MetroPlus Health

Policy and Procedure

Title: UM-PT016 Erythropoiesis Stimulating Agents	**Division: Medical Management Department: Pharmacy**
Approval Date: 4/28/2023	**LOB: Medicaid, HIV SNP, HARP, QHP, EP, Gold, GoldCare, CHP**
Effective Date: 4/28/2023	**Policy Number: UM-PT016**
Review Date: 11/22/2024	**Cross Reference Number:**
Retired Date:	**Page 1 of 8**

I. POLICY DESCRIPTION:

Erythropoiesis-Stimulating Agent (ESA) – Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Mircera (methoxy polyethylene glycol-epoetin beta), Procrit (epoetin alfa), Retacrit (epoetin alfa)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Aranesp, Epogen, Procrit and Retacrit are erythropopoiesis stimulating agents (ESAs) that stimulate erythropoiesis by the same mechanisms as endogenous erythropoietin by recombinant DNA technology.

Mircera is an erythropopoiesis stimulating agent that stimulates erythropoiesis by interacting with the erythropoietin receptor that is found on progenitor cells in the bone marrow.

IV. POLICY:

Epoetin alfa and darbepoetin alfa will be considered medically necessary once the following coverage criteria is met approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

Epogen and Procrit requires trial and failure of Retacrit.

INITIAL REQUEST:

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Epogen, Procrit, Retacrit, or Aranesp. Members may not use Epogen, Procrit, Retacrit, or Aranesp concomitantly with other erythropoiesis stimulating agents.

1. **Anemia Due to Chronic Kidney Disease (CKD)**
   A. Confirmation of dialysis status and clarification of dose and frequency requested;
   AND
   B. Pretreatment hemoglobin <10 g/dL;
   AND
   C. Authorization is for no more than 12 weeks

2. **Anemia in Members with Malignancy**
   A. Member's on cancer chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy;
   AND
   B. Pretreatment hemoglobin <10 g/dL;
   AND
   C. Authorization is for no more than 12 weeks

3. **Anemia due to Zidovudine in HIV-infected Patients [Epogen, Procrit, Retacrit]**
   A. Member's currently receiving zidovudine administered at ≤ 4,200 mg/week;
   AND
   B. Pretreatment hemoglobin <10 g/dL;
   AND
   C. Pretreatment endogenous serum erythropoietin levels of ≤ 500 mUnits/mL;
   AND
   D. Authorization is for no more than 12 weeks

4. **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvasvular Surgery [Epogen, Procrit, Retacrit]**
   A. Member's scheduled to have an elective, noncardiac, nonvascular surgery;
   AND
   B. Preteatment hemoglobin >10 g/dL to ≤13 g/dL;
   AND
   C. Authorization is for no more than 30 days

5. **Anemia due to Rheumatoid Arthritis [Epogen, Procrit, Retacrit]**
   A. Pretreatment hemoglobin <10 g/dL;
   AND
   B. Authorization is for no more than 12 weeks

6. **Anemia in Congestive Heart Failure [Epogen, Procrit, Retacrit]**
   A. Pretreatment hemoglobin <9 g/dL;
   AND
   B. Authorization is for no more than 12 weeks

7. **Anemia due to Hepatitis C Treatment [Epogen, Procrit, Retacrit]**
   A. Member's receiving ribavirin in combination with either interferon alfa or peginterferon alfa;
   AND
   B. Pretreatment hemoglobin <10 g/dL;
   AND

C. Authorization is for no more than 12 weeks

8. **Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions [Epogen, Procrit, Retacrit, Aranesp]**
   A. Pretreatment hemoglobin <10 g/dL;
   AND
   B. Authorization is for no more than 12 weeks

9. **Anemia in Myelodysplastic Syndromes (MIDS) [Epogen, Procrit, Retacrit, Aranesp]**
   A. Authorization is for no more than 12 weeks

10. **Anemia in Primary Myelofibrosis (MF), Post-polcythemia Vera MF, or Post-Essential Thrombocythemia MF [Epogen, Procrit, Retacrit, Aranesp]**
    A. Pretreatment hemoglobin <10 g/dL and pretreatment serum erythropoietin (EPO) level <500 mU/mL;
    AND
    B. Authorization is for no more than 12 weeks

RENEWAL REQUEST:

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Epogen, Procrit, Retacrit, or Aranesp. Members may not use Epogen, Procrit, Retacrit, or Aranesp concomitantly with other erythropoiesis stimulating agents.

