Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Erythropoiesis Stimulating Agents (ESAs)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***July 2005 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The erythropoiesis stimulating agents (ESAs), darbepoetin alfa (Aranesp®), epoetin alfa (Epogen®, Procrit®, or Retacrit®), and methoxy polyethylene glycol epoetin beta (Mircera®) are subject to the prior authorization process.

Darbepoetin alfa (Aranesp®) is indicated for:

- Treatment of anemia of chronic renal failure, including members on dialysis (end stage renal disease [ESRD]) and members not on dialysis
- Treatment of anemia with non-myeloid malignancies due to concomitant chemotherapy
    - Not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy
    - Not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure
    - Minimum of two additional months of planned chemotherapy

Epoetin alfa (Epogen®) is indicated for:

- Treatment of anemia of chronic renal failure members, including members on dialysis (end stage renal disease [ESRD]) and members not requiring dialysis

- Treatment of anemia of HIV members
- Treatment of anemia in cancer patients on chemotherapy
    - Not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy
    - Not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure
    - Not indicated for the treatment of anemia in cancer patients due to other factors such as iron or folate deficiencies, hemolysis, or gastrointestinal bleeding
    - Minimum of two additional months of planned chemotherapy

Epoetin alfa (Procrit®) is indicated for:

- Treatment of anemia of chronic renal failure, including members on dialysis (end stage renal disease [ESRD]) and members not on dialysis
- Treatment of anemia of HIV members
- Treatment of anemia in cancer patients on chemotherapy
    - Not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy
    - Not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure
    - Not indicated for the treatment of anemia in cancer patients due to other factors such as iron or folate deficiencies, hemolysis, or gastrointestinal bleeding
    - Minimum of two additional months of planned chemotherapy
- Reduction in allogeneic blood transfusion in surgery members

Epoetin alfa (Retacrit®) is indicated for:

- Treatment of anemia of chronic kidney disease, including members on dialysis (end stage renal disease [ESRD]) and members not on dialysis
- Treatment of anemia of HIV members
- Treatment of anemia in cancer patients on chemotherapy
    - Not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy
    - Not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure
    - Not indicated for the treatment of anemia in cancer patients due to other factors such as iron or folate deficiencies, hemolysis, or gastrointestinal bleeding
    - Minimum of two additional months of planned chemotherapy

- Reduction in allogeneic blood transfusion in surgery members

➢ Even though the indications differ for Retacrit®, Procrit®,and Epogen®, the three drugs are considered therapeutically interchangeable.

Methoxy polyethylene glycol-epoetin beta (Mircera®) is indicated for:

- Treatment of anemia due to chronic kidney disease in adult patients on dialysis and patients not on dialysis

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The erythropoiesis stimulating agents (ESAs), darbepoetin alfa (Aranesp®), epoetin alfa (Epogen®, Procrit®, or Retacrit®), and methoxy polyethylene glycol epoetin beta (Mircera®) are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Epogen, Procrit, Aranesp, and Mircera are subject to the preferred medical drug list program. This program applies to the ESA products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a non-preferred product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Erythropoiesis stimulating agents

	Product(s)
Preferred	• Retacrit (epoetin alfa)
Non-preferred	• Epogen (epoetin alfa) • Procrit (epoetin alfa) • Aranesp (darbepoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta)

II. EXCEPTION CRITERIA (*Use for Epogen, Procrit, Aranesp, and Mircera Requests Only*)

This program applies to members requesting treatment for an indication that is FDA approved for the preferred product.

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

A. Member is currently receiving treatment with either of the non-preferred products, Aranesp or Mircera, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member is requesting either the non-preferred product Aranesp or Mircera and has a documented inadequate response or intolerable adverse event to the preferred product, Retacrit.
C. Member is requesting either of the non-preferred products Epogen or Procrit, and has had a documented intolerable adverse event to the preferred product Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the criteria listed under the respective diagnosis:

