Orenitram® (treprostinil) – Expanded indication

- On October 21, 2019, United Therapeutics announced the FDA approval of Orenitram (treprostinil), for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity.
    - The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).
    - Previously, Orenitram was only indicated for the treatment of PAH to improve exercise capacity.
- The FDA approval for the expanded indication is based on data from a randomized, placebo-controlled study of 690 patients with WHO Group 1 PAH. The primary efficacy endpoint was the time to first clinical worsening (morbidity or mortality) event.
    - Treatment with Orenitram resulted in a significant increase in the time to first clinical worsening event vs. placebo, which was associated with a reduction in the risk of an event (HR = 0.75; 95% CI: 0.57, 0.99; p = 0.039).
    - The beneficial effect of Orenitram was primarily attributable to a delay in disease progression, defined as a 15% decline in six minute walk distance plus an increase in either WHO Functional Class or worsening of signs or symptoms of right heart failure (HR = 0.39; 95% CI: 0.23, 0.66). There was no effect on the other components of clinical worsening.
- The recommended initial dose of Orenitram is 0.125 mg orally three times daily with food taken approximately 8 hours apart or 0.25 mg twice daily with food, taken approximately 12 hours apart.
    - Refer to the Orenitram drug label for further titration instructions and dose modifications.