The first FDA-approved biosimilar to Epogen®/Procrit® (epoetin alfa)[1-3*†]

RETACRIT® (epoetin alfa-epbx) product and reimbursement information for your practice

RETACRIT Injection, Solution for Intravenous or Subcutaneous Use

Ordering RETACRIT – What You Need to Know[2,4]

Strength	2,000 Units/mL	3,000 Units/mL	4,000 Units/mL	10,000 Units/mL	40,000 Units/mL	20,000 Units/mL	20,000 Units/2 mL
Unit of Sale NDC	0069-1305-10	0069-1306-10	0069-1307-10	0069-1308-10	0069-1309-04	0069-1311-10	0069-1318-10
Unit of Sale Quantity	1 carton (10 SDVs)	1 carton (10 SDVs)	1 carton (10 SDVs)	1 carton (10 SDVs)	1 carton (4 SDVs)	1 carton (10 MDVs)	1 carton (10 MDVs)
Unit of Sale List Price‡	$220.60	$330.90	$441.20	$1,103.00	$1,764.80	$2,206.00	$2,206.00

HCPCS Code[5]	Descriptor
Q5105	Injection, epoetin alfa-epbx, biosimilar, (RETACRIT) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa-epbx, biosimilar, (RETACRIT) (for non-ESRD use), 1,000 units

MDV=multiple-dose vial; SDV=single-dose vial.

*Biosimilar means that the biological product is approved based on the data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar and the reference product.[2]

†RETACRIT does not have a designation of interchangeability with Epogen/Procrit.[2]

‡As of May 2021.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

WARNINGS: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE

CHRONIC KIDNEY DISEASE

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL**
- **No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks**
- **Use the lowest RETACRIT® dose sufficient to reduce the need for red blood cell (RBC) transfusions**

(Important Safety Information, including BOXED WARNINGS, continued on the next page.)

Please see Important Safety Information and Indications throughout and full Prescribing Information, including BOXED WARNINGS and Medication Guide, available at RetacritHCP.com.

INJECTION Retacrit® epoetin alfa-epbx Pfizer

IMPORTANT SAFETY INFORMATION AND INDICATIONS (CONTINUED)

WARNINGS: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE (CONTINUED)

CANCER

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers**
- **To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions**
- **Use ESAs only for anemia from myelosuppressive chemotherapy**
- **ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure**
- **Discontinue following the completion of a chemotherapy course**

PERISURGERY

- **Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended**

CONTRAINDICATIONS

RETACRIT® is contraindicated in patients with:

- Uncontrolled hypertension
- Pure red cell aplasia (PRCA) that begins after treatment with RETACRIT® or other erythropoietin protein drugs
- Serious allergic reactions to RETACRIT® or other epoetin alfa products

RETACRIT® from multiple-dose vials contains benzyl alcohol and is contraindicated in:

- Neonates, infants, pregnant women, and lactating women. When therapy with RETACRIT® is needed in these patient populations, use single-dose vials; do not admix with bacteriostatic saline containing benzyl alcohol

INCREASED MORTALITY, MYOCARDIAL INFARCTION, STROKE, AND THROMBOEMBOLISM

- In controlled clinical trials of patients with chronic kidney disease (CKD) comparing higher hemoglobin targets (13 - 14 g/dL) to lower targets (9 - 11.3 g/dL), epoetin alfa increased the risk of death, myocardial infarction, stroke, congestive heart failure, thrombosis of hemodialysis vascular access, and other thromboembolic events in the higher target groups
- Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with coexistent cardiovascular disease and stroke. Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of greater than 1 g/dL over 2 weeks may contribute to these risks
- In controlled clinical trials of patients with cancer, epoetin alfa increased the risks for death and serious adverse cardiovascular reactions. These adverse reactions included myocardial infarction and stroke
- In controlled clinical trials, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and the risk of deep venous thrombosis (DVT) in patients undergoing orthopedic procedures

INCREASED MORTALITY AND/OR INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE IN PATIENTS WITH CANCER

- ESAs resulted in decreased locoregional control/progression-free survival (PFS) and/or overall survival (OS). Adverse effects on PFS and/or OS were observed in studies of patients receiving chemotherapy for breast cancer, lymphoid malignancy, and cervical cancer; in patients with advanced head and neck cancer receiving radiation therapy; and in patients with non-small cell lung cancer or various malignancies who were not receiving chemotherapy or radiotherapy

HYPERTENSION

- RETACRIT® is contraindicated in patients with uncontrolled hypertension. Following initiation and titration of epoetin alfa, approximately 25% of patients on dialysis required initiation of or increases in antihypertensive therapy; hypertensive encephalopathy and seizures have been reported in patients with CKD receiving RETACRIT®
- Appropriately control hypertension prior to initiation of and during treatment with RETACRIT®. Reduce or withhold RETACRIT® if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions

SEIZURES

- Epoetin alfa products, including RETACRIT®, increase the risk of seizures in patients with CKD. During the first several months following initiation of RETACRIT®, monitor patients closely for premonitory neurologic symptoms. Advise patients to contact their healthcare practitioner for new-onset seizures, premonitory symptoms or change in seizure frequency

LACK OR LOSS OF HEMOGLOBIN RESPONSE TO RETACRIT®

- For lack or loss of hemoglobin response to RETACRIT®, initiate a search for causative factors (eg, iron deficiency, infection, inflammation, bleeding). If typical causes of lack or loss of hemoglobin response are excluded, evaluate for PRCA. In the absence of PRCA, follow dosing recommendations for management of patients with an insufficient hemoglobin response to RETACRIT® therapy

PURE RED CELL APLASIA

- Cases of PRCA and of severe anemia, with or without other cytopenias that arise following the development of neutralizing antibodies to erythropoietin have been reported in patients treated with epoetin alfa. This has been reported predominantly in patients with CKD receiving ESAs by subcutaneous administration. PRCA has also been reported in patients receiving ESAs for anemia related to hepatitis C treatment (an indication for which RETACRIT® is not approved)
- If severe anemia and low reticulocyte count develop during treatment with RETACRIT®, withhold RETACRIT® and evaluate patients for neutralizing antibodies to erythropoietin. **Contact Pfizer Inc. at 1-800-438-1985 to perform assays for binding**

(CONTINUED ON NEXT PAGE)

IMPORTANT SAFETY INFORMATION AND INDICATIONS (CONTINUED)

PURE RED CELL APLASIA (CONTINUED)

and neutralizing antibodies. Permanently discontinue RETACRIT® in patients who develop PRCA following treatment with RETACRIT® or other erythropoietin protein drugs. Do not switch patients to other ESAs

SERIOUS ALLERGIC REACTIONS

- Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur with epoetin alfa products. Immediately and permanently discontinue RETACRIT® and administer appropriate therapy if a serious allergic or anaphylactic reaction occurs

SEVERE CUTANEOUS REACTIONS

- Blistering and skin exfoliation reactions, including erythema multiforme and Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN), have been reported in patients treated with ESAs (including epoetin alfa) in the postmarketing setting. Discontinue RETACRIT® therapy immediately if a severe cutaneous reaction, such as SJS/TEN, is suspected

RISK OF SERIOUS ADVERSE REACTIONS DUE TO BENZYL ALCOHOL PRESERVATIVE

- RETACRIT® from multiple-dose vials contains benzyl alcohol and is contraindicated for use in neonates, infants, pregnant women, and lactating women. In addition, do not mix RETACRIT® with bacteriostatic saline (which also contains benzyl alcohol) when administering RETACRIT® to these patient populations
- Serious and fatal reactions including "gasping syndrome" can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including RETACRIT® multiple-dose vials. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. There is a potential for similar risks to fetuses and infants exposed to benzyl alcohol in utero or in breastfed milk, respectively. RETACRIT® multiple-dose vials contain 8.5 mg of benzyl alcohol per mL. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known

RISK IN PATIENTS WITH PHENYLKETONURIA

- Phenylalanine can be harmful to patients with phenylketonuria (PKU). RETACRIT® single-dose vials contain phenylalanine, a component of aspartame. Each 1 mL single-dose vial of 2,000, 3,000, 4,000, 10,000, and 40,000 Units of epoetin alfa-epbx injection contains 0.5 mg of phenylalanine. Before prescribing RETACRIT® single-dose vials to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including RETACRIT®

DIALYSIS MANAGEMENT

- Patients may require adjustments in their dialysis prescriptions after initiation of RETACRIT®. Patients receiving RETACRIT® may require increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis

ANEMIA IN PATIENTS WITH CHRONIC KIDNEY DISEASE

- Adverse reactions in ≥5% of epoetin alfa-treated patients on dialysis were hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion and upper respiratory tract infection

ANEMIA DUE TO CHEMOTHERAPY IN PATIENTS WITH CANCER

- Adverse reactions in ≥5% of epoetin alfa-treated patients in clinical studies were nausea, vomiting, myalgia, arthralgia, stomatitis, cough, weight decrease, leukopenia, bone pain, rash, hyperglycemia, insomnia, headache, depression, dysphagia, hypokalemia, and thrombosis

SURGERY/PERISURGERY

- Adverse reactions in ≥5% of epoetin alfa-treated patients in clinical studies were nausea, vomiting, pruritus, headache, injection site pain, chills, deep vein thrombosis, cough, and hypertension

ANEMIA DUE TO ZIDOVUDINE IN PATIENTS WITH HIV INFECTION

- Adverse reactions in ≥5% of epoetin alfa-treated patients in clinical studies were pyrexia, cough, rash, and injection site irritation

INDICATIONS

ANEMIA DUE TO CHRONIC KIDNEY DISEASE

RETACRIT® is indicated for the treatment of anemia due to CKD, including patients on dialysis and not on dialysis, to decrease the need for RBC transfusion.

ANEMIA DUE TO ZIDOVUDINE IN PATIENTS WITH HIV INFECTION

RETACRIT® is indicated for the treatment of anemia due to zidovudine administered at ≤4,200 mg/week in patients with HIV infection with endogenous serum erythropoietin levels of ≤500 mUnits/mL.

ANEMIA DUE TO CHEMOTHERAPY IN PATIENTS WITH CANCER

RETACRIT® is indicated for the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

REDUCTION OF ALLOGENEIC RED BLOOD CELL TRANSFUSIONS IN PATIENTS UNDERGOING ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY

RETACRIT® is indicated to reduce the need for allogeneic RBC 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. RETACRIT® is not indicated for patients who are willing to donate autologous blood preoperatively.

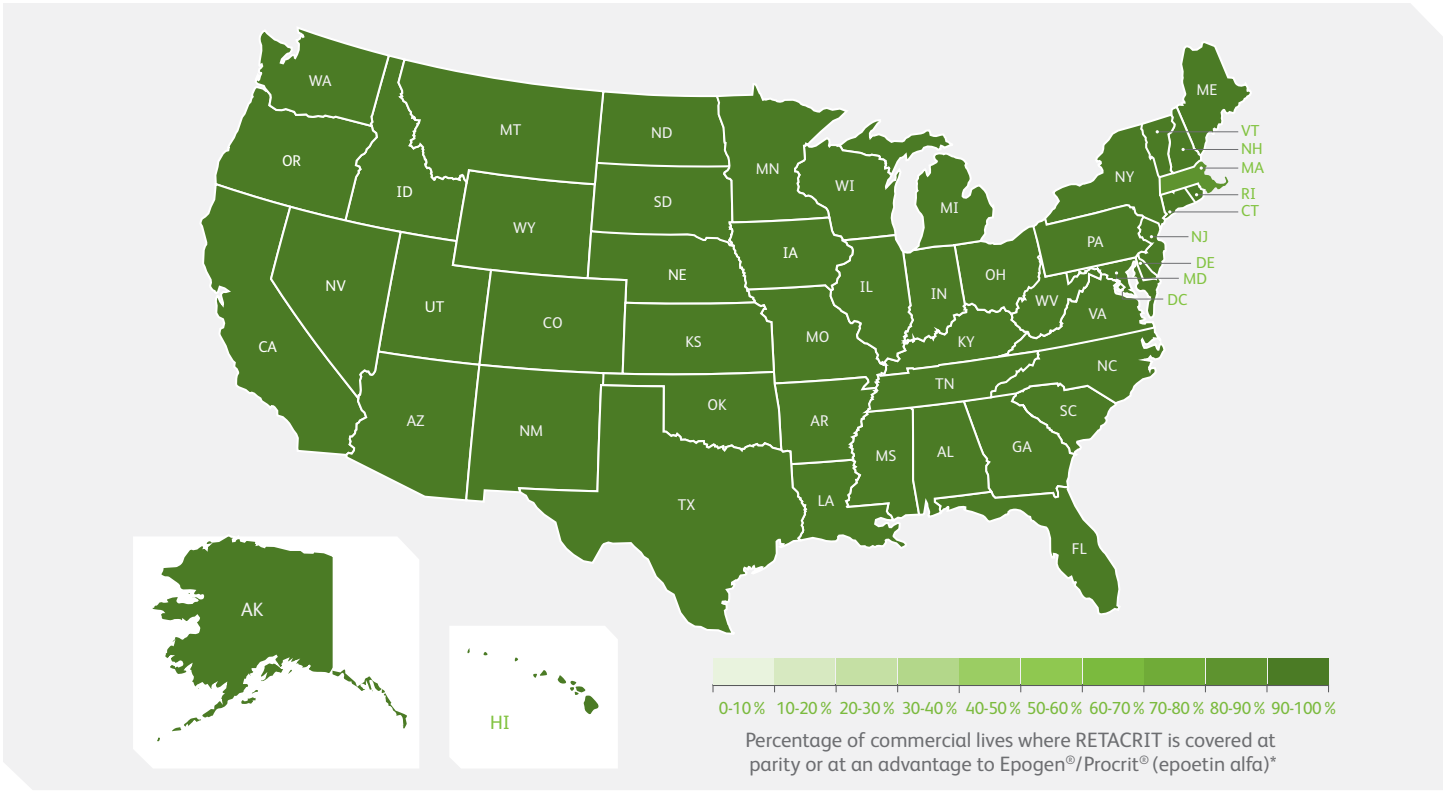
Limitations of Use

RETACRIT® has not been shown to improve quality of life, fatigue, or patient well-being.

RETACRIT® is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure
- In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion
- In patients scheduled for surgery who are willing to donate autologous blood
- In patients undergoing cardiac or vascular surgery
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

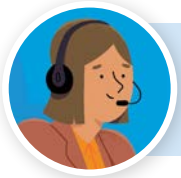
RETACRIT Payer Coverage Nationwide[4]



96%
of Medicare lives covered, including managed Medicare[4†]

99%
of commercially insured patients have access to RETACRIT nationwide[4†]

*As of September 2021.
†The information provided in this communication is not a guarantee of coverage or payment (partial or full). Actual benefits are determined by each plan administrator with its respective policy and procedures. Nothing herein may be construed as an endorsement, approval, recommendation, or warranty of any kind by any plan or insurer.



FOR LIVE, PERSONALIZED SUPPORT
Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

VISIT
PfizerOncologyTogether.com

References: 1. FDA approves first epoetin alfa biosimilar for the treatment of anemia [press release]. US Food and Drug Administration; May 15, 2018. **2.** RETACRIT [prescribing information]. New York, NY: Pfizer Inc.; August 2020. **3.** McGowan S, Jesse M, Biehn B. U.S. Biosimilar Report. AmerisourceBergen. September 17, 2021. Accessed October 6, 2021. https://amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-092321-v5.pdf. **4.** Data on file. Pfizer Inc.; New York, NY. **5.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File.

Please see Important Safety Information and Indications throughout and full Prescribing Information, including BOXED WARNINGS and Medication Guide, available at RetacritHCP.com.

