MED RX POLICY

POLICY: Complement Inhibitors – Eculizumab Products Med Rx Policy
- Bkemv™ (eculizumab-aeeb intravenous infusion – Amgen)
- Epysqli® eculizumab-aagh intravenous infusion – Samsung Bioepis)
- Soliris® (eculizumab intravenous infusion – Alexion)

REVIEW DATE: 04/23/2025

OVERVIEW

Eculizumab, a complement C5 inhibitor, is indicated for the following uses:[1]

- **Atypical hemolytic uremic syndrome** (aHUS), to inhibit complement-mediated thrombotic microangiopathy.
  Limitation of Use. Eculizumab is not indicated for the treatment of patients with Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome.
- **Generalized myasthenia gravis** (gMG), in adults and pediatric patients ≥ 6 years of age who are anti-acetylcholine receptor (AChR) antibody-positive.
- **Neuromyelitis optica spectrum disorder** (NMOSD), in adults who are anti-aquaporin-4 (AQP4) antibody-positive.
- **Paroxysmal nocturnal hemoglobinuria** (PNH), to reduce hemolysis.

Eculizumab has a Boxed Warning about serious meningococcal infections.[1] Soliris and biosimilars are only available through a restricted access program (Risk Evaluation and Mitigation Strategy [REMS]).

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the standard *Complement Inhibitors – Eculizumab Products Utilization Management Medical Policy* criteria. This program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the standard *Complement Inhibitors – Eculizumab Products Utilization Management Medical Policy*.

Documentation: Documentation is required for use Bkevmv or Soliris as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Products: Soliris, Bkemv
Non-Preferred Product: Epysqli

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Epysqli	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Complement Inhibitors – Eculizumab Products Utilization Management Medical Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried one of Bkemv or Soliris **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

REFERENCES

1. Soliris® intravenous infusion [prescribing information]. Boston, MA: Alexion; June 2024.
2. Bkemv™ intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; October 2024.
3. Epysqli® intravenous infusion [prescribing information]. Yeonsu-gu, Incheon, Republic of Korea; November 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/23/2025; Effective 07/01/2025