

Complement Inhibitors Epysqli (eculizumab-aagh) Effective 11/17/2025

Plan	✓ MassHealth UPPL☐ Commercial/Exchange	Dua suasa Tima	☑ Prior Authorization
Benefit	□ Pharmacy Benefit⋈ Medical Benefit	Program Type	☐ Quantity Limit ☐ Step Therapy
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Epysqli is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Atypical hemolytic-uremic syndrome (aHUS)

- 1. Diagnosis of aHUS
- 2. Prescriber is a hematologist or nephrologist or consult notes from specialist are provided
- 3. Appropriate dosing

Generalized Myasthenia Gravis (MG), AChR-antibody+

- 1. Diagnosis of generalized MG
- 2. Member is \geq 6 years of age
- 3. Member is AChR antibody positive
- 4. Prescriber is a neurologist or consult notes from specialist are provided
- 5. Inadequate response, adverse reaction, or contraindication to pyridostigmine
- 6. ONE of the following:
 - a. BOTH of the following:
 - i. Member has severe disease requiring faster onset medication

- ii. Inadequate response, adverse reaction or contraindication to IVIG or plasmapheresis with glucocorticoids
- b. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following immunosuppressant trials
 - i. Azathioprine
 - ii. Cyclosporine
 - iii. Glucocorticoids (e.g., prednisone)
 - iv. Mycophenolate
 - v. Tacrolimus
- 7. Appropriate dosing

Neuromyelitis optica spectrum disorder (NMOSD)

- 1. Diagnosis of NMOSD
- 2. Prescriber is a neurologist or consult notes from specialist are provided
- 3. Positive serologic test for anti-aquaporin-4 (AQP4)
- 4. Member is ≥ 18 years of age
- 5. Appropriate dosing

Paroxysmal nocturnal hemoglobinuria (PNH)

- 1. Diagnosis of PNH
- 2. Prescriber is a hematologist or consult notes from specialist are provided
- 3. Member is ≥ 18 years of age
- 4. Appropriate dosing

Protein-losing enteropathy (PLE), or complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease

- 1. Diagnosis of CD55-deficient PLE/CHAPLE disease
- 2. Member is ≥2 months of age
- 3. Prescriber is a specialist in rare genetic or hematologic diseases or consult notes from specialist are provided
- 4. Results from genetic testing confirming a CD55 loss-of-function mutation
- 5. Appropriate dosing

Continuation of Therapy

aHUS, PNH, NMOSD

Resubmission by prescriber will infer a positive response to therapy.

qMG

Prescriber must provide documentation of positive response to therapy.

PLE/CHAPLE disease

Prescriber must submit medical records documenting ALL of the following:

1. Improvement or no worsening of clinical symptoms (e.g., abdominal pain, bowel movements, facial and peripheral edema)



- 2. ONE of the following:
 - a. Increase in current serum albumin concentration from baseline serum albumin concentration
 - b. Serum albumin concentration stabilized above lower threshold for normal range (≥3.5 g/dL)
- 3. ONE of the following:
 - a. Increase in current serum IgG concentration from baseline serum IgG concentration
 - b. Serum IgG concentration stabilized above lower threshold for age-adjusted normal range

Limitations

- 1. Initial approvals will be granted based on indication
 - a. gMG: 6 months
 - b. aHUS, PNH, NMOSD, and PLE/CHAPLE: 12 months
- 2. Reauthorizations will be granted for 12 months.

References

1. Epysqli [package insert] Parsippany (NJ): Teva Pharmaceuticals; 2025 Apr

Review History

10/8/25 – Created for P&T. New drug, Epysqli, will be managed on medical benefit with PA. As part of the HOPA implementation, criteria is aligned. Effective 11/17/25

