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OHSU Drug Effectiveness Review Project Summary Report – Newer Agents for Myasthenia Gravis

Date of Review: June 2026

Date of Last Review: Amifampridine (Nov 2019)
Efgartigimod (Feb 2023)
Remaining agents subject to Orphan Drug policy
Literature Search: through 12/12/24

Current Status of PDL Class:
See **Appendix 1**.

Plain Language Summary:

- Generalized myasthenia gravis (gMG) and Lambert-Eaton myasthenic syndrome (LEMS) are diseases that cause muscle weakness. The weakness often worsens over time and with more activity.
- People with these diseases often take a medicine called pyridostigmine and oral medicines that affect the immune system to manage symptoms. Some patients may still have many symptoms, or a crisis, even with these medicines. A myasthenia crisis is when a ventilator is needed to help patients breathe because the muscles used for breathing become too tired.
- The Food and Drug Administration has approved several new medicines that may help myasthenia gravis symptoms, including patients who still have many symptoms on standard treatment. These medicines affect the immune system and cannot be used with one another. Most of them must be injected into a vein or the skin.
- These medicines have been tested compared to placebo (saline injection). None of these medicines have been compared to another to know which is better or safer.
- The Drug Use Research and Management group recommends medicines be available with prior authorization. Prior authorization is when providers explain to the Oregon Health Authority why a patient needs that medicine before the Oregon Health Plan will pay for it.

Research Questions:

1. What is the effectiveness of the newer agents for generalized myasthenia gravis (gMG) and Lambert-Eaton myasthenic syndrome (LEMS) in adults?
2. What are the harms of the newer agents for generalized myasthenia gravis (gMG) and Lambert-Eaton myasthenic syndrome (LEMS) in adults?

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Conclusions:

- There is no head-to-head comparative evidence between agents.[1]
- All evidence is based on 1 to 2 RCTs using placebo comparisons.[1] These studies vary widely in study size, population (e.g. antibody types), duration, design, and include both phase 2 and phase 3 trials.[1] Most certainty of evidence (CoE) is low to very low and all studies were rated as having moderate or high risk of bias (RoB).[1]
- There is insufficient evidence to show clinical superiority or improved safety for one agent over another. Agents vary by route of administration and administration interval.[1]

Recommendations:

- No changes recommended to preferred drug list (PDL) or prior authorization (PA) criteria based on clinical evidence.
- Review costs in executive session.

Summary of Prior Reviews and Current Policy

- Newer agents for myasthenia gravis are separated into multiple classes (orphan drug policy, biologic agents for rare diseases, potassium channel blockers). All have prior authorization restricting use to indications approved by the Food and Drug Administration (FDA). Efgartigimod alfa-fcab was reviewed for use in myasthenia gravis in April 2022. Amifampridine for LEMS was reviewed in November 2019. Other agents were added to the orphan drug policy without a specific review of the evidence.
- Rituxumab, an off-label therapy for myasthenia gravis, is available through the Targeted Immune Modulators therapy prior authorization criteria. It was not included in this DERP summary.

Methods:

The June 2025 drug class report on Myasthenia Gravis by the Drug Effectiveness Review Project (DERP) at the Center for Evidence Based Policy at the Oregon Health & Science University (OHSU) was used to inform recommendations for this drug class.

The original report is available to Oregon Pharmacy and Therapeutics Committee members upon request.

The purpose of the DERP reports is to make available information regarding the comparative clinical effectiveness and harms of different drugs. DERP reports are not usage guidelines, nor should they be read as an endorsement of or recommendation for any particular drug, use, or approach. OHSU does not recommend or endorse any guideline or recommendation developed by users of these reports.

