

Pfizer Oncology together™

INJECTION  
**Retacrit™**  
epoetin alfa-epbx  
Pfizer Oncology

## RETACRIT™ Billing and Coding Guide



Please see Important Safety Information and Indications on pages 14-16, and full Prescribing Information, including BOXED WARNING and Medication Guide, available at [RetacritHCP.com](https://www.RetacritHCP.com).

RETACRIT is a trademark of Pfizer Inc.

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## Introduction

Pfizer Inc. has developed this reference guide to assist healthcare providers (HCPs) with understanding coding for RETACRIT (epoetin alfa-epbx), an epoetin alfa biosimilar approved for use in the United States, for intravenous or subcutaneous use.

**The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for RETACRIT. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for RETACRIT.**

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## Making your patients' support needs a priority. Together.

At Pfizer Oncology Together, patient support is at the core of everything we do. We've gathered resources and developed tools to help patients and their loved ones throughout RETACRIT treatment. From helping to identify financial assistance options to connecting patients to resources for emotional support, your patients' needs are our priority.\*



### Benefits Verification

We can help determine a patient's coverage and out-of-pocket costs.

### Prior Authorization (PA) Assistance

We can coordinate with a patient's insurer to determine the PA requirements. After a PA request is submitted, we can follow up with the payer until a final outcome is determined.

### Appeals Assistance

We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

### Billing and Coding Assistance for Injectable Products

For your patient claim submissions, we provide easy access to sample forms and template letters, along with billing and coding information for physician office and hospital outpatient settings of care.

### Patient Financial Assistance

We can help patients understand their benefits and connect them with financial assistance resources.



**FOR LIVE, PERSONALIZED SUPPORT**

Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

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\*Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

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## Coding Overview

In the physician office, hospital outpatient department, and dialysis sites of care, Medicare Administrative Contractors (MACs), private commercial payers, and Medicaid may recognize the following codes for reporting RETACRIT on claim forms. RETACRIT will be covered under the End-Stage Renal Disease (ESRD) Prospective Payment System for utilization in the dialysis setting.

## Coding for RETACRIT

The Centers for Medicare & Medicaid Services (CMS) assigned RETACRIT product-specific Healthcare Common Procedure Coding System (HCPCS) codes to identify ESRD and non-ESRD utilization of RETACRIT. The HCPCS code used to report RETACRIT is different for ESRD and non-ESRD use. HCPs may use the following HCPCS codes for all payers in all settings of care.<sup>1</sup>

| HCPCS Code <sup>1</sup> | Descriptor   |
|-------------------------|--|
| <b>Q5105</b>            | Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), <b>100</b> units |
| <b>Q5106</b>            | Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), <b>1,000</b> units   |

Modifiers may be included on ESRD and non-ESRD claims to provide additional information. The JW modifier is used to report the amount of the drug that is unused after administration to a patient. For Medicare and some payers, the unused amount should be reported on a separate line of the claim form, and the claim should include the drug code, modifier, and number of units discarded.<sup>2</sup> When reporting the administration of erythropoiesis-stimulating agents (ESAs) on non-ESRD claims, Medicare and some payers may require modifier EA, EB, or EC to specify anemia.<sup>3</sup> Modifier ED or EE and GS may be used to describe hematocrit levels.<sup>4</sup> For ESRD claims, some payers may require modifiers JA or JB to be reported, indicating the route of administration.<sup>5</sup> Additional modifiers may also be considered appropriate when submitting claims.

| HCPCS Modifier <sup>1</sup> | Descriptor   |
|-----------------------------|--|
| <b>JW</b>                   | Drug amount discarded/not administered to any patient  |
| <b>EA</b>                   | ESA administered to treat anemia due to chemotherapy   |
| <b>EB</b>                   | ESA administered to treat anemia due to radiotherapy   |
| <b>EC</b>                   | ESA administered to treat anemia not due to radiotherapy or chemotherapy   |
| <b>ED</b>                   | Hematocrit level has exceeded 39% (or hemoglobin level has exceeded 13.0 G/dL) for 3 or more consecutive billing cycles immediately prior to and including the current cycle         |
| <b>EE</b>                   | Hematocrit level has not exceeded 39% (or hemoglobin level has not exceeded 13.0 G/dL) for 3 or more consecutive billing cycles immediately prior to and including the current cycle |
| <b>EJ</b>                   | Subsequent claims for a defined course of therapy, e.g., EPO, sodium hyaluronate, infliximab   |
| <b>GS</b>                   | Dosage of erythropoietin stimulating agent has been reduced and maintained in response to hematocrit or hemoglobin level   |
| <b>JA</b>                   | Administered intravenously   |
| <b>JB</b>                   | Administered subcutaneously  |

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## RETACRIT National Drug Codes for Pfizer

