DRUG DETERMINATION POLICY

Title: DDP-18 Erythropoietin Stimulating Agents (ESAs)

Effective Date: 06/03/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

ESAs are oncology and anti-infective specialty drugs indicated for a number of diagnoses and are associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Chronic kidney disease (CKD)-induced anemia.
    1. Diagnosis and severity (both below):
        a. Requiring blood transfusions in dialysis and non-dialysis patients.
        b. Hemoglobin (Hgb) at or below 10gm/dL or HCT at or below 30%.
    2. Dosage regimen: IV administration preferred for patients on dialysis.
        a. Initial:
            i. Epogen/Procrit/Retacrit intravenous (IV) or subcutaneous (SC) (epoetin alfa): 50 to 100u/Kg three times per week.
            ii. Mircera intravenous (IV) or subcutaneous (SC) (methoxy polyethylene glycol-epoetin beta): 0.6mg/kg every two weeks or 1.2mg/kg every four weeks in stabilized patients.

b. Titration:

i. Maintain hemoglobin (Hgb) below 11g/dL.

ii. Inadequate or lack of response over 12-week escalation: further increase not justified.

3. Approval.

a. Initial: six months.

b. Re-approval:

i. Hgb below 11g/dL or hematocrit (HCT) below 33%.

ii. Six months.

B. Cancer patients on chemotherapy-induced anemia.

1. Diagnosis and severity (both below):

a. Patient receiving myelosuppressive chemotherapy to treat non-myeloid malignancies for more than two months.

b. Hgb below 10g/dL.

2. Dosage regimen:

a. Initial: Epogen/Procrit/Retacrit intravenous (IV) or subcutaneous (SC) (epoetin alpha): 150u/Kg three times per week or 40,000u one time per week until completion of chemotherapy.

b. Titration: maintain Hgb below 11g/dL.

3. Approval:

a. Initial: four months.

b. Re-approval: Hgb below 11g/dL; approve four more months.

C. Zidovudine use in HIV infection-induced anemia.

1. Diagnosis and severity:

a. Endogenous erythropoietin levels equal or below 500mu/mL and zidovudine doses equal or below 4,200mg per week.

b. Hgb at or below 12g/dL.

2. Dosage regimen.

a. Initial: Epogen/Procrit/Retacrit I intravenous (IV) or subcutaneous (SC) (epoetin alpha) - 100units/kg.

b. Titration:

i. Maintain Hgb below 12g/dL.

ii. Maximum dose: Epogen/Procrit/Retacrit (epoetin) 300u/Kg; discontinue if Hgb goal not reached in eight weeks.

3. Approval.

a. Initial: four months.

b. Re-approval: Hgb at or below 12g/dL.

D. Surgery.

1. Indication: to reduce allogenic RBC transfusions (both below):

a. Elective non-cardiac, non-vascular surgery.

b. Hgb above 10 to at or below 13g/dL.

2. Dosage regimen: Epogen/Procrit/Retacrit intravenous (IV) or subcutaneous (SC) (epoetin alpha):

a. 300u/kg for 15 days given ten days pre-op through four days post-op **OR**

b. 600u/kg one time per week for four doses given three, two and one week pre-op and day of surgery.

E. Non-preferred (Aranesp): contraindicated, failed or had significant adverse effects to Epogen/Procrit/Retacrit or Mircera.

F. Exclusions:

1. Cancer patients receiving hormonal treatment, therapeutic biologics, or radiation (unless on concurrent myelosuppressive chemotherapy).
2. Surgery patients who are willing to donate autologous blood.
3. Surgery patients undergoing cardiac or vascular surgery.
4. As a substitute for red blood cell transfusion in patients requiring immediate correction of anemia.

4.0 Coding:

APPLICABLE CODES				
HCPCS Code	**Brand**	**Generic**	**HCPCS billing (1U)**	**Prior Approval**
J0885	Epogen/Procrit/Retacrit	Epoetin alpha	1,000U	Y
J0887, J0888	Mircera	Methoxy polyethylene glycol-epoetin beta	1mcg	Y

5.0 References, Citations & Resources:

1. National Government Services. Erythropoietin Stimulating Agents (ESA) – Supplemental Instructions (DRUG-AC-07-06-02)12/01/07.
2. FDA Alert 11/8/07: Information for Healthcare Professionals: Erythropoiesis Stimulating Agents (ESA).
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Epoetin Alpha, Aranesp and Mircera accessed March 2020.

6.0 Appendices:

See page 5.

7.0 Revision History:

Original Effective Date: 08/13/2008

Next Review Date: 03/25/2021

Revision Date	Reason for Revision
4/19	Moving to new format; presented and approved at P&T Committee.
3/20	Annual review; replaced abbreviations, added drug Retacrit

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Erythroid Stimulant Agents: Epogen, Procrit, Retacrit (epoetin alpha recombinant) Mircera (methoxy polyethylene glycol-epoetin beta)	• Cardiovascular: hypertension (27.7%), vascular occlusion (8%) • Musculoskeletal: arthralgia (16%) • Pregnancy. Category: C	• Central Nervous System: watch for Premonitory neurological symptoms • Cardiovascular: blood pressure especially those with pre-existing CV disease • Labs: serum Ferritin pre- and post-treatment Hgb weekly until stable then monthly	• Medication Guide: dispensed with product. • Web site: epogen - https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103234s5360s5364lbl.pdf#page=58 • Procrit http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088988.pdf • Retacrit https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125545s000lbl.pdf#page=28 • Mircera https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125164s078lbl.pdf#page=23