BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Erythropoiesis Stimulating Agents

Policy Number: 9.609
Version Number: 2.0
Version Effective Date: 3/1/2022

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
- Retacrit

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

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	Epogen,Retacrit Documentation of the following: 1. One of the following clinical conditions: a. Chronic Kidney Disease (with or without dialysis) to reduce the need for red blood cell transfusions b. Chemotherapy-induced anemia in non-myeloid malignancy (current or history of chemotherapy within the last 30 days)

+ *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.

	c. Anemia secondary to zidovudine treatment for HIV d. Myelodysplastic Disease e. Anemia secondary to peginterferon/ribavirin treatment for Hepatitis C f. 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 Epogen, an inadequate response, intolerance, or contraindication to Retacrit or a clinical rationale for use of the requested agent instead of Retacrit. ***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. For Epogen, an inadequate response, intolerance, or contraindication to Retacrit or a clinical rationale for use of the requested agent instead of Retacrit.
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. Member has met initial criteria for diagnosis; **AND**

	2. Clinical response to the ESA agent as evidenced by increase in hemoglobin, or decreased need for blood transfusion; ***AND*** 3. Lab documentation confirming HgB level less than or equal to 12 g/dL (within the last 30 days); ***AND*** 4. 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*** 5. For Epogen, an inadequate response, intolerance or contraindication to Retacrit

Code	Medication
J0885	(Epoetin Alfa; Epogen 1000 units; non-ESRD use)
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-ESRD use), 1,000 units

Clinical Background Information and References

1. Berns JS. Treatment of anemia in nondialysis chronic kidney disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed Oct. 2021.
2. 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.
3. 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
4. Schrier SL, Camaschella C. Anemia of chronic disease (anemia of [chronic] inflammation). Up to Date®, accessed December 2013; available from http://www.uptodate.com
5. Prescribing Information. Epogen, epoetin alfa. Amgen Inc., Thousand Oaks, CA 81320-1799. Accessed Oct. 2021.
6. 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.
7. 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.
8. 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.
9. Retacrit (epoetin alfa-epbx) [prescribing information]. Lake Forest, IL: Hospira, Inc.; Accessed Oct. 2021.

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

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;moved Procrit, Aranesp and Mircera to Non preferred	1/1/2021	P&T Committee
11/11/2021	No reccommended changes	3/1/2022	P&T Committee

Next Review Date

2022

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.