Shaping the Future of Generalized Myasthenia Gravis Management: A Focus on Novel Treatment Approaches

NEUROLOGY DAY OF Education 2025

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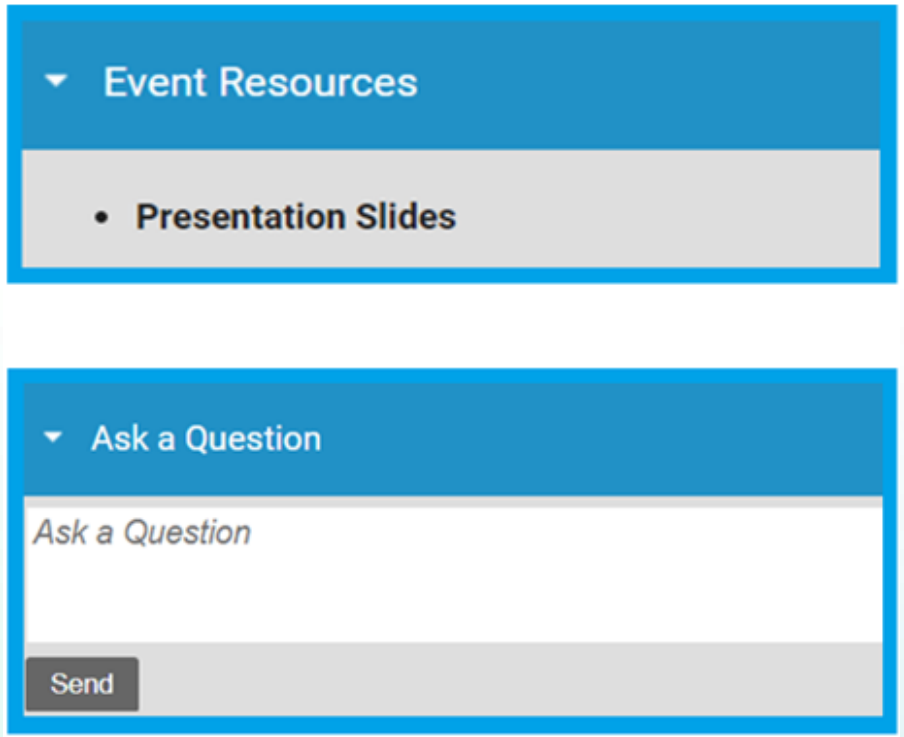

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Release Date: July 29, 2025

Activity Type: Application

Fee: Free

How to Obtain Credit

Instructions on how to obtain credit for this activity will be provided at the end of this presentation.

This activity is supported by an educational grant from UCB Inc.

Educational Objectives

After completion of this activity, participants will be able to:

- Examine real-world data to highlight current limitations in existing treatment of generalized myasthenia gravis (gMG) and their implications for long-term disease management
- Explain the role of novel targets such as FcRn inhibitors and complement pathways in reshaping the therapeutic landscape of gMG
- Employ strategies to address psychosocial factors and caregiver support, ensuring a holistic approach to improving patient-reported outcomes in gMG care

Pretest Questions

Pretest Question 1

Which statement is true concerning conventional treatments for myasthenia gravis such as corticosteroids and immunosuppressants?

A. Patients often achieve remission within 1 year on an acetylcholinesterase inhibitor and prednisone combination therapy.

B. Corticosteroids are well tolerated long term and rarely lead to discontinuation.

C. Many patients continue to experience fluctuating symptoms and functional impairment despite corticosteroid and immunosuppressant therapy.

D. Acetylcholinesterase inhibitors are curative for patients with AChR+ gMG.

Pretest Question 2

Which complement-targeting therapy for generalized myasthenia gravis (gMG) is administered subcutaneously and approved for self-administration?

A. Eculizumab
B. Efgartigimod
C. Ravulizumab
D. Zilucoplan

Pretest Question 3

A 42-year-old woman with generalized myasthenia gravis (gMG) reports ongoing fatigue, frustration with her fluctuating symptoms, and difficulty maintaining her job due to unpredictable weakness. Her caregiver, who is her spouse, expresses emotional burnout and a lack of support navigating the health care system. She is stable on pharmacologic therapy with no recent exacerbations.

Which of the following pharmacist actions best supports a holistic approach to care in this scenario?

A. Recommend increasing the dose of her current medication to better control fatigue.

B. Suggest switching to a newer biologic agent with a different mechanism of action.

C. Refer the patient and caregiver to a local MG support group and provide educational resources.

D. Advise the caregiver to seek individual counseling separate from the patient's care team.

Pretest Question 4

Before participating in the activity, how confident are you in your ability to counsel and monitor patients with gMG to optimize their therapy and manage barriers?

A. Not at all
B. Somewhat
C. Moderately
D. Very
E. Extremely

Myasthenia Gravis Disease State Overview

Disease Burden: Meet Teresa

Click here to learn about Teresa’s patient journey:

https://www.mg-united.com/a-mystery-to-me

https://www.youtube.com/watch?v=r3tIDKJbsG0; A mystery to me. MG United. Accessed June 18, 2025. https://www.mg-united.com/a-mystery-to-me

What Is Myasthenia Gravis (MG)?

An antibody-mediated autoimmune disease that causes autoantibodies to disrupt binding at the postsynaptic membrane at the neuromuscular junction leading to muscle weakness

Class II hypersensitivity reaction involving IgG autoantibodies

Latin and Greek roots meaning “grave muscle weakness”

Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30; Dresser L et al. *J Clin Med*. 2021;10(11):2235; Myasthenia Gravis Foundation of America. Accessed June 24, 2025. https://myasthenia.org/; Conti-Fine BM et al. *J Clin Invest.* 2006;116(11):2843-2854.

Epidemiology

Prevalence: 150-200 cases per million individuals

- Steady increase over past 50 years due to recognition, diagnosis, treatment, and increase in life expectancy

Incidence: North America and Japan: 3-9.1 cases per million person-years

Europe: 4.1-30 cases per million person-years

- Variable age of onset, peaks in younger adult women (30-50 years) and older men (60-89 years)
- Pediatric cases represent 10% of patient population
- Slightly higher in African Americans

Mortality rate: 5%-9%, slightly higher in males than females

- In-hospital mortality rate 2.2% and 4.7% for those with MG crisis

Dresser L et al. *J Clin Med*. 2021;10(11):2235.

Myasthenia Gravis Overview

Ocular

- Ptosis (eyelid drooping)
- Diplopia (double vision)
- ≈15% of patients

Generalized

- Oculobulbar muscle weakness (affects talking, chewing, holding head up)
- Weakness in limbs, can affect gait
- Respiratory muscle weakness
- ≈85% of patients

Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30; Myasthenia Gravis (MG) - Signs and Symptoms | Muscular Dystrophy Association. Published December 27, 2015. https://www.mda.org/disease/myasthenia-gravis/signs-and-symptoms

