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Response to PALKO from Alexion (to be submitted to PALKO):

We would like to thank PALKO for the possibility to respond to the draft recommendation of "Ravulitsumabi yleistyneen myasthenia graviksen (gMG) hoidossa". According to the draft recommendation, ravulizumab is not part of the national range of services in the treatment of generalized myasthenia gravis (gMG).

Alexion finds the PALKO draft recommendation for use of Ultomiris in gMG surprising, particularly PALKO's view of Ultomiris risk benefit ratio. In summary of the draft recommendation, PALKO states that the evidence of clinical efficacy of ravulizumab is uncertain as to the suitability of the instruments used in the study for clinical use. The effect of concomitant conventional therapy on the results of the study cannot be completely excluded. PALKO believes that the adverse effects of ravulizumab treatment are significant in relation to the potential clinical benefit of the treatment. We find it strange that the local authority can do such evaluation in matter of weeks, when the marketing authorization authority have used months to investigate the clinical and safety of ravulizumab in the treatment on gMG and found the risk benefit ratio as positive.

The PALKO recommendations should be based on the best available clinical and economic information at the time of approval. We would like to bring attention to recently published data such that PALKO can utilize the latest available evidence in making the final recommendation. Furthermore, we also respond to specific comments made in the draft.

Ultomiris received marketing authorization in the EU on July 2, 2019 and is currently approved for use in four indications. In September 2022, Ultomiris was approved as an addition to standard therapy for treating adult patients with generalized gMG who are positive for anti-acetylcholine receptor (AChR) antibodies. According to the public assessment report, the Committee for Medicinal Products for Human Use (CHMP) concludes that the efficacy of ravulizumab has been sufficiently demonstrated to support its use, with the overall benefit/risk ratio of Ultomiris being positive (CHMP assessment report Procedure No. EMEA/H/C/004954/II/0026). Alexion would like to stress that there are over 26 000 patient years of exposure globally across the four approved indications (Alexion safety database including both clinical trial and real-world data). There is moreover extensive use of Ultomiris in gMG. In fact, Alexion estimates that approximately 4 500 gMG patients are treated with Ultomiris worldwide (internal estimate).

Efficacy of ravulizumab in Myasthenia Gravis

The phase 3 study CHAMPION gMG demonstrates a statistically significant difference between ravulizumab and placebo for the primary and key secondary end points, despite a notable placebo effect (Vu et al 2022). In line with this, the EMA assessment report concludes that *"The effect of ravulizumab over placebo on the control of symptoms assessed by the patient (MG-ADL score, primary endpoint) and by the physician (QMG score; secondary endpoint) has been demonstrated"*.

The majority of patients (90%) in the CHAMPION study were receiving immunosuppressive therapies (ISTs) at baseline and 47% were receiving two or more immunosuppressive therapies (Vu et al 2022). The treatment arms were balanced in terms of clinical characteristics at baseline;

consequently, the clinical outcomes are valid. Moreover, the efficacy of ravulizumab is further supported by the reduction in IST use during the open label extension (OLE), which is further described in the section describing the long-term benefits of Ultomiris.

Clinical relevance of effect size

The clinical relevance of effect size in evaluating treatment efficacy can sometimes be challenging, especially in heterogeneous diseases like gMG. There is currently no consensus on minimal clinical important difference (MCID) in gMG due to limited evidence on absolute thresholds for MCID in the gMG assessment scores (Meisel et al. 2024). Moreover, the threshold for a MCID depends on the methodology and setting utilized, which is also acknowledged by the FIMEA and CHMP: *"The clinical relevance of the treatment effect could be questioned based on the fact that it did not achieve the accepted thresholds for clinical meaningfulness for the utilized scales established in literature (i.e. MCID of 2 point) (Wolfe et al 1999 and Muppidi et al 2011). It should be considered that this difference has been defined by absolute change from baseline in individual patients, and not as differences in average changes between groups (Chung et al 2017). In this regard, these thresholds should be used for individual responder analyses and not as a reference point for a population-average drug-placebo treatment effect. Admittedly, this criterion could be considered as a cut-off value in responder analysis, as this is based on an "individual level" approach".*

The treatment effect documented in the CHAMPION gMG study is clinically relevant. In the CHAMPION gMG study, a total of 47 of 78 patients (60.3%) in the ravulizumab group and 30 of 82 patients (36.6%) in the placebo group achieved an improvement of 3 points or more in MG-ADL total score from baseline at week 26 (adjusted percentages: 56.7% [95% CI, 44.3 to 68.3] vs. 34.1% [95% CI, 23.8 to 46.1], respectively (Vu et al 2022).

