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Precision in Practice

Individualizing FcRn Inhibitor Use in Generalized Myasthenia Gravis



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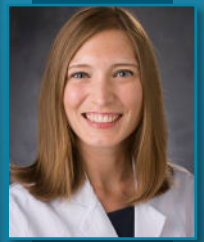
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Patient, Nurse Educator, and Patient Advocate

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PATIENT ADVOCATE

LEARNING OBJECTIVES

1. Identify appropriate clinical and diagnostic features in patients with newly diagnosed or early gMG who may be appropriate candidates for FcRn-directed therapy using clinical phenotype, antibody status, and current evidence.

2. Individualize FcRn-targeted therapy strategies based on product-specific dosing, safety considerations, and patient-specific factors in gMG.

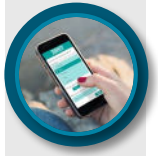
3. Select collaborative, team-based approaches to patient-centered monitoring and SDM strategies that individualize treatment plans around symptom fluctuation, route and frequency preference, safety, and goals such as minimal symptom expression.



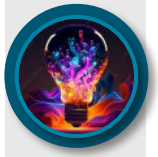
PATIENT PERSPECTIVE: The Diagnostic Journey

Tsungani — Patient Advocate











What made your early symptoms difficult to recognize as something more than just having an “off day?”

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When a Negative AChR Antibody Result Delays the Diagnosis

Recognizing Candidates for FcRn-Directed Therapy Through Phenotype and Antibody Status



PATIENT CASE

Beverley

Presenting Symptoms

- 42-year-old woman is referred to a community neurologist for a six-month history of fluctuating weakness
- Intermittent right ptosis and diplopia, worse late in the day
- Increasing difficulty chewing through a full meal
- Occasional coughing when drinking water
- Nasal speech after prolonged conversation
- Arm fatigue while washing or drying her hair
- Mild in the morning, worse with repeated activity, partially improved by rest
- Previously evaluated in the emergency department; brain MRI was unrevealing and AChR binding antibody testing was negative

Patient Concerns

- Told MG was unlikely and that anxiety and occupational stress might be contributing, but symptoms have continued to progress
- Avoids foods requiring prolonged chewing; meals take longer
- Coworkers notice her speech is less clear at end of shift
- Concerned that swallowing could worsen and reluctant to miss more work for testing that may again be called normal
- Lives approximately 75 miles from the nearest neuromuscular center

Current Medications

- Sertraline 50 mg daily
- Combined oral contraceptive
- No aminoglycoside, fluoroquinolone, magnesium, or beta blocker use reported

MG = myasthenia gravis; MRI = magnetic resonance imaging; AChR = acetylcholine receptor.



PATIENT CASE: Physical Examination and Workup

Beverley

Ocular and facial

- Mild right ptosis at rest
- Ptosis increases and diplopia develops after sustained upward gaze
- Mild weakness of eye closure

Bulbar and axial

- Increasing nasal quality of speech during prolonged counting
- Mild neck flexor weakness with repeated effort
- No dyspnea at rest
- Able to manage oral secretions

Limb and neurologic examination

- Mild proximal arm weakness after repeated shoulder abduction
- Distal limb strength normal
- Sensation intact
- Deep tendon reflexes normal
- Gait normal



PATIENT CASE: Prior Diagnostic Evaluation

Beverley

Parameter/Workup	Result
Brain MRI	No acute intracranial abnormality
AChR binding antibody	Negative
MuSK antibody	Not performed
LRP4 antibody	Not performed
RNS	Not performed
Single-fiber EMG (SFEMG)	Not performed
Chest imaging (CT or MRI)	Not performed
Neuromuscular referral	Not arranged

Current status:
Diagnostic evaluation remains incomplete; no gMG directed therapy has been initiated

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MuSK = muscle-specific kinase; LRP4 = low-density lipoprotein receptor-related protein 4; RNS = repetitive nerve stimulation; EMG = electromyography; CT = computed tomography.



AUDIENCE POLLING

Which next step most appropriately advances the diagnostic evaluation of this patient?

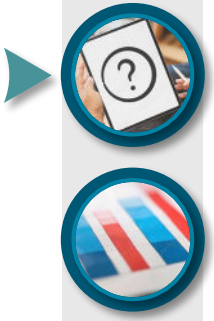
A. Reassure the patient that autoimmune MG has been excluded because the AChR binding antibody result was negative

B. Repeat the AChR binding antibody test in six months and pursue additional evaluation only if the result becomes positive

C. Order MuSK antibody testing, arrange targeted electrodiagnostic testing for a neuromuscular junction disorder, and facilitate neuromuscular specialist referral

D. Diagnose seronegative gMG based on the clinical presentation and initiate FcRn-directed therapy without further diagnostic confirmation

E. Initiate pyridostigmine for suspected gMG and defer additional antibody and electrodiagnostic testing unless symptoms persist or worsen



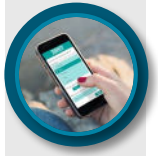
FcRn = neonatal Fc receptor.



EXPERT FACULTY

Case Response — Beverley









Decision Point

Patient Case: Beverley

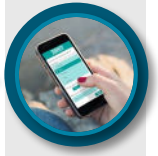
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COMMUNITY NEUROLOGIST

Audio Recording — Case 1, Beverley









E Initiate pyridostigmine for suspected gMG…

- **Pyridostigmine is inexpensive and familiar,** making it a practical initial treatment when access to specialty evaluation is difficult.
- **A clinical response may support the suspected diagnosis** while additional antibody and electrodiagnostic testing are held in reserve.
- **Travel and work burden influence the decision:** the patient lives 75 miles from the neuromuscular center and wants to avoid additional missed work.

Why not defer confirmation?

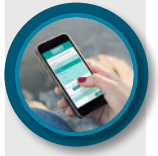
- **A partial response could delay diagnostic confirmation,** even if symptoms improve with pyridostigmine.
- **Limited EMG access and long scheduling delays** make immediate confirmation difficult, but the clinician recognizes the risk of postponing further evaluation.



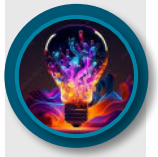
RURAL NEUROMUSCULAR SPECIALIST

Audio Recording — Case 1, Beverley









C Order MuSK antibody testing arrange targeted electrodiagnostic …

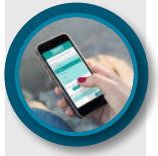
- **Proceed with additional antibody testing:** obtain MuSK antibodies rather than stopping the evaluation after the negative AChR result.
- **Use targeted electrodiagnostic testing:** perform repetitive nerve stimulation, with single fiber EMG if needed to further evaluate for a neuromuscular junction disorder.
- **Assess respiratory status:** obtain a baseline FVC and provide clear warning signs given her bulbar symptoms and distance from emergency care.

Why not defer confirmation?

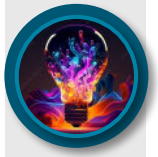
- **Travel burden makes option E tempting,** but it postpones diagnostic confirmation.
- **Deferring confirmation is a poor trade in a patient with bulbar symptoms,** particularly when access to an ICU is limited.











Additional Responses for Case 1

RESPONDENT 1	C Order MuSK antibody…
RESPONDENT 2	C Order MuSK antibody…
RESPONDENT 3	C Order MuSK antibody…



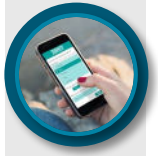
KOL: KARISSA L. GABLE, MD

Case 1, Beverley

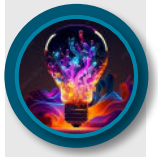
C Order MuSK antibody testing, arrange targeted electrodiagnostic…











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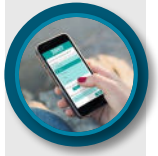


KOL: MICHAEL K. HEHIR, MD

Case 1, Beverley

C Order MuSK antibody testing, arrange targeted electrodiagnostic…











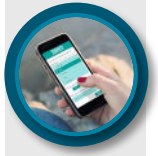


AI: ChatGPT 5.6

User-Fed Response – Patient Case (Beverley)

New chat → Here's the case's subjective, objective, and plan/multiple choice question. Based on the information provided, which answer choice would you choose and what is your brief rationale for your chosen answer and unchosen options?









