Rivfloza® (nedosiran) – Expanded indication

- On March 27, 2025, the FDA approved Novo Nordisk's Rivfloza (nedosiran) to **lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function**, e.g., estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2.
    - Rivfloza was previously approved for this indication in children 9 years of age and older and adults.
- The approval of Rivfloza for the expanded indication was based on a single-arm study in 15 patients 2 years to less than 12 years of age with PH1 and eGFR ≥ 30 mL/min/1.73 m^2. Efficacy was based on the percent change from baseline at month 6 in spot urinary oxalate to creatinine ratio.
    - **Treatment with Rivfloza reduced the spot urinary oxalate to creatinine ratio by 64%** (95% CI: 44, 84) from baseline, with an absolute risk reduction of 0.25 mmol/mmol (95% CI: 0.21, 0.29).
- The recommended **once monthly subcutaneous** dose of Rivfloza for the expanded age group (children 2 to 9 years of age) is dependent on body weight:
    - Less than 39 kg: 3.3 mg/kg
    - 39 kg to less than 50 kg: 128 mg
    - 50 kg and above: 160 mg.
- Refer to the Rivfloza drug label for dosing for previously indicated age groups.