Ultomiris is effective also in difficult to treat refractory population as demonstrated by post hoc analysis of a treatment refractory patient population. This refractory population was defined as patients who have a prior history of using at least 2 immunosuppressant therapies as monotherapy or in combination for at least 12 months OR patients with a prior history of using at least 1 immunosuppressant therapy and chronic IVIg/PLEX for at least 12 months AND have functional impairment (MG-ADL ≥ 6) despite current stable treatment with at least 1 immunosuppressant therapy. Post hoc data demonstrate improvement in the MG-ADL total score and QMG during the open label extension period in the treatment subgroup was consistent with results in the total population (data on file).

Long term efficacy of Ultomiris in Myasthenia Gravis

The long-term efficacy of Ultomiris is further supported by the results from the recently published 164- week CHAMPION gMG OLE data, showing sustained improvements in clinical outcomes over time (Vu et al 2025).

In this publication, ravulizumab was associated with sustained, long-term improvements in MG-ADL total scores. In the ravulizumab-ravulizumab group, LS mean (95% CI) change from

randomized controlled period to baseline at week 164 was −4.0 (−5.3, −2.8; $p < 0.0001$) and from OLE baseline was −0.3 (−1.5, 0.8; $p = 0.5772$) (Vu et al 2025).

Among patients who achieved a ≥ 2-point improvement from baseline in MG-ADL total score, 71 (77.2%) sustained a ≥ 2-point improvement for > 75% of their remaining time in the study after first response. Similarly, 68 (67.3%) of patients who achieved a ≥ 3-point improvement from baseline sustained this status for > 75% of their remaining time (Vu et al 2025), demonstrating long term clinically relevant benefits.

During the extension period, when changes in background therapy were permitted (unlike the randomized controlled period), 50.3% of patients experienced a change in concomitant MG medication. The most common adjustment was a decrease in corticosteroids for systemic use due to improved MG symptoms, with 20.7% of patients reducing their dosage and 6.5% discontinuing corticosteroids entirely. This supports the efficacy of ravulizumab compared to the standard of care, including its ability to reduce the serious side effects associated with steroid use.

Relevance of the Measures of Clinical Response in Myasthenia Gravis

Evaluation of clinical response in the CHAMPION gMG study uses robust and validated measurement tools, which is critical for assessing treatment effects. Two of the most widely used scales for evaluating clinical response in patients with MG, are the MG-ADL and the QMG score, which are validated tools for measurement of patient- and clinician-reported responses, respectively.

Both the QMG and MG-ADL have been used in numerous Phase 3 clinical trials as the primary and/or secondary outcome measures in the evaluation of efficacy in patients with MG and have supported regulatory approvals in the case of eculizumab (Soliris) and efgartigimod (Vyvgart).

The medical community recommends using these scales both in clinical trials and to follow benefits in clinical practice: “The MG-ADL is recommended as the primary endpoint in clinical trials, with the QMG as a co-primary or key secondary endpoint. Consistent use of the MG-ADL scale should be applied in clinical practice to understand gMG disease burden” (Meisel et al. 2024).

Safety of Ultomiris in Myasthenia Gravis

An essential consideration in the therapeutic use of Ultomiris is its safety profile, especially given the rarity of gMG. The benefit risk ratio is assessed by EMA where CHMP considered that the available safety data supports the use of ravulizumab in the approved indication. In the final analysis of CHAMPION study (Vu et al 2025), safety data were consistent with the known safety profiles of ravulizumab and eculizumab and no new safety signals were identified. Long term C5 safety data (10-year pharmacovigilance data of eculizumab in PNH and aHUS) concluded that the overall safety profile of eculizumab is consistent with that reported from clinical trials and no new safety signals affecting the benefit-risk profile of eculizumab were detected (Socie et al 2018). This conclusion aligns with findings from the up to 6 years of follow-up study with ravulizumab in PNH (Kulasekararaj et al 2025).

