Drug Policy:

Erythropoiesis Stimulating Agents

POLICY NUMBER UM ONC_1138	**SUBJECT** Erythropoiesis Stimulating Agents (ESAs) and Biosimilars – Epogen, Procrit, Aranesp, Mircera and Retacrit	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 07/22/11, 09/12/12, 06/13/13, 07/10/13, 07/24/14, 06/22/16, 07/26/16, 08/24/16, 09/12/16, 03/04/17, 05/10/17, 09/13/17, 08/08/18, 07/10/19, 12/11/19, 03/11/20, 08/12/20	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 07/22/11, 09/12/12, 06/13/13, 07/10/13, 07/24/14, 06/22/16, 07/26/16, 08/24/16, 09/12/16, 03/04/17, 05/10/17, 09/13/17, 08/08/18, 07/10/19, 12/11/19, 03/11/20, 08/12/20
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Erythropoiesis Stimulating Agents (ESAs) and biosimilar- Epogen and Procrit (epoetin alfa), Aranesp (darbepoetin alfa), Mircera (epoetin beta), and Retacrit (epoetin alfa-epbx) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision.
5. When available, generic alternatives are preferred over brand-name drugs AND
6. Retacrit (epoetin alfa-epbx) is the PREFERRED medication whenever Epoetin or Darbepoetin is requested AND
7. Non-preferred ESA will be approved only if there is a contraindication/intolerance to the PREFERRED medication.

B. Chemotherapy induced anemia (CIA)

1. ESA is being used in solid tumors or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent and such chemotherapy is ongoing or has been completed ≤ 8 weeks prior to initiation or continuation of ESA, and the member meets ALL of the following criteria:
   a. For initial/continuation requests the baseline Hgb is < 10 g/dL or HCT is < 30 prior to the initiation of ESA therapy (levels are obtained within the last 4 weeks) AND
   b. Prior to initiating ESA therapy, concomitant iron deficiency has been ruled out and serum ferritin is ≥ 100 ng/mL AND/OR transferrin saturation is ≥ 20%. For continuation requests, above levels should be available at least 12 months prior to the continuation request.

C. Anemia of Chronic Kidney Disease (CKD)

1. The member has chronic kidney disease defined as GFR < 60 ml/min over a period of at least three months AND concomitant iron deficiency has been ruled out (serum ferritin ≥ 100 ng/mL AND/OR transferrin saturation ≥ 20% with levels obtained within the last 12 months) AND
2. ESA can be initiated when Hgb < 10 g/dL or HCT < 30 and continued when Hgb ≤ 11 g/dL or HCT ≤ 33 (levels are obtained within the last 4 weeks).

D. Myelodysplastic Syndrome (MDS)

1. The member has lower risk MDS (IPSS Low and INT-1) AND ESA is being used for the following:
   a. For member with symptomatic anemia with serum erythropoietin level < 500 mU/mL AND
   b. ESA can be initiated when Hgb < 10 g/dL or HCT < 30 and continued when Hgb ≤ 11 g/dL or HCT ≤ 33 (levels are obtained within the last 4 weeks) AND
   c. ESA is being used with serum ferritin ≥ 100 ng/mL AND/OR transferrin saturation ≥ 20% (levels are obtained within the last 12 months) OR if iron stains in the bone marrow show adequate iron AND
   d. ESA is being used as a single agent in members with < 10% blasts in the bone marrow OR

e. ESA is being used in combination with filgrastim in members with < 10% blasts in the bone marrow and the Hgb is unresponsive to a trial of ESA.

III. EXCLUSION CRITERIA

A. Mircera (epoetin beta) is not indicated in CIA and MDS.

B. The member is on chemotherapy with curative intent.

C. Patient completed myelosuppressive chemotherapy more than 8 weeks prior to initiation of ESA therapy for CIA.

D. ESA is not used for myeloid malignancies (i.e. acute and chronic myeloid leukemia, myelofibrosis, polycythemia vera, or essential thrombocytopenia) or intermediate risk and high risk MDS OR MDS with a bone marrow blast count of ≥ 10%.

E. The member has any of the following causes of anemia:

1. Deficiencies in B12, folate, or iron
2. Hemolysis, occult blood loss, hypothyroidism, or nutritional deficiency

F. ESA is being used for the acute correction of anemia or as a substitute for RBC transfusions.

G. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Requests for ESAs shall be reviewed for appropriateness as per FDA approved product labeling, NKF KDOQI anemia in CKD guidelines, ASCO and NCCN clinical practice guidelines, or CMS approved compendia.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Aranesp Product Information. Amgen, Inc. Thousand Oaks, CA. 2019.

B. Epogen Product Information. Amgen, Inc. Thousand Oaks, CA. 2018.

C. Procrit Product Information. Amgen, Inc. Thousand Oaks, CA. 2019.

D. Mircera Product Information. Genentech, Inc. South San Francisco, CA 2015.

E. Retacrit Product Information. Pfizer Laboratories Div Pfizer Inc. New York, NY 2020

F. Clinical Pharmacology Elsevier Gold Standard. 2020.

G. Micromedex® Healthcare Series: Thompson Micromedex, Greenwood Village, Co. 2020.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.

I. Locatelli F, et al. Kidney for anemia in chronic kidney disease: 2007 update of hemoglobin target. Disease Outcomes Quality Initiative (K/DOQI). KDOQI Clinical Practice Guideline and Clinical Practice Recommendations Am J Kidney Dis 2007;50:471–530.

J. Rizzo JD, 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;28:4996-5010.

For AHCCCS members: when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy for a list of NON-preferred products.