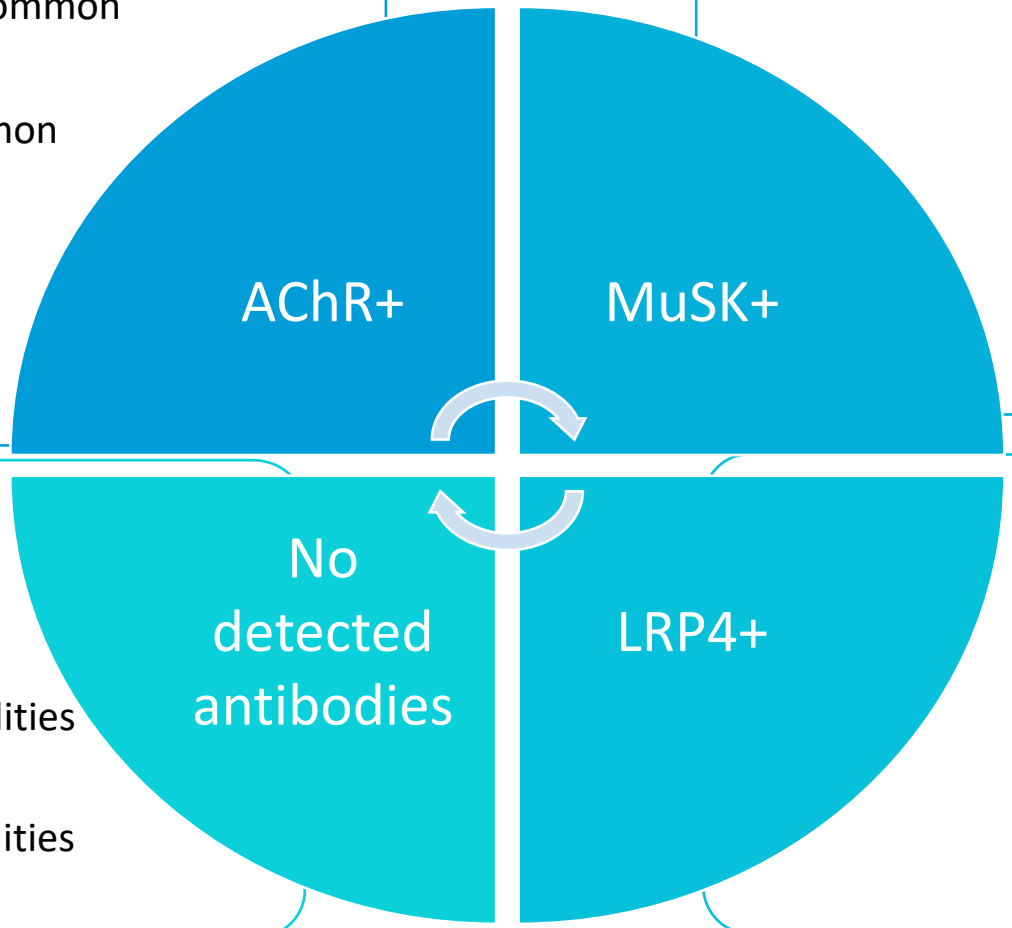
Myasthenia Gravis Subtypes

EARLY-ONSET MG
- <50 years, hyperplasia common

LATE-ONSET MG
- ≥50 years, atrophy common

THYMOMA MG
- Type AB and B thymoma

OCULAR MG
- Variable thymus abnormalities



MuSK MG
- No thymus abnormalities

OCULAR MG
- Variable thymus abnormalities

SERONEGATIVE MG
- Variable thymus abnormalities

OCULAR MG
- Variable thymus abnormalities

LRP4+
- No thymus abnormalities

OCULAR MG
- Variable thymus abnormalities

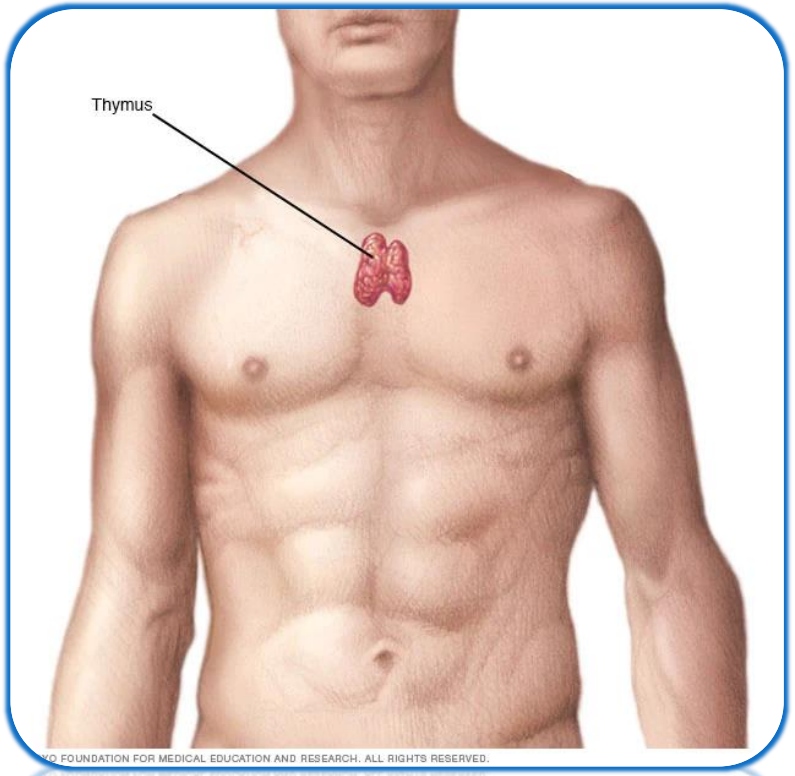
SUBTYPE CATEGORIZATION

- Clinical presentation
- Presence of autoantibodies
- Age of onset
- Thymus pathology

Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30.

Abbreviations: Acetylcholine receptor (AChR), Muscle Specific Kinase (MuSK), Lipoprotein-receptor-related protein 4 (LRP4)

The Thymus and Myasthenia Gravis



Thymus

Gland that plays an important role in the immune system beginning in early fetal development until puberty

Normal

After puberty, gland gets smaller until it is replaced by fat

Myasthenia Gravis

Thymic abnormalities are common

Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30; Myasthenia gravis. National Institute of Neurological Disorders and Stroke. Accessed June 18, 2025. https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis#toc-what-is-myasthenia-gravis-

The Thymus and Myasthenia Gravis

Up to 10% of patients have thymoma and >80% have thymic follicular hyperplasia

Thymus

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Normal

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Myasthenia Gravis

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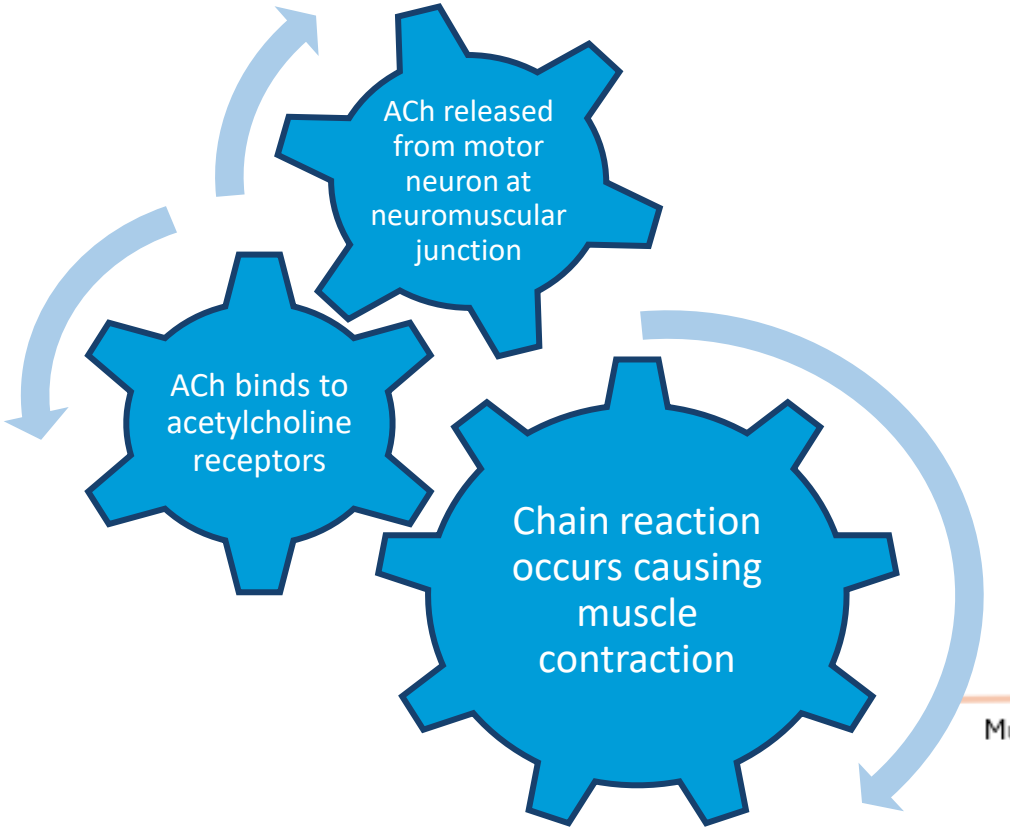
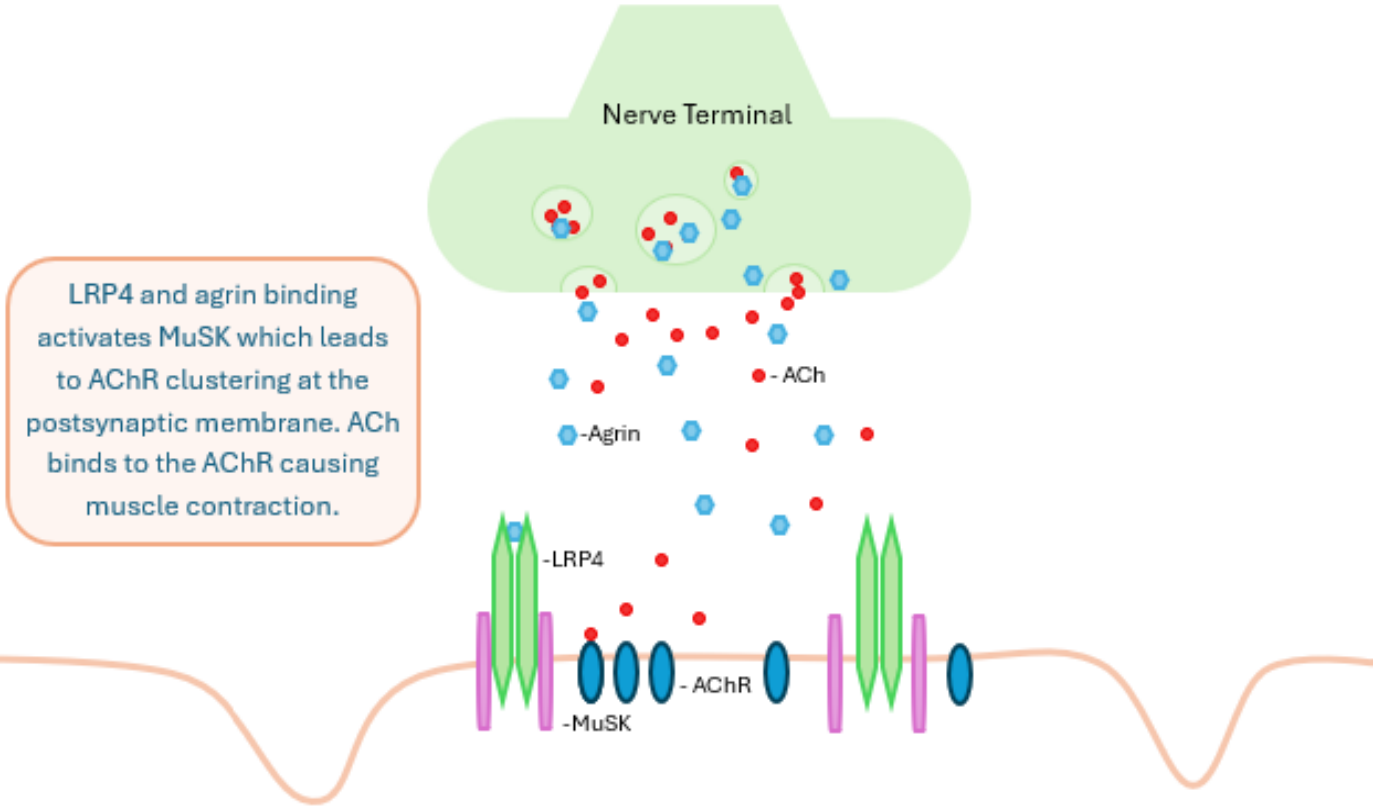
Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30; Myasthenia gravis. National Institute of Neurological Disorders and Stroke. Accessed June 18, 2025. https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis#toc-what-is-myasthenia-gravis-