Deaths/ Adverse Events Related to COVID-19:

While assessing safety, it's essential to consider any adverse events reported during the study, including those related to COVID-19, and whether related to study drug or not. The CHAMPION gMG study was ongoing during the COVID-19 pandemic. CHMP states in the assessment report: *"A total of 7 deaths occurred in the study by the time of 60-week CSR addendum (2 in the randomized control period and 5 in the Open Label Extension Period). None of the deaths were related to study drug by the Investigator". "Six patients had COVID-19 related SAEs; however, upon additional medical review 1 of the 6 patients had an SAE of viral pneumonia which was not confirmed to be related to COVID-19. Three patients died during the study due to COVID-19; all 3 patients had multiple underlying risk factors for COVID-19 complications (such as metabolic, respiratory, and cardiovascular disease and obesity)."*

Clinical studies have shown overactivation of complement in SARS, H1N1 and COVID-19 and preclinical findings provide a rationale for blocking complement activation at C5 to improve survival in severe respiratory illness without compromising the immunoprotective and immunomodulatory functions served by other components of the complement pathway. There is a proof-of-concept study with C5 (eculizumab) as emergency treatment showing significantly improved survival for adult patients with severe COVID-19 in the intensive care unit (Annane et al. 2020). This finding is supported by case reports and a retrospective analysis (Ruggenenti et al 2021, Laurence et al. 2020).

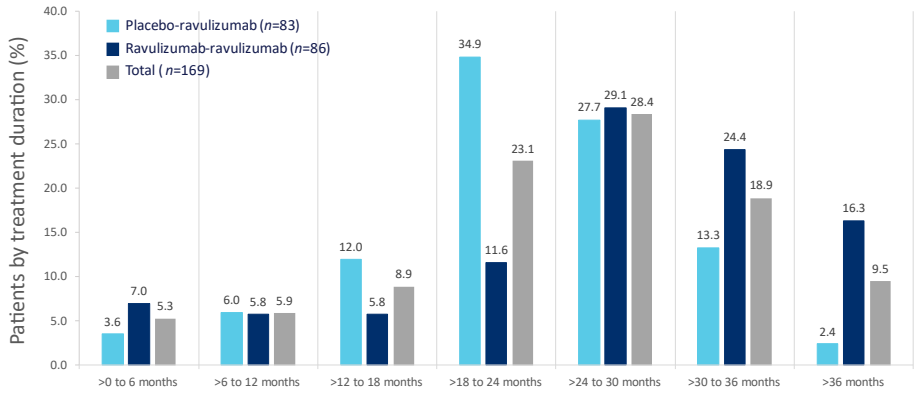
Economic value, price and cost effectiveness

In the context of healthcare resource allocation, understanding the context for the referenced treatment cost, economic value of Ultomiris is central. Ultomiris has been assessed by HTA bodies and is currently reimbursed in the most major EU countries. In addition, the German guidelines are recommending ravulizumab) for use in patients with highly disease that are AChR-Ab-positive (Wiendel at al 2023).

The CHMP assessment report concludes that *"Supportive evidence derives also from the clinical impact of ravulizumab in the course of the disease. Ravulizumab treated patients experienced less clinical deterioration, less MG-related hospitalization, and required less rescue therapy than placebo treated patients. The interpretation of these outcomes is limited by the reduced numbers of events by group and the exploratory nature of the endpoints. However, a consistent response has been shown in the scales measured, which reinforces the observed effect".*

Alexion estimates that there are only approximately 20 gMG patients that are eligible for Ultomiris in Finland. These patients are refractory with remaining symptoms despite receiving the currently available treatments in Finland. The recently published OLE data illustrates that treatment is not lifelong, where only ca 10% are treated more than 36 months (Figure 1). The budget impact of Ultomiris is thus very limited, with the number of patients being low and the treatment likely not being lifelong.

