Sivextro® (tedizolid) – Expanded indication

- On April 4, 2025, the FDA approved Merck's Sivextro (tedizolid), for the **treatment of acute bacterial skin and skin structure infections** (ABSSSI) caused by susceptible isolates of the following gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis*, in adult and **pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg)**.
    - Sivextro was previously approved for this indication in adult and pediatric patients 12 years of age and older.
- The approval of Sivextro for the expanded indication was based on a randomized, single blind, active-controlled study in 100 pediatric patients 4 months to < 12 years of age with clinically documented ABSSSI. Patients were randomized to receive Sivextro for 6 to 10 days or comparator for 10 to 14 days. Comparator therapy was selected from a pre-specified list by the investigator and dosed per local standard of care.
    - Clinical success at test of cure was 93.3% in the Sivextro group and 92.0% in the comparator group (difference: 1.3, 95% CI: -10.7, 13.4).
- The most common adverse reactions (> 2%) with Sivextro use in pediatric patients (less than 12 years of age) were infusion- or injection-related adverse reactions and vomiting.
- The recommended intravenous dosage of Sivextro for pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg) is weight-based. Refer to the drug label for complete dosing and administration recommendations.
- The recommended oral dosage of Sivextro for pediatric patients weighing greater than or equal to 35 kg is 200 mg once daily for 6 days.

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