National Drug Codes (NDCs) are unique 10-digit, 3-segment numbers used to identify drugs.<sup>6</sup>

| Strength <sup>7</sup> | Vial Size             | 10-Digit NDC |
|-----------------------|-----------------------|--------------|
| 2,000 Units/mL        | 1 mL single-dose vial | 0069-1305-01 |
| 3,000 Units/mL        | 1 mL single-dose vial | 0069-1306-01 |
| 4,000 Units/mL        | 1 mL single-dose vial | 0069-1307-01 |
| 10,000 Units/mL       | 1 mL single-dose vial | 0069-1308-01 |
| 40,000 Units/mL       | 1 mL single-dose vial | 0069-1309-01 |

### NDC Conversion Example

For reimbursement purposes, some payers may require the HCP to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a “0” (zero) where appropriate to create a 5-4-2 configuration. The zero is added in front of the first segment of numbers when the 10-digit format is the 4-4-2 configuration. See placement of the red zero in the example below.

| Strength       | Vial Size             | 10-Digit NDC | 11-Digit NDC          |
|----------------|-----------------------|--------------|-----------------------|
| 2,000 Units/mL | 1 mL single-dose vial | 0069-1305-01 | <u>0</u> 0069-1305-01 |

Please see [Important Safety Information](#) and [Indications](#) on pages 14-16, and [full Prescribing Information, including BOXED WARNING and Medication Guide](#), available at [RetacritHCP.com](http://RetacritHCP.com).

## Coding for RETACRIT Administration Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians.<sup>8</sup>

The following codes may be used to report the administration of RETACRIT:

| Type of Code                               | Code/Descriptor  | Relevant Sites of Service   |
|--|--|---|
| Administration:<br>CPT® codes <sup>8</sup> | <b>96372:</b> Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular  |   |
|  | <b>96374:</b> Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); IV push, single or initial substance/drug (Used for a short IV infusion lasting 15 min or less)  | Physician office, hospital outpatient department, dialysis facility |
|  | <b>96375:</b> Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential IV push of a new substance/drug (list separately in addition to code for primary procedure) (Used for a short IV infusion lasting 15 min or less) |   |

Hospital outpatient departments and dialysis facilities use revenue codes to report specific accommodations and/or ancillary charges.<sup>9</sup>

| Type of Code                | Code/Descriptor  | Relevant Sites of Service                         |
|-----------------------------|--|---|
| Revenue codes <sup>10</sup> | <b>0634:</b> Drugs requiring specific identification – EPO under 10,000 units (For RETACRIT)   | Hospital outpatient department, dialysis facility |
|                             | <b>0635:</b> Drugs requiring specific identification – EPO 10,000 units or more (For RETACRIT) |   |
|                             | <b>0636:</b> Drugs requiring specific identification – detailed coding (For RETACRIT)          | Hospital outpatient department                    |
|                             | <b>0510:</b> Clinic – general classification (For IV injection administered in the clinic)     |   |

Key: CPT – Current Procedural Terminology; IV – intravenous; EPO – erythropoietin.  
Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

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## Diagnosis Coding for RETACRIT

RETACRIT (epoetin alfa-epbx) is an FDA-approved biosimilar.

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, as appropriate, to report the patient-specific diagnosis.

RETACRIT is typically reported using a primary diagnosis code for anemia and a secondary diagnosis code for a disease indication. Payer-specific coding requirements should be verified by the HCP, including the order (eg, primary, secondary, etc) of required codes. HCPs should verify payer-specific coding requirements before submitting a claim, as these may vary by payer.

### Coding to Report Anemia and Related Conditions

ICD-10-CM codes to report anemia and related conditions may include, but are not limited to, the following codes:

| ICD-10-CM Code <sup>11</sup> | Code Descriptor  |
|------------------------------|--|
| B20                          | Human immunodeficiency virus disease ( <b>Code first human immunodeficiency virus [HIV] disease complicating pregnancy, childbirth, and the puerperium, if applicable [O98.7-]. Use additional code[s] to identify all manifestations of HIV infection</b> ) |
| D63.1*                       | Anemia in chronic kidney disease ( <b>Code first underlying chronic kidney disease [N18.-]</b> )   |
| D64.81                       | Anemia due to antineoplastic chemotherapy  |
| I12.0                        | Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end-stage renal disease ( <b>Use additional code to identify the stage of chronic kidney disease [N18.5, N18.6]</b> )   |
| N18.3                        | Chronic kidney disease, stage 3 (moderate)   |
| N18.4                        | Chronic kidney disease, stage 4 (severe)   |
| N18.5                        | Chronic kidney disease, stage 5  |
| Z21                          | Asymptomatic human immunodeficiency virus infection status ( <b>Code first human immunodeficiency virus disease complicating pregnancy, childbirth, and the puerperium, if applicable [O98.7-]</b> )   |

Key: ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification.

