Pemgarda™ (pemivibart) – Emergency use authorization approval

- On March 22, 2024, the FDA announced the emergency use authorization (EUA) approval of Invivyd's Pemgarda (pemivibart), for the preexposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg):
    - Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2; and
    - Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate response to COVID-19 vaccination.
- Pemgarda is not authorized for use:
    - For treatment of COVID-19, or
    - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with Pemgarda is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have recently received a COVID-19 vaccine, Pemgarda should be administered at least 2 weeks after vaccination.
- Pemgarda is a half-life extended monoclonal antibody. Pemgarda targets the SARS-CoV-2 spike protein receptor binding domain, thereby inhibiting virus attachment to the human ACE2 receptor on host cells.
- The EUA approval of Pemgarda was based on CANOPY, an ongoing clinical trial evaluating Pemgarda for the preexposure prophylaxis of COVID-19 in adults ≥18 years of age in two cohorts – Cohort A (n = 306): single-arm, open-label trial in adults who have moderate-to-severe immune compromise; Cohort B (n = 317): placebo-controlled, randomized trial in adults who do not have moderate-to-severe immune compromise.
    - The calculated serum neutralizing antibody titers against JN.1 were consistent with the titer levels associated with efficacy in prior clinical trials of other monoclonal antibody products. JN.1 is currently the dominant variant circulating in the U.S. according to estimates from the CDC.
- Pemgarda carries a boxed warning for anaphylaxis.
- Additional warnings and precautions for Pemgarda include hypersensitivity and infusion-related reactions; risk of cross-hypersensitivity with COVID-19 vaccines; and risk for COVID-19 due to SARS-CoV-2 viral variants not neutralized by Pemgarda.
- The most common adverse reactions (≥ 2%) with Pemgarda use were systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

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- The initial dosage of Pemgarda in adults and adolescents (12 years of age and older weighing at least 40 kg) is 4500 mg administered as a single intravenous (IV) infusion.
    - The repeat dosage is 4500 mg of Pemgarda administered as a single IV infusion every 3 months.
    - Repeat dosing should be timed from the date of the most recent Pemgarda dose. The recommendations for dosing are based on the totality of the scientific evidence including clinical pharmacology data, antiviral activity data, and clinical study data.
- Invivyd plans to launch Pemgarda imminently. Pemgarda will be available as a 500 mg/4 mL (125 mg/mL) single-dose vial.

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