Myasthenia Gravis Pathophysiology

Pathophysiology: Normal Muscle Contraction

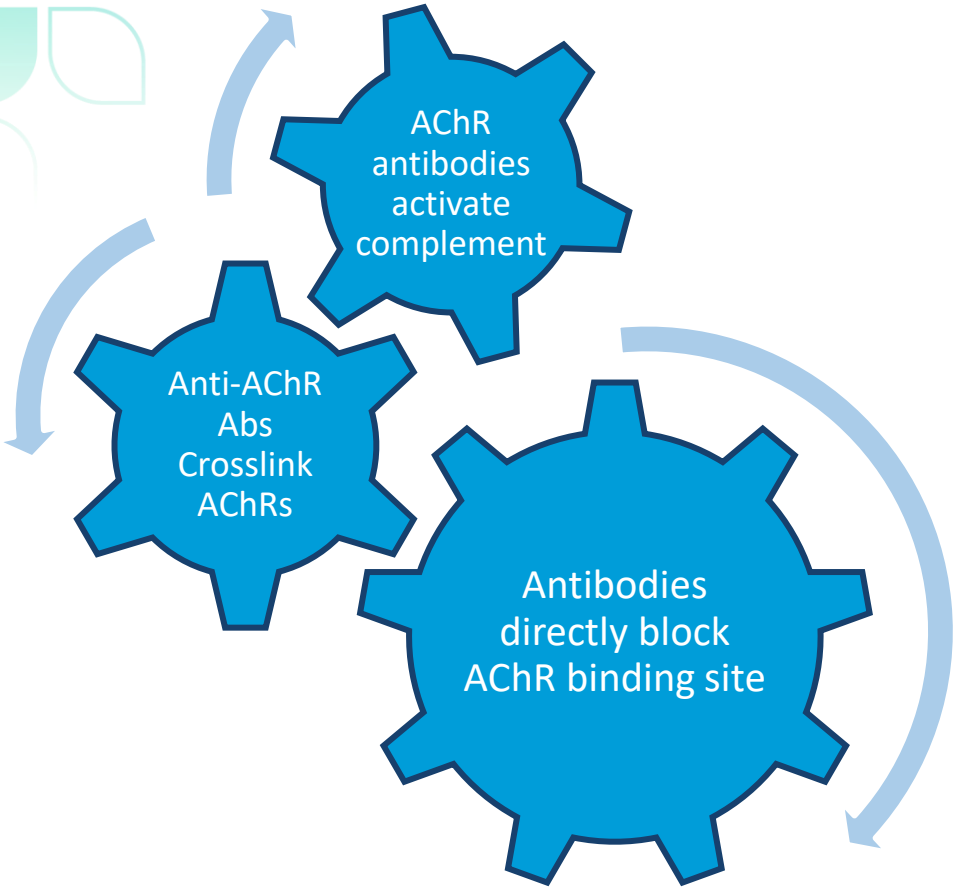


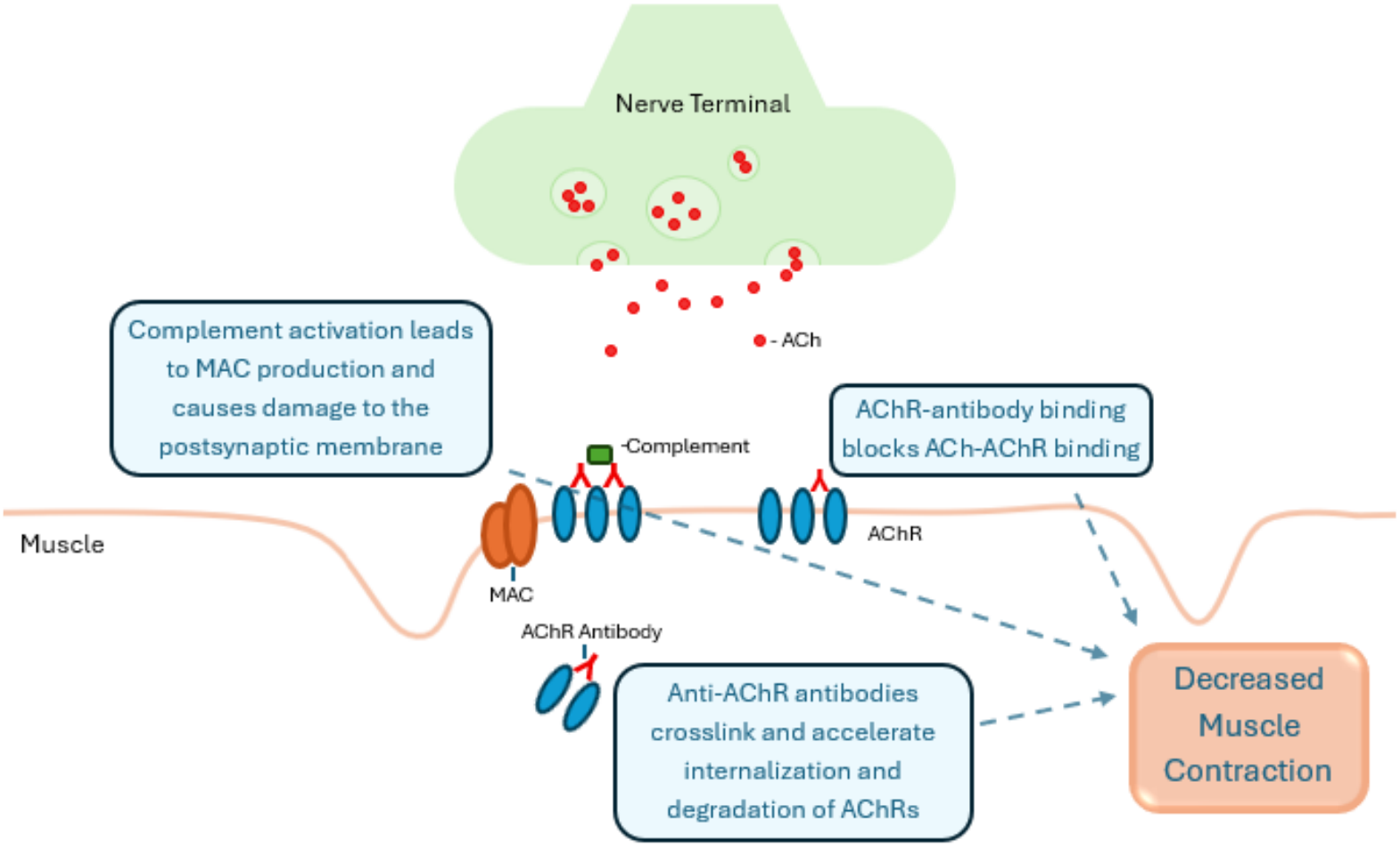


Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30.

