Pharmacy Policy

Erythropoiesis Stimulating Agents

Policy Number: 9.609
Revision Number: R1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☒ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Epogen (Preferred)
- Procrit
- Retacrit (Preferred)
- Aranesp
- Mircera

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	Aranesp, Epogen, Procrit , Retacrit Documentation of the following: 1. One of the following clinical conditions: - Chronic Kidney Disease (with or without dialysis) to reduce the need for red blood cell transfusions

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	- Chemotherapy-induced anemia in non-myeloid malignancy (current or history of chemotherapy within the last 30 days) - Anemia secondary to zidovudine treatment for HIV* - Myelodysplastic Disease* - Anemia secondary to peginterferon/ribavirin treatment for Hepatitis C* - Anemia of chronic disease* (must include underlying condition); ***AND*** 2. Lab documentation confirming HgB level less than 10 g/dL (within the last 30 days); ***AND*** 3. Lab documentation confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation greater than or equal to 20% (within the last 90 days); ***AND*** 4. For Procrit and Aranesp, an inadequate response, intolerance, or contraindication to Retacrit or Epogen, or a clinical rationale for use of the requested agent instead of Retacrit or Epogen, ***OR*** Documentation of the following: 1. An indication of intended high-risk surgery (must be elective, non-cardiac, and non-vascular); ***AND*** 2. Lab documentation confirming HgB level between 10 -13 g/dL within the last 30 days; ***AND*** 3. Lab documentation confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation greater than or equal to 20% within the last 90 days; ***AND*** 4. An inadequate response, intolerance, or contraindication to Retacrit, or Epogen, or a clinical rationale for use of the requested agent instead of Retacrit.or Epogen Mircera Documentation of the following: 1. A diagnosis of Chronic Kidney Disease with or without dialysis; ***AND*** 2. Lab documentation confirming HgB level less than 10 g/dL (within the last 30 days); ***AND*** 3. Lab documentation confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation greater than or equal to 20% (within the last 90 days); ***AND*** 4. An inadequate response, intolerance, or contraindication to Retacrit or Epogen, or a clinical rationale for use of the requested agent instead of Retacrit or Epogen. *Applies to Epogen, Procrit and Retacrit only
Age Restriction	None
Prescriber Restriction	None
Coverage Duration	Anemia of Chronic Kidney Disease: 6 month intervals Anemia secondary to zidovudine treatment of HIV: 3 month intervals Anemia secondary to peginterferon/ribavirin treatment for Hepatitis C: 3 month intervals

	Anemia of chronic disease: 3 month intervals Myelodysplastic disease: 3 month intervals Chemotherapy-induced anemia: 8 week intervals or less based in scheduled completion of chemotherapy Pre-surgery: 1 month interval
Other criteria	Reauthorization criteria: Documentation of the following: 1. Clinical response to the ESA agent as evidenced by increase in hemoglobin, or decreased need for blood transfusion; ***AND*** 2. Lab documentation confirming HgB level less than or equal to 12 g/dL (within the last 30 days); ***AND*** 3. Lab documentation confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation greater than or equal to 20% (within the last 90 days); ***AND*** 4. For Aranesp, Procrit and Mircera, , an inadequate response, intolerance or contraindication to Retacrit or Epogen

Code	Medication
J0881, J0882	darbepoetin (Aranesp)
J0885, Q4081	epoetin alfa (Procrit, Epogen)
Q5106, Q5105	Inj Retacrit
J0887, J0888	methoxy polyethylene glycol-epoetin beta (Mircera)

Clinical Background Information and References

1. Rizzo JD, Somerfield MR, Hagerty KL, et al. American Society of Hematology / American Society of Clinical Oncology 2007 clinical practice guideline update on the use of epoetin and darbepoetin in Adult patients with cancer. Journal of Clinical Oncology, 28 (33), 2010: p.4996-5010.
2. Kelliher TB, Afdhal NH. Management of the side effects of peginterferon and ribavirin being used for treatment of chronic hepatitis C virus infection. Up to Date®, accessed December 2013; available from: http://www.uptodate.com
3. Schrier SL, Camaschella C. Anemia of chronic disease (anemia of [chronic] inflammation). Up to Date®, accessed December 2013; available from http://www.uptodate.com
4. Prescribing Information. Aranesp, darbepoietin alfa. Amgen Inc., Thousand Oaks, CA 81320-1799. December 2013.
5. Prescribing Information. Epogen, epoetin alfa. Amgen Inc., Thousand Oaks, CA 81320-1799. April 2014.
6. Prescribing Information. Procrit, epoetin alfa. Ortho Biotech Products LP, Raritan, NJ 08869-0670. December 2013.

7. FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. Available from http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm.
8. Prescribing information. Omontys, peginesatide. Takeda Pharmaceuticals Inc. Deerfield, IL 60015. November 2012.
9. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335.
10. Berns JS. Anemia of chronic kidney disease: Target hemoglobin/hematocrit for patients treated with erythropoietic agents. UpToDate®, last updated Oct 1, 2015. Accessed December 2015.
11. Prescribing Information. Mircera, methoxy polyethylene glycol-epoetin beta. Hoffmann-La Roche Inc., South San Francisco, CA. October 2014.
12. Retacrit (epoetin alfa-epbx) [prescribing information]. Lake Forest, IL: Hospira, Inc.; May 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.161 Erythropoeisis Stimulating Agents Policy retired, new policy created; updated policy to align products with state PDL requirements	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

9.080 Non Preferred Policy
9.015 Quantity Limitation Policy
9.### Step Therapy Policy

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.