C Order MuSK antibody testing, arrange targeted electrodiagnostic testing for a neuromuscular junction disorder, and facilitate neuromuscular specialist referral

Rationale: Beverley has a highly characteristic pattern of fluctuating, fatigable ocular and bulbar/proximal weakness with sustained or repeated activity that improves with rest. A negative AChR binding antibody result does not exclude gMG. The appropriate response is therefore to expand antibody testing, especially MuSK, and obtain neuromuscular junction focused electrodiagnostic testing, while involving a neuromuscular specialist.

Rule outs

Reassure because AChR is negative
A negative AChR result does not exclude MG when the clinical phenotype remains strongly suggestive.

Repeat AChR testing in 6 months
Repeating the same test later would delay the broader diagnostic evaluation warranted now.

Diagnose seronegative gMG and start FcRn therapy
The diagnosis and antibody status are not yet established; treatment should not precede diagnostic clarification.

Start pyridostigmine and defer testing
Symptomatic treatment may be considered, but it should not replace antibody and electrodiagnostic evaluation.

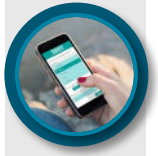
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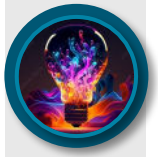
PATIENT PERSPECTIVE

Tsungani — Patient Advocate











When the diagnosis was still uncertain, what happened, next, and what would have helped you get the right evaluation or specialist care sooner?

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A Negative AChR Result Does Not End the Diagnostic Evaluation

When the clinical phenotype remains strongly suggestive of MG, a negative AChR result **should not end the workup.** Additional antibody testing, electrodiagnostic evaluation, and referral should be pursued as appropriate.

Step 1: Recognize the Pattern

Look for **fatigable, fluctuating weakness** involving ocular, bulbar, axial, limb, or respiratory muscles.

Let the **clinical pattern**, not age or sex, drive suspicion; MG presentation **varies across individuals**.



Step 2: Broaden Antibody Evaluation

Use **broader upfront or sequential antibody testing as appropriate**, including AChR, MuSK, and, when appropriate, LRP4.

Know and document the assay used; RIPA, ELISA, and cell-based assays differ in sensitivity and specificity.

A negative result on **one antibody or assay does not exclude MG**.

Do not equate AChR negative with seronegative; broader antibody evaluation is needed before applying a seronegative label.

Step 3: Escalate Electrodiagnostics

Perform **RNS** in clinically involved muscles.

If RNS is unrevealing but suspicion remains, proceed to **SFEMG**.

If clinically safe, follow the testing laboratory protocol for withholding pyridostigmine before RNS or SFEMG.

After MG is diagnosed, obtain chest CT or MRI to evaluate for thymoma.

Step 4: Refer

Refer to a specialist when:

- The diagnostic workup **cannot be completed locally**
- Antibody or electrodiagnostic testing is **unavailable or inconclusive despite persistent suspicion**
- Bulbar or respiratory weakness is present, with urgent or emergency escalation based on severity.



RIPA = radioimmunoprecipitation assay; ELISA = enzyme-linked immunosorbent assay.

Pesa JA, et al. *J Neurol Sci*. 2026;480:125700. Vesperinas A, et al. *Neuromuscul Disord*. 2026;59:106284. Narayanaswami P, et al. *Neurology*. 2021;96(3):114-122. Jacob S, et al. *Pract Neurol*. 2025;25:422-437. Myasthenia Gravis Foundation of America [MGFA]. *MGFA Lexicon*. 2025. https://myasthenia.org/wp-content/uploads/2025/11/MGFA-Lexicon.pdf.

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Early Disease: What the Evidence Supports Today

What Is Established Today

- Consensus guidance supports initial symptomatic therapy in most patients, with immunotherapy added when treatment goals are not met; the treatment goal is minimal manifestations or better
- The pivotal phase III FcRn trials studied patients with established gMG receiving stable background therapy, rather than treatment naive new onset disease
- ADAPT EARLY is recruiting adults with new onset AChR positive gMG who are treatment naive or receiving only an AChE inhibitor, without prior gMG immunosuppression

What Is Not Yet Established

- Whether early FcRn use should change routine treatment sequencing in newly diagnosed gMG
- Does not address Beverley's current situation: her diagnosis is incomplete and her AChR antibody test is negative
- No efficacy or safety conclusions can yet be drawn from ADAPT EARLY; no results are posted



Narayanaswami P, et al. *Neurology*. 2021;96(3):114-122. Jacob S, et al. *Pract Neurol*. 2025;25:422-437. ClinicalTrials.gov. Identifier: NCT06909214. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536. Howard JF Jr, et al. *Neurotherapeutics*. 2024;21(5):e00378.

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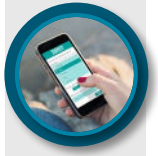


CASE PERSPECTIVE SUMMARY

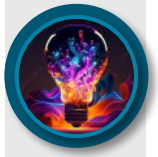
How the Perspectives Answered — Beverley

Answer Option	Community/ Rural	KOLs	AI
A. Reassure the patient that autoimmune MG has been excluded because the AChR binding antibody result was negative	—	—	—
B. Repeat the AChR binding antibody test in six months and pursue additional evaluation only if the result becomes positive	—	—	—
C. Order MuSK antibody testing, arrange targeted electrodiagnostic testing for a neuromuscular junction disorder, and facilitate neuromuscular specialist referral	4	2	1
D. Diagnose seronegative gMG based on the clinical presentation and initiate FcRn-directed therapy without further diagnostic confirmation	—	—	—
E. Initiate pyridostigmine for suspected gMG and defer additional antibody and electrodiagnostic testing unless symptoms persist or worsen	1	—	—









Survey Signal

HCP: 47.6% identified symptoms being attributed to anxiety, depression, or deconditioning as a contributor to delayed or missed diagnosis.

Patients: 52.6% reported having been told they were simply tired or out of shape; 36.8% reported anxiety or stress as an explanation.



FACULTY DISCUSSION – Beverley

What have we learned from each of the diverse groups?

1

2

3

4

- ✓ Treat a single negative AChR result as an incomplete panel, not a rule-out.
- ✓ Act on the pattern, which includes fatigable ocular, bulbar, and proximal involvement together, rather than on any one finding.
- ✓ Broaden antibody evaluation before applying a seronegative label.
- ✓ Escalate to electrodiagnostic testing promptly when suspicion persists, particularly with progressive bulbar or other concerning features.
- ✓ Name the referral trigger and act on it, even when the patient lives at distance from the center.
- ✓ Treat an attribution to anxiety or stress as a hypothesis, not a workup endpoint.



AUDIENCE POLLING REVISITED

Now, what would you do next?