Normal Muscle Contraction. *Image created by author.*

Pathophysiology AChR+ MG



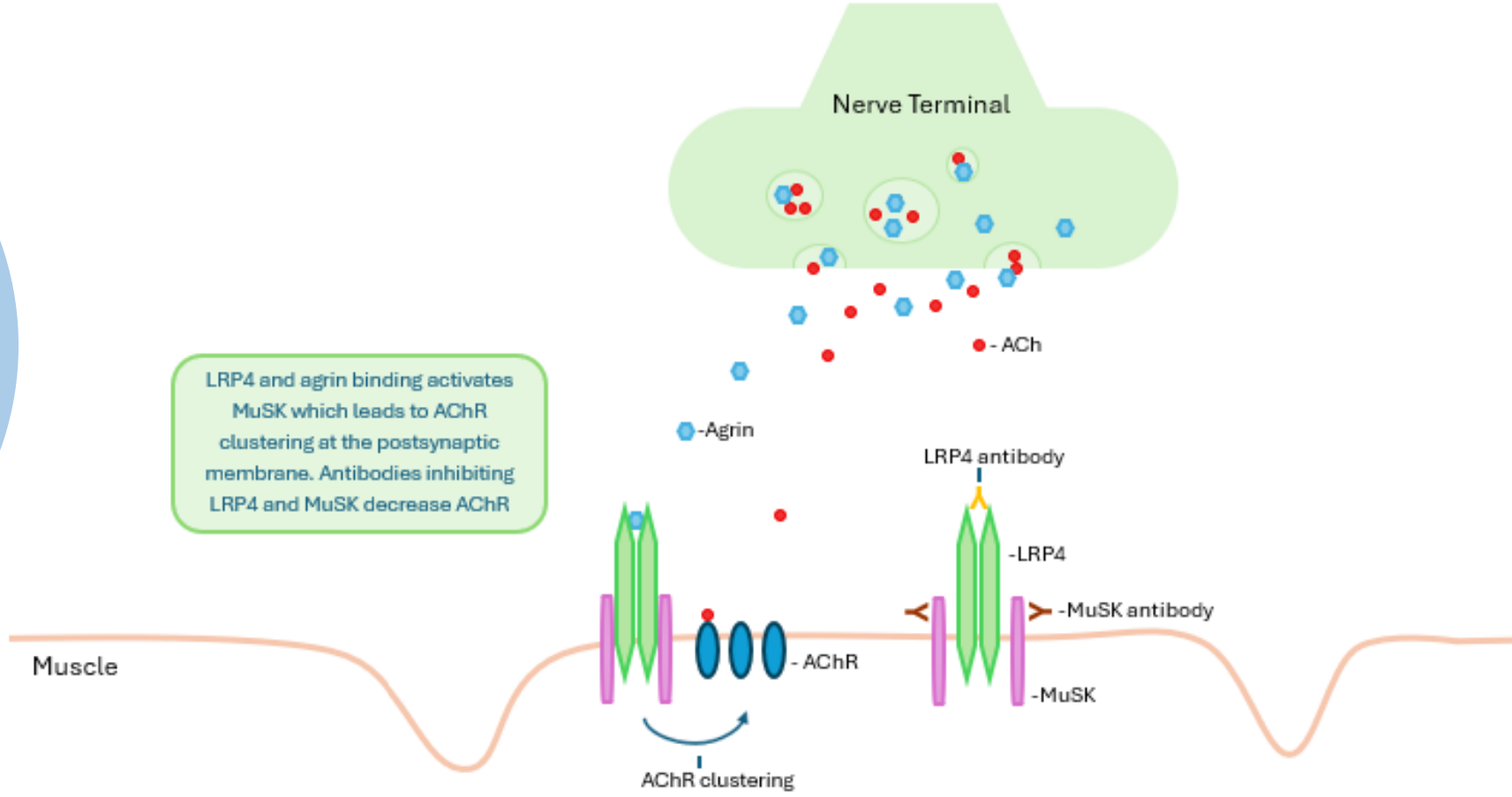


Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30.

Pathophysiology AChR+ MG. *Image created by author.*

Pathophysiology MuSK+ and LRP4+ MG

MuSK and LRP4 antibodies reduce AChR clustering on the postsynaptic membrane



Gilhus NE et al. *Nat Rev Dis Primers*. 2019;5(1):30.

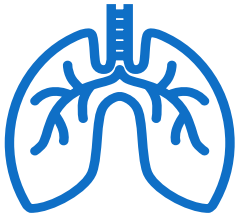
Pathophysiology MuSK+ and LRP4+ MG. *Image created by author.*

Signs and Symptoms

- Blurred or double vision (diplopia)
- Drooping of one or both eyelids (ptosis)

- Generalized weakness (arms, hands, fingers, legs, and neck)

- Difficulty swallowing (dysphagia)
- Difficulty chewing
- Change in facial expression
- Impaired speech



- Shortness of breath
- Respiratory failure

Myasthenia gravis. National Institute of Neurological Disorders and Stroke. Accessed June 18, 2025. https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis#toc-what-is-myasthenia-gravis-

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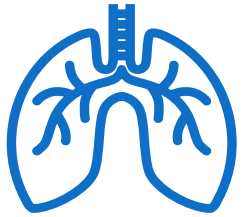


- Shortness of breath
- Respiratory failure

Signs of possible myasthenic crisis !

Myasthenia gravis. National Institute of Neurological Disorders and Stroke. Accessed June 18, 2025. https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis#toc-what-is-myasthenia-gravis-

Myasthenic Crisis

Complication of gMG characterized by symptom worsening to the point of respiratory failure

Epidemiology

15%-20% of gMG patients will have a myasthenic crisis at least once

Initial presentation for up to 1/5th of gMG patients

Signs & Symptoms

Respiratory dysfunction:

↓ Vital capacity

↓ Positive expiratory force

Triggers

Common triggers

Medication triggers

Wendell LC, Levine JM. *Neurohospitalist*. 2011;1(1):16-22.

Myasthenic Crisis

Common Triggers

- Infection
- Surgery
- Pregnancy
- Physical or emotional stress

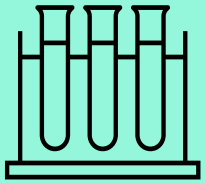
Medication Triggers

- Class Ia antiarrhythmics
- Macrolides
- Aminoglycosides
- Beta-blockers
- Prednisone
- Many more…

Wendell LC, Levine JM. *Neurohospitalist*. 2011;1(1):16-22; Sheikh S et al. *J Clin Med*. 2021;10(7):1537.

Myasthenia Gravis Diagnosis and Treatment

Myasthenia Gravis Diagnosis

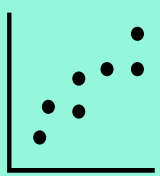


Laboratory Testing

- Blood test to determine pathogenic autoantibody
- Helps define disease subtype
- Most certain diagnostic criteria

Pharmacologic Testing

- Use of immediate onset acetylcholinesterase inhibitor (ex: neostigmine)
- Medication will periodically improve symptoms
- May worsen symptoms in anti-MuSK patients



Electrodiagnostic Studies

- Repetitive nerve stimulation (RNS)
- Single fiber electromyography; "neuromuscular jitter study"

The "Ice Pack" Test

- Symptoms may improve with exposure to cold
- Place an ice pack over the eye for 2-5 minutes and look for improvement
- Mainly used in ocular MG

Thymus Imaging

- Advised in all confirmed or strongly suspected cases of MG

Rousseff RT. *J Clin Med.* 2021;10(8):1736.

Myasthenia Gravis Foundation of America (MGFA) Clinical Classification

Class I: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.

Class II: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.

- IIa: Predominantly affecting limb, axial muscles, or both.
- IIb: Predominantly affecting oropharyngeal, respiratory muscles, or both.

Class III: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity

- IIIa: Predominantly affecting limb, axial muscles, or both.
- IIIb: Predominantly affecting oropharyngeal, respiratory muscles, or both.

Class IV: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity

- IVa: Predominantly affecting limb, axial muscles, or both.
- IVb: Predominantly affecting oropharyngeal, respiratory muscles, or both. Patients using a feeding tube without intubation.

Class V: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management.

Trouth AJ et al. *Autoimmune Dis*. 2012;2012:874680.

Myasthenia Gravis Assessment

Myasthenia Gravis Activities of Daily Living (MG-ADL) scale

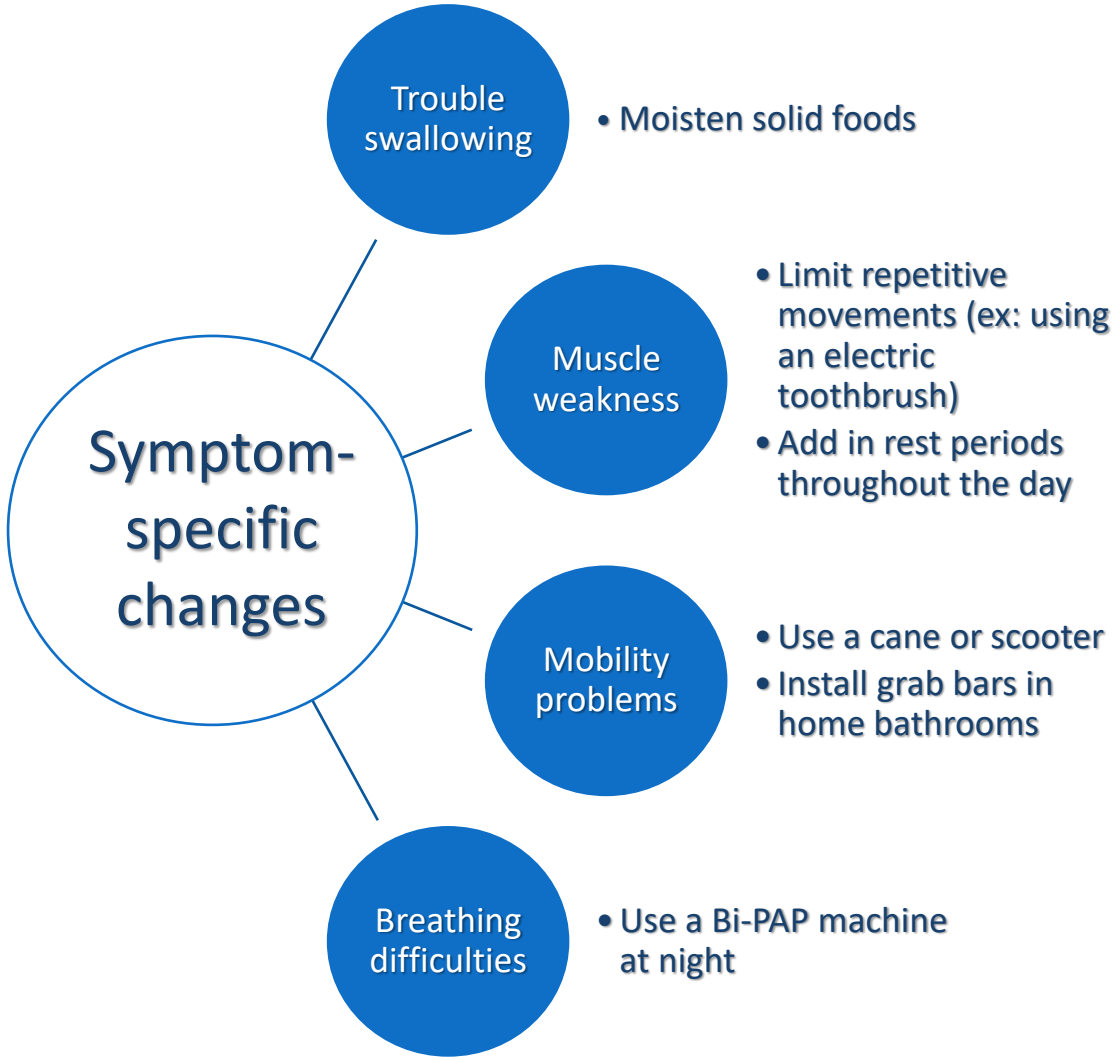
	0 = Normal	1	2	3 = Most Severe	
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal speech, but can be understood	Difficult-to-understand speech	____
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	____
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	____
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	____
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	____
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	____
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	____
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	____
				Total Score	____