\*Only to be billed by a nephrologist.<sup>12</sup>

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## RETACRIT Billing Units

### ESRD

The RETACRIT HCPCS code Q5105 is described as “Injection, epoetin alfa, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units.” Each dose increment of 100 Units equals 1 billing unit. For example, a 2,000 Units/mL vial of RETACRIT represents 20 billing units of Q5105. See the chart below correlating a vial of RETACRIT administered with the number of billing units based on the description of Q5105.

| <b>Strength</b> | <b>Vial Size</b>      | <b>Number of Q5105 Billing Units (100 Units epoetin alfa-epbx biosimilar per 1 billing unit)<br/>Equivalent to the Units of RETACRIT in Each Vial</b> |
|-----------------|-----------------------|---|
| 2,000 Units/mL  | 1 mL single-dose vial | 20 units  |
| 3,000 Units/mL  | 1 mL single-dose vial | 30 units  |
| 4,000 Units/mL  | 1 mL single-dose vial | 40 units  |
| 10,000 Units/mL | 1 mL single-dose vial | 100 units   |
| 40,000 Units/mL | 1 mL single-dose vial | 400 units   |

### Non-ESRD

The RETACRIT HCPCS code Q5106 is described as “Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD on dialysis) 1,000 Units.” Each dose increment of 1,000 Units equals 1 billing unit. For example, a 2,000 Units/mL vial of RETACRIT represents 2 billing units of Q5106. See the chart below correlating a vial of RETACRIT administered with the number of billing units based on the description of Q5106.

| <b>Strength</b> | <b>Vial Size</b>      | <b>Number of Q5106 Billing Units (1,000 Units epoetin alfa-epbx biosimilar per 1 billing unit)<br/>Equivalent to the Units of RETACRIT in Each Vial</b> |
|-----------------|-----------------------|---|
| 2,000 Units/mL  | 1 mL single-dose vial | 2 units   |
| 3,000 Units/mL  | 1 mL single-dose vial | 3 units   |
| 4,000 Units/mL  | 1 mL single-dose vial | 4 units   |
| 10,000 Units/mL | 1 mL single-dose vial | 10 units  |
| 40,000 Units/mL | 1 mL single-dose vial | 40 units  |

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## Claims Submission Checklist

The following may be considered to assist with submitting claims completely and accurately, which is important for timely claims processing, for appropriate payment, and to avoid denied claims.



- ✓ Provide the patient name, address, and insurance identification number, and review these for accuracy
- ✓ Include the HCP's name, National Provider Identifier (NPI), and payer-specific provider ID (if applicable)
- ✓ Indicate the appropriate place of service code (2-digit code) for where the treatment was provided
- ✓ Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers (if applicable) are consistent with information included in the patient's medical record
- ✓ Review the RETACRIT-specific information (eg, name of drug, HCPCS code, NDC, number of units, route and frequency of administration)

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# Sample Claim Form: CMS-1500, Physician Office Setting (Non-ESRD)

**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare)  MEDICAID (Medicaid)  TRICARE (TRICARE)  CHAMPVA (Member ID#)  GROUP HEALTH PLAN (ID#)  FECA BLK (LUNG) (ID#)  OTHER (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM/DD/YY) SEX (M/F)

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other)

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. OTHER INSURED'S POLICY OR GROUP NUMBER

13. EMPLOYMENT? (Current or Previous) YES/NO

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) (MM/DD/YY)

15. OTHER QUALIFYING DATE (MM/DD/YY)

16. CURRENT OCCUPATION (MM/DD/YY)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM/TO)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES/NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E))

22. ICD-10-CM CODE (A. Q5106, B., C., D., E., F., G., H., I., J., K., L.)

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From/To) B. PLACE OF SERVICE C. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS) D. MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. UNITS H. ICD-10-CM I. ID. QUAL. J. RENDERING PROVIDER ID. #

25. PT ASSIGNMENT? YES/NO

26. TOTAL CHARGE \$

27. AMOUNT PAID \$

28. BILLING PROVIDER INFO & PH #

**Item 21:** Specify appropriate ICD-10-CM diagnosis code(s)

**Item 19:** If additional information is required to describe RETACRIT (eg, NDC), this information may be captured in Item 19

**Item 21:** Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM)

**Item 24G:** Specify the billing units. For example, 1 billing unit = 1,000 Units of epoetin alfa-epbx biosimilar (RETACRIT) for HCPCS code Q5106. To bill 2,000 Units of RETACRIT, enter 2 billing units. To bill 1 96xxx for drug administration, enter 1 billing unit

**Item 24D:** Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5106 for RETACRIT
- Administration: 96xxx for administration

**Item 24E:** Enter reference to the diagnosis for the CPT and HCPCS codes from Item 21

Please see **Important Safety Information and Indications** on pages 14-16, and **full Prescribing Information, including BOXED WARNING and Medication Guide**, available at [RetacritHCP.com](http://RetacritHCP.com).