Figure 1: Percentage of patients by ravulizumab treatment duration category



The prices mentioned in the draft PALKO report are significantly higher than the actual prices in Finland. It is important to keep in mind that Ultomiris is included in hospital tenders (with new even lower tender prices from 1 January 2026). The actual net price paid by hospitals and the Finnish healthcare system is therefore significantly lower than the first-year care cost of €379,000 stated in the PALKO report. Furthermore, the net price offered in Finland and other countries is confidential. Consequently, the ICER from CDA-AMC cited in the PALKO report for ravulizumab, marked at $2,996,852/QALY compared to rituximab, reflects list price levels and is therefore not applicable. Moreover, since Ultomiris is intended to be used post rituximab, the ICER comparing to rituximab is not relevant for the healthcare settings in Finland or the Nordic region.

PALKO notes that the cost of ravulizumab is an addition to the standard care costs. It is important to remember that current standard of care treatments are off-patent and relatively inexpensive. Additionally, none of the therapies currently used in clinical practice for gMG have been specifically developed for this condition or have regulatory approval for use in gMG.

gMG is associated with high clinical and economic burden. A recent analysis of gMG patients in the US, demonstrated that among patients with gMG who initiated ravulizumab within 2 years of gMG diagnosis, statistically significant reductions in hospitalizations, intensive care unit (ICU) encounters, exacerbations, crises, corticosteroid dose escalations, and other healthcare resources were experienced post- vs pre-ravulizumab initiation ($p<0.001$) (Snook et al 2025, Appendix 1). Ultomiris is administered every eight weeks, which in addition reduces the burden on healthcare resources as this dosing schedule means patients require fewer hospital visits for infusions compared to many other treatments.

Conclusion:

Alexion is requesting PALKO to conditionally recommend the use of Ultomiris in gMG. Since its approval in the EU, ravulizumab has demonstrated significant clinical efficacy and a positive safety profile in multiple studies. The CHAMPION gMG study shows consistent improvements in patient outcomes, underscoring its therapeutic value. Recently published long-term data further validates

its sustained benefits and safety, offering a promising option for gMG patients with demonstrated needs for effective treatment. Ultomiris is included in hospital tenders with significant confidential discounts including new tender prices from 1 January 2026. In addition to these new confidential prices, Alexion is willing to further negotiate a risk sharing agreement to allow Ultomiris to be conditionally recommended for use in gMG.

Given the rarity and complexity of gMG, Ultomiris provides an essential advancement in treatment options that align with both clinical effectiveness and economic feasibility. We encourage PALKO to integrate the comprehensive clinical and economic evidence presented into their final recommendation, facilitating improved patient care and healthcare outcomes for gMG patients in Finland.

Abbreviations

AChR: anti-acetylcholine receptor
gMG: generalized myasthenia gravis
AChR: anti-acetylcholine receptor
CHMP: Committee for Medicinal Products for Human Use
EMA: European Medicines Agency
HTA: Health technology assessment
IST: Immuno Suppressive Therapy
MCID: Minimal Clinical Important Difference
MG-ADL: Myasthenia Gravis Activities of Daily Living
QMG: Quantitative Myasthenia Gravis
MGC: Myasthenia Gravis Composite
MG-QoL15r: MG Quality of Life 15-item revised
OLE: Open Label Extension
RCP: Randomized Control Period
CI: Confidence Interval
C5: complement component 5
AE: Adverse Event
PSUR: Periodic Safety Update Report
CSR: Clinical Study Report
SAE: Serious Adverse Event
ICER: Incremental Cost-Effectiveness Ratio
CDA-AMC: Center for Drug Evaluation and Research
QALY: Quality-Adjusted Life Year

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Clinical Review Report: Eculizumab (Soliris), Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2020 Dec, Indication: Adult patients with generalized myasthenia gravis

Appendix 1

Healthcare resource utilization in early initiators of ravulizumab for treatment of generalized myasthenia gravis in the USA