Myasthenia. MG activities of daily living (MG-ADL) scale. Conquer Myasthenia Gravis. September 29, 2022. Accessed June 25, 2025. https://myastheniagravis.org/mg-activities-of-daily-living-mg-adl-scale/

Lifestyle Modifications

Avoid Triggers

- Stress (physical & emotional)
- Extreme temperatures
- Lack of sleep
- Infection



Wendell LC, Levine JM. *Neurohospitalist*. 2011;1(1):16-22; Sheikh S et al. *J Clin Med*. 2021;10(7):1537; Living day to day with MG. Conquer Myasthenia Gravis. Published January 11, 2022. Accessed June 20, 2025. https://www.myastheniagravis.org/life-with-mg/save-your-strength/

Myasthenia Gravis Treatment

Maintenance Therapies

AChE Inhibitors	Immunosuppressants	Biologic Therapies
Ex: pyridostigmine, neostigmine	Ex: glucocorticoids, azathioprine, mycophenolate	Ex: rituximab, efgartigimod, rozanolixizumab, nipocalimab, ravulizumab, eculizumab, zilucoplan
Pyridostigmine is 1st line for symptomatic treatment	Indicated for those who remain symptomatic while on AChE therapy	Monoclonal antibodies, FcRn inhibitors, and complement inhibitors used as chronic therapy
Bothersome muscarinic adverse effects (ex: drooling, diarrhea)	Glucocorticoids are first line BUT they may cause transient worsening of symptoms	IV/SC infusions and injections

AChE, acetylcholinesterase; ACh, acetylcholine; NMJ, neuromuscular junction.

Alhaidar MK et al. *J Clin Med.* 2022;11(6):1597; Gerischer L et al. *BioDrugs.* 2025;39(2):185-213.

Myasthenia Gravis Treatment

Severe Myasthenia Gravis and Myasthenic Crisis

Plasma Exchange (PLEX)

Plasma is separated from the patient's blood and replaced

↓

Directly removes autoantibodies from the bloodstream

↓

Mainly used in myasthenic crisis

IVIG

Pooled immunoglobulin from thousands of donors

↓

Thought to neutralize autoantibodies and decrease immune response by blocking key pathways

↓

Generally used in myasthenic crisis but may be used as a bridge to slower immunotherapies

Alhaidar MK et al. *J Clin Med.* 2022;11(6):1597; Arumugham VB, Rayi A. Intravenous Immunoglobulin (IVIG) Updated July 3, 2023. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. Accessed July 21, 2025. https://www.ncbi.nlm.nih.gov/books/NBK554446/

Myasthenia Gravis Treatment

Surgical Interventions

Thymectomy

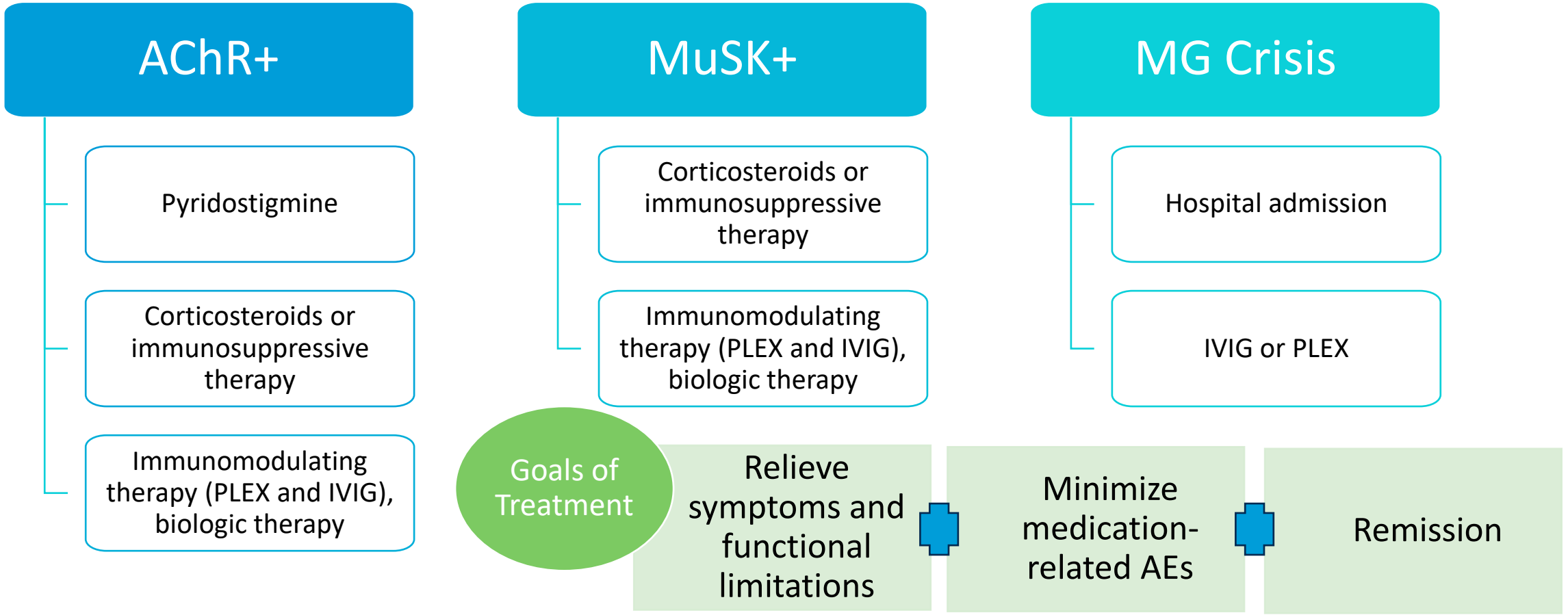
Considered to be mandatory if a thymoma is present

Numerous studies showing clear benefit and links to remission of MG symptoms

Evidence supports use in AChR antibody+ patients; not validated in MuSK antibody+ patients

Alhaidar MK et al. *J Clin Med.* 2022;11(6):1597.

Treatment Algorithm in MG



Skeie GO et al. *Eur J Neurol.* 2010;17:893-902; Sanders DB et al. *Neurology*. 2016;87(4):419-425; Weindl H et al. *Ther Adv Neurol Disord*. 2023;16:17562864231213240; Mena Alrais Dellarocca, PharmD, RPh. The treatment of myasthenia mravis. *U.S. Pharmacist.* January 18, 2024. Accessed July 21, 2025. www.uspharmacist.com/article/the-treatment-of-myasthenia-gravis
Reyes-Leiva D et al. Eur J Neurol. 2024; 32(1); e16463

