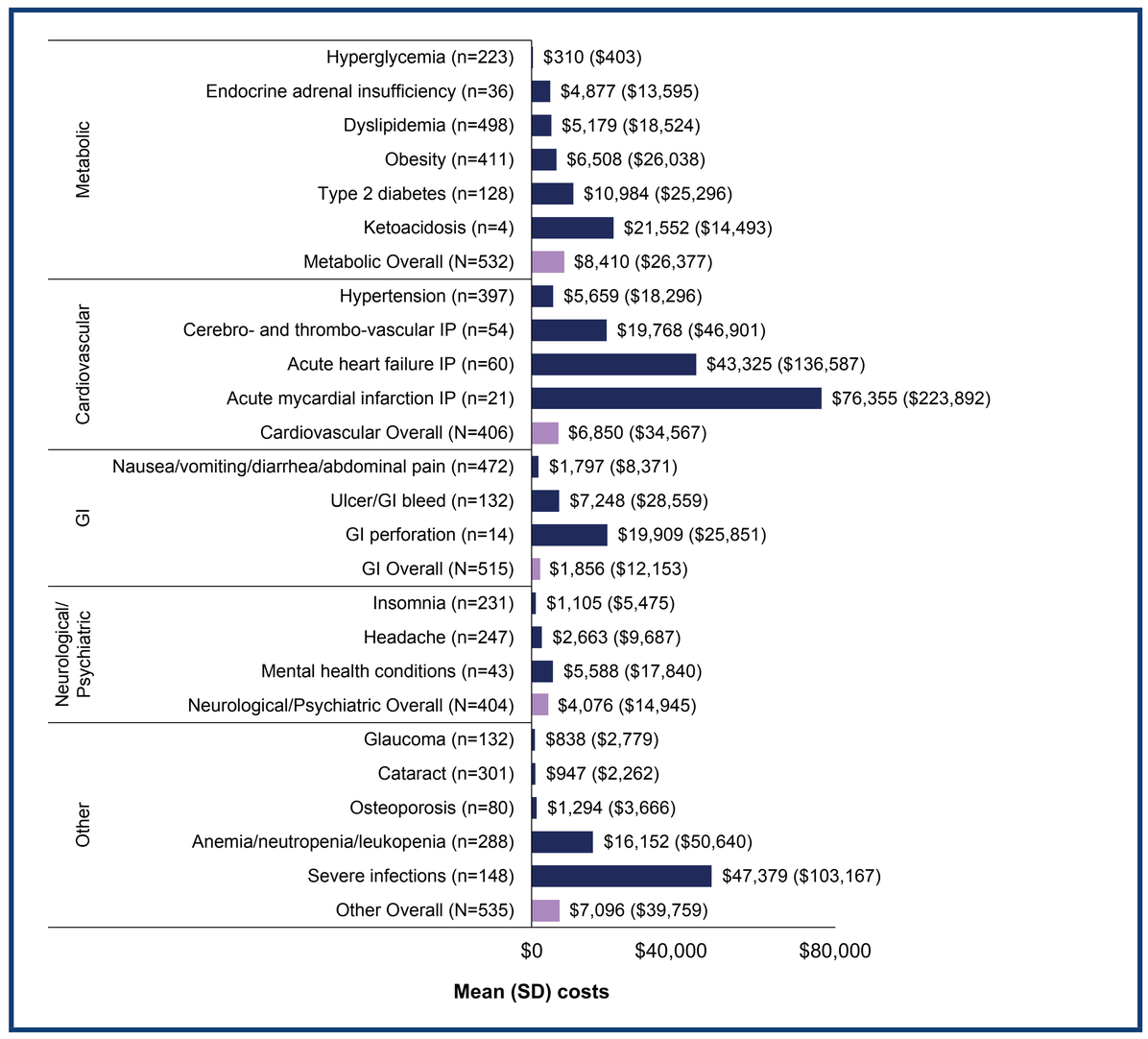


**Mental health conditions include anxiety, depression, mania, attention deficit disorder, psychosis, bipolar; *Severe infections include any infection resulting in an emergency room visit or inpatient admission, or a systemic infection (bacteremia, septicemia, and systemic inflammatory response syndrome) in any setting.

GI; gastrointestinal, IP; inpatient, MG, Myasthenia Gravis.

- During the 12 months following systemic treatment initiation, metabolic AE's were the most common (37.7% with any metabolic AE, including 25.9% with dyslipidemia), followed by cardiovascular AEs (24.3% with any cardiovascular AE, including 23.6% with hypertension), GI AEs (20.6% with any GI AE, including 18.6% with nausea, vomiting, and diarrhea), and neurological/psychiatric AEs (16.6% with any neurological AE, including 9.5% with headache) (**Figure 2**)

Figure 3. Medical costs of adverse events during 12 months of follow-up after initiation of systemic treatment for MG, among patients with the event



GI; gastrointestinal, IP; inpatient, MG; Myasthenia Gravis, SD; standard deviation.

- Individual AEs with the highest mean (SD) medical costs included acute myocardial infarction ($76,355 [$223,892]), severe infection ($47,379 [$103,167]), acute heart failure ($43,325 [$136,587]), ketoacidosis ($21,552 [$14,493]), and GI perforation ($19,909 [$25,851]) (**Figure 3**)

LIMITATIONS

- Results may not be generalizable to patients without employer-sponsored commercial or Medicare Supplemental or Advantage insurance coverage, or those who are uninsured
- Patients with MG who did not meet minimum database enrollment requirements may have different outcomes than those who met all inclusion/exclusion criteria
- Treatment use was largely based on outpatient pharmacy claims for filled prescriptions, but actual usage cannot be confirmed
- There is a potential for information bias due to the nature of claims data; a condition classified as an AE may be due to increase in severity of the disease, or due to another concurrent disease, or may have occurred regardless of treatment use

CONCLUSIONS

- **Patients with MG often initiate treatment on traditional medications, despite the availability of novel, safe, and effectives treatments**
- **These results indicate that the incidence and costs of treatment-related AEs during the first 12 months following treatment initiation (representing only a portion of the total cost associated with MG) are substantial**
- **The observed AE burden contributes to the overall disease burden of MG and underscores the need for alternative treatment approaches which may alleviate AE incidence and associated costs**

REFERENCES

1. Dresser L, et al. *J Clin Med.* 2021;10(11). **2.** Suh J, et al. *Yale J Biol Med* 2013;86(2):255–260. **3.** Cortés-Vicente E, et al. *Ann Clin Transl Neurol.* 2022;9(2):122–131.

DISCLOSURES

LAMW, LSL, and **YE** are employees of Immunovant, Inc. **NP** and **CRL** are employees of Merative, which was contracted by Immunovant to conduct this analysis. **NS** is a paid consultant of Immunovant.

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