Summary Findings:

Both generalized myasthenia gravis (gMG), and Lambert-Eaton myasthenic syndrome (LEMS), are chronic autoimmune disorders which are characterized by chronic, progressive muscle weakness resulting from miscommunication at the neuromuscular junction.[1] Myasthenia gravis prevalence is estimated at 37:100,000 people in the United States and is more common in people over 50, though women often have a younger age of onset and it is slightly more

common in African American individuals.[1] Common autoantibodies present in gMG include anti-acetylcholinesterase receptor antibodies (AChR), anti-muscle-specific kinase antibodies (MUSK), and anti-low-density lipoprotein–related protein 4 antibodies (LPR4). About 85% of individuals are AChR positive (AChR+).[1] Thymomas, present in roughly 10% of gMG patients, also result in autoantibody production.[1] LEMS is more rare than gMG, though gender and age distribution are similar.[1] Other forms of myasthenia gravis (ocular, congenital, and transient neonatal) were not the focus of this report.

Muscle weakness fluctuates with rest and activity. Patients can present with a myasthenic crisis when ventilator support is needed to support breathing.[1] Initial treatment for gMG often begins with acetylcholinesterase inhibitors such as pyridostigmine and chronic oral immunotherapies such as glucocorticoids or nonsteroidal immunosuppressive agents (i.e. azathioprine).[1] Other therapies can include intravenous immune globulin, rituximab, plasmapheresis, and thymectomy.[1] Newer antibody-based therapies, often employed for more refractory cases, are the focus of this review (**Table 1**).[1]

Multiple outcomes were used across the studies. Symptom severity was most commonly assessed using Myasthenia Gravis Composite (MGC; range 0-50, higher scores correlate to greater severity, minimum clinically important difference [MCID] 3) or Quantitative Myasthenia Gravis (QMG; range 0-39, higher scores correlate to greater severity, MCID 2.6-3.5 based on baseline with most studies using 3).[1] The Myasthenia Gravis Activities of Daily Living (MG-ADL) was used as a function outcome marker for many approval studies and relates to functional activities of ocular, bulbar, respiratory, and gross motor or limb impairment.[1] Scores range from 0 to 24 points with higher scores indicating greater disease severity.[1] A change of 2 points is considered a MCID and was used in these trials.[1] Quality of life (QoL) was often assessed with the original or revised 15 item Myasthenia Gravis Quality of life scale (MG-QoL 15; range 0-60, no MCID)(MG-QoL 15r; range 0-30; no MCID).[1] Higher scores correlate to worse severity for both versions.[1] Alternative assessment tools were also used in some studies.

Literature search found 896 records from database searches. After eligibility review, 13 randomized controlled trials (RCTs) were included.[1] All were placebo-controlled RCTs with no head-to-head comparisons between agents in completed or ongoing studies of currently approved agents.[1] One ongoing study was identified for inebilizumab-cdon. Inebilizumab-cdon received FDA approval for gMG after publication of this DERP report but was included as a pipeline agent. Ongoing studies of amifampridine, efgartigimod, and nipocalimab were also identified, in addition to several pipeline agents without current gMG or LEMS approval.[1]

Table 1. FDA approved newer agents for adults with gMG or LEMS included in report[1]

Generic Name	**Brand Name**	**Indications***	**Mechanism of Action**	**Route and Maintenance Interval of Administration**
Amifampridine phosphate	Firdapse, Rizurgi	LEMS; ≥6y	Potassium channel blocker	Oral; daily
Eculizumab	Soliris; biosimilars	AChR+ gMG; ≥6y	Complement inhibitor	IV; every 2 weeks
Efgartigimod alfa-fcab	Vyvgart	AChR+ gMG;	Neonatal FC receptor inhibitor	IV; weekly for 4 weeks, other cycles as needed
Efgartigimod alfa + hyaluronidase-qvfc	Vyvgart Hytrulo	AChR+ gMG	Neonatal FC receptor inhibitor	SC (provider administered); weekly for 4 weeks, other cycles as needed
Inebilizumab-cdon	Uplizna	AChR+ or MUSK+ gMG	Anti-CD19 antibody	IV; every 6 months