Maintenance Therapies

AChE Inhibitors and Immunosuppressants

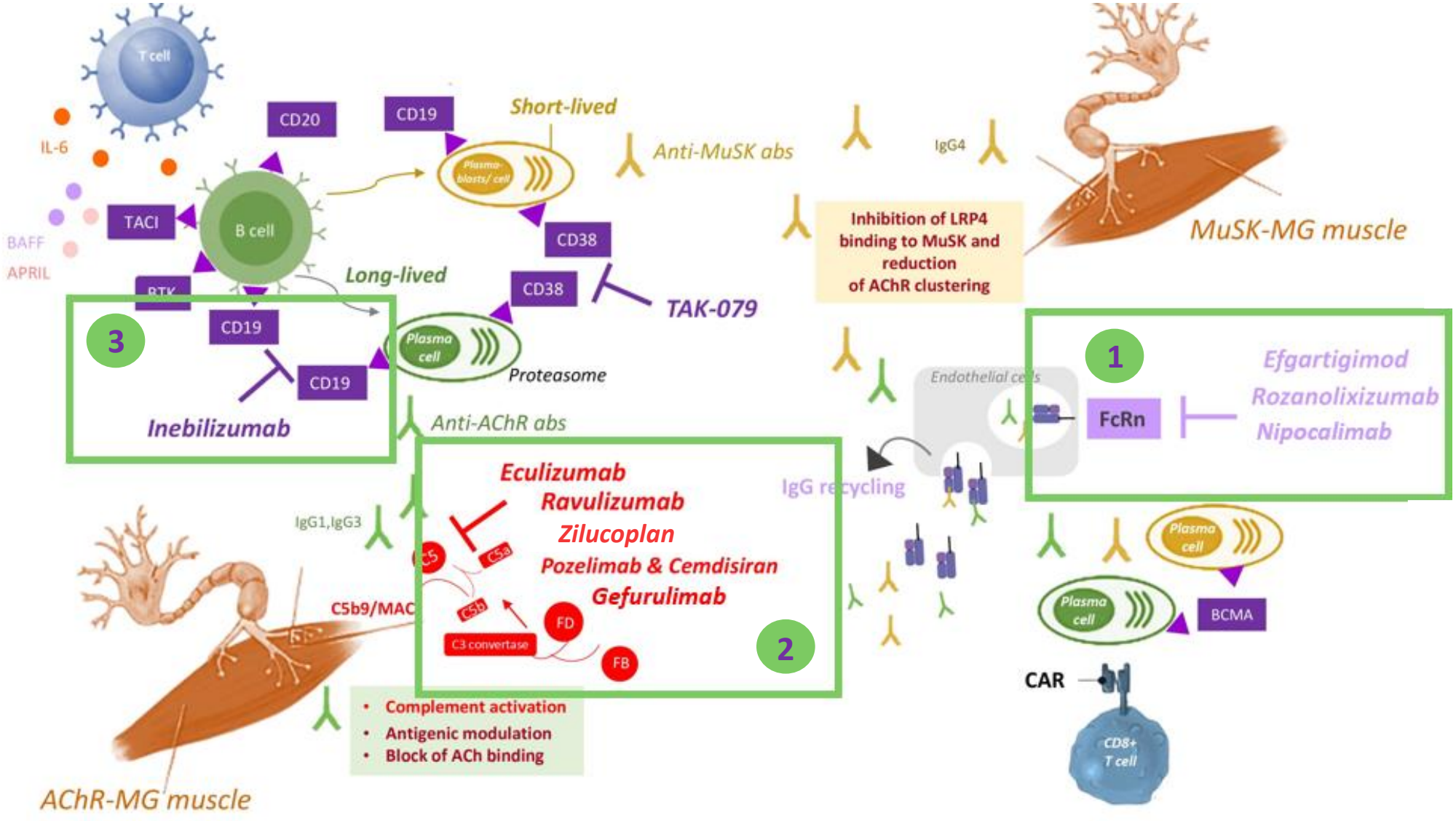
Drug/Class	Mechanism of Action	Key Adverse Effects	Practice Considerations
AChE Inhibitors Pyridostigmine, neostigmine	Inhibit AChE to ↑ ACh at NMJ	GI upset, salivation	Patient response varies; paradoxical weakness can occur with high doses; ineffective in MuSK+; can use loperamide or glycopyrrolate for adverse effect mitigation
Corticosteroids Prednisone	Immunosuppressant, reducing antibody production	HTN, weight gain, ulcers, ↑ infection risk	Rapid onset; start low dose, titrate slowly to avoid paradoxical steroid weakness
Nonsteroidal immunosuppressants			
Azathioprine	↓ Purine synthesis → ↓ T/B cell production	Flu-like symptoms, myelosuppression, hepatotoxicity, pancreatitis	Delayed onset of action; steroid sparing TPMT screening; monitor labs
Mycophenolate	Inhibits IMPDH → ↓ guanosine nucleotides → ↓ T/B cell production	GI effects, leukopenia, opportunistic infections	Delayed onset of action; consider when steroids not tolerated/contraindicated Avoid in pregnancy
Cyclosporine	Calcineurin inhibitor → ↓ IL-2, T-cell activity	Nephrotoxicity, HTN, tremor, gingival hyperplasia	Monitor renal function; avoid in pregnancy
Tacrolimus		Hyperglycemia, tremors, GI effects, paresthesia	Rapid onset; may reduce steroid need Avoid in pregnancy

AChE, acetylcholinesterase; ACh, acetylcholine; NMJ, neuromuscular junction; GI, gastrointestinal; HTN, hypertension; T/B cell, T- and B-lymphocyte; IMPDH, inosine monophosphate dehydrogenase; IL-2, interleukin-2; TPMT, thiopurine methyltransferase.

Alhaidar MK et al. *J Clin Med*. 2022;11(6):1597; Kim SC, Hernandez-Diaz. *Arthritis Rheumatol*. 2014;66(2):246-248.

Biologic Therapy

Biologic Drug Targets for Myasthenia Gravis



Fc Receptor Inhibitors

MOA: Human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG

Drug	Indication	Dose	Adverse Effects	Practice Considerations/ Key Trials
Efgartigimod alfa-fcab (IV)	Adults with gMG who are AChR+	• 10 mg/kg (max dose 1200 mg) IV weekly x 4 • Subsequent treatment cycles may be considered ≥50 days from start of previous cycle based on clinical evaluation	Hypersensitivity and infusion-related reactions Common: respiratory infections, headache, and UTI	>2 pt MG-ADL improvement in 68%; ≈33% needed 2nd cycle after 6-7 weeks ADAPT trial
Efgartigimod alfa and hyaluronidase -qvfc (SC)	Adults with gMG who are AChR+	• Prefilled syringe: 1000 mg efgartigimod alfa and 10,000 units hyaluronidase SC over ≈20 to 30 seconds • Vial: 1008 mg efgartigimod alfa and 11,200 units hyaluronidase SC over ≈30 to 90 seconds • Administered in once-weekly cycles x 4 weeks • Subsequent cycles may begin ≥50 days after the start of the previous cycle if clinically appropriate	↑ risk of infection, hypersensitivity and injection-related reactions Common: respiratory infections, headache, and UTI	Comparable pharmacodynamic effect to the IV formulation ADAPT-SC Trial

Alhaidar MK et al. *J Clin Med.* 2022;11(6):1597; Howard JF et al. *Lancet Neurol.* 2021;20(7):526-536; Howard JF et al. *Neurotherapeutics*. 2024;21(5):e00378; Vygart (efgartigimod alfa-fcab). Prescribing information. Argenx BV; 2025; Vygart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). Prescribing information. Argenx BV; 2025.

Fc Receptor Inhibitors

MOA: Human IgG4 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG

Drug	Indication	Dose	Adverse Effects	Practice Considerations/ Key Trials

Rozanolixizumab (SC inf)	Adults with gMG who are AChR+ or MuSK+	• Weight-based dose once weekly x 6 weeks
		  • <50 kg = 420 mg/3 mL
		  • 50 kg to <100 kg = 560 mg/4 mL
		  • ≥100 kg = 840 mg/6 mL
		• May repeat cycle ≥63 days from start of prior, if clinically indicated
			Aseptic meningitis, hypersensitivity reactions, ↑ risk of infection
			
			Common: headache, infection, diarrhea, pyrexia, nausea
				MG-ADL improvement: –3.4 points
				
				MycarinG trial

Bril V et al. *Lancet Neurol*. 2023;22(5):383-394; Rystiggo (rozanolixizumab). Prescribing information. UCB, Inc; 2025.