1. Darbepoetin alfa (Aranesp)

- Must be prescribed by or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, or an infectious disease physician
- Must have ONE of the following diagnoses and hemoglobin levels:
  - Anemia of chronic renal failure and on renal dialysis when Hgb <10g/dL
  - Anemia of chronic renal failure not requiring dialysis when Hgb <10g/dL
  - Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy (Hgb <10g/dL) and there is a minimum of two additional months of planned chemotherapy
  - Anemia associated with the use of ribavirin when Hgb <10g/dL OR a 3g/dL decrease from baseline Hgb with symptoms. If ribavirin is being prescribed as part of a triple-therapy regimen (including a protease

inhibitor), documentation that an attempt at ribavirin dose reduction was not able to resolve the anemia must be provided
    - Anemia associated with myelodysplastic syndrome when Hgb <10g/dL
- Must be on supplemental iron therapy if serum ferritin is either below 100mcg/L (200mcg/L in members with chronic kidney disease receiving hemodialysis) or if serum ferritin saturation is below 20%
- Must not have uncontrolled hypertension
- Must not have a known hypersensitivity to the active substance or any of the excipients of the product
- Must be using a dose within the recommended dosing guidelines

2. Epoetin alfa (Epogen, Retacrit, or Procrit)

- Must be prescribed by or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, or an infectious disease physician
- Must have ONE of the following diagnoses and hemoglobin levels:
    - Anemia of chronic renal failure and on renal dialysis when Hgb <10g/dL
    - Anemia of chronic renal failure not requiring dialysis when Hgb <10g/dL
    - Zidovudine treatment-induced anemia in HIV members when lab value showing Hgb <10g/dL
    - Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy when Hgb <10g/dL and there is a minimum of two additional months of planned chemotherapy
    - Anemic members with lab value showing Hgb >10 and < 13g/dL, who are at high risk for perioperative transfusions secondary to significant, and anticipated blood loss and are scheduled to undergo elective, non-cardiac, or nonvascular surgery to reduce the risk for allogeneic blood transfusions
    - Anemia associated with the use of ribavirin when Hgb <10g/dL OR a 3g/dL decrease from baseline Hgb with symptoms. If ribavirin is being prescribed as part of a triple-therapy regimen (including a protease inhibitor), documentation that an attempt at ribavirin dose reduction was not able to resolve the anemia must be provided
    - Anemia associated with myelodysplastic syndrome when Hgb <10g/dL
- Must be on supplemental iron therapy if serum ferritin is either below 100mcg/L (200mcg/L in members with chronic kidney disease receiving hemodialysis) or if serum ferritin saturation is below 20%
- Must not have uncontrolled hypertension
- Must not have a known hypersensitivity to the active substance or any of the excipients of the product
- Must be using a dose within the recommended dosing guidelines

3. Methoxy polyethylene glycol-epoetin beta (Mircera)

- Must be prescribed by or in consultation with a nephrologist
- Must be age 18 years or older
- Must have anemia due to chronic kidney disease and Hgb <10g/dL
- Must be on supplemental iron therapy if serum ferritin is either below 100mcg/L or if serum transferrin saturation is <20%
- Must not have uncontrolled hypertension
- Must not have a known hypersensitivity to the active substance or any of the excipients of the product
- Must be using a dose within the recommended dosing guidelines

<u>Reauthorization Criteria</u>:

1. Darbepoetin alfa (Aranesp) and epoetin alfa (Epogen, Retracrit, or Procrit)

- A clinical and lab reassessment is conducted to determine if the authorization may be extended:
    - Approve for 6 months if diagnosis of anemia of chronic renal failure and on renal dialysis and Hgb <11g/dL
    - Approve for 6 months if diagnosis of anemia of chronic renal failure not requiring dialysis and Hgb <10g/dL
    - Approve for 6 months if diagnosis of anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy and Hgb <12g/dL
    - Approve for 6 months if diagnosis of anemia associated with myelodysplastic syndrome and Hgb <12g/dL
    - Approve for 6 months if diagnosis of Zidovudine treatment-induced anemia in HIV members when lab value showing <12g/dL **[epoetin alfa (Epogen or Procrit) only]**
    - Approve for 2 months if diagnosis of anemia associated with the use of ribavirin and Hgb <12g/dL
- Must be on supplemental iron therapy if serum ferritin is either below 100mcg/L (200mcg/L in members with chronic kidney disease receiving hemodialysis) or if serum ferritin saturation is below 20%

2. Methoxy polyethylene glycol-epoetin beta (Mircera)

- A clinical and lab reassessment is conducted to determine if the authorization may be extended:
    - Approve for 6 months if diagnosis of anemia due to chronic kidney disease and on dialysis and Hgb <11g/dL
    - Approve for 6 months if diagnosis of anemia due to chronic kidney disease not requiring dialysis and Hgb <10g/dL

- Must be on supplemental iron therapy if serum ferritin is either below 100mcg/L or if serum transferrin saturation is <20%

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 2 months
Reauthorization	Dependent on diagnosis. See reauthorization criteria above.

