Pfizer Oncology together™

INJECTION
Retacrit®
epoetin alfa-epbx
Pfizer Oncology

RETACRIT® (epoetin alfa-epbx) Billing and Coding Guide

Please see Important Safety Information and Indications on pages 14-16 and full Prescribing Information, including BOXED WARNINGS and Medication Guide, at RetacritHCP.com.

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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 notice. The HCP 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

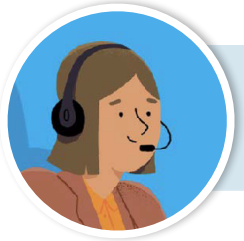
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

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)

VISIT
PfizerOncologyTogether.com

*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.[1]

HCPCS Code[1]	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

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.[2] 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.[3] Modifier ED or EE and GS may be used to describe hematocrit levels.[4] For ESRD claims, some payers may require modifier JA or JB to be reported, indicating the route of administration.[5] Additional modifiers may also be considered appropriate when submitting claims.

HCPCS Modifier[1]	Descriptor
JW	Drug amount discarded/not administered to any patient
EA	ESA administered to treat anemia due to chemotherapy
EB	ESA administered to treat anemia due to radiotherapy
EC	ESA administered to treat anemia not due to radiotherapy or chemotherapy
ED	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
EE	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
EJ	Subsequent claims for a defined course of therapy, e.g., EPO, sodium hyaluronate, infliximab
GS	Dosage of erythropoietin stimulating agent has been reduced and maintained in response to hematocrit or hemoglobin level
JA	Administered intravenously
JB	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.[6]

Strength[7]	*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
20,000 Units/mL	1 mL multiple-dose vial	0069-1311-01
20,000 Units/2 mL	2 mL multiple-dose vial	0069-1318-01

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	00069-1305-01

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Coding for RETACRIT Administration Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians.[8]

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

Type of Code	Code/Descriptor	Relevant Sites of Service
Administration: CPT® codes[8]	**96372:** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Physician office, hospital outpatient department, dialysis facility
	96374: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous (IV) push, single or initial substance/drug	
	96375: 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)	

Hospital outpatient departments and dialysis facilities use revenue codes to report specific accommodations and/or ancillary charges.[9]

Type of Code	Code/Descriptor	Relevant Sites of Service
Revenue codes[10]	**0634:** Drugs requiring specific identification – EPO under 10,000 units	Hospital outpatient department, dialysis facility
	0635: Drugs requiring specific identification – EPO 10,000 units or more	
	0636: Drugs requiring specific identification – detailed coding	Hospital outpatient department
	0500: Outpatient services – general classification	
	0510: Clinic – general classification	

Key: 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[11]	*Code Descriptor*
B20	Human immunodeficiency virus disease **(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)**
D63.1*	Anemia in chronic kidney disease **(Code first underlying chronic kidney disease [N18.-])**
D64.81	Anemia due to antineoplastic chemotherapy
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end-stage renal disease **(Use additional code to identify the stage of chronic kidney disease [N18.5, N18.6])**
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
Z21	Asymptomatic human immunodeficiency virus infection status **(Code first human immunodeficiency virus disease complicating pregnancy, childbirth, and the puerperium, if applicable [O98.7-])**

*Only to be billed by a nephrologist.[12]

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RETACRIT Billing Units

ESRD

The RETACRIT HCPCS code Q5105 is described as "Injection, epoetin alfa-epbx, 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.

Strength	Vial Size	*Number of Q5105 Billing Units (100 Units epoetin alfa-epbx biosimilar per 1 billing unit) Equivalent to the Units of RETACRIT in Each Vial*
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
20,000 Units/mL	1 mL multiple-dose vial	200 units
20,000 Units/2 mL	2 mL multiple-dose vial	200 units

Non-ESRD

The RETACRIT HCPCS code Q5106 is described as "Injection, epoetin alfa-epbx, 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.