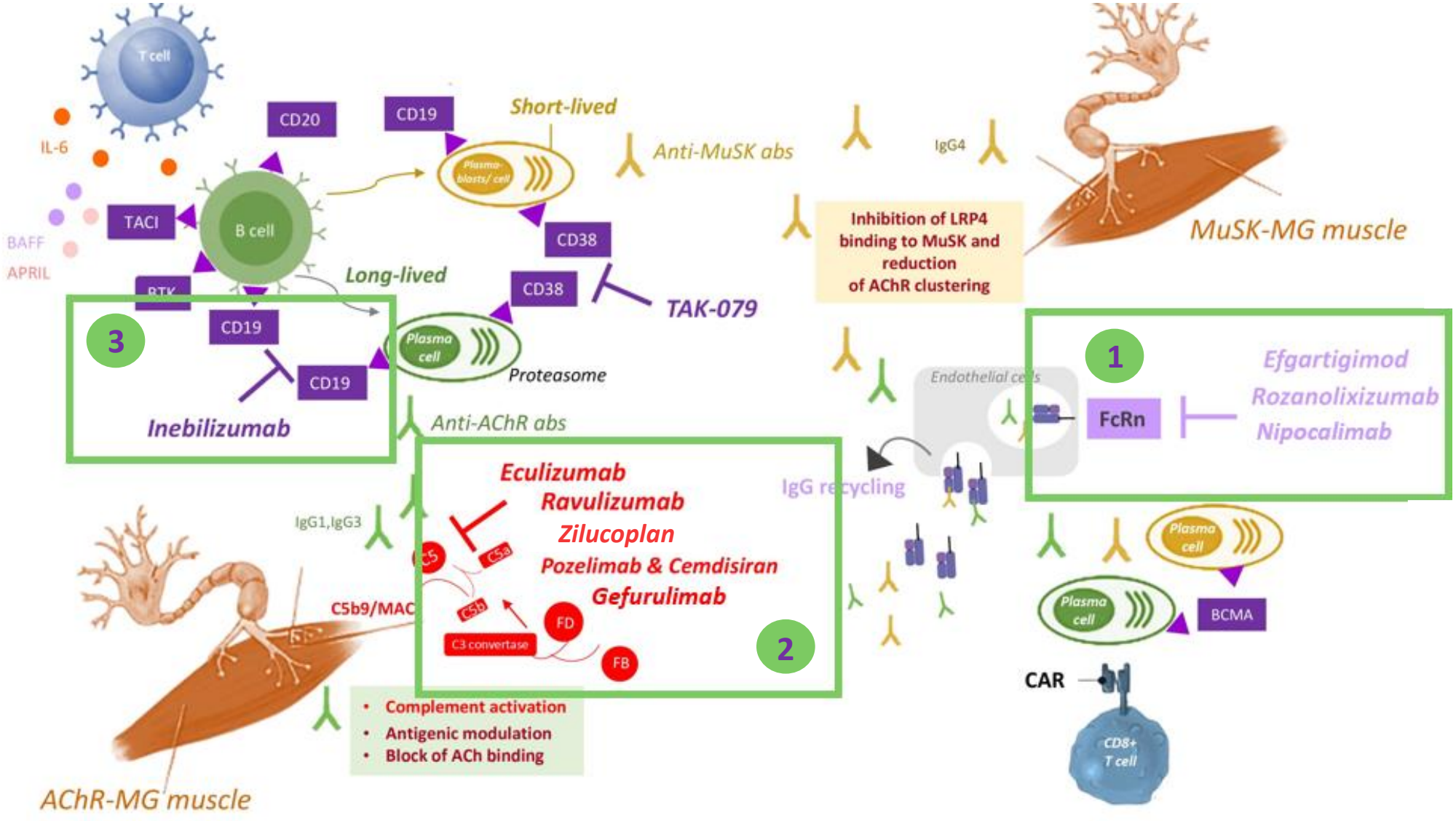
Fc Receptor Inhibitors

MOA: human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG

Drug	Indication	Dose	Adverse Effects	Practice Considerations/ Clinical Trial
Nipocalimab (IV)	Adults and pediatric patients ≥12 years of age with gMG who are AChR+ or MuSK+	• Initial: 30 mg/kg IV over ≥30 min x 1 • Maintenance: 15 mg/kg IV every 2 weeks (start 2 weeks post-initial) over ≥15 min	Infections, infusion-related and hypersensitivity reactions Common: respiratory infection, peripheral edema, muscle spasm	**Mean MG-ADL improvement:** –4.7 points **VIVACITY-MG3**

Antozzi C et al. *Lancet Neurol*. 2025;24(2):105-116; Imaavy (nipocalimab). Prescribing information. Janssen Biotech, Inc; 2025.

Biologic Drug Targets for Myasthenia Gravis



C5 Inhibitors

MOA: Terminal complement inhibitor that binds C5, blocking its cleavage into C5a and C5b, and preventing membrane attack complex (MAC) formation. Exact mechanism in myasthenia gravis is unknown but thought to involve the reduction of complement activity at the neuromuscular junction.

Drug	Indication	Dose	Adverse Effects	Practice Considerations
Eculizumab (IV)	Adults with gMG who are AChR+ and refractory to prior therapy	• 900 mg IV weekly x 4 weeks, then 1200 mg in week 5, then 1200 mg every 2 weeks	REMS for *Neisseria meningitis* Headache, nausea, infections	**MG-ADL change: -4.2** points **REGAIN trial** REMS required
Ravulizu-mab (IV)	Adults with gMG who are AChR+	Weight-based dosing: • 40–<60 kg: 2400 mg load, 3000 mg q8wk • 60–<100 kg: 2700 mg load, 3300 mg q8wk • ≥100 kg: 3000 mg load, 3600 mg q8wk (maintenance starts 2 wk post-loading)	REMS for *Neisseria meningitis*; risk of serious infection Common: URTI, diarrhea	**MG-ADL change: -4.0** points **CHAMPION MG trial** REMS program for meningococcal infection

REMS, Risk Evaluation and Mitigation Strategy.

Howard JF et al. *Lancet Neurol*. 2017;16(12):976-986; Vu TH et al. *Eur J Neurol*. 2025;32(4):e70158; Ultomiris (ravulizumab-cwvz). Prescribing information. Alexion Pharmaceuticals, Inc; 2024; Soliris. Prescribing information. Alexion Pharmaceuticals, Inc; 2025.

C5 Inhibitors

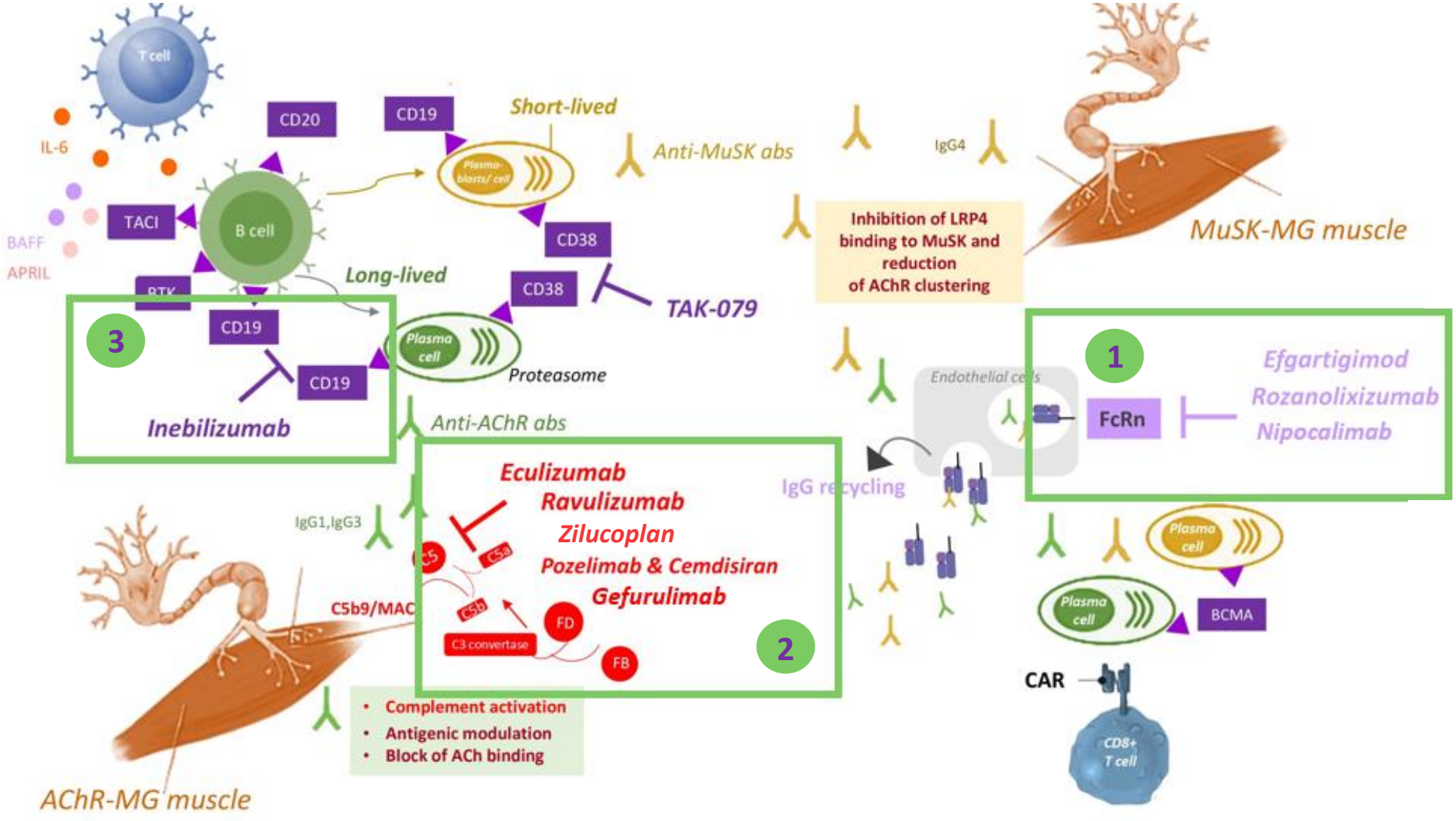
MOA: Terminal complement inhibitor that binds C5, blocking its cleavage into C5a and C5b, and preventing membrane attack complex (MAC) formation. Exact mechanism in myasthenia gravis is unknown but thought to involve the reduction of complement activity at the neuromuscular junction.

Drug	Indication	Dose	Adverse Effects	Practice Considerations
Zilucoplan (SC)	Adults with gMG who are AChR+ or MuSK+	Weight based: • <56 kg: 16.6 mg daily • 56–<77 kg: 23 mg daily • ≥77 kg: 32.4 mg daily	REMS for *Neisseria meningitis*; pancreatitis and pancreatic cysts, ↑ liver enzymes Common: injection-site reactions, URTI, diarrhea	**MG-ADL change:** -4.4 points **RAISE trial** REMS program for risk of serious meningococcal infections

Howard JF et al. *Lancet Neurol*. 2023;22(5):395-406; Zilbrysq (zilucoplan). Prescribing information. UCB, Inc; 2025.

Emerging Therapies

Biologic Drug Targets for Myasthenia Gravis



Emerging Therapies

Drug	MOA	Study	Route	Adverse Effects	Results
Inebilizumab	Humanized monoclonal antibody that depletes CD19+ B cells, which are central to disease pathogenesis	Phase 3, double-blind, randomized, placebo-controlled trial in adults with AChR+ and MuSK+ generalized myasthenia gravis (gMG)	MuSK: 300 mg IV on day 1-15 AChR: 300 mg IV on day 1-15 and on day 183	Headache, cough, nasopharyngitis, infusion-related reactions, urinary tract infections	Primary end point: Mean MG-ADL score improvement from baseline to week 26 was −4.2 (inebilizumab) vs −2.2 (placebo); statistically significant (P <0.001)

PDUFA: 12/14/2025.

PDUFA, Prescription Drug User Fee Act.

