Member Health & Wellness Procedure Manual

Section:  Chapter 7A Prescription Medication Prior Authorization  
Number: 07.058

Title:  erythropoietin, epoetin alfa (Procrit, Epogen)  
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Approval: Robert Bonnell, M.D., Med. Dir.  
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Responsible Party: CPM Director  
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Distribution: Member Health & Wellness  
P&T Review: 11/16/16  
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, CPM associates are responsible for the development of guidelines and criteria for use by Member Health & Wellness associates.

2.0 Associates have access to the Member Health & Wellness Procedure Manual and receive notice from management when procedures are developed, revised, or archived:

3.1 On an annual basis or more often when indicated, Member Health & Wellness Procedures are reviewed by associates and Medical Directors:

3.1.1 New, significantly revised or archived procedures are presented at applicable committees for review and additional revision if needed.

Background Information:

Medication Summary

- Epoetin alfa is a glycoprotein produced by recombinant DNA technology. Recombinant Erythropoietin has the same biological activity as the endogenous hormone, erythropoietin. Erythropoietin is produced in the kidneys and induces erythropoiesis by stimulating the division and differentiation of red blood cells in bone marrow.

- Epoetin alfa is indicated for the treatment of anemia associated with Chronic Renal Disease. Epoetin alfa is used to elevate or maintain the red blood cell levels as determined by the hematocrit and hemoglobin level and to decrease the need for blood transfusions.
Background Information, continued:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Coverage Guidelines

- Member must be eligible and have applicable benefit coverage within the specified date(s) of service.
- For Medicare Members, will need to determine if Part B versus Part D for each indication.
- Hemoglobin and Hematocrit levels drawn within 30 days of request.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Hypersensitivity to mammalian-cell derived products, or to albumin (human);
- Untreated iron or folate deficiencies, hemolysis, or GI bleeding;
- Uncontrolled Hypertension;
- Need for immediate correction of severe anemia;
- Inadequate iron stores including transferrin saturation <20% and ferritin <100ng/mL (Levels drawn within 6 months of request).

Additional Information

- The target range for hemoglobin (Hgb) should be Hgb 10-12g/dL, which corresponds to a target hematocrit (Hct) of 30-36%.
- The time required to elicit a clinically significant change in hematocrit (increase or decrease) following any dose adjustment may be two (2) to six (6) weeks.
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Background Information, continued:

Additional Information, continued

- The rate of Hgb increase should not exceed 1g/dL in a 2-week period.
- The dose of Procrit should be based upon maintaining a Hgb level within the range of 10-12g/dL.
- Requests received for Medicare Members will be reviewed using CMS “LCD for Erythropoiesis Stimulating Agents”
- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.0 Request for initial therapy with Procrit requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying at least one (1) of the following:

1.1 Members with cancer on chemotherapy OR received last dose of chemotherapy within the past eight (8) weeks AND has anemia due to chemotherapy, as defined by:

   1.1.1 Hemoglobin level < 10g/dl OR Hematocrit level < 30%;

1.2 Myelodysplastic Syndrome:

   1.2.1 Hemoglobin level < 10g/dL OR Hematocrit level < 30%; AND

1.3 Anemia associated with chronic renal failure (CRF):

   1.3.1 Hemoglobin level <10g/dl OR Hematocrit < 30%; AND
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Procedure, continued:

1.0 Request for initial therapy with Procrit requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying at least one (1) of the following:

1.4 Anemia in Zidovudine-treated, HIV-infected Members:
   1.4.1 Hemoglobin level < 10g/dl OR Hematocrit < 30%; AND

1.5 Reduction of allogenic blood transfusion in surgery Members:
   1.5.1 Hemoglobin level > 10g/dl AND ≤ 13 g/dl; AND

1.6 Multiple myeloma:
   1.6.1 Hemoglobin level < 10g/dl OR Hematocrit < 30%; AND

1.7 Anemia associated with treatment of Hepatitis C infection:
   1.7.1 Hemoglobin level < 10g/dl OR Hematocrit < 30%; AND

1.8 Anemia associated with rheumatoid arthritis (RA):
   1.8.1 Hemoglobin level < 10g/dl OR Hematocrit < 30%;

1.9 If criteria are met, Procrit may be approved for up to 90 days.

2.0 Request for continuation of therapy beyond initial authorization period requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the criteria required for initial therapy (listed under section 1.0) has been met:

2.1 Procrit may be approved for up to 90 days.
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