Strength	Vial Size	*Number of Q5106 Billing Units (1,000 Units epoetin alfa-epbx biosimilar per 1 billing unit) Equivalent to the Units of RETACRIT in Each Vial*
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
20,000 Units/mL	1 mL multiple-dose vial	20 units
20,000 Units/2 mL	2 mL multiple-dose vial	20 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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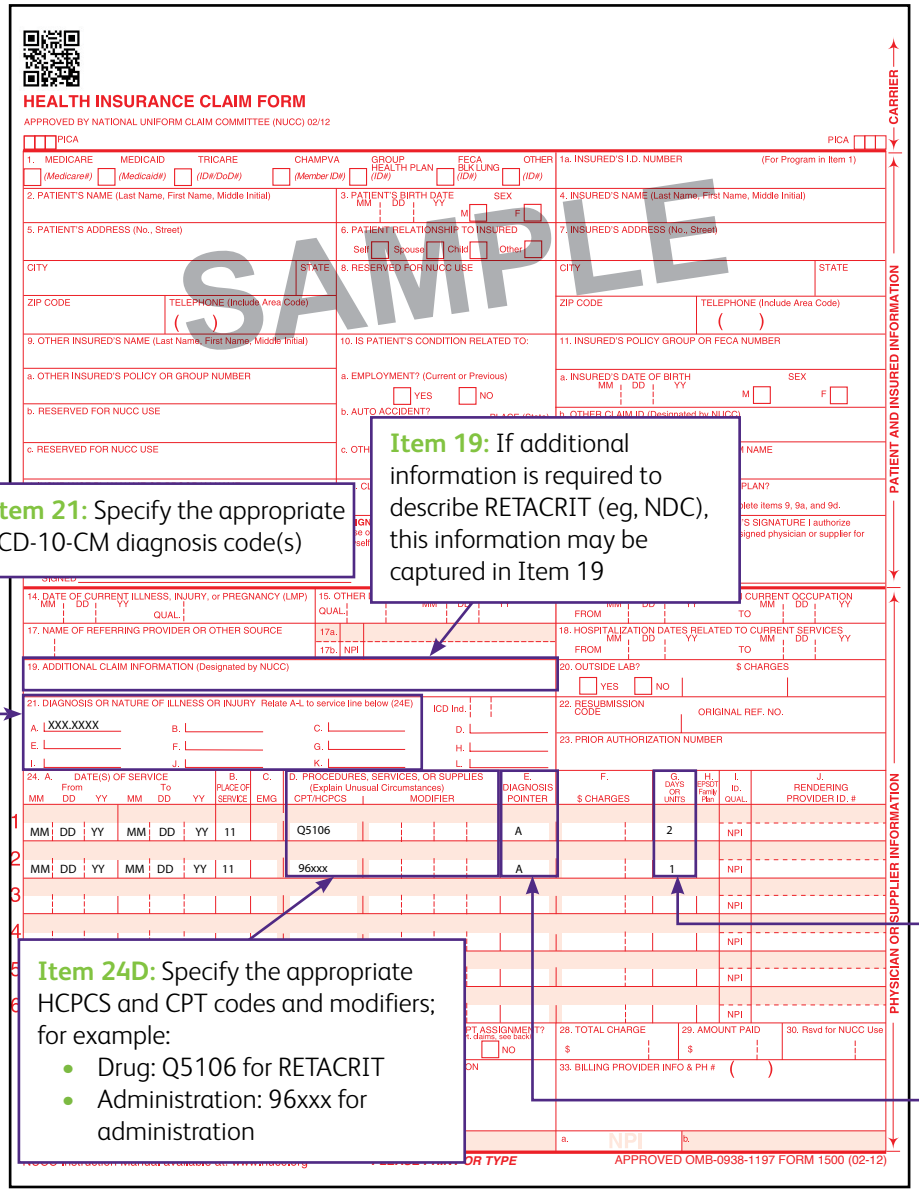
Sample Claim Form: CMS-1500, Physician Office Setting (Non-ESRD)



Item 21: Specify the 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 24D: Specify the appropriate HCPCS and CPT codes and modifiers; for example:

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

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

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.

