

Bkemv® (eculizumab-aeeb) – First-time biosimilar and interchangeable launch

- On April 2, 2025, Amgen launched <u>Bkemv (eculizumab-aeeb)</u>, biosimilar and *interchangeable* to AstraZeneca's Soliris (eculizumab).
 - Per Amgen, Bkemv was available to order on March 3, 2025, and available to ship on April 2, 2025.
 - Teva/Samsung Bioepis has also launched biosimilar <u>Epysqli (eculizumab-aagh)</u> on April 7, 2025.
- The FDA approved Bkemv in May 2024.
- Bkemv, Epysqli, and Soliris share the following indications:
 - Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
 - Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
 - Treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor antibody positive and neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 receptor (AChR) antibody positive.
- Soliris is also indicated for the following:
 - Treatment of gMG in pediatric patients six years of age and older who are AChR antibody positive
 - Treatment of neuromyelitis optica spectrum disorder in adult patients who are antiaquaporin-4 antibody positive.



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