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INTRODUCTION

- Generalized myasthenia gravis (gMG) is a debilitating autoimmune neuromuscular disease characterized by muscle weakness and fatigue[1,2]
- Approximately 80% of patients with gMG have anti-acetylcholine receptor antibodies which can lead to destruction of acetylcholine receptors and activation of the complement system[2]
- gMG may be associated with recurrent exacerbations, including myasthenic crisis with respiratory failure requiring mechanical ventilation,[1,3] which are associated with a high economic and clinical burden[4]
  - One longitudinal study showed that 39% of patients with gMG were hospitalized at least once over a median follow-up period of 47 months after diagnosis[3]
- Ravulizumab is a complement component 5 inhibitor (C5IT) indicated for adults with gMG who are anti-acetylcholine receptor antibody-positive[5]
- C5ITs potentially reduce clinical deteriorations in gMG, especially in early disease; in the phase 3 CHAMPION-MG study, investigating the long-term safety and efficacy of ravulizumab,[6,7] fewer patients in the ravulizumab arm (8/86; 9.3%) experienced study-defined clinical deterioration events versus those in the placebo arm (15/89; 16.9%)[6]
- A post hoc analysis of CHAMPION-MG, also suggested early initiation of complement inhibitors could reduce disease burden[8]

OBJECTIVES

- The objective of this analysis was to assess the effect of ravulizumab on gMG exacerbations and crises as well as healthcare resource utilization (HCRU) in patients with gMG initiating ravulizumab within 2 years of diagnosis in the US

CONCLUSIONS

- Among patients with gMG who initiated ravulizumab within 2 years of gMG diagnosis, statistically significant reductions in hospitalizations, intensive care unit (ICU) encounters, exacerbations, crises, corticosteroid dose escalations, and other healthcare resources were experienced post- vs pre-ravulizumab initiation (p<0.001)

METHODS

Study design and eligibility criteria

- The retrospective cohort study of patients with gMG in the US was conducted using claims data between Jan 2016–Aug 2024 from a large US multi-payer, hybrid open and closed claims database (Atlas Definitive Health)
- The target population included patients with gMG who received ravulizumab within 2 years as first-line FDA-approved treatment
- Eligible patients had ≥1 year of continuous follow-up in medical claims, both before and after initiation of ravulizumab (i.e. ≥2 years of continuous follow-up overall); were identified as early initiators (first dose of ravulizumab received within 2 years of their first gMG diagnostic claim [ICD-10 G.70.0]); and had not received other approved biologic therapies (full analysis set)

Outcome assessments

- Clinical outcomes and HCRU endpoints were assessed after gMG diagnosis and compared between the periods before versus after ravulizumab initiation
  - Myasthenia gravis (MG) exacerbation was defined as any hospitalization with ICD10 G70.0 in the primary position
  - MG crisis was defined as MG exacerbation AND (acute respiratory failure OR intubation OR mechanical ventilation)
- Rate ratios were estimated to compare pre- and post-initiation periods using generalized estimating equations with repeated measures within patients

RESULTS

- In total, 121,811 patients with gMG were evaluated for inclusion, and of those, 114 met the inclusion criteria for the study. Among the 114 eligible patients (full analysis set), 59 remained in the pharmacy outcomes analysis subset **(Figure 1)**
- In the full analysis set, patients were predominantly aged ≥55 years and were evenly balanced between male and female patients; half (50%) were insured through private/commercial health plans while 41% were insured through Original Medicare (Parts A/B) or Medicare Advantage (Part C) plans **(Table 1)**
- There were statistically significant (p<0.05) reductions in most endpoints after initiation of ravulizumab per-patient-per-year (PPPY), including MG exacerbations (Pre: 0.9 vs post: 0.2), crises (Pre: 0.4 vs post: 0.1), inpatient days (Pre: 6.6 vs post: 1.6), 30-day readmission rates (Pre: 0.2 vs post: 0.0), inpatient admissions (Pre: 1.0 vs post: 0.2), ICU encounters (Pre: 0.4 vs post: 0.1), and ED encounters (Pre: 1.3 vs post: 0.9) **(Figures 2 and 3)**
  - There was also a significant (p<0.001) 83% reduction in corticosteroid dose escalations, defined as a ≥10 mg increase in daily dose, post-ravulizumab initiation **(Figures 2 and 3)**
  - Doses of symptom-control medications (pyridostigmine, 121.0 vs 218.2; oral corticosteroids, 61.3 vs 149.8) and rescue IVIg (1.3 vs 10.7) PPPY were also significantly (p<0.001) reduced post- vs pre-initiation of ravulizumab **(Figures 2 and 3)**
  - Hospitalization causes pre- and post-ravulizumab initiation are provided in **(Supplementary Table 1)**, accessible through scanning the QR code