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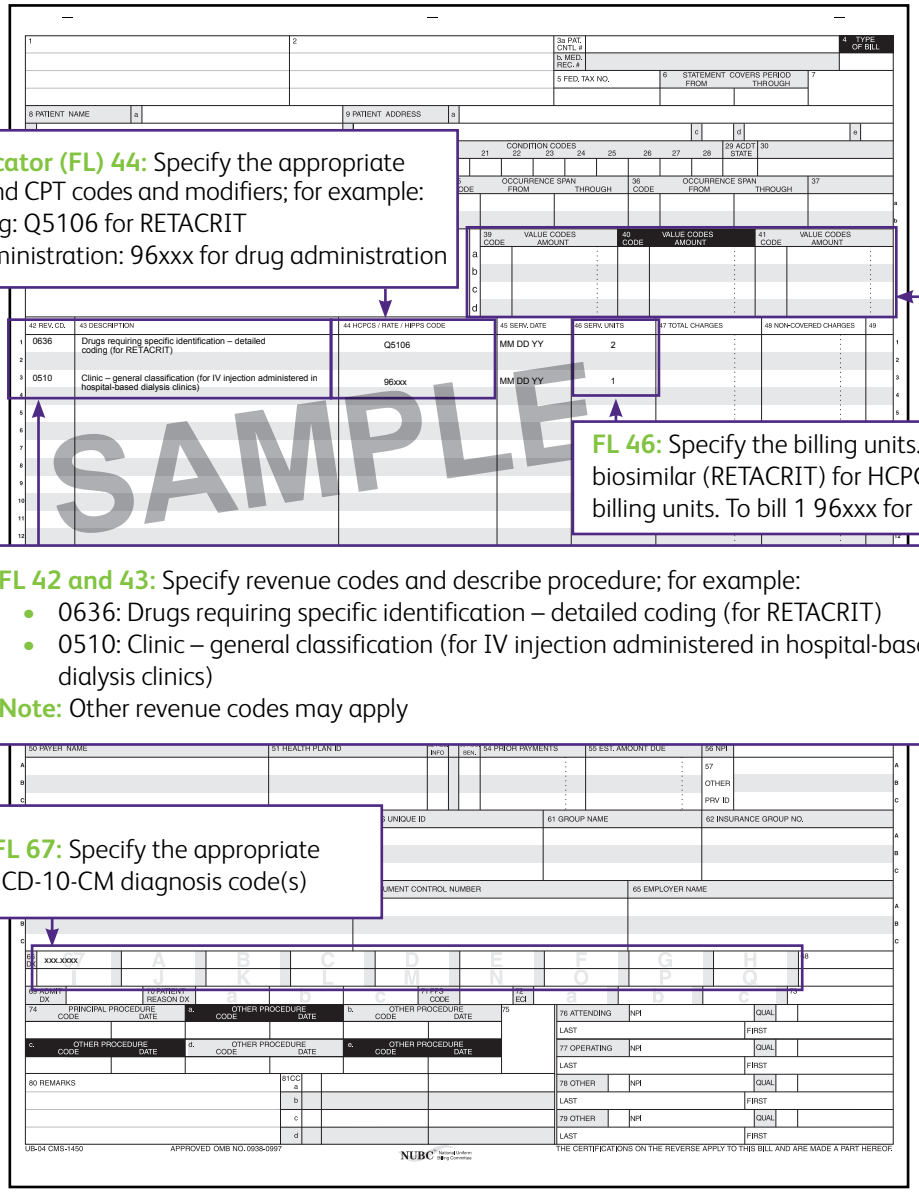
Sample Claim Form: UB-04, Hospital Outpatient Setting (Non-ESRD)



Form Locator (FL) 44: Specify the 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 the appropriate ICD-10-CM diagnosis code(s)

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.

