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

- On June 7, 2018, the FDA announced the approval of Vifor's Mircera (methoxy polyethylene glycol-epoetin beta), for the treatment of anemia associated with chronic kidney disease (CKD) in pediatric patients 5 to 17 years of age on hemodialysis (HD) who are converting from another erythropoietin stimulating agent (ESA) after their hemoglobin (Hb) 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.
    - Mircera is not indicated and is not recommended in the treatment of anemia due to cancer chemotherapy or as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
    - Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

- The approval of Mircera for the new indication was based on an open-label study in 64 pediatric patients with CKD on HD and who had stable Hb levels while previously receiving another ESA. Eligible patients were administered Mircera intravenously (IV) once every 4 weeks for 20 weeks. Efficacy was established based on the change in Hb concentration between the baseline and evaluation periods.
    - The mean change in Hb concentration was -0.15 g/dL (95% CI: -0.49, 0.2).
    - In addition, 75% of patients maintained Hb values within ± 1 g/dL of baseline and 81% maintained Hb values within 10 to 12 g/dL during the evaluation period.
    - The use of Mircera in this pediatric age group is also supported by evidence from adequate and well-controlled studies of Mircera in adults.

- 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.

- The recommended dosage of Mircera in pediatric patients converting from another ESA is dosed IV once every 4 weeks based on total weekly Epogen®/Procrit® (epoetin alfa) or Aranesp® (darbepoetin alfa) dose at time of conversion.
    - Administer Mircera either IV or subcutaneously in adult patients and only IV in pediatric patients.
    - When initiating or adjusting therapy, monitor Hb levels at least weekly until stable, then monitor at least monthly.
    - Consult the Mircera drug label for adult dosing recommendations.