MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	10/06/2016	10/06/2015

Policy Name	Policy Number
Hematopoietic Growth Factors	**SRx-0034**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Hematopoietic Growth Factors

- Epoetin alfa (Epogen, Procrit) Injection
- Darbepoetin alfa (Aranesp) Injection

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

Hematopoietic Growth Factors stimulate erythropoiesis by the same mechanism as endogenous erythropoietin.

The intent of the Hematopoietic Growth Factors (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of **erythropoiesis stimulating agents (Epogen, Procrit and Aranesp)**, and consider its use medically necessary when the following criteria have been met for:

A. Anemia in cancer patients on chemotherapy

B. Anemia in chronic renal failure patients
C. Anemia in zidovudine-treated, HIV-infected
D. Anemia associated with myelodysplastic syndrome

II. Epogen, Procrit and Aranesp must meet **ALL** the below in addition to the condition specific criteria:
A. Patient must meet **ALL** of the criteria below:
1. Patient individual's iron status reveals **ALL** of the following:
1.1 Transferrin saturation is at least 20%
1.2 Ferritin is at least 100 mg/mL
1.3 Patient is on supplemental iron therapy (unless serum ferritin level > 800mcg/L)
2. Must have recent lab test (within the last 14 days)
2.1 Treatment naive - Hgb ≤ 10 g/dL
2.2 Currently receiving therapy - Hgb ≤ 11 g/dL
B. Anemia in cancer patients with non-myeloid malignancies on chemotherapy
1. Darbepoetin alfa (Aranesp) and Epoetin alfa (Epogen, Procrit) are considered **medically necessary** when **ALL** of the following is met:
1.1 Prescribed by an oncologist
1.2 Chemotherapy to be administered for **2 (two) or more** months
1.3 Myelosuppressive chemotherapy without curative intent
1.4 Anemia due to chemotherapy
C. Anemia in chronic renal failure patients
1. Darbepoetin alfa (Aranesp) and Epoetin alfa (Epogen, Procrit) are considered **medically necessary** for the treatment of anemia associated with chronic kidney disease when **ALL** of the following is met:
1.1 Diagnosis of chronic kidney disease
1.2 Prescribed by a nephrologist
D. Anemia in zidovudine-treated, HIV-infected patients
1 Epoetin alfa (Epogen, Procrit) is considered **medically necessary** for anemia related to therapy with zidovudine in HIV-infected patients when **ALL** of the following is met:
1.1 Diagnosis of HIV
1.2 Prescribed by an immunologist or an infectious disease specialist
1.3 HIV-infected patient receiving zidovudine treatment
1.4 Serum erythropoietin 500mU/mL or less
E. Anemia associated with myelodysplastic syndrome
1. Darbepoetin alfa (Aranesp) and Epoetin alfa (Epogen, Procrit) is considered **medically necessary** for anemia associated with myelodyspastic syndrome when **ALL** of the following is met:
1.1 Endogenous serum erythropoietin level of 500mU/mL or less
1.2 Normal karyotype (i.e., no 5q deletion or other cytogenetic abnormality)
1.3 Prescribed by an oncologist

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE

PLACE OF SERVICE

Office, Outpatient, Home
***Preferred place of service is in the home*.
Note: CareSource supports administering inject able medications in various setting as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

HCPCS J0881 Aranesp (Non ESRD)
J0882 Aranesp (ESRD)
J0885 Procrit, Epogen (Non ESRD)
J0886 Procrit, Epogen (ESRD)

CPT

Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD

Approved initial authorizations are valid for 3 (three) months (if applicable). Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility. Subsequent approval requires documentation of treatment success, Hgb↑ ≥ 1g/dL in 12 weeks, Hgb > 11g/dL or 50%↓in transfusion.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 03/14/2013, 09/26/2014, 10/06/2015
Date Revised:	03/14/2013, 09/26/2014 05/01/2015 – Placed in new template and policy number assigned. 10/06/2015 – removed Colony Stimulating Factors to own policy, revised individual iron status criteria

G. REFERENCES

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.