A. Reassure the patient that autoimmune MG has been excluded because the AChR binding antibody result was negative

B. Repeat the AChR binding antibody test in six months and pursue additional evaluation only if the result becomes positive

C. Order MuSK antibody testing, arrange targeted electrodiagnostic testing for a neuromuscular junction disorder, and facilitate neuromuscular specialist referral

D. Diagnose seronegative gMG based on the clinical presentation and initiate FcRn-directed therapy without further diagnostic confirmation

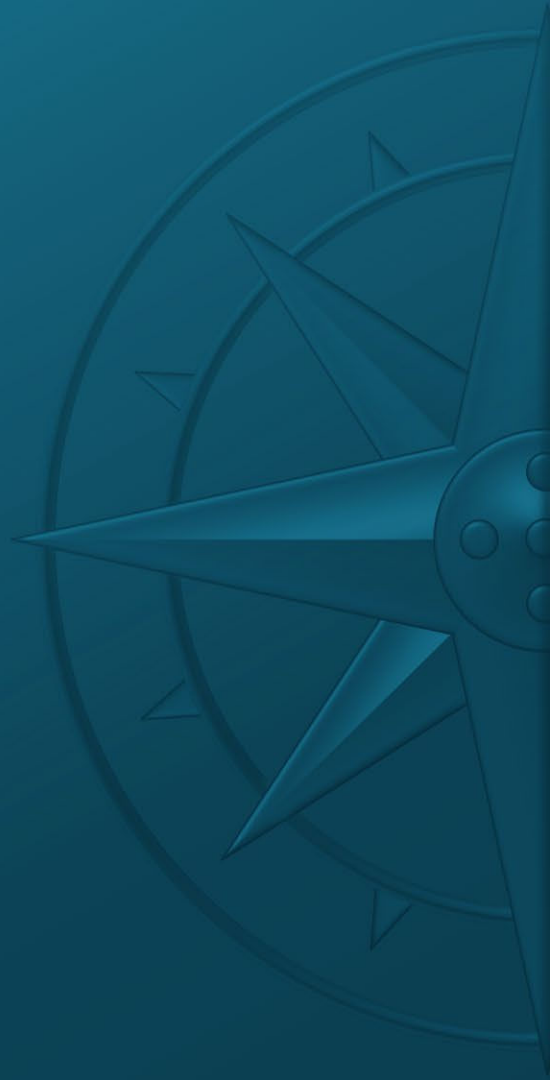
E. Initiate pyridostigmine for suspected gMG and defer additional antibody and electrodiagnostic testing unless symptoms persist or worsen





When Persistent Symptoms and Steroid Toxicity Prompt Treatment Reassessment

Tailoring FcRn Therapy Selection to Dosing, Safety, and Patient Circumstances





PATIENT CASE

Marcus

AChR antibody positive gMG with persistent symptoms

Clinical Picture

- 58-year-old man with AChR Ab+ gMG presents for follow-up because his symptoms remain incompletely controlled
- Presented three years ago with fluctuating ptosis, diplopia, neck weakness, and difficulty climbing stairs
- Ocular symptoms improved after treatment was initiated
- Continues to have arm and neck fatigue late in the day, difficulty chewing a full meal, and intermittent speech change after prolonged conversation
- Reports consistent medication adherence
- Limits evening activity because he cannot predict his strength after work
- No hospitalization or rescue therapy in the past year

Treatment Burden and Patient Priorities

- Weight gain, worsening glucose control, insomnia, and easy bruising while receiving prednisone
- Wants to reduce corticosteroid exposure
- Would prefer fewer clinic visits, but is apprehensive about administering injections himself
- Works full time; limited flexibility for recurring weekday appointments
- Values predictable symptom control; wants to know whether one schedule would interfere less with work than another
- Spouse available to assist with treatment at home if needed



PATIENT CASE: Examination and Objective Measures

Marcus

Examination

- Mild bilateral ptosis after sustained upward gaze
- Mild neck flexor weakness
- Mild proximal arm weakness that increases with repeated effort
- Distal limb strength normal
- Sensation intact
- Deep tendon reflexes normal
- Gait normal
- No respiratory distress

Assessment	Findings
MG-ADL	6 of 24
QMG	12 of 39
Serum IgG	Within laboratory reference range
CBC and CMP	No clinically significant abnormality

Prior Diagnostic Confirmation
AChR antibody positive
Chest CT: no thymoma
RNS: findings consistent with impaired neuromuscular transmission

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CBC = complete blood count; CMP = comprehensive metabolic panel; IgG = immunoglobulin G; MG-ADL = Myasthenia Gravis Activities of Daily Living; QMG = Quantitative Myasthenia Gravis.



PATIENT CASE: Current Regimen and Practical Considerations

Marcus

Current Medication	Regimen
Prednisone	20 mg daily
Mycophenolate mofetil	1,000 mg twice daily
Pyridostigmine	60 mg four times daily
Metformin	1,000 mg twice daily
Lisinopril	20 mg daily
Calcium and vitamin D	Supplementation

Treatment and Access Considerations

- No active infection
- No history of recurrent serious infections
- Meningococcal vaccination series not yet completed
- Works full time with limited flexibility for recurring weekday appointments
- Lives approximately 70 minutes from the nearest infusion center
- Spouse is available to assist with treatment at home if needed
- Prefers fewer clinic visits
- Apprehensive about self injection
- Values predictable symptom control







AUDIENCE POLLING

Which approach most appropriately guides selection among available FcRn targeted therapies for this patient?

A. Select a cyclic FcRn therapy because treatment-free intervals may reduce treatment burden and clinic visits

B. Select a continuous intravenous FcRn therapy because scheduled dosing may provide more predictable administration and avoid self-injection

C. Select continued conventional therapy with prednisone tapering and reconsider FcRn targeted therapy if his symptoms worsen

D. Select a subcutaneous FcRn targeted therapy because fewer clinic visits may better accommodate Marcus' work schedule and travel distance

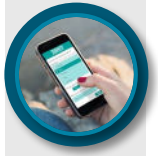
E. Select a FcRn targeted therapy after comparing product-specific indication, route, administration setting, dosing cadence, safety requirements, and Marcus' treatment priorities



EXPERT FACULTY

Case Discussion — Marcus









Decision Point
Patient Case: Marcus

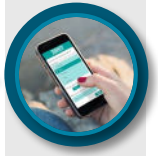
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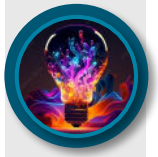
NEUROMUSCULAR SPECIALIST

Audio Recording — Case 2, Marcus









E Select a FcRn targeted therapy after comparing…

- **FcRn therapies differ in** indication, route, who administers treatment, cyclic versus continuous dosing, and monitoring.
- **Treatment selection should align these differences to patient priorities** rather than optimize a single treatment characteristic.
- **SC home administration may reduce treatment burden:** the efgartigimod prefilled syringe can be administered by a patient or caregiver after training.
- **Continuous IV administration offers predictable dosing but requires more travel:** nipocalimab is administered by a provider every two weeks.

Rule out

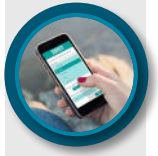
- **Other options prioritize a single variable** rather than considering the full set of treatment and patient factors.
- **Continued conventional therapy with prednisone tapering leaves** persistent disease activity and corticosteroid toxicity insufficiently addressed



RURAL NEUROMUSCULAR SPECIALIST

Audio Recording — Case 2, Marcus









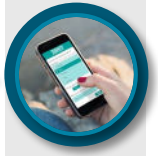
D Select a subcutaneous FcRn targeted therapy…

- **Marcus lives 70 minutes from an infusion center** and cannot take recurring weekday time off.
- **Home subcutaneous treatment with spousal assistance** addresses the largest practical barrier.
- **Access strongly influences adherence:** prioritize a treatment that patients can realistically receive on an ongoing basis.
- **Practical treatment burden**: A continuous IV regimen would require about 26 round trips of 140 minutes each year.

WCV-156 Healthcare Provider Survey. CME Outfitters. September 2026.











Additional Responses for Case 2

RESPONDENT 1	C	Select continued conventional therapy…
RESPONDENT 2	A	Select a cyclic FcRn therapy…
RESPONDENT 3	E	Select a FcRn targeted therapy…

WCV-156 Healthcare Provider Survey. CME Outfitters. September 2026.



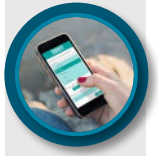
KOL: KARISSA L. GABLE, MD

Case 2, Marcus

E Select a FcRn targeted therapy after comparing product-specific…











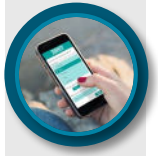
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KOL: MICHAEL K. HEHIR, MD

Case 2, Marcus









E Select a FcRn targeted therapy after comparing product-specific…



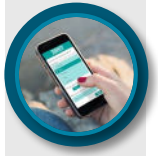


AI: ChatGPT 5.6

User-Fed Response – Patient Case (Marcus)

New chat → Here's the case's subjective, objective, and plan/multiple choice question. Based on the information provided, which answer choice would you choose and what is your brief rationale for your chosen answer and unchosen options?









