

340B Notice Regarding End of Limited Distribution Plan for Mircera® (methoxy polyethylene glycol-epoetin beta) injection

April 15, 2019

This notice provides information for 340B Covered Entities regarding the distribution of Mircera (methoxy polyethylene glycol-epoetin beta), which is marketed by Vifor Pharma. Mircera is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia associated with chronic kidney disease (CKD) in (i) adult patients on dialysis and patients not on dialysis; and (ii) 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 not indicated and is not recommended for use in the treatment of anemia due to cancer chemotherapy.

Until now, Vifor Pharma has implemented a limited distribution plan pursuant to which Mircera was only available to Covered Entities that were dialysis clinics whose locations and/or drug purchasing and inventory systems were separate from those of hospitals. Effective April 22, 2019, Vifor Pharma will begin distribution of Mircera to customers in all health care settings. Accordingly, all 340B Covered Entities will be able to purchase Mircera in the normal course.

If you have any questions, please contact Vifor Pharma at 1-800-576-8295.