Avycaz® (ceftazidime/avibactam) – Expanded indication

- On March 18, 2019, Allergan announced the FDA approval of Avycaz (ceftazidime/avibactam), for the treatment of complicated intra-abdominal infections (cIAI), used in combination with metronidazole; and in complicated urinary tract infections (cUTI), including pyelonephritis, in adult and pediatric patients 3 months and older caused by susceptible gram-negative microorganisms.
    - Microorganisms in cIAI include Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii complex, and Pseudomonas aeruginosa.
    - Microorganisms in cUTI include Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter freundii complex, Proteus mirabilis, and Pseudomonas aeruginosa.
    - Previously, Avycaz was indicated for the treatment of cIAI and cUTI in patients 18 years and older.

- Avycaz is also approved for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years or older caused by the following susceptible Gram-negative microorganisms*: Klebsiella pneumoniae*, *Enterobacter cloacae*, *Escherichia coli*, *Serratia marcescens*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Haemophilus influenzae*.

- The approval of Avycaz for cIAI in pediatric patients was based on a study of 83 patients treated with Avycaz + metronidazole or meropenem for at least 72 hours with an optional switch to oral therapy for a total of 7 – 15 days of antibacterial therapy.
    - At 8 – 15 days after the last dose of antibacterial therapy, 91.8% of Avycaz + metronidazole treated patients vs. 95.5% of meropenem treated patients demonstrated clinical cure.
    - The microbiological cure rates were 90% in the Avycaz + metronidazole group vs. 94.7% in the meropenem group.

- The approval of Avycaz for cUTI in pediatric patients was based on a study of 95 patients treated with Avycaz or cefepime for at least 72 hours with an optional switch to oral therapy for a total of 7 – 14 days of antibacterial therapy.
    - At 8 – 15 days after the last dose of antibacterial therapy, 88.9% of Avycaz treated patients vs. 82.6% of cefepime treated patients demonstrated clinical cure.
    - The microbiological cure rates were 79.6% in the Avycaz group vs. 60.9% in the cefepime group.

- In addition, use of Avycaz in pediatric patients is supported by evidence from adequate and well-controlled studies of Avycaz in adults with cUTI and cIAI and additional pharmacokinetic and safety data from pediatric trials.

- The most common adverse reactions (≥ 3%) with Avycaz use in pediatric patients treated for cIAI or cUTI were vomiting, diarrhea, rash, and infusion site phlebitis.

- The recommended dose of Avycaz in pediatric patients for the treatment of cIAI or cUTI is administered every 8 hours by intravenous infusion over 2 hours as follows:

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Age Range	Dose Every 8 hours	Duration of Treatment
2 years to less than18 years	62.5 mg/kg to a maximum of 2.5 grams (ceftazidime 50 mg/kg and avibactam 12.5 mg/kg to a maximum dose of ceftazidime 2 grams and avibactam 0.5 grams)	cIAI: 5 to 14 days cUTI: 7 to14 days
6 months to less than 2 years	62.5 mg/kg (ceftazidime 50 mg/kg and avibactam 12.5 mg/kg)	
3 months to less than 6 months	50 mg/kg (ceftazidime 40 mg/kg and avibactam 10 mg/kg)	

- For the treatment of cIAI, metronidazole should be given concurrently.
- Consult the metronidazole drug label for dosing recommendations.
- Consult the Avycaz drug label for adult dosing recommendations in cIAI, cUTI and HABP/VABP.

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