E Select a FcRn targeted therapy after comparing product-specific indication, route, administration setting, dosing cadence, safety requirements, and Marcus' treatment priorities

Rationale: Marcus has persistent symptomatic AChR antibody positive gMG, significant corticosteroid toxicity, and competing priorities involving predictable symptom control, clinic visits, travel, self injection, and treatment burden. E captures the individualized, product specific decision-making process rather than prematurely selecting a therapy based on only one characteristic.

Rule outs

Cyclic FcRn therapy
Treatment-free intervals alone do not make a cyclic regimen best for Marcus; efficacy, durability, logistics, safety, and preferences also matter.

Continuous IV FcRn therapy
Avoiding self injection may appeal to Marcus, but IV treatment adds infusion travel and should not drive selection by itself.

Continue conventional therapy
Marcus has persistent symptoms and significant prednisone related adverse effects; waiting for deterioration before considering targeted therapy is not appropriate.

Subcutaneous FcRn therapy
SC therapy may fit Marcus, but fewer clinic visits alone do not make it preferable; dosing, administration, and his priorities still matter.

OpenAI. Generated by ChatGPT, model 5.6. Used 2026.



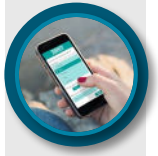
PATIENT PERSPECTIVE

Tsungani — Patient Advocate

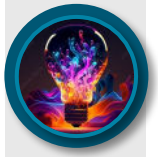


When choosing among treatment options, what matters most to you, and how does treatment convenience fit into that decision?









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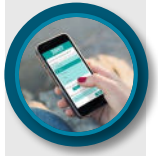


CASE PERSPECTIVE SUMMARY

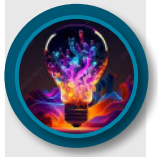
How the Perspectives Answered — Marcus

Answer Option	Community/ Rural	KOLs	AI
A. Select a cyclic FcRn therapy because treatment-free intervals may reduce treatment burden and clinic visits	1	—	—
B. Select a continuous intravenous FcRn therapy because scheduled dosing may provide more predictable administration and avoid self-injection	—	—	—
C. Select continued conventional therapy with prednisone tapering and reconsider FcRn targeted therapy if his symptoms worsen	1	—	—
D. Select a subcutaneous FcRn targeted therapy because fewer clinic visits may better accommodate Marcus' work schedule and travel distance	1	—	—
E. Select a FcRn targeted therapy after comparing product-specific indication, route, administration setting, dosing cadence, safety requirements, and Marcus' treatment priorities	2	2	1









Survey Signal

Patients: 85% prioritized feeling stronger, 70% less tired, and 55% fewer symptom fluctuations, while only 25% selected a treatment that fits life and schedule among their top goals.

HCP: only 25.3% reported routinely discussing route and self-administration and 20% travel, time away from work, and out-of-pocket burden when selecting or adjusting therapy.

Current gMG Treatment Landscape: Where Major Options Fit

Treatment Option	Role in Care	Status in gMG
Guideline-Directed But Not FDA-Approved For gMG		
Corticosteroids	Rapid-onset immunosuppression; broad first-line disease control	Standard of care by consensus
IVIG and plasma exchange	Short-term control for exacerbation, crisis, and perioperative optimization	Guideline- and consensus-recommended
Nonsteroidal immunosuppressants	Steroid-sparing maintenance immunosuppression	Guideline-recommended
Thymectomy	Disease-modifying surgery in selected patients	Surgical procedure, not a labeled drug therapy
FDA-Approved For gMG: Non-Targeted		
Pyridostigmine	Symptomatic acetylcholinesterase inhibition	Approved for MG
FDA-Approved For gMG: Targeted		
CD19-directed B cell therapy	Depletion of CD19-expressing B cells	Adults with AChR or MuSK antibody positive gMG
Complement inhibitors	Terminal complement blockade at the neuromuscular junction	Anti-AChR antibody positive gMG
Neonatal Fc receptor (FcRn) antagonists	Targeted reduction of circulating IgG, including pathogenic autoantibody	Approved in gMG; indicated population differs by product

CD19 = cluster of differentiation 19; IVIG = intravenous immunoglobulin.

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Narayanaswami P, et al. *Neurology*. 2021;96(3):114-122. Jacob S, et al. *Pract Neurol*. 2025;25:422-437. Efgartigimod alfa-fcab and efgartigimod alfa and hyaluronidase-qvfc [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761195s016lbl761304s018lbl.pdf. Rozanolixizumab-noli [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761286s007lbl.pdf. Nipocalimab-aahu [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf. Eculizumab [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125166s448,761108s038lbl.pdf. Eculizumab-aeeb [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761333s008lbl.pdf. Eculizumab-aagh [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761340s024lbl.pdf. Ravulizumab-cwvz [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761108s041lbl.pdf. Zilucoplan [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/216834s013lbl.pdf. Inebilizumab-cdon [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761142s004lbl.pdf.

Role of FcRn Antagonists in gMG



What is FcRn?

- Neonatal Fc receptor – MHC class I-like molecule
- Prevents IgG degradation, promotes recycling
- Extends IgG half-life to ~21 days

How FcRn Antagonists Work

- Competitive receptor binding
- Recycling pathway disruption
- Accelerated lysosomal degradation
- Selective serum clearance

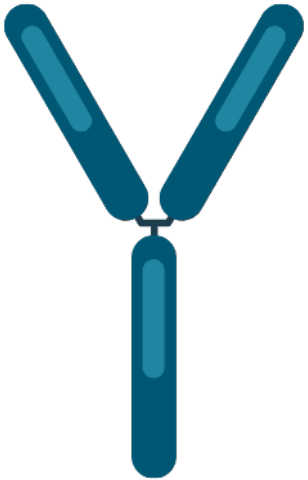
MuSK+ Relevance
Effective FcRn antagonists target all IgG subtypes including IgG4 (predominant in MuSK+ MG)

In Autoimmune Disease

- FcRn protects pathogenic autoantibodies (anti-AChR, anti-MuSK) from degradation, maintaining elevated serum concentrations

Distinctions From Plasma Exchange

- Albumin generally preserved with FcRn antagonism, whereas PLEX removes circulating plasma proteins more broadly
- PLEX requires apheresis capability and may require vascular access; FcRn administration varies by product



IgG4 = immunoglobulin G subclass 4; MHC = major histocompatibility complex; PLEX = plasma exchange.

CASEWISE™ by CME OUTFITTERS

Roopenian DC, et al. *Nat Rev Immunol*. 2007;7(9):715-725. Patel DD, et al. *J Allergy Clin Immunol*. 2020;146(3):467-478. Gable KL, et al. *Front Immunol*. 2020;10:3052. Ulrichts P, et al. *J Clin Invest*. 2018;128(10):4372-4386. Howard JF Jr., et al. *Front Neurol*. 2023;14:1284444. Mina-Osorio P, et al. *Transfus Med Rev*. 2024;38(1):150767. Ma G, et al. *JCI Insight*. 2024;9(10):e176166. Vakrakou AG, et al. *Front Immunol*. 2023;14:1212757. Nelke C, et al. *Neurotherapeutics*. 2022;19(3):729-740.