For all indications below: All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of ESA treatment must show a response with a rise in hemoglobin of $\geq$ 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of $\geq$ 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

A. ALL Indications:
   A. Member's current hemoglobin is <12 g/dL;
   AND
   B. Authorization is for no more than 12 weeks

V. LIMITATIONS/ EXCLUSIONS:

Epogen, Procrit, Retacrit, and Aranesp are not indicated for:

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

Mircera is not indicated:

- For the treatment of anemia due to cancer chemotherapy
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J0881	Injection, darbepoetin alfa (non-esrd use), 1 mcg (Aranesp)
J0885	Injection, epoetin alfa (for non-esrd use), 1000 units (Epogen, Procrit)
J0887	Injection, epoetin beta, 1 microgram, (for esrd on dialysis) (Mircera)
J0888	Injection, epoetin beta, 1 microgram, (for non esrd use) (Mircera)
Q4081	Injection, epoetin alfa (for esrd on dialysis), 100 units (Epogen, Procrit)
Q5106	Injection, epoetin alfa-apbx, biosimilar (for non-esrd use), 1000 units, (Retacrit)

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
B20	Human immunodeficiency virus [HIV] disease
D55.21	Anemia due to pyruvate kinase deficiency
D55.29	Anemia due to other disorders of glycolytic enzymes
D59.10	Autoimmune hemolytic anemia, unspecified
D59.11	Warm autoimmune hemolytic anemia
D59.12	Cold autoimmune hemolytic anemia
D59.13	Mixed type autoimmune hemolytic anemia
D59.19	Other autoimmune hemolytic anemia

D59.19	Other autoimmune hemolytic anemia
D63.1	Anemia in chronic kidney disease
D64.81	Anemia due to antineoplastic chemotherapy
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecific chronic kidney disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.12	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I3.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
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 kidn Chronic kidney disease, stage 5ey disease, stage 5
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic Kidney Disease, unspecified

VIII. REFERENCES:

1. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Procrit [package insert]. Horsham, PA: Janssen Products.; April 2024.
3. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.
4. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012; Suppl 2:279-335.
6. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. *J Clin Oncol*. 2010;28(33):4996-5010.
7. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org.
8. Qaseem A, Humphrey LL, Fitterman N, Starkey M, Shekelle P, for the Clinical Guidelines Committee of the American College of Physicians. Treatment of Anemia in Patients with Heart Disease: A Clinical Practice Guideline from the American College of Physicians. *Ann Intern Med*. 2013;159:770-779.
9. Henry DH, Beall GN, Benson CA, Carey J, Cone LA, Eron LJ, et al. Recombinant Human Erythropoietin in the Treatment of Anemia Associated with Human Immunodeficiency Virus (HIV) Infection and Zidovudine Therapy: Overview of Four Clinical Trials. Ann Intern Med.; 117:739–748. doi: 10.7326/0003-4819-117-9-739.
10. Gabrilove J, Paquette R, Lyons R, Mushtaq C, Sekeres M, et al. Phase 2, single-arm trial to evaluate the effectiveness of darbepoetin alfa for correcting anemia in patients with myelodysplastic syndromes. Br J Haematol. 2008 Aug; 142(3): 379–393.
11. NCCN hematopoietic growth factors. Short-term recommendations specific to issues with COVID-19 (SARS-CoV-2). National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org/covid-19/pdf/HGF_COVID-19.pdf.
12. Mircera [package insert]. Vifor Pharma Inc; June 2024.
13. Mircera. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com.

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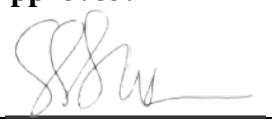
REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	JC	4/28/2023
Update	AKC	8/8/2023
Update	AKC	11/28/2023
Annual Review	AKC	11/22/2024

Approved: **Date:** 11/22/2024 Suzana Patel **Suzana Patel, PharmD** **Senior Director of Pharmacy**	**Approved:** **Date:**  04.03.26 **Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.