

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

- On June 7, 2018, the <u>FDA announced</u> the approval of Vifor's <u>Mircera (methoxy polyethylene glycolepoetin beta)</u>, 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 <a href="Epogen"/Procrit">Epogen</a> (Procrit</a> (epoetin alfa) or <a href="Aranesp" (darbepoetin alfa">Aranesp</a> (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.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.