FDA-Approved FcRN Antagonists

Agent	Target Population	Route and Schedule	Administration Setting	Key Safety/Monitoring
Efgartigimod alfa-fcab	Adults; the indication carries no antibody status restriction	**IV,** once weekly for 4 weeks per cycle; subsequent cycles based on clinical evaluation*	HCP-administered IV infusion; clinic or infusion center	Delay for active infection; monitor during administration and for **1 hour after infusion** for hypersensitivity reactions
Efgartigimod alfa and hyaluronidase-qvfc		**SC,** once weekly for 4 weeks per cycle; subsequent cycles based on clinical evaluation	Prefilled syringe: patient or caregiver after training Vial: HCP only in clinic	Delay for active infection; monitor for hypersensitivity reactions for **at least 30 minutes after administration**
Nipocalimab-aahu	Adults and pediatric patients age ≥ 12 with AChR or MuSK antibody positive gMG	**IV,** 30 mg/kg once, then 15 mg/kg 2 weeks later and every 2 weeks thereafter	HCP-administered IV infusion	Delay for active infection; monitor during treatment and for **30 minutes after each infusion** for hypersensitivity or infusion related reactions
Rozanolixizumab-noli	Adults with AChR or MuSK positive	**SC** infusion; weight-based dose once weekly for 6 weeks; subsequent cycles based on clinical evaluation**	HCP-administered SC infusion using an infusion pump; clinic or infusion center	Delay for active infection; monitor during administration and for **15 minutes after infusion** for hypersensitivity reactions

*Safety of subsequent cycles initiated 7 to 28 days after the last dose of the prior cycle has been evaluated.
**Safety of initiating a subsequent cycle sooner than 63 days from the start of the previous treatment cycle has not been established.

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Efgartigimod alfa-fcab and efgartigimod alfa and hyaluronidase-qvfc [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761195s016lbl761304s018lbl.pdf. Rozanolixizumab-noli [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761286s007lbl.pdf. Nipocalimab-aahu [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf.

FcRn Antagonists in gMG: Non-Comparative Key Clinical Evidence by Agent*

Efgartigimod alfa

PIVOTAL PHASE III

- **ADAPT**
  - n = 167
  - Primary efficacy population n = 129 AChR-Ab+

PRIMARY ENDPOINT

- MG-ADL responders, cycle 1 **67.7%** vs **29.7%**
- ***p* < 0.0001**

ADDITIONAL EVIDENCE

- **ADAPT+/ADAPT SC/ADAPT SC+:**
  - Long-term extension and SC formulation; ADAPT+ completed and reported
  - ADAPT SC: SC noninferior to IV for total IgG reduction at week 4
- **ADAPT SERON:**
  - AChR antibody negative gMG
  - Supported May 2026 expansion of the adult indication, no antibody restriction

Nipocalimab-aahu

PIVOTAL PHASE III

- **Vivacity MG3**
  - n = 199 overall
  - Primary efficacy population n = 153; antibody positive
  - AChR, MuSK, or LRP4

PRIMARY ENDPOINT

- LS mean MG-ADL difference versus placebo over weeks 22 to 24: **−1.45**; ***p* = 0.002**

ADDITIONAL EVIDENCE

- **Vivacity OLE:**
  - Ongoing; week 96 mean change: MG-ADL −6.47, QMG −5.97; $p < .001$ for both
- **VibranceMG:**
  - Open-label phase II/III, ongoing; n = 7, ages 12 to < 18, all AChR-Ab+
  - Primary endpoint, total serum IgG at week 24: −68.98%
  - Week 24: MG-ADL −2.40, QMG −3.80; 4 of 5 completers reached MG-ADL 0 to 1

Rozanolixizumab

PIVOTAL PHASE III

- **MycarinG**
  - n = 200
  - AChR Ab+ or MuSK Ab+

PRIMARY ENDPOINT

- LS mean MG-ADL change at day 43: **−3.37** with 7 mg/kg**; −3.40** with 10 mg/kg vs **−0.78** with placebo
- ***p* < .0001** for both active arms

ADDITIONAL EVIDENCE

- **MG0004/MG0007:**
  - MG0004 (completed): chronic weekly ≤ 52 weeks, n = 70; max mean MG-ADL −3.1 (7 mg/kg), −4.1 (10 mg/kg)
  - MG0007 (completed): 6-week cycles, repeated on symptom worsening
  - Pooled (MycarinG + MG0004 first 6 wks + MG0007), n = 129 with ≥ 2 cycles: MG-ADL day 43 −3.2 to −6.0 across cycles 1 to 13; maintained to week 130
- **roMyG:**
  - Phase II/III **pediatric** study, ages 2 to 17; active, not recruiting; no results to date; **no pediatric indication**

*Trial populations, endpoints, analytic populations, dosing regimens, and follow up differ. Results shown are within trial and should not be interpreted as comparative efficacy across agents. OLE findings are descriptive and uncontrolled.
OLE = open-label extension; LS = least squares.

CASEWISE™ by CME OUTFITTERS

Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536. Howard JF Jr, et al. *Neurotherapeutics*. 2024;21(5):e00378. Bril V, et al. *Lancet Neurol*. 2023;22(5):383-394. Antozzi C, et al. *Lancet Neurol*. 2025;24(2):105-116. ClinicalTrials.gov. Identifier: NCT06298552. Efgartigimod alfa-fcab and efgartigimod alfa and hyaluronidase-qvfc [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761195s016lbl761304s018lbl.pdf. Jacob S, et al. *Pract Neurol*. 2025:25:422-437; Rozanolixizumab-noli [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761286s007lbl.pdf. Nipocalimab-aahu [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf. Antozzi C, et al. *Neurology*. 2026;106(11 Suppl 1). Bril V, et al. *Ther Adv Neurol Disord*. 2026;19:17562864261458532. Strober J, et al. AANEM Annual Meeting; 2024. Abstract No. MG100. https://www.mdaconference.org/abstract-library/safety-and-effectiveness-of-nipocalimab-in-adolescent-participants-in-the-open-label-phase-2-3-vibrance-mg-clinical-study/.

Safety Profiles of FcRn-Directed Therapies*

Efgartigimod formulations

COMMON ADVERSE REACTIONS (≥ 10%)
- IV: respiratory tract infection, headache, urinary tract infection
- SC: injection site reactions, headache

WARNINGS AND PRECAUTIONS
- Infections
- Hypersensitivity reactions
  - Angioedema
  - Anaphylaxis**
- Infusion or injection-related reactions

ADAPT SERIOUS EVENTS
- Serious AEs: 5% vs 8% placebo
- Fatal outcomes: none

Nipocalimab-aahu

COMMON ADVERSE REACTIONS (≥ 10%)
- Respiratory tract infection
- Peripheral edema
- Muscle spasms

WARNINGS AND PRECAUTIONS
- Infection risk, including risk of latent viral infection activation
- Serious AEs in Vivacity-MG3
  - 9% with nipocalimab
  - 14% with placebo

VIVACITY MG3 SERIOUS EVENTS
- Serious AEs: 9% vs 14% placebo
- Fatal outcomes: 1 vs 2 placebo

Rozanolixizumab-noli

COMMON ADVERSE REACTIONS (≥ 10%)
- Headache
- Infections
- Diarrhea
- Pyrexia
- Hypersensitivity reactions
- Nausea

WARNINGS AND PRECAUTIONS
- Infections
- Aseptic meningitis
- Hypersensitivity reactions, including angioedema and rash

MycarinG SERIOUS EVENTS
- Serious TEAEs: 8% to 10% across active dose vs 9% with placebo
- Fatal outcomes: none

*Serious event rates are shown within each pivotal trial for context; differences across trials should not be interpreted as comparative safety.
**Anaphylaxis reported postmarketing with IV efgartigimod.
AE = adverse event; TEAE = treatment-emergent adverse event.

CASEWISE™ by CME OUTFITTERS

Howard JF Jr, et al. *Lancet Neurol.* 2021;20(7):526-536. Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105-116. Bril V, et al. *Lancet Neurol.* 2023;22(5):383-394. Efgartigimod alfa-fcab and efgartigimod alfa and hyaluronidase-qvfc [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761195s016lbl761304s018lbl.pdf. Rozanolixizumab-noli [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761286s007lbl.pdf. Nipocalimab-aahu [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf. Antozzi C, et al. Lancet Neurol. 2025;24(2):105-116.

Positioning FcRn Therapy Among gMG Treatment Options

Optimize Conventional Therapy



Consider when: Conventional therapy has not yet been adequately optimized or given sufficient time to work.

IVIG/Plasma Exchange



Consider when: Rapid, short-term disease control is needed.

Marcus
Persistent symptoms + corticosteroids toxicity
How should these factors change his treatment strategy?