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. A randomized double-blind placebo-controlled study with subcutaneous recombinant human erythropoietin in patients with low-risk myelodysplastic syndromes. Italian Cooperative Study Group for rHuEpo in myelodysplastic syndromes. *Br J Haematol*. 1998;103(4):1070-1074.
2. Adamson J. Epoetin alfa as an adjunct to autologous blood donation in patients with a low hematocrit scheduled for elective orthopedic surgery. *Semin Hematol.* 1996;33(2 Suppl 2):15-17.
3. Afdahl NH, Dieterich DT, Pockros PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. *Gastroenterology*. 2004;126(5):1302-1311.
4. Agroyannis B, Loutsicos D, Tzanatou-Exarchou H, et al. Combined recombinant human erythropoietin-blood letting strategy for treating anemia and iron overload in hemodialysis patients. *Int J Artif Organs*. 1991;14:403-406.
5. Aranesp® Product Information. Amgen Inc. Thousand Oaks, CA. March 2011.
6. Bessho M, Hirashima K, Asano S, et al. Treatment of the anemia of aplastic anemia patients with recombinant human erythropoietin in combination with granulocyte colony-stimulating factor: a multicenter randomized controlled study. Multicenter Study Group. *Eur J Haematol.* 1997;58:265-272.
7. Biaggioni I, Robertson D, Krantz S, et al. The anemia of primary autonomic failure and its reversal with recombinant erythropoietin. *Ann Intern Med.* 1994;121:181-186.
8. Bilgrami S, Bartolomeo A, Synnott V, et al. Management of hemosiderosis complicated by coexistent anemia with recombinant human erythropoietin and phlebotomy. *Acta Haematol*. 1993;89:141-143.
9. Bokemeyer C, Aapro MS, Courdi A, et al. EORTC guidelines for the use of erythropoietic proteins in anaemic patients with cancer. *Eur J Cancer*. 2004;40(15):2201-2216.
10. Brecher ME, Goodnough LT, Monk T. Where does preoperative erythropoietin therapy count? A mathematical perspective. *Transfusion.* 1999;39:392-395.
11. Brown MS, Keith JF. Comparison between two and five doses a week of recombinant human erythropoietin for anemia of prematurity: a randomized trial. *Pediatrics*. 1999;104(2 Pt 1):210-215.
12. Brugnara C, Chambers LA, Malvnn E, et al. Red blood cell regeneration induced by subcutaneous recombinant erythropoietin: iron-deficient erythropoiesis in iron-replete subjects. *Blood*. 1993;81:956-964.
13. Brunkhorst R, Bommer J, Braun J, et al; German Aranesp Study Group. Darbepoetin alfa effectively maintains haemoglobin concentrations at extended dose intervals relative to intravenous or subcutaneous recombinant human erythropoietin in dialysis patients. Nephrol Dial Transplant. 2004;19(5):1224-1230.

14. Catlin DH, Hatton CK. Use and abuse of anabolic and other drugs for athletic enhancement. Use and abuse of anabolic and other drugs for athletic enhancement. *Adv Intern Med*. 1991;36:399-424.
15. Charu V, Belani CP, Gill AN, et al. A controlled, randomized, open-label study to evaluate the effect of every-2-week darbepoetin alfa for anemia of cancer. Proc Am Soc Clin Oncol. 2004; Abstract 8084 and poster.
16. Coyle D, Lee KM, Fergusson DA, et al. Economic analysis of erythropoietin use in orthopaedic surgery. *Transfus Med.* 1999;9:21-30.
17. de Andrade JR, Jove M. Baseline hemoglobin as a predictor of risk of transfusion and response to epoetin alpha in orthopedic surgery patients. Am J Orthoped. 1996;25(8):533-542.
18. Dieterich DT, Wasserman R, Brau N, et al. Once-weekly epoetin alfa improves anemia and facilitates maintenance of ribavirin dosing in hepatitis C virus-infected patients receiving ribavirin plus interferon alfa. Am J Gastroenterol. 2003;98(11):2491-2499.
19. Dohil R, Hassall E, Wadsworth LD, et al. Recombinant human erythropