

Emblaveo[™] (aztreonam/avibactam) – New drug approval

- On February 7, 2025, [AbbVie announced](#) the FDA approval of [Emblaveo \(aztreonam/avibactam\)](#), in combination with metronidazole, in patients 18 years and older who have limited or no alternative options for the **treatment of complicated intra-abdominal infections (cIAI) including those caused by the following susceptible gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Enterobacter cloacae* complex, *Citrobacter freundii* complex, and *Serratia marcescens*.**
 - Approval of this indication is based on limited clinical safety and efficacy data for Emblaveo.
- Emblaveo combines two components: aztreonam, a monobactam antibiotic, and avibactam, a β -lactamase inhibitor that protects aztreonam from serine β -lactamase hydrolysis and restores its activity against bacteria that co-produce Metallo- β -lactamases (MBLs) and serine β -lactamases.
- The efficacy of Emblaveo was supported in part by the previous findings of the efficacy and safety of aztreonam for the treatment of cIAI. The contribution of avibactam to Emblaveo was primarily established *in vitro* and in animal models of infection.
 - Emblaveo was studied in one randomized, active-controlled study in patients with cIAI or hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) (not an approved indication for Emblaveo). The trial was not designed with any formal hypotheses for inferential testing against the active comparator.
- Warnings and precautions for Emblaveo include hypersensitivity reactions, serious skin disorders, hepatic adverse reactions, *Clostridioides difficile*-associated diarrhea, and development of drug-resistant bacteria.
- The most common adverse reactions (> 5%) with Emblaveo use were hepatic adverse reactions, anemia, diarrhea, hypokalemia, and pyrexia.
- The recommended loading dose of Emblaveo is 2.67 grams (aztreonam 2 grams and avibactam 0.67 grams) by intravenous infusion and a maintenance dose of 2 grams (aztreonam 1.5 grams and avibactam 0.5 grams) every 6 hours for 5 to 14 days.
- AbbVie plans to launch Emblaveo in the third quarter of 2025. Emblaveo will be available as a lyophilized powder in a single-dose vial containing 2 grams (1.5 grams aztreonam and 0.5 grams avibactam).