Selecting Therapy in gMG

- Clinical need
- Disease phenotype
- Safety
- Patient preference

FcRn-Directed Therapy

Consider when: Persistent symptomatic gMG where targeted reduction of pathogenic IgG is appropriate.

Complement Inhibition



Consider when: AChR antibody positive gMG where terminal complement blockade is clinically appropriate.

B Cell-Directed Therapy



Consider when: A B cell-depleting strategy is appropriate based on disease phenotype and clinical circumstances.

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Narayanaswami P, et al. *Neurology*. 2021;96(3):114-122. Jacob S, et al. *Pract Neurol*. 2025;25:422-437. Eculizumab [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125166s448,761108s038lbl.pdf. Eculizumab-aeeb [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761333s008lbl.pdf. Eculizumab-aagh [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761340s024lbl.pdf. Ravulizumab-cwvz [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761108s041lbl.pdf. Zilucoplan [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/216834s013lbl.pdf. Inebilizumab-cdon [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761142s004lbl.pdf.

Real-World Considerations Impact Treatment Selection

1. Confirm candidacy

- Antibody serotype: AChR, MuSK, or seronegative
- All available FcRn therapies include AChR antibody positive gMG, so serotype alone does not narrow the options

LEADS → HANDS OFF TO
Neurologist/Neuromuscular specialist → NP or PA

2. Fit to daily life

- Travel time and distance to infusion care
- Work schedule and weekday flexibility: weekly-for-four, weekly-for-six, and every-two-weeks maintenance carry different burdens

LEADS → HANDS OFF TO
NP or PA with scheduling → specialty pharmacist

3. Plan administration

- Who administers, patient, caregiver, or HCP, and what training is required first
- Caregiver capability is a real option only where the label supports it

LEADS → HANDS OFF TO
DNP-led nursing and pharmacist → patient and caregiver

4. Protect and monitor

- Vaccination history and product-specific prophylaxis if complement inhibition is considered
- How response is measured over time and whether control supports corticosteroid reduction

LEADS → HANDS OFF TO
Primary care and pharmacist → neurologist with NP or PA

Navigation is continuous and two-way: every handoff comes back to the team

Ask yourself: At which handoff does your team lose the patient, and what changes without one profession?

NM = neuromuscular; NP = nurse practitioner; PA = physician associate; DNP = doctor of nursing practice.

CASEWISE™ by CME OUTFITTERS

Zovi A, et al. *Drugs Ther Perspect.* 2026:1-12.



FACULTY DISCUSSION – Marcus

What have we learned from each of the diverse groups?

1. ✓ Name the patient's clinical needs and practical constraints before choosing a treatment.
2. ✓ Persistent symptoms plus corticosteroid toxicity should prompt treatment reassessment and escalation.
3. ✓ Compare reasonable treatment options using disease phenotype, safety, route, administration setting, frequency, treatment burden, and patient goals.
4. ✓ Address modifiable barriers, such as vaccination gaps and access, rather than prematurely excluding an otherwise appropriate option.
5. ✓ Use a systematic comparison across treatment options rather than defaulting to one class or one appealing feature.







AUDIENCE POLLING REVISITED

Now, what would you do next?

A. Select a cyclic FcRn therapy because treatment-free intervals may reduce treatment burden and clinic visits

B. Select a continuous intravenous FcRn therapy because scheduled dosing may provide more predictable administration and avoid self-injection

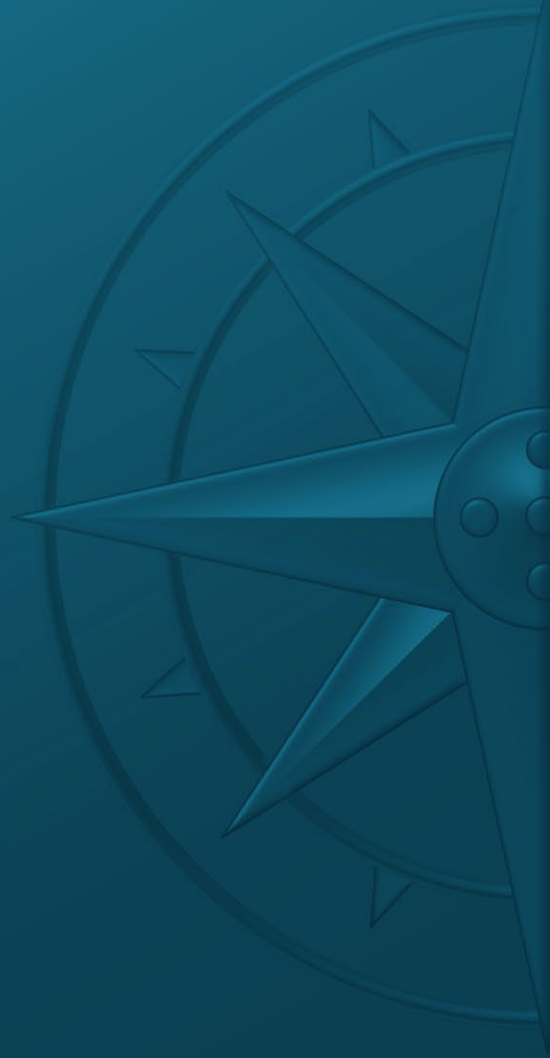
C. Select continued conventional therapy with prednisone tapering and reconsider FcRn targeted therapy if his symptoms worsen

D. Select a subcutaneous FcRn targeted therapy because fewer clinic visits may better accommodate Marcus' work schedule and travel distance

E. Select a FcRn targeted therapy after comparing product-specific indication, route, administration setting, dosing cadence, safety requirements, and Marcus' treatment priorities

Reassessing Ongoing Symptoms During FcRn Therapy

Aligning Monitoring and Shared Decision-Making With Patient-Defined Goals





PATIENT CASE

Maya

- 35-year-old high school counselor with **AChR Ab+ gMG**
- Six months ago, Maya initiated **subcutaneous FcRn therapy**, administered once weekly for 4 weeks per treatment cycle, with subsequent cycles based on clinical evaluation
- Ptosis and chewing difficulty improved substantially since starting treatment
- No rescue therapy and no emergency care since starting
- Can complete basic activities such as dressing, showering, and preparing a simple meal without assistance
- Fatigue sometimes becomes more noticeable after completing a treatment cycle and before the next cycle begins
- Clinic treatment requires her to miss part of the workday
- **Persistent disabling fatigue** after approximately **4 to 5 hours** of work
- Difficulty concentrating and sense that arms and legs will no longer sustain activity
- **Reduced work** schedule to **4 days per week**
- No longer participates in evening school events
- Often spends the evening in bed after a full workday and may require much of the next day to recover
- **Goal:** to work a full school day and a full school week, and to take part regularly in family social activities



PATIENT CASE: Examination

Maya

Examination

- No ptosis at rest
- Mild ptosis after sustained upward gaze
- Normal speech during routine conversation
- No facial or bulbar weakness on brief examination
- Mild proximal arm fatigability after repeated shoulder abduction
- Normal distal limb strength
- Sensation intact
- Deep tendon reflexes normal
- Gait normal
- No respiratory distress

Pertinent Current History

- No current dysphagia or difficulty managing secretions
- No dyspnea at rest or orthopnea
- No recent infection
- No recent change in sleep schedule
- No new medication associated with fatigue or neuromuscular weakness
- No current symptoms suggesting an acute exacerbation

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PATIENT CASE: Recent Monitoring

Maya

Assessment	Before FcRn Therapy	Most Recent Clinic Assessment
MG-ADL	8	1
QMG	13	5
• No rescue therapy since starting FcRn treatment		

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PATIENT CASE: Treatment

Maya

Current Treatment

- FcRn-directed therapy according to the prescribed cyclic regimen
- Prednisone 5 mg daily
- Pyridostigmine 60 mg as needed
- Calcium and vitamin D supplementation

Treatment Context

- FcRn treatment administered once weekly for 4 weeks per cycle
- Subsequent cycles based on clinical evaluation
- Symptoms sometimes become more noticeable after completing a cycle and before the next cycle begins
- Treatment is administered in clinic and requires Maya to miss part of the workday







AUDIENCE POLLING

Which next step most appropriately aligns ongoing management with Maya's treatment response and goals?

