PDL NEW DRUG REVIEW

Proprietary Name: Omontys™

Common Name: peginesatide

PDL Category: Erythropoetins

Comparable Products	Preferred Drug List Status
Procrit™	Preferred with Conditions

Summary

Indications and Usage: Treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis. Limitations of use include not recommended for use in those with CKD not on dialysis, in those receiving treatment for cancer and whose anemia is not due to CKD, and as a substitute for RBC transfusions in those who require immediate correction of anemia. Furthermore, Omontys® has not been shown to improve symptoms, physical functioning, or health-related quality of life. This is a pregnancy category C medication. The safety and efficacy of use in children under the age of 18 have not been established.

Dosage Forms: Multiple use vials (with preservative): 10mg/ml & 20mg/2ml

Drug Interactions: Formal drug interaction studies have not been performed with Omontys®.

Recommended Dosage: Therapy should be initiated when hemoglobin levels are <10g/dl, with a recommended starting dose in those who are not currently being treated with an erythropoiesis stimulating agent (ESA) of 0.04mg/kg once monthly as an SC or IV dose. Hemoglobin levels should be monitored at least every 2 weeks until stable, and then monthly thereafter. Subsequent dose increases should not be made more than once every 4 weeks. If hemoglobin levels approach or exceeds 11g/dl, reduce or interrupt a dose. Once a dose has been withheld and the hemoglobin levels begin to decrease, Omontys° may be restarted at a dose reduced by ≥25% of the previous dose. Please refer to the package insert for dosing Omontys® if converting patients from epoetin alfa or darbepoetin.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions = reported % incidence for drug minus reported % incidence for epoetin.* The most commonly reported adverse events included diarrhea (2.5%), nausea (0%), vomiting (2%), dyspnea (0%), cough (0%), headache (0%), muscle spasms (0%), pain in extremity (0%), back pain (0%), arthralgia (0%), hypotension (0%), hypertension (1.8%), pyrexia (0%), hyperkalemia (0%), and upper respiratory tract infections (0%). All adverse events listed above with a 0% had a reported incidence of at least 8% with Omontys®; however, the reported incidence with Omontys® was less than with epoetin.

Contraindications: In those with uncontrolled hypertension.

Manufacturer: Takeda Pharmaceuticals America, Inc.

Analysis: Peginesatide, the active ingredient of Omontys® is a synthetic, pegylated dimeric peptide that binds to and activates human erythropoietin receptors and thus stimulates erythropoiesis in human red cell precursors. As with all erythropoiesis stimulating agents (ESAs), Omontys® has a boxed warning regarding the potential for increased risk of death, MI, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence with use. The warning suggests that the greater risks for death, serious CV reactions, and stroke occur when ESAs are given to target hemoglobin levels of >11g/dl. Furthermore, no clinical trial has established a hemoglobin level, ESA dose, or dosing strategy that does not increase these risks. It is therefore recommended that the lowest Omontys® dose be used that is adequate to reduce the need for RBC transfusions.

It is recommended that laboratory monitoring be performed when treating with Omontys®. Transferrin saturation and serum ferritin levels should be obtained prior to and during treatment. Supplemental iron should be given if serum ferritin is <100mcg/L or when serum transferrin saturation is <20%. After starting therapy and after each dose adjustment, hemoglobin levels should be monitored every 2 weeks until hemoglobin is stable and sufficient to minimize the need for a RBC transfusion. Subsequently, hemoglobin levels should be obtained at least monthly.

There were two randomized, active-controlled, open-label studies performed to assess the safety and efficacy of Omontys® in a population on dialysis being treated with another ESA at the time of the start of the study. The primary outcome for each study was the change in hemoglobin from baseline to the evaluation period (weeks 29-36). Results suggest that in study 1, there was a -0.24g/dl change from baseline to week 29-36 with Omontys® as compared with a -0.09g/dl change. In study 2, there was a -0.07g/dl change with Omontys® as compared with a -0.17g/dl change with epoetin. Results suggest that hemoglobin levels were maintained. In addition, a main secondary endpoint was a composite CV safety endpoint, consisting of death, MI, stroke, or serious adverse event of CHF, unstable angina, or arrhythmia. 22.8% of the Omontys® group experienced one of these events vs 24.4% of the epoetin group.

There is no evidence at this time to support that Omontys® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Omontys® remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

PDL Placement:

- ☐ **Preferred**
- ☐ **Non-Preferred**
- ☒ **Non-Preferred with Conditions**

References

[1] Omontys [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; 2012.