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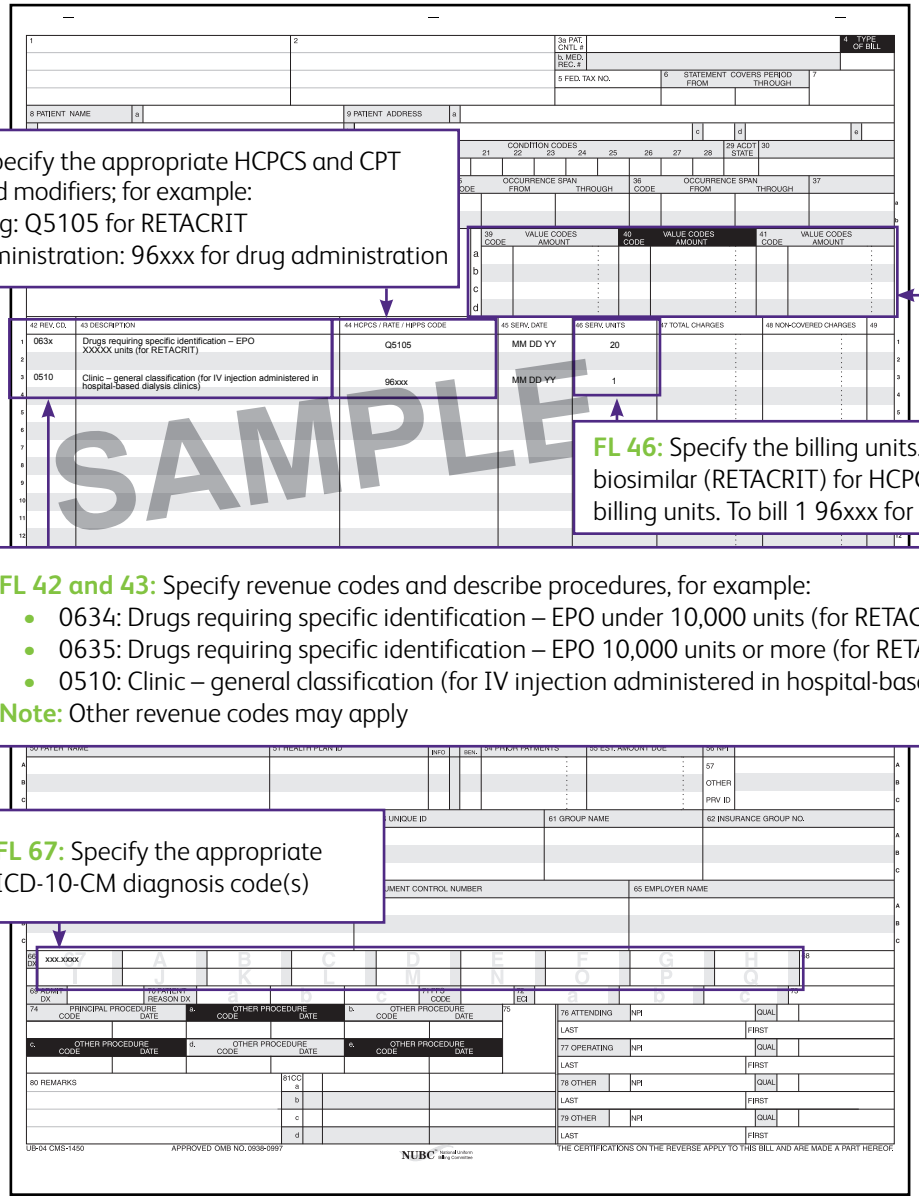
Sample Claim Form: UB-04, Dialysis Provider for Use in Dialysis (ESRD)



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

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

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 the appropriate ICD-10-CM diagnosis code(s)

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 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

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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

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

Continued on the next page

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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 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®

Continued on the next page

Please see full Prescribing Information, including BOXED WARNINGS and Medication Guide, at RetacritHCP.com.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

Please see full Prescribing Information, including BOXED WARNINGS and Medication Guide, at RetacritHCP.com.

INJECTION Retacrit® epoetin alfa-epbx

Pfizer Oncology

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