A. Reassess MG activity, fatigue pattern, quality of life, other contributors, treatment burden, and Maya's goals before modifying therapy

B. Continue the current FcRn regimen and monitor MG-ADL and QMG at routine follow-up before considering treatment changes

C. Shorten the interval between FcRn treatment cycles to address symptoms occurring near the end of the current interval

D. Discontinue FcRn therapy and return to her previous immunotherapy because persistent fatigue continues to limit daily function

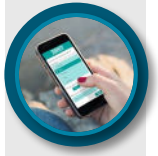
E. Continue the current FcRn regimen and refer Maya to primary care for evaluation of other potential causes of fatigue



EXPERT FACULTY

Case Discussion — Maya

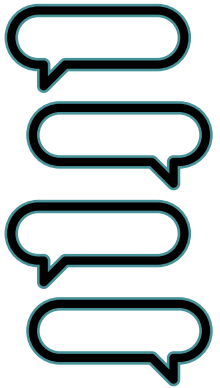








Decision Point
Patient Case: Maya



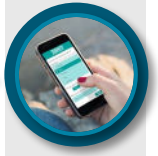
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NEUROMUSCULAR SPECIALIST

Audio Recording — Case 3, Maya









A Reassess MG activity, fatigue pattern, quality of life…

- **Objective response is strong,** but disabling fatigue persists and worsens near the end of each cycle.
- **Reassess whether symptoms reflect MG fluctuation or other contributors,** including sleep, mood, deconditioning, and steroid effects.
- **Treatment burden also matters:** self-injection may reduce missed work for clinic visits.

Rule out

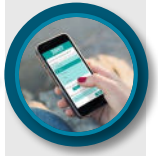
- **Shortening the cycle before full assessment may treat the wrong problem,** and safety of starting a new cycle sooner than 4 weeks has not been established.
- **Good scores should not obscure persistent disability,** and discontinuing therapy would abandon a clear treatment response.



COMMUNITY NEUROLOGIST

Audio Recording — Case 3, Maya









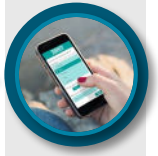
B Continue the current FcRn regimen…

- **Objective measures show a substantial response:** MG-ADL improved from 8 to 1 and QMG from 13 to 5, with no need for rescue therapy.
- **By standard measures, she is responding to treatment,** supporting continuation of the current regimen with ongoing monitoring.
- **In a 15-minute visit,** standardized scores provide a practical way to document treatment response.
- **There is no quick clinic tool being used to capture fatigue,** making this symptom harder to assess alongside MG-ADL and QMG.
- **The clinician recognizes that favorable scores may still miss** important aspects of a patient's experience and daily function.



Additional Responses for Case 3









RESPONDENT 1	C	Shorten the interval between FcRn treatment…
RESPONDENT 2	E	Continue the current FcRn regimen…
RESPONDENT 3	A	Reassess MG activity, fatigue pattern…

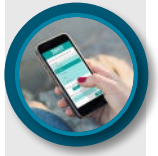
WCV-156 Healthcare Provider Survey. CME Outfitters. September 2026.



KOL: KARISSA L. GABLE, MD

Case 3, Maya









A Reassess MG activity, fatigue pattern, quality of life…

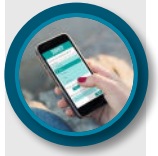




KOL: MICHAEL K. HEHIR, MD

Case 3, Maya









E Continue the current FcRn regimen and refer…

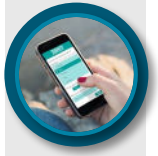




AI: ChatGPT 5.6

User-Fed Response – Patient Case (Maya)









New chat → Here's the case's subjective, objective, and plan/multiple choice question. Based on the information provided, which answer choice would you choose and what is your brief rationale for your chosen answer and unchosen options?

A Reassess MG activity, fatigue pattern, quality of life, other contributors, treatment burden, and Maya's goals before modifying therapy

Rationale: Maya has had a strong objective and functional response to FcRn therapy, but still has clinically meaningful fatigue and activity limitation. Her residual fatigue needs to be characterized before changing treatment, including residual MG fatigability, nonspecific fatigue, deconditioning, medication effects, sleep issues, mood, anemia, or endocrine problems. End of cycle worsening is important, but does not by itself establish that shortening the interval is appropriate.

Rule outs

Continue current regimen and monitor routinely
Too passive given disabling fatigue and activity limitation; focused reassessment is warranted now.

Shorten the treatment cycle interval
End of cycle worsening raises a legitimate question, but the case has not established that waning treatment effect is the primary cause of fatigue.

Discontinue FcRn therapy
FcRn therapy is producing substantial benefit; persistent fatigue alone is not a reason to abandon therapy without further assessment.

Refer only to primary care for fatigue
Evaluating non-MG causes is appropriate, but the neuromuscular team must also assess residual MG activity, treatment cycle wearing off, and broader contributors.

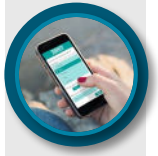
OpenAI. Generated by ChatGPT, model 5.6. Used 2026.



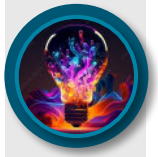
PATIENT PERSPECTIVE

Tsungani — Patient Advocate











What does meaningful control of MG look like in your daily life, and what activities would show that treatment is truly helping?

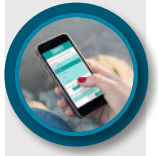
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CASE PERSPECTIVE SUMMARY

How the Perspectives Answered — Maya









Answer Option	Community/ Rural	KOLs	AI
A. Reassess MG activity, fatigue pattern, quality of life, other contributors, treatment burden, and Maya's goals before modifying therapy	2	1	1
B. Continue the current FcRn regimen and monitor MG-ADL and QMG at routine follow-up before considering treatment changes	1	—	—
C. Shorten the interval between FcRn treatment cycles to address symptoms occurring near the end of the current interval	1	—	—
D. Discontinue FcRn therapy and return to her previous immunotherapy because persistent fatigue continues to limit daily function	—	—	—
E. Continue the current FcRn regimen and refer Maya to primary care for evaluation of other potential causes of fatigue	1	1	—

Survey Signal

Patients: all 20 respondents identified energy and stamina as affecting daily life; 65% identified work or school. **HCP:** 34.7% reported using none of the listed monitoring tools routinely; only 23.2% reported routine MG-ADL use.

Shared Decision-Making (SDM)

Choosing the Right FcRn Antagonist

Clinical Factors

Antibody Status/Indicated Population:

- **Efgartigimod:** adult gMG; no antibody status restriction
- **Rozanolixizumab:** adult AChR-Ab+ or MuSK-Ab+ gMG
- **Nipocalimab:** AChR-Ab+ or MuSK-Ab+ gMG in adults and pediatric patients ≥ 12 years

Disease Stability Needs:

- Discuss fixed-interval versus cyclic regimens in the context of symptom pattern, product-specific dosing and retreatment instructions, treatment burden, and patient preference

Safety Considerations:

- Headache history/concerns → review agent-specific AE profiles; headache is common with rozanolixizumab
- Pregnancy potential → review PI; FcRn antagonists may reduce maternal IgG and fetal/infant passive immunity (nipocalimab)

Patient Factors

Treatment Burden:

- Compare administration frequency and setting, self- or caregiver-administration where labeled, work/travel burden, and the patient's preference for a fixed versus individualized treatment schedule

Administration Preference:

- Home administration → SC self-administration option (efgartigimod SC PFS; after training)
- Clinic/HCP administration → SC infusion (rozanolixizumab) or IV infusions
- Infusion center comfort → IV options

Lifestyle and Socioeconomic Factors:

- Work/travel schedule, caregiver availability, distance to infusion center
- Insurance coverage, prior authorization, out of pocket costs, and support for underinsured or uninsured patients

PFS = prefilled syringe; HCP = health care professional.

