Retacrit™ (epoetin alfa-epbx) – New biosimilar approval

- On May 15, 2018, the FDA announced the approval of Retacrit (epoetin alfa-epbx), Hospira/Pfizer's biosimilar to Amgen's Epogen® (epoetin alfa) and Janssen's Procrit® (epoetin alfa).
    - Retacrit is the first FDA-approved biosimilar to Epogen and Procrit.
- Epogen, Procrit and Retacrit share the same indications:
    - Treatment of anemia due to chronic kidney disease (CKD), chemotherapy, or use of zidovudine in patients with human immunodeficiency virus-infection
    - Reduce the need for allogeneic red blood cell transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery
- Epogen, Procrit, and Retacrit have not been shown to improve quality of life, fatigue, or patient well-being.
- A biosimilar product is a biological agent that is considered highly similar to an already approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
- A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, the biosimilar product may be approved for the indication(s) and condition(s) that have been FDA-approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
    - The facilities where the biosimilars are manufactured must also meet the FDA's standards.
- The approval of Retacrit was based on review of evidence that included structural and functional characterization, immunogenicity information and other clinical safety and effectiveness data that demonstrates Retacrit is biosimilar to Epogen/Procrit.
- Retacrit has been approved as a biosimilar to Epogen/Procrit, ***not*** as an interchangeable product.
- Similar to Epogen and Procrit, Retacrit carries a boxed warning for erythropoiesis-stimulating agents increasing the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.
- Retacrit is contraindicated in patients with uncontrolled hypertension, pure red cell aplasia that begins after treatment with Retacrit or other erythropoietin protein drugs, and serious allergic reactions to Retacrit or other epoetin alfa products.
- Additional warnings and precautions of Retacrit include hypertension, seizures, lack or loss of hemoglobin response to Retacrit, severe cutaneous reactions, risks in patients with phenylketonuria, and dialysis management.

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- The most common adverse reactions (≥ 5%) with Retacrit use in patients with CKD are hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion, and upper respiratory tract infection.

- The most common adverse reactions (≥ 5%) with Retacrit use in patients on zidovudine are pyrexia, cough, rash, and injection site irritation.

- The most common adverse reactions (≥ 5%) with Retacrit use in patients with cancer on chemotherapy are nausea, vomiting, myalgia, arthralgia, stomatitis, cough, weight decrease, leukopenia, bone pain, rash, hyperglycemia, insomnia, headache, depression, dysphagia, hypokalemia, and thrombosis.

- The most common adverse reactions (≥ 5%) with Retacrit use in surgery patients are nausea, vomiting, pruritus, headache, injection site pain, chills, deep vein thrombosis, cough, and hypertension.

- The recommended dosages of Retacrit are as follows:

Indication	Dose
Patients with CKD*	Initial dose: 50 to 100 units/kg SC or IV 3 times weekly (adults) and 50 units/kg SC or IV 3 times weekly (pediatric patients)
Patients on zidovudine	100 units/kg IV or SC 3 times weekly
Patients with Cancer on Chemotherapy	40,000 units SC weekly or 150 units/kg SC 3 times weekly (adults); 600 units/kg IV weekly (pediatric patients > 5 years)
Surgery Patients	300 units/kg SC per day daily for 15 days or 600 units/kg SC weekly

* Individualize the maintenance dose. IV route recommended for patients on hemodialysis.

- Hospira/Pfizer's launch plans for Retacrit are pending. Analysts estimate that Retacrit will be launched in the near term. Retacrit will be available as 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, and 40,000 units/mL in single-dose vials.

    — Vifor will be marketing Retacrit to the dialysis market.