Intelence® (etravirine) – Expanded indication

- On July 16, 2018, the FDA announced the approval of Janssen's Intelence (etravirine), in combination with other antiretroviral (ARV) agents, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in ARV treatment-experienced patients ages 2 years and older, who have evidence of viral replication and HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor and other ARV agents.
    - Previously, Intelence was only approved for patients ≥ 6 years.
- The expanded indication for Intelence was demonstrated in a study evaluating the pharmacokinetics, safety, tolerability, and efficacy of Intelence in 20 ARV treatment-experienced HIV-1 infected pediatric subjects 2 years to less than 6 years of age. Virologic response, defined as achieving plasma viral load < 400 HIV-1 RNA copies/mL, was evaluated.
    - At week 24, the proportion of subjects with < 400 HIV-1 RNA copies/mL was 88%.
    - In addition, the use of Intelence in pediatric patients 2 years to less than 18 years of age is supported by evidence from adequate and well-controlled studies in adults.
- The most common adverse drug reactions (≥ 2%) with Intelence use in pediatric patients were rash and diarrhea.
- The recommended dose of Intelence for pediatric patients 2 years to less than 18 years of age and weighing at least 10 kg is based on body weight, not exceeding the recommended adult dose taken orally following a meal as follows:

Body Weight (kg)	Dose
≥ 10 kg to < 20 kg	100 mg twice daily
≥ 20 kg to < 25 kg	125 mg twice daily
≥ 25 kg to < 30 kg	150 mg twice daily
≥ 30 kg	200 mg twice daily

    - Consult the Intelence drug label for adult dosing recommendations.