Nipocalimab	Imaavy	AChR+ or MUSK+ gMG; ≥12y	Neonatal FC receptor inhibitor	IV; every 2 weeks
Ravulizumab-cwvz	Ultomiris	AChR+ gMG	Complement inhibitor	IV; every 8 weeks
Rozanolixizumab-noli	Rystiggo	AChR+ or MUSK+ gMG	Neonatal FC receptor inhibitor	SC (provider administered); weekly for 6 weeks, other cycles as needed
Zilucoplan	Zilbrysq	AChR+ gMG	Complement inhibitor	SC; daily
Abbreviations: AChR+ = Acetylcholine receptor antibody positive; gMG = generalized myasthenia gravis; IV = intravenous; LEMS = Lambert-Eaton myasthenic syndrome; MUSK+ = anti-muscle specific tyrosine kinase antibody positive; SC = subcutaneous; y = years. *some agents have additional indications unrelated to gMG and LEMS				

Amifampridine in LEMS[1]

Evidence is based on 2 RCTs (n=64; both high RoB) and very low CoE for all outcomes. Study duration was 2 weeks for one RCT (n=38) and 4 days for the other RCT (n=26).

Efficacy

- Symptom severity increased for all patients, was statistically significantly smaller in amifampridine treated patients, but this was not always clinically meaningful.
- Function measures were mixed where one study showed statistically significant improvement and the other no difference compared to placebo.
- Quality of life was not assessed in these RCTs.

Safety

- No difference in total adverse events (AEs) in one RCT, while the other reported 3 events with amifampridine and 11 with placebo treated patients. Most common AEs were muscle weakness, fatigue, oral and digital paresthesia, headache, nausea, and diarrhea.
- No severe adverse events (SAEs) reported in either group.

Amifampridine in gMG[1] (off-label)

Evidence is based on 1 RCT (n=7; high RoB) and very low CoE for all outcomes for the MuSK antibody positive subtype, while AChR antibody status not reported. The RCT had a cross-over design where amifampridine or placebo was given in 1-week intervals with no washout period between treatment arms for a 3 total of weeks. Patients receiving 2 weeks of a treatment (ex. placebo, then amifampridine, then placebo) would be counted twice for that treatment.

Efficacy

- Symptom severity scores worsened for all participants for both outcome measures used, though amifampridine had a statistically significantly smaller and clinically meaningful smaller increase.
- Function and QoL measures showed statistically significant and clinically meaningful improvement.

Safety

- Total AEs were not separated by treatment group, though paresthesias were most common.
- No SAEs were reported in either group.

Eculizumab in gMG[1]

Evidence is based on 2 RCTs, one (n=14) crossover study of 16-week treatment periods and a 5-week washout with high RoB and one (n=126) with 26-week duration and moderate risk of bias. All patients were AChR+ and had inadequate control with standard immunotherapy; MuSK antibodies were not reported.

Efficacy

- Symptom severity scores of QMG (very low CoE) and MGC (low CoE) both decreased for all participants and eculizumab had a statistically significant and clinically meaningful decrease compared to placebo.
- Function measures were statistically significantly improved in both studies but only clinically meaningful in 1 RCT (very low CoE).
- QoL measures were statistically significantly and clinically meaningfully improved (low CoE).

Safety

- Total AEs were similar in both groups and were most commonly headache, upper respiratory infection, nasopharyngitis, nausea, and diarrhea (very low CoE).
- SAEs were similar between groups but varied between studies (1% vs. 1% and 15% vs. 29%) (low CoE).

Efgartigimod in gMG[1]

Evidence is based on 2 RCTs with high RoB, one (n=24) where all patients were AChR+ and MuSK status was not reported; patients were followed for 80 days. The second trial (n=167) included a mixed population of antibody status (77% AChR+, 4% MuSK+) and patients were followed for 10 weeks.

Approval of the combination product with hyaluronidase was based on pharmacokinetic data and comparison of antibody reduction to the single agent product.

Efficacy

- Symptom severity scores using two scales showed clinically meaningful reductions, but benefits waned over time after conclusion of a treatment cycle (low CoE).
- Function scores showed statistically significant and clinically meaningful reductions which waned over time (low CoE).
- QoL improved for all participants and the score reduction was statistically significantly greater than placebo with the maximum difference around week 4, with the difference waning over time (low CoE).
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Safety

- Most patients experienced an AE, and the most common AEs were headache, nasopharyngitis, nausea, diarrhea, upper respiratory tract infection, itching, and urinary tract infection (moderate CoE).
- Very few SAEs were reported, and there was no difference between groups (low CoE).

