Sirturo® (bedaquiline) – Expanded indication

- On August 9, 2019, Janssen announced the FDA approval of Sirturo (bedaquiline), as part of combination therapy in the treatment of adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB).
    - Sirturo was previously only approved for this indication in adults.
    - Sirturo should be reserved for use when an effective treatment regimen cannot otherwise be provided.
    - This indication is approved under accelerated approval based on time to sputum culture conversion. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- The approval of Sirturo for the expanded indication was based on a single-arm, open-label study of Sirturo in combination with a background regimen in 15 patients 12 to less than 18 years of age with confirmed or probable pulmonary MDR-TB infection.
    - In the subset of patients with culture positive pulmonary MDR-TB at baseline, treatment with Sirturo resulted in conversion to a negative culture in 75.0% (6/8 patients) at week 24.
- Sirturo carries a boxed warning for increased mortality and QT prolongation.
- The most common adverse reactions (≥ 10%) with Sirturo use in pediatric patients were arthralgia, nausea and abdominal pain.
- The recommended dose of Sirturo for the treatment of MDR-TB infection in adult and pediatric patients is 400 mg orally once daily for 2 weeks followed by 200 mg 3 times per week (with at least 48 hours between doses) for 22 weeks.
    - Sirturo should be administered by directly observed therapy.
- Refer to the Sirturo drug label for additional dosing and administration recommendations.