Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Erythropoiesis Stimulating Agents (ESAs)

CG-DRUG-05

Override(s)	Approval Duration
Prior Authorization	Initial therapy: 2 months (8 weeks)*** Continued therapy: 2 months (8 weeks)*** ***Requests will NOT be approved for longer than 2 months (8 weeks) at a time.

Medications
Procrit (epoetin alfa)
Epogen (epoetin alfa)
Retacrit (epoetin alfa-epbx)

APPROVAL CRITERIA

Requests for Procrit (epoetin alfa), Epogen (epoetin alfa), or Retacrit (epoetin alfa-epbx) may be approved when the following criteria are met:

I. The individual has a hemoglobin (Hgb) levels less than 10 g/dL, prior to initiation of therapy; **AND**
II. Prior to initiation of therapy, evaluation of the individual's iron status reveals:
   A. Transferrin saturation is at least 20%; **or**
   B. Ferritin is at least 80 ng/mL; **or**
   C. Bone marrow demonstrates adequate iron stores; **AND**
III. For individuals with hypertension, blood pressure is adequately controlled before *initiation* of therapy and closely monitored and controlled during therapy; **AND**
IV. The individual meets as least one of the following:
   A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain hemoglobin levels within the range of 10 to 11 g/dL; **OR**
   B. Anemia associated with chronic kidney disease (CKD) for individuals **not** on dialysis, to achieve and maintain hemoglobin levels of 10g/dl; **OR**
   C. Cancer chemotherapy known to produce anemia (myelosuppressive) when **all** of the following are met:
      1. Chemotherapy is planned for a minimum of 2 months; **AND**
      2. The individual has a diagnosis of non-myeloid cancer and the anticipated outcome is not cure; **OR**
   D. Myelodysplastic syndrome with an endogenous erythropoietin level less than 500

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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mU/mL; **OR**

E. Zidovudine in human immunodeficiency virus (HIV)-infected individuals when the endogenous serum erythropoietin level is less than or equal to 500 mUnits/mL and when the dose of Zidovudine is less than or equal to 4200 mg/week; **OR**
F. Hepatitis C virus infection in individuals who are being concomitantly treated with the combination of ribavirin and interferon alfa, or ribavirin and peginterferon alfa; **OR**
G. Myelosuppressive drugs (for example, disease modifying anti-rheumatic drugs) known to produce anemia in individuals with a diagnosis of a chronic inflammatory disease; **OR**
H. Allogeneic Bone Marrow Transplantation.

Requests for Procrit (epoetin alfa), Epogen (epoetin alfa), or Retacrit (epoetin alfa-epbx) may also be approved when the criteria following are met:

I. Elective, non-cardiac, non-vascular surgery to reduce the need for allogeneic blood transfusion when the individual meets **all** of the following criteria:
   A. Individual's hemoglobin levels are greater than 10 to less than or equal to 13 g/dL; **AND**
   B. Individual is at high risk for perioperative transfusions with significant, anticipated blood loss; **AND**
   C. Individual is unable or unwilling to donate autologous blood; **AND**
   D. Antithrombotic prophylaxis has been considered; **AND**
   E. Prior to initiation of therapy, evaluation of the individual's iron status reveals:
      i. Transferrin saturation is at least 20%; **or**
      ii. Ferritin is at least 80 ng/mL; **or**
      iii. Bone marrow demonstrates adequate iron stores; **AND**
   F. For individuals with hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy.

Continued use of epoetin alfa or epoetin alfa-epbx may only be approved beyond 8 weeks if the hemoglobin does not exceed 11 g/dL AND iron stores (including transferrin saturation and ferritin) are adequately maintained and monitored periodically during therapy;

Requests for Procrit (epoetin alfa), Epogen (epoetin alfa), or Retacrit (epoetin alfa-epbx) may **not** be approved for all of the following:

I. When above criteria are not met;
II. To treat anemia in any indication not listed above, including but not limited to anemia of prematurity;

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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III. Continued use when the hemoglobin level exceeds 11 g/dL unless otherwise specified above (except when the dose of epoetin alfa is adjusted to achieve and maintain target hemoglobin not to exceed 11 g/dL) ;
IV. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease;
V. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS) ;
VI. Use beyond 8-9 weeks in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia;
VII. To treat anemia in individuals due to other factors such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria) ;
VIII. As a treatment in the presence of sudden loss of response with severe anemia and low reticulocyte count;
IX. To treat anemia in individuals with cancer receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy;
X. To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure;
XI. To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion;
XII. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed;
XIII. Pre-operative use for individuals who are willing to donate autologous blood.

Note: Erythropoiesis-stimulating agents (ESAs) have black box warnings related to the increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence. Individuals with chronic kidney disease (CKD) are at a greater risk for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target hemoglobin (Hgb) levels greater than 11 g/dL in clinical studies. No trial has identified a target Hgb level, ESA dose, or dosing strategy that does not increase these risks. Use of ESAs in individuals with certain tumor types (i.e., breast, non-small cell lung, head and neck, lymphoid, cervical), shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies. Recommended to use the lowest ESA dose needed to avoid RBC transfusions and serious cardiovascular and thromboembolic reactions. ESAs should only be used for treatment of anemia due to concomitant myelosuppressive chemotherapy, and discontinue following the completion of a chemotherapy course. Individuals receiving myelosuppressive chemotherapy should not be treated with ESAs when the anticipated outcome is cure. Deep venous thrombosis prophylaxis should be considered when epoetin alfa is used perisurgically. Prescribers and hospitals must enroll in and comply with the

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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ESA APPRISE Oncology Program to prescribe and/or dispense epoetin alfa to individuals with cancer.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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