Nowak RJ et al. *N Engl J Med*. 2025;392(23):2309-2320; Myasthenia Gravis Inebilizumab Trial (MINT). Updated February 20, 2025. Accessed July 21, 2025. https://clinicaltrials.gov/study/NCT04524273?term=NCT04524273&rank=1

Emerging Therapies

Drug	MOA	Study	Results
Pozelimab (+ Cemdisiran)	Humanized monoclonal IgG4 antibody against complement factor 5 (C5)	Phase 3, randomized, double-blind, placebo-controlled trial in adults with AChR+ or LRP4+ generalized myasthenia gravis (gMG)	Trial ongoing; primary end point is change in MG-ADL from baseline to week 24. Results not reported yet
Gefurulimab	Bispecific nanoantibody that binds complement C5 preventing terminal complement complex formation, and binds albumin for half-life extension	Phase 3, randomized, double-blind, placebo-controlled trial in adults with AChR+ generalized myasthenia gravis (gMG)	Trial ongoing; primary end point is MG-ADL score change at week 26. Results not reported yet

Clinicaltrials.gov/study/NCT05556096. Updated June 12, 2025. Accessed June 23, 2025; Hoy SM. *Drugs*. 2023;83(16):1551-1557; Clinicaltrials.gov/study/NCT05070858. Updated June 8, 2025. Accessed June 23, 2025; Meglio M. October 17, 2024. Phase 3 PREVAIL study to test bispecific nanoantibody gefurulimab in generalized myasthenia gravis. *Neurology Live*. https://www.neurologylive.com/view/phase-3-prevail-study-test-bispecific-nanoantibody-gefurulimab-generalized-myasthenia-gravis

Severe Myasthenia Gravis and Myasthenic Crisis

Plasma Exchange (PLEX)

Therapy	MOA	Complications	Practice Considerations
Plasma exchange: 1 plasma volume for 5 sessions	Direct removal of pathogenic autoantibodies and complement components, with increased interleukin-10 levels	Complex treatment requiring hospitalization due to need for central venous access Risk for pneumothorax, line infection, and thromboembolism	May be preferred over IVIG in critically ill patients due to fast response May be used to prepare patients for surgery

Alhaidar MK et al. *J Clin Med*. 2022;11(6):1597.

Intravenous Immunoglobulin (IVIG)

Dose	MOA	Adverse Effects	Rare but Severe Side Effects	Practice Considerations
Exacerbation dose: 2 g/kg divided over a period of 3-5 days Maintenance dose: 0.4 g/kg given as a single dose every 3-6 weeks	Contains antibodies that neutralize the pathogenic autoantibodies and interrupts the immune response by down regulating B and T cells blocking the Fc receptors and inhibiting the complement system activation	Headache, rash, myalgia, chills, fever, shortness of breath, and nausea	Aseptic meningitis, acute renal failure, and thromboembolic events	Used to prevent paradoxical worsening during the initiation of high-dose steroids. First line for MG crisis with comparable efficacy to PLEX and better side effect profile

Alhaidar MK et al. *J Clin Med*. 2022;11(6):1597; Dalakas MC. *JAMA*. 2004;291(19):2367-2375.

Myasthenia Gravis Economic Burden

Economic Burden

CONTRIBUTING FACTORS

- ICU, ventilation, thymectomy, plasma exchange, and IVIg
- Costs of transportation and lost wages
- QOL burden requiring care: difficulty swallowing, eating, lifting arms above head, physical activity, and respiratory symptoms
- Total mean cost per patient charge per hospital admission for MG crises rose 135% from 2003 to 2013

DIRECT

- Single IVIg treatment $90,760
- Annual hospitalization costs range from $2550 to $164,730
- Mean cost MG crisis $98,800
- Mean cost non-MG crisis hospitalization $39,460

INDIRECT

- Annual indirect cost per patient per year range from $80 to $3550
- Annual cost for those needing assistance with daily living $56,800

Annual cost per patient per year adjusted to USD $760-$28,780 (2018)

Landfeldt E et al. *Pharmacoeconomics*. 2020;38(7):715-728.

Role of the Specialty Pharmacist in Supporting MG Management

Access Support

- Facilitate insurance approvals
- Ensure complete documentation
- Navigate formulary requirements
- Coordinate benefits to support access to high-cost therapies
- Verify REMS requirements are met

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Adverse Effect Management and Counseling

- Educate patients on expected side effects
- Provide strategies to help manage common adverse reactions
- Monitor for symptoms or serious adverse effects
- Reinforce medication adherence and provide strategies to improve adherence
- Collaborate with prescribers when needed

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Medication Education and Administration

- Educate on adverse effects and medication storage
- Train patients on proper administration or assist in coordinating HCP administration
- Review dosing schedules and what to do for a missed dose
- Educate on injection-site reactions

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Monitoring and Clinical Follow-Up

- Assess treatment response using tools such as MG-ADL
- Monitor for disease progression
- Evaluate adherence and tolerability
- Review lab values to ensure safety
- Verify vaccine requirements are met when necessary
- Coordinate with the multidisciplinary team

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Coordination of Care

- Act as a liaison among patients, prescribers, insurers, and infusion centers to help streamline access and care
- Collaborate with multidisciplinary team, including nurses, neurologists, caregivers, physical or occupational therapists
- Facilitate transitions in care
- Aid in enrolling in financial assistance programs

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Adherence Support and Identification of Barriers

- Use adherence tools to proactively address adherence issues
- Address logistical issues such as shipping, transportation to infusion centers
- Educate on missed doses and importance of continuity to prevent flares
- Empower patient with tools such as calendars or symptom trackers
- Utilize technology to make refilling medication easier, such as texting or apps

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Patient Advocacy and Education

- Empower patients through education
- Support medication safety and adherence
- Coordinate care with a multidisciplinary health care team
- Advocate for patients to help them navigate insurance and gain access to treatment

Botts SR et al. *Am J Health Syst Pharm*. 2017; 74 (18): 1437-1445

Zuckerman AD et al. *Am J Health Syst Pharm*. 2022; 79 (21): 1906-1918

Access

Adverse Effects

Education

Monitoring

Care Coordination

Adherence

Advocacy

Conclusion

- Generalized myasthenia gravis (gMG) is a complex autoimmune disorder that affects people of all backgrounds and requires highly individualized care.
- The rapid emergence of targeted therapies such as biologics for both AChR+ and MuSK+ patients is transforming the treatment landscape and making remission a more achievable goal.
- Specialty pharmacists are uniquely positioned to:
  - Optimize medication regimens and access
  - Evaluate key factors such as age, thymus status, and antibody profile
  - Support safe, effective use of newly approved therapies
  - Address patient-specific needs including family planning and comorbidities
- As the treatment landscape evolves, pharmacists play a vital role in helping patients and providers navigate personalized therapy for lasting treatment success.

Additional Resources

Resource	Link
Sánchez-Tejerina D, Sotoca J, Llaurado A, López-Diego V, Juntas-Morales R, Salvado M. New targeted agents in myasthenia gravis and future therapeutic strategies. *J Clin Med*. 2022;11(21):6394. doi:10.3390/jcm11216394	https://pubmed.ncbi.nlm.nih.gov/36362622/
Wiendl H, Abicht A, Chan A, et al. Guideline for the management of myasthenic syndromes. *Ther Adv Neurol Disord*. 2023;16:17562864231213240. doi:10.1177/17562864231213240	https://pmc.ncbi.nlm.nih.gov/articles/PMC10752078/
The Assistance Fund	https://enroll.tafcares.org/
MG Cautionary Drug List	MGFA-Cautionary-Drug-List.pdf

Posttest Questions

Posttest Question 1

Which statement is true concerning conventional treatments for myasthenia gravis such as corticosteroids and immunosuppressants?

A. Patients often achieve remission within 1 year on an acetylcholinesterase inhibitor and prednisone combination therapy.

B. Corticosteroids are well tolerated long term and rarely lead to discontinuation.

C. Many patients continue to experience fluctuating symptoms and functional impairment despite corticosteroid and immunosuppressant therapy.

D. Acetylcholinesterase inhibitors are curative for patients with AChR+ gMG.

Posttest Question 2

Which complement-targeting therapy for generalized myasthenia gravis (gMG) is administered subcutaneously and approved for self-administration?

A. Eculizumab
B. Efgartigimod
C. Ravulizumab
D. Zilucoplan

Posttest Question 3

A 42-year-old woman with generalized myasthenia gravis (gMG) reports ongoing fatigue, frustration with her fluctuating symptoms, and difficulty maintaining her job due to unpredictable weakness. Her caregiver, who is her spouse, expresses emotional burnout and a lack of support navigating the health care system. She is stable on pharmacologic therapy with no recent exacerbations.

Which of the following pharmacist actions best supports a holistic approach to care in this scenario?

A. Recommend increasing the dose of her current medication to better control fatigue.

B. Suggest switching to a newer biologic agent with a different mechanism of action.

C. Refer the patient and caregiver to a local MG support group and provide educational resources.

D. Advise the caregiver to seek individual counseling separate from the patient's care team.

Posttest Question 4

After participating in the activity, how confident are you in your ability to counsel and monitor patients with gMG to optimize their therapy and manage barriers?

A. Not at all
B. Somewhat
C. Moderately
D. Very
E. Extremely

Question and Answer Session

How to Obtain Credit

Please follow the instructions below to claim your credit:

- Go to: https://www.pharmacytimes.org/credit
- Enter credit code: **XXXX**
  - To continue, you will need to be logged into your *PT*CE account.
  - If you do not have a *PT*CE account, create one using the prompt on the page.
- Once logged in, answer the activity evaluation and click "Complete Survey."
- After completing the survey, click the blue arrow button to complete the activity and request credit.
- Your credit will be uploaded to CPE Monitor. You may view your credit within 48 hours at www.mycpemonitor.net

NOTE: Participation data will not be uploaded into CPE Monitor if you do not have your NABP (e-profile ID) number and date of birth entered in your profile.

All participants must request credit by September 29, 2025.

PTce

Thank you!