

Title: erythropoietin, epoetin alfa (PROCRIT, EPOGEN)

Origination: 11/03/06	Revised: 11/22/11	Annual Review: 12/15/11
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Purpose:

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

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.

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.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage within the specified date(s) of service.
- *Epogen can be used by Members on dialysis only.
- For Commercial Members, Procrit or Epogen* will be a:
 - Medical benefit when the diagnosis is anemia secondary to ESRD on home-dialysis;
 - Pharmacy benefit with applicable co-payment, when the diagnosis is anemia secondary to Chronic Kidney Disease (CKD);
- For Medicare Members, will need to determine if Part B versus Part D for each indication.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Background Information, continued:

Exclusions

- 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.

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.
- 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 (L29168)” – Refer to Attachment A or view on-line at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from=%2525271mrpcontractor%252527&contractor=197&name=First+Coast+Service+Options%25252C+Inc%25252E+%25252809102%25252C+MAC+%25252D+Part+B%252529&letter_range=4&retired

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 Cancer patient 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 < 11g/dL **OR** Hematocrit level < 33%; **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 < 12g/dl **OR** Hematocrit < 36%; **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 < 12g/dl **OR** Hematocrit < 36%; **AND**
 - 1.7 Anemia associated with treatment of Hepatitis C infection:
 - 1.7.1 Hemoglobin level < 11g/dl **OR** Hematocrit < 33%; **AND**
 - 1.8 Anemia associated with rheumatoid arthritis (RA):
 - 1.8.1 Hemoglobin level < 12g/dl **OR** Hematocrit < 36%;
 - 1.9 If criteria are met, Procrit may be approved for up to 45 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):
 - 2.1 If criteria are met, Procrit may be approved for up to 45 days.

References:

1. Procrit (epoetin alfa) Package Insert. Ortho Biotech. April 2009.
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2006. Am J Kidney Dis 47:S1-S145, 2006 (suppl 3).
3. National Kidney Foundation. KDOQI clinical practice guideline and clinical practice recommendations for anemia in chronic kidney disease: 2007 update of hemoglobin target. Am J Kidney Dis 2007 Sep;50(3):471-530.

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References, continued:

4. Centers for Medicare & Medicaid Services, US Department of Health and Human Services. Local Coverage Determination (LCD) for Epoetin alpha (#L5984). 4th Quarter 2006 update. Revision 10, effective 6/19/2006.
5. Provenzano R, Garcia-Mayol L, Suchinda P, et al. Once weekly epoetin alfa for treating the anemia of chronic kidney disease. *Clin Nephrol* 2004;61(6):392-405.
6. Sarac E, Smavatkul C, Boolchand V, et al. Hemoglobin and hematocrit response for alternate dosing strategies of epoetin alfa in pre-dialysis chronic kidney disease [abstract]. *Am J Kidney Dis* 2004;43(4):A41 (ABS 106).
7. Miguel JL, Traver JA, Jofre RM, et al. Erythropoietin treatment in pre-dialysis patients. *Nefrologia* 1995;15(2):148-55.
8. Provenzano R, Bhaduri S, Singh AK, for the PROMPT Study Group. Extended epoetin alfa dosing as maintenance treatment for the anemia of chronic kidney disease: the PROMPT Study. *Clin Nephrol* 2005;64(2):113-23.
9. MedWatch Safety Alert. *2007 Safety Alert: Erythropoiesis Stimulating Agents*. March 2007.
10. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com Updated 2010.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.