Figure 1. Patient waterfall and analytic samples

Adult patients with gMG (≥2 claims for ICD-10 G70.0 ≥30 days apart) (n = 121,811)

↓

Ravulizumab initiators with ≥2 claims prior to MG diagnosis (n = 1,362)

↓

Ravulizumab as first-line approved biologic therapy for gMG and ≥1 year continuous use (n = 257)

↓

Early initiators of ravulizumab (<2 years since gMG diagnosis) (n = 114)*

↓

Pharmacy outcomes analysis subset (n = 59)

Figure 2. Outcomes pre- versus post-ravulizumab initiation

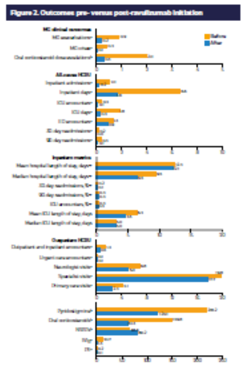
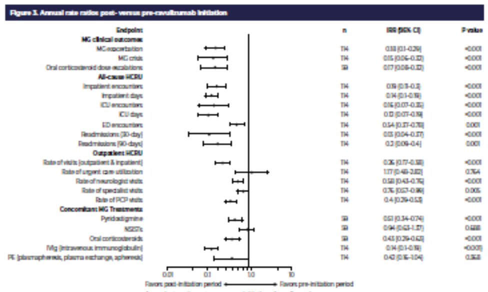


Table 1. Patient baseline demographics (n=114)*

Factor, n (%)	Patients
Age group	
18–<35 years	7 (6.1)
35–<55 years	16 (14.0)
55–<65 years	17 (14.9)
65–<75 years	45 (39.5)
75+ years	29 (25.4)
Sex	
Female	50 (43.9)
Male	51 (44.7)
Unknown	13 (11.4)
Payer type	
Commercial	57 (50.0)
Medicare (Original)	32 (28.1)
Medicare Advantage (Part C)	15 (13.2)
Medicaid	3 (2.6)
Other	7 (6.1)

*Full analysis set.

Figure 3. Annual rate ratios post- versus pre-ravulizumab initiation



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Disclosures

Riley Snook has received honoraria payment for participation in argenx advisory boards. Michael Blackowicz is an employee of Alexion, AstraZeneca Rare Disease. Emma Weiskopf is an employee of Alexion, AstraZeneca Rare Disease. Dan Fogarty has no disclosures. Neha Arora has no disclosures. Raghav Govindarajan has received payment or honoraria for lectures, presentations, speaker bureaus, manuscript writing, or educational events from Alexion, Amgen, argenx, and UCB, and has royalties with Taylor & Francis.

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Poster | Supplementary material

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Healthcare resource utilization in early initiators of ravulizumab for treatment of generalized myasthenia gravis in the USA

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SUPPLEMENTARY INFORMATION

Supplementary Table 1. Hospitalization causes pre- and post-initiation of ravulizumab

Pre-initiation of ravulizumab, counts*	
Total hospitalizations	**243**
Total diagnosis	
MG with (acute) exacerbation	118
MG without (acute) exacerbation	99
Axial/bulbar symptoms	10
Cardiovascular disease	4
Respiratory disease	3
Cellulitis of left lower limb	2
Hypocalcemia	1
Other disorders of lung	1
Mixed simple and mucopurulent chronic bronchitis	1
Acute epiglottitis without obstruction	1
Encounter for fitting and adjustment of other specified devices	1
Paresthesia of skin	1
Aortic aneurysm of unspecified site, without rupture	1
Post-initiation of ravulizumab, counts*	
Total hospitalizations	**34**
Total diagnosis	
MG with (acute) exacerbation	15
MG without (acute) exacerbation	13
Hematuria, unspecified	1
Localized swelling, mass and lump, upper limb, bilateral	1
Abnormal ECG	1
Acute cholecystitis	1
Disorder of prostate, unspecified	1
Cardiovascular disease	1

*Counts represent individual hospitalization events.
MG, abbreviation for; MG, myasthenia gravis.

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