Yung M, et al. *Health Sci Rep*. 2024;7:e70081. Jacob S, et al. *Pract Neurol*. 2025;25:422-437.
Efgartigimod alfa-fcab and efgartigimod alfa and hyaluronidase-qvfc [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761195s016lbl761304s018lbl.pdf.
Rozanolixizumab-noli [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761286s007lbl.pdf.
Nipocalimab-aahu [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf.

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Choose the Measure to Match the Question

Measure*	What It Captures	What It Does Not Capture	When to Use It	Who Administers It
MG-ADL	Patient-reported symptom burden across 8 daily activities	Fatigue, endurance across a full day, work capacity, quality of life	Every visit; the standard longitudinal tracker	Trained clinician
QMG	Clinician-scored objective strength and endurance across 13 items	Patient perceived burden, day to day fluctuation, and quality of life	When the clinical picture is incomplete or the patient report and examination diverge	Trained clinician
MGC	5 clinician and 5 patient reported items assessing MG severity	Fatigue as a distinct construct; quality of life	When a single composite is preferred over separate instruments	Combination patient-completed and trained clinician
MG-QOL15r	Patient-reported quality of life across 15 revised items	Objective disease activity; anything that would guide a dose or regimen change on its own	When a patient reports that the disease measures do not match their experience	Patient-completed

Fatigue is not captured by any of these instruments — ask for it directly. Query endurance across a full day, recovery time, and work capacity.

Assess at every visit, not once: repeat MG-ADL, adding QMG when the picture is incomplete; note when fatigue occurs relative to dosing and to activity; screen other contributors; and confirm the symptom state and functional goals the patient finds acceptable.

In order to detect, you must measure!

APP = advanced practice provider; MGC = Myasthenia Gravis Composite; MG-QOL15r = Myasthenia Gravis Quality of Life 15-item revised.

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Muppidi S, et al. *Muscle Nerve*. 2011;44(5):727-731. Burns TM, et al. *Neurology*. 2010;74(18):1434-1440. Myasthenia Gravis Rare Disease Network [MGNet]. *Quantitative Myasthenia Gravis-Revised Score*. 2022. https://mgnet.rarediseasesnetwork.org/sites/default/files/2023-04/quantitative-myasthenia-gravis-revised-score.pdf. Katzberg HD, et al. *Muscle Nerve*. 2014;49(5):661-665. Narayanaswami P, et al. *Neurol Clin Pract*. 2026;16(4):e200644. Funke M, et al. *J Neurol*. 2024;271(8):5665-5670.

Assign Clear Ownership for Longitudinal Monitoring

Team Member	Assessment and Monitoring	Safety Surveillance	Handoff Trigger
Neurologist/Neuromuscular specialist	Diagnosis and serologic phenotype; QMG or MGC; therapy and dosing or retreatment decisions	Disease activity change; exacerbation and crisis risk	Coordinates interval monitoring with the APP and primary care evaluation of possible non-MG contributors to fatigue
APP	Obtains or reviews MG-ADL and MG-QoL15r at interval visits; fluctuation history; goal review	Infection symptoms; adherence and administration concerns	Escalates to neurology when scores worsen, goals are unmet, or new bulbar or respiratory symptoms emerge
Pharmacist	Regimen review; interaction screening; vaccination status	Cumulative immunosuppression and infection risk; medications that may worsen MG	Alerts the prescriber to medication, interaction, or vaccination concerns
Infusion/Specialty nursing	Administration tolerance; injection site and infusion reactions; training where labeled	Reaction monitoring during and after administration	Notifies the prescriber promptly for clinically significant reactions
Primary care	Comorbidity- and corticosteroid-related risk monitoring; sleep, mood, endocrine, hematologic, and other contributors	Vaccination completion; routine preventive care	Coordinates with neurology when fatigue persists, function worsens, or MG-related symptoms emerge

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Narayanaswami P, et al. *Neurol Clin Pract.* 2026;16(4):e200644. Agency for Healthcare Research and Quality [AHRQ]. *The SHARE Approach - Essential Steps of Shared Decision-Making: Expanded Reference Guide With Sample Conversation Starters.* 2014. https://www.ahrq.gov/sites/default/files/wysiwyg/sdm/share-approach/share-facilitator-guide.pdf. Beland B, et al. *Pract Neurol.* 2025:pn-2025-004656.



FACULTY DISCUSSION – Maya

What have we learned from each of the diverse groups?

1. ✓ Ask what the score does not capture, at every visit where the score has improved.
2. ✓ Treat minimal symptom expression as a meaningful target, not the end of reassessment.
3. ✓ Pair disease measures with the patient's acceptable symptom state, function, and goals.
4. ✓ Characterize persistent fatigue and evaluate MG related and other contributors before modifying treatment.
5. ✓ Assign clear ownership for between visit monitoring and escalation.
6. ✓ Revisit the patient's goals as you reassess the patient at each visit.



AUDIENCE POLLING REVISITED

Now, what would you do next?

A. Reassess MG activity, fatigue pattern, quality of life, other contributors, treatment burden, and Maya's goals before modifying therapy

B. Continue the current FcRn regimen and monitor MG-ADL and QMG at routine follow-up before considering treatment changes

C. Shorten the interval between FcRn treatment cycles to address symptoms occurring near the end of the current interval

D. Discontinue FcRn therapy and return to her previous immunotherapy because persistent fatigue continues to limit daily function

E. Continue the current FcRn regimen and refer Maya to primary care for evaluation of other potential causes of fatigue







Put information into action!

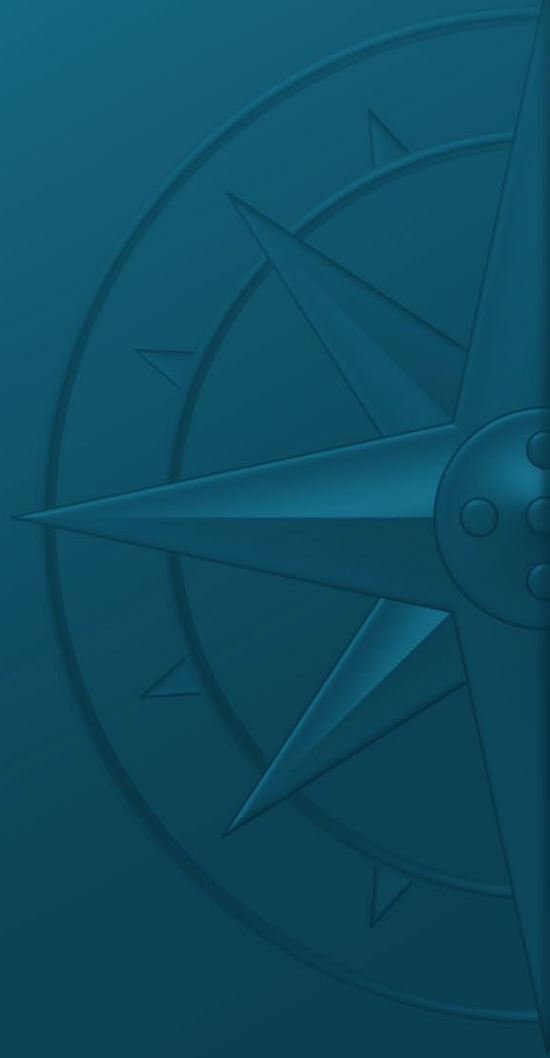
Takeaways from this program can be implemented into your practice to improve patient care.

- **Increase** *complete serologic and clinical phenotyping* in patients with newly diagnosed or early gMG being evaluated for FcRn-directed therapy.
- **Improve** *individualization of FcRn therapy selection* by weighing dosing schedule, administration route, and safety profile against patient circumstances.
- **Strengthen** *patient-centered monitoring* by using validated gMG assessments together with patient-stated goals when evaluating treatment response.

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