Zinplava™ (bezlotoxumab) – Expanded indication

- On May 26, 2023, the FDA approved Merck's Zinplava (bezlotoxumab), to reduce recurrence of *Clostridioides difficile* infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.
    - Zinplava was previously approved for this indication in adults only.
    - Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug. Zinplava should only be used in conjunction with antibacterial drug treatment of CDI.
- The use of Zinplava in pediatric patients 1 year of age and older is supported by evidence from adequate and well-controlled trials in adults with additional pharmacokinetic and safety data in pediatric patients aged 1 year and older. The adverse reactions and the pharmacokinetics observed in pediatric patients were comparable to that observed in adult patients.
- The most common adverse reactions (> 10%) with Zinplava use in pediatric patients were pyrexia and headache
- The recommended dose of Zinplava is a single dose of 10 mg/kg administered as an intravenous infusion over 60 minutes. The safety and efficacy of repeat administration of Zinplava in patients with CDI have not been studied.