Nipocalimab in gMG[1]

Evidence is based on a single phase 2 RCT (n=68 divided into 4 dosing groups or placebo) over 8 weeks in patients with refractory gMG with moderate RoB. Patients had mixed antibody profiles (MuSK+ 7.1% and AChR+ 92-93%) and insufficient symptom control with standard immunotherapy.

Efficacy

- Symptom severity ratings were no different between all groups (low CoE).
- Function scores were no different between all groups (low CoE).
- QoL had no overall difference between drug and placebo, though the 30 mg/kg every 4-week dosage was statistically significantly different than placebo (low CoE). This is not the current FDA approved dosing interval.

Safety

- There were no differences in AEs between treatment and placebo, and the most common AEs were headache, diarrhea, nasopharyngitis, and rash (moderate CoE).
- There were few SAEs and no differences between various treatment and placebo groups (low CoE).

A phase 3 trial (n=196) was published after the literature search end date which did show a statistically significant, but not clinically significant difference in function (MG-ADL).[2] The treatment effect was more pronounced in male patients compared to female patients.[2] Total AE and SAE were similar between treatment and placebo groups.[2]

Ravulizumab in gMG[1]

Evidence is based on 1 RCT (n=175) of 26-week duration and moderate RoB. All patients were AChR+ while MuSK status was not reported.

Efficacy

- Symptom severity decrease was statistically significant compared to placebo, but the change was not clinically meaningful (low CoE).
- Function status improvement was statistically significant compared to placebo, but the change was not clinically meaningful (low CoE).
- QoL scores improved, but were not statistically significant between groups (low CoE).

Safety

- Roughly 34% of patients experienced an AE attributed to the treatment, and there were no differences between groups (low CoE). The most common AEs were headache, diarrhea, and nausea.
- SAEs were reported in both groups (23% vs. 16%) with no difference between groups (moderate CoE).

Rozanolixizumab in gMG[1]

Evidence is based on 2 RCTs. One was a phase 2a study (n=43) over 4 weeks where most patients were AChR+ (90%-95%) and few were MuSK+ (0%-5%) with high RoB. The other was a phase 3 trial (n=200) over 6 weeks with 88%-91% AChR+ and 8%-12% MuSK+ patient representation. Two treatment dosage groups were included in addition to placebo.

Efficacy

- Symptom severity was statistically significantly improved in both RCT using two screening tools, but only clinically meaningful in the larger, phase 3 trial (very low CoE).
- Function was statistically significantly improved in both RCT, but only clinically meaningful in the larger, phase 3 trial (very low CoE)
- QoL assessment was not included.

Safety

- There were statistically significantly more AEs in the 10mg/kg dosage group in 1 study, while 7mg/kg did not differ from placebo in either study (moderate CoE). The most common AEs were nausea, vomiting, diarrhea, headache, fatigue, dizziness, fatigue, muscle pain, and nasopharyngitis.
- There was no difference in SAEs between study groups (0% for 7 mg/kg dosage, 3% for 10 mg/kg dosage) (moderate CoE).

Zilucoplan in gMG[1]

Evidence is based on 2 RCT. One was a 12-week phase 2 study (n=45) where all patients were AChR+ and MuSK status was not reported (high RoB). The other was a phase 3 RCT (n=174) of 12-week duration where all patients were AChR+ and 0% were MuSK+ (moderate RoB).

Efficacy

- Symptom severity was statistically significantly improved using two screening tools for 0.3 mg/kg dosage, the difference was just below the MCID threshold (low CoE).
- Function improvement was statistically significantly and clinically meaningfully improved in all treatment dosage groups (low CoE).
- QoL results were mixed between the different studies and dosage groups. There was statistically significant improvement in the 0.1 mg/kg dosage group in the phase 2 study but not the 0.3 mg/kg group. In the phase 3 study, there was statistically significant improvement in the treatment group (0.3 mg/kg) (low CoE). MCID is unknown for the QoL assessment tool used.

