Avycaz® (ceftazidime/avibactam) – New indication

- On February 1, 2018, Allergan announced the FDA approval of Avycaz (ceftazidime/avibactam), for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by the following susceptible gram-negative microorganisms: *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Escherichia coli*, *Serratia marcescens*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Haemophilus influenzae* in patients 18 years or older.
    - To reduce the development of drug-resistant bacteria and maintain the effectiveness of Avycaz and other antibacterial drugs, Avycaz should be used to treat only indicated infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

- Avycaz is also indicated in patients 18 years or older to treat the following:
    - In combination with metronidazole, for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible gram-negative microorganisms: *E. coli*, *K. pneumoniae*, *P. mirabilis*, *Enterobacter cloacae*, *K. oxytoca*, *Citrobacter freundii* complex, and *P. aeruginosa*
    - Complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible gram-negative microorganisms: *E. coli*, *K. pneumoniae*, *Enterobacter cloacae*, *Citrobacter freundii* complex, *P. mirabilis*, and *P. aeruginosa*.

- HABP/VABP is currently the second most common type of nosocomial infection in the U.S.
    - HABP/VABP are associated with increased healthcare costs, high morbidity and mortality, and lengthened hospital stays.

- The new indication for Avycaz was approved based on a trial of 870 patients with HABP/VABP treated with Avycaz or meropenem for 7 – 14 days. The primary endpoint was 28-day all-cause mortality rates.
    - Avycaz was non-inferior to meropenem with regard to the primary endpoint (9.6% vs. 8.3%, respectively; treatment difference = 1.5 [95% CI: -2.4, 5.3]).
    - In addition, the clinical cure rates for Avycaz were seen in 67.2% of patients and in 69.1% of meropenem-treated patients (treatment difference = -1.9 [95% CI: -8.1, 4.3]).

- The recommended dosage of Avycaz for all indications is 2.5 grams (ceftazidime 2 grams/avibactam 0.5 grams) administered every 8 hours by intravenous infusion over 2 hours in patients with normal renal function.
    - Patients with cIAI should also be given metronidazole and treated for 5 – 14 days.
    - Patients with cUTI and HABP/VABP should be treated for 7 – 14 days.
    - Refer to Avycaz's drug label for dosing recommendations for patients with renal impairment.