Bkemv™ (eculizumab-aeeb) – New first-time interchangeable biosimilar approval

- On May 28, 2024, the FDA approved Amgen's Bkemv (eculizumab-aeeb), biosimilar and *interchangeable* to AstraZeneca's Soliris® (eculizumab).
    - Bkemv is the first FDA-approved biosimilar to Soliris.
- Bkemv and Soliris share the following indications:
    - The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
    - The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- Bkemv and Soliris are *not* indicated for the treatment of patients with Shiga toxin *E. coli* related HUS.
- Soliris is also approved for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive and neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive.
- The approval of Bkemv is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Soliris.
- Evidence also demonstrated that Bkemv met the other legal requirements to be *interchangeable* with Soliris at the pharmacy level.
- Bkemv and Soliris carry a boxed warning for serious meningococcal infections.
    - Because of the risk of serious meningococcal infections, Bkemv and Soliris are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Bkemv REMS and Ultomiris® (ravulizumab -cwvz) and Soliris REMS, respectively.
- Bkemv is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.
- Additional warnings and precautions for Bkemv include other infections, monitoring disease manifestations after Bkemv discontinuation, thrombosis prevention and management, and infusion-related reactions.
- The most common adverse reactions (≥ 10% overall and greater than placebo) with Bkemv use in a PHN randomized trial were headache, nasopharyngitis, back pain, and nausea.
- The most common adverse reactions (≥ 20%) with Bkemv use in an aHUS single arm prospective trial were headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.
- The recommended dosage of Bkemv in PHN in patients 18 years of age and older is 600 mg weekly as an intravenous (IV) infusion for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, then 900 mg every 2 weeks thereafter.

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- The recommended dosage of Bkemv in aHUS in patients 18 years of age and older is 900 mg as an IV infusion weekly for the first 4 weeks, followed by 1,200 mg for the fifth dose 1 week later, then 1,200 mg every 2 weeks thereafter.

- For patients less than 18 years of age for the treatment of aHUS, administer Bkemv based upon body weight, according to the schedule found in Bkemv's drug label.

- Amgen has signed a settlement agreement with AstraZeneca allowing for the launch of Bkemv on March 1, 2025. Bkemv will be available as a 300 mg/30 mL (10 mg/mL) solution in a single-dose vial.

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