Safety

- Most patients experienced an AE, and AEs were more common in treatment groups compared to placebo, though differences were not significant. (moderate CoE). The most common AEs were headache, injection-site reactions, nausea, vomiting, diarrhea, rash, and urinary tract infections.
- SAEs ranged from 0% to 20% and were inconsistent between placebo and different dosages (moderate RoB).

References:

1. Lyon J, Vintro A, Yeddala S, Shaw B, Anderson R. Newer agents for myasthenia gravis. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University; 2025.

2. Antozzi C, Vu T, Ramchandren S, et al. Safety and efficacy of nipocalimab in adults with generalised myasthenia gravis (Vivacity-MG3): a phase 3, randomised, double-blind, placebo-controlled study. *Lancet Neurol*. Feb 2025;24(2):105-116. doi:10.1016/S1474-4422(24)00498-8

Appendix 1: Current Preferred Drug List

Generic	Brand	Route	Form	PDL
amifampridine phosphate	FIRDAPSE	ORAL	TABLET	N
eculizumab	SOLIRIS	INTRAVEN	VIAL	
eculizumab-aagh	EPYSQLI	INTRAVEN	VIAL	N
eculizumab-aeeb	BKEMV	INTRAVEN	VIAL	N
efgartigimod alfa-fcab	VYVGART	INTRAVEN	VIAL	N
efgartigimod-hyaluronidas-qvfc	VYVGART HYTRULO	SUBCUT	SYRINGE	
efgartigimod-hyaluronidas-qvfc	VYVGART HYTRULO	SUBCUT	VIAL	
inebilizumab-cdon	UPLIZNA	INTRAVEN	VIAL	
nipocalimab-aahu	IMAAVY	INTRAVEN	VIAL	
ravulizumab-cwvz	ULTOMIRIS	INTRAVEN	VIAL	
rozanolixizumab-noli	RYSTIGGO	SUBCUT	VIAL	
zilucoplan sodium	ZILBRYSQ	SUBCUT	SYRINGE	N

Amifampridine

Goal(s):

- Promote safe and effective use of amifampridine in the treatment of LEMS symptoms

Length of Authorization:

- Initial: 14 days
- Renewal: 1 to 3 months

Requires PA:

- Amifampridine

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1: Maximum Recommended Dose

Formulation	Minimum age (years)	Weight (kg)	Single Dose Maximum	Cumulative Daily Maximum
Ruzurgi®	≥ 6	< 45	15 mg	50 mg
		≥ 45	30 mg	100 mg
Firdapse®	≥ 6	< 45	15 mg	50 mg
		≥ 45	20 mg	100 mg

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3

Approval Criteria		
3. Is the diagnosis for Lambert-Eaton Myasthenic Syndrome (LEMS)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
~~4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product?~~ ~~Message:~~ • ~~Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee.~~	~~**Yes:** Inform prescriber of preferred alternatives.~~	~~**No:** Go to #5~~
4. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is there evidence based on chart notes or claims that the patient has a seizure disorder diagnosis or history of seizures?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #6
6. Is there evidence based on chart notes or claims that the patient has active brain metastases?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7
7. Does the patient have a documented baseline ECG in the past 12 months demonstrating a QT interval < 450 milliseconds?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the amifampridine dose within the appropriate limits? (See **Table 1** in criteria)	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
9. Has the patient been assessed with a baseline quantitative myasthenia gravis (QMG) exam (score>5), 3TUG walking test, or other validated measure of LEMS patient physical functioning?	**Yes:** Go to #10 Document baseline results.	**No:** Pass to RPh. Deny; medical appropriateness
10. Does the patient have follow-up appointments scheduled during weeks 1 and 2 after the proposed therapy initiation date?	**Yes:** Go to #11 Document appointment dates.	**No:** Pass to RPh. Deny; medical appropriateness
11. Will the patient and provider comply with all case management interventions and adherence monitoring requirements required by the Oregon Health Authority?	**Yes:** Approve for 2 weeks	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the patient been taking amifampridine for ≥1 week AND has there been documented improvement from baseline in ambulation or physical functioning as assessed via the 3TUG, QMG score, or other validated LEMS assessment scale?	**Yes:** Document follow-up assessment scores Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the amifampridine dose within appropriate limits? (See **Table 1** in criteria)	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Has the patient experienced any new adverse effects since starting amifampridine therapy (e.g. seizures, arrhythmias)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #4

Renewal Criteria		
4. Does the patient have documented evidence of >90% adherence to amifampridine for the previous approval period?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient been on >30 days of continuous amifampridine therapy?	**Yes:** Approve for 3 months	**No:** Approve for 30 days; Renewal consideration will require documentation of tolerance, clinical benefit, and adherence.

P&T/DUR Review: 6/26 (SF); 11/19 (DE)
Implementation: TBD; 1/1/2019

Efgartigimod (VYVGART, VYVGART HYTRULO)

Goal(s):

~~Restrict use to OHP-funded conditions.~~

- Promote use that is consistent with medical evidence.

Length of Authorization:

- Up to 12 months

Requires PA:

Efgartigimod alfa-fcab (VYVGART) and efgartigimod alfa-hyaluronidase-qvfc (VYVGART HYTRULO) pharmacy and provider administered claims.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
~~2. Is the diagnosis funded by OHP?~~	~~**Yes:** Go to #4~~	~~**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP~~ ~~If eligible for EPSDT review: Go to #3.~~
~~3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?~~	~~**Yes:** Go to #4~~	~~**No:** Pass to RPh. Deny; medical necessity.~~
~~4.~~ 2. Is this an FDA approved indication?	**Yes**: Go to #~~35~~	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #~~46~~
4. Does the patient have an active infection?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #~~57~~
5. Has the patient received, or have contraindications to, all routine immunizations recommended for their age? Note: Routine vaccinations for patients at least 2 years of age typically included hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least 2 doses of measles, mumps, rubella, and varicella. Immunization with live vaccines is not recommended during efgartigimod treatment.	**Yes:** Go to #~~68.~~ Document physician attestation of immunization history	**No:** Pass to RPh. Deny; medical appropriateness. Administer vaccines before initiation of a new treatment cycle of efgartigimod

Approval Criteria		
6. Does the patient have a positive serological test for anti-acetylcholine receptor (AchR) antibodies?	**Yes:** Go to #79	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have a Myasthenia Gravis Foundation of America Clinical Classification of class II, III or IV?	**Yes:** Go to #810	**No:** Pass to RPh. Deny; medical appropriateness
8. Does the patient have a myasthenia gravis-specific activities of daily living scale (MG-ADL) total score of 5 points or more?	**Yes:** Go to #911 Record baseline MG-ADL score	**No:** Pass to RPh. Deny; medical appropriateness
9. Has the patient received or is currently receiving two immunosuppressant therapies (as monotherapy or in combination) for at least one year without adequate symptom control or do they have contraindications to these therapies? Example immunosuppressant therapies: - Azathioprine - Cyclosporine - Mycophenolate mofetil - Tacrolimus - Methotrexate - Cyclophosphamide	**Yes:** Go to #102	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of immunosuppressant therapy
10. Is the request for efgartigimod dosing that corresponds to FDA labeling? • ~~10 mg/kg once weekly for 4 weeks~~ • ~~For patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion~~	**Yes:** Approve for up to two cycles. Each cycle is 1 dose/week for 4 weeks. The second cycle should not be administered sooner than 50 days from start of previous cycle.	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has it been 50 days or more from the start of the previous efgartigimod treatment cycle?	**Yes**: Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is this request for the first renewal of efgartigimod?	**Yes**: Go to #3	**No:** Go to #4
3. Has the patient experienced a reduction in symptoms of at least 2 points from MG-ADL total baseline score?	**Yes**: Approve for up to 5 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle. Record MG-ADL score	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient maintained a stable MG-ADL score over the last 12 months of efgartigimod therapy?	**Yes**: Approve for up to 7 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle. Record MG-ADL score	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 6/26 (SF); 2/23 (DM); 4/22 (KS)
Implementation: TBD; 4/1/23; 5/1/22