Teflaro® (ceftaroline fosamil) – Expanded indication

- On September 13, 2019, the FDA approved Allergan's Teflaro (ceftaroline fosamil), in adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.
    - Teflaro was previously approved for this indication in adult and pediatric patients 2 months of age and older.
- Teflaro is also approved in adult and pediatric patients 2 months of age and older for the treatment of community-acquired bacterial pneumonia.
- The use of Teflaro in pediatric patients less than 2 months of age was supported by pharmacokinetic and safety data in 11 infants at least 34 weeks gestational age and 12 days postnatal age.
- The recommended dose of Teflaro for the treatment of pediatric patients less than 2 months of age (gestational age 34 weeks and older and postnatal age 12 days and older) with ABSSSI is 6 mg/kg administered every 8 hours by intravenous infusion over 30 to 60 minutes.
    - Refer to the Teflaro drug label for dosing for all its other indications.