Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Erythropoiesis Stimulating Agents (ESAs)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	6 months

Medications	Quantity Limit
Procrit (epoetin alfa)	May be subject to quantity limit
Epogen (epoetin alfa)	
Retacrit (epoetin alfa-epbx)	

APPROVAL CRITERIA

*In addition to criteria outlined below, requests for Procrit (epoetin alfa) must also meet the following criteria:

I. Individual has had a trail and inadequate response or intolerance to Retacrit (epoetin alfa-epbx).

**Step Therapy does not apply to Florida Healthy Kids*

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

I. Individual has a baseline hemoglobin (Hgb) levels less than 10 g/dL; **AND**
II. Baseline iron status is adequate as defined by one of the following:
   A. Transferrin saturation 20% or greater; **OR**
   B. Ferritin 80 ng/mL or greater; **OR**
   C. Bone marrow demonstrates adequate iron stores;

AND

III. Individual is using for one of the following:
   A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11 g/dL; **OR**
   B. Anemia associated with CKD for individuals **not** on dialysis, to achieve and maintain Hgb levels of 10g/dL; **OR**
   C. Myelosuppressive chemotherapy when the following are met:
      1. Chemotherapy is planned for a minimum of 2 months; **AND**
      2. Individual has a diagnosis of non-myeloid cancer and the anticipated outcome is not cure; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

D. Myelodysplastic syndrome with an endogenous erythropoietin level less than 500 mU/mL (NCCN 2A); **OR**
E. HIV infection, receiving zidovudine at a dose less than or equal to 4200 mg/week, with endogenous erythropoietin level is less than or equal to 500 mU/mL.

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

I. Individual is undergoing elective, non-cardiac, non-vascular surgery and requires Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) to reduce the need for allogeneic blood transfusions; **AND**
   A. Baseline Hgb level is greater than 10 g/dL and 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. Baseline iron status is adequate as defined by one of the following:
      1. Transferrin saturation 20% or greater; **OR**
      2. Ferritin is 80 ng/mL or greater; **OR**
      3. Bone marrow demonstrates adequate iron stores.

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

I. Continued use when the Hgb level exceeds 11 g/dL unless otherwise specified for example, pediatric individuals with CKD where target Hgb levels within the range of 10 to 12 g/dL); **OR**
II. Individuals with uncontrolled hypertension;
III. Use beyond 12 weeks in the absence of response in individuals with (CKD); **OR**
IV. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS); **OR**
V. Use beyond 8 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; **OR**
VI. As treatment in the presence of sudden loss of response with severe anemia and low reticulocyte count; **OR**
VII. To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; **OR**
VIII. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed; **OR**
IX. Pre-operative use for individuals who are willing to donate autologous blood.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Note:
Erythropoiesis-stimulating agents (ESAs) have black box warnings for an increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.
For CKD: In controlled trials, individuals experienced greater risks for death, serious adverse cardiovascular reactions and stroke when ESAs were administered to target a Hgb level greater than 11 g/dL. Use the lowest dose needed to reduce the need for red blood cell (RBC) transfusions.
For Cancer: In controlled trials, ESAs shortened overall survival and/or increased the risk for tumor progression or recurrence in individuals with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy when the anticipated outcome is not cure and discontinue ESAs following completion of a chemotherapy course.
For Perisurgery: Deep venous thrombosis (DVT) prophylaxis is recommended due to increased risk for DVTs.

ESAs are contraindicated in individuals with uncontrolled hypertension. Blood pressure should be adequately controlled prior to initiation and during treatment with ESAs.

Key References:

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter*. 2012; Suppl 2: 279–335. Available from: https://www.kidney.org/professionals/guidelines/guidelines_commentaries/anemia. Accessed on: June 13, 2019.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 13, 2019.
    - Hematopoietic Growth Factors. Version 2.2019. Revised March 27, 2019.