# Sample Claim Form: UB-04, Hospital Outpatient Setting (Non-ESRD)

This sample form is intended as a reference for the coding and billing of RETACRIT. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

**Form Locator (FL) 44:** Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5106 for RETACRIT
- Administration: 96xxx for drug administration

**FL 39-41:** Enter value code 48 with **hemoglobin** level reading or value code 49 with **hematocrit** level reading

**FL 46:** Specify the billing units. For example, 1 billing unit = **1,000** Units of epoetin alfa-epbx biosimilar (RETACRIT) for HCPCS code Q5106. To bill 2,000 Units of RETACRIT, enter 2 billing units. To bill 1 96xxx for drug administration, enter 1 billing unit

**FL 42 and 43:** Specify revenue codes and describe procedure; for example:

- 0636: Drugs requiring specific identification – detailed coding (For RETACRIT)
- 0510: Clinic – general classification (For IV injection administered in hospital-based dialysis clinics)

**Note:** Other revenue codes may apply

**FL 67:** Specify appropriate ICD-10-CM diagnosis code(s)

**FL 66:** Identify the type of ICD diagnosis code used (eg, enter a “0” for ICD-10-CM)

Please see **Important Safety Information and Indications** on pages 14-16, and **full Prescribing Information, including BOXED WARNING and Medication Guide**, available at [RetacritHCP.com](http://RetacritHCP.com).

## Sample Claim Form: UB-04, Dialysis Provider for Use in Dialysis (ESRD)

This sample form is intended as a reference for the coding and billing of RETACRIT. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

**FL 44:** Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5105 for RETACRIT
- Administration: 96xxx for drug administration

**FL 39-41:** Enter value code 48 with **hemoglobin** level reading or value code 49 with **hematocrit** level reading

**FL 46:** Specify the billing units. For example, 1 billing unit = **100** Units of epoetin alfa-epbx biosimilar (RETACRIT) for HCPCS code Q5105. To bill 2,000 Units of RETACRIT, enter 20 billing units. To bill 1 96xxx for drug administration, enter 1 billing unit

**FL 42 and 43:** Specify revenue codes and describe procedures, for example:

- 0634: Drugs requiring specific identification – EPO under 10,000 units (For RETACRIT), or
- 0635: Drugs requiring specific identification – EPO 10,000 units or more (For RETACRIT)
- 0510: Clinic – general classification (For IV injection administered in hospital-based dialysis clinics)

**Note:** Other revenue codes may apply

**FL 67:** Specify appropriate ICD-10-CM diagnosis code(s)

**FL 66:** Identify the type of ICD diagnosis code used (eg, enter a “0” for ICD-10-CM)

Please see **Important Safety Information and Indications** on pages 14-16, and **full Prescribing Information, including BOXED WARNING and Medication Guide**, available at [RetacritHCP.com](http://RetacritHCP.com).

## References

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## IMPORTANT SAFETY INFORMATION

### 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.

#### 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.

Please see **full Prescribing Information, including BOXED WARNING and Medication Guide, available at [RetacritHCP.com](http://RetacritHCP.com).**

#### INCREASED MORTALITY, MYOCARDIAL INFARCTION, STROKE, AND THROMBOEMBOLISM

- In controlled clinical trials of patients with 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™.

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## IMPORTANT SAFETY INFORMATION (Continued)

- 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 (e.g., 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 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 IN PATIENTS WITH PHENYLKETONURIA

- Phenylalanine can be harmful to patients with phenylketonuria (PKU). RETACRIT™ contains 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™ 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.

Please see **full Prescribing Information, including BOXED WARNING and Medication Guide, available at [RetacritHCP.com](http://RetacritHCP.com).**

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## IMPORTANT SAFETY INFORMATION (Continued)

### SURGERY/PERISURGERY

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

## INDICATIONS AND LIMITATIONS OF USE

### ANEMIA DUE TO CHRONIC KIDNEY DISEASE

RETACRIT™ is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis, to decrease the need for red blood cell (RBC) transfusion.

### ANEMIA DUE TO ZIDOVUDINE IN PATIENTS WITH HIV-INFECTION

RETACRIT™ is indicated for the treatment of anemia due to zidovudine administered at  $\leq 4,200$  mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of  $\leq 500$  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  $\leq 13$  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.

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.

Please see **full Prescribing Information, including BOXED WARNING and Medication Guide, available at [RetacritHCP.com](http://RetacritHCP.com).**

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