Mircera® (methoxy polyethylene glycol-epoetin beta) – Expanded indication

- On April 30, 2024, the FDA approved Vifor's Mircera (methoxy polyethylene glycol-epoetin beta), for the treatment of anemia associated with chronic kidney disease (CKD) in **pediatric patients 3 months to 17 years of age on dialysis or not on dialysis** who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
    - Mircera was previously approved for this indication in **pediatric patients 5 to 17 years of age on hemodialysis** who are converting from another ESA after their hemoglobin level was stabilized with an ESA.
- Mircera is also approved for the treatment of anemia associated with CKD in adult patients on dialysis and adult patients not on dialysis.
- Additionally, the FDA approved a subcutaneous (SC) route of administration for pediatric patients. Previously, pediatric patients could only use the intravenous (IV) route of administration.
- The approval of Mircera for the updated label was supported by an open-label, single-arm, study to ascertain the optimal starting dose of Mircera administered SC for the maintenance treatment of anemia in 40 pediatric patients with CKD on dialysis, or not on dialysis when switching from stable SC treatment with epoetin alfa, epoetin beta or darbepoetin alfa. Efficacy was established based on the change in Hb concentration (g/dL) between the baseline and evaluation periods.
    - For the 38 patients who had Hb concentration data available during the evaluation period (weeks 17 to 21), the mean change in Hb concentration between the baseline and the evaluation period was 0.48 g/dL with 95% CI (0.15, 0.82).
    - Supportive efficacy results demonstrated that 50% of patients maintained Hb values within ± 1 g/dL of baseline and 63% maintained Hb values within 10 to 12 g/dL during the evaluation period.
- Mircera carries a boxed warning for ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.
- Refer to the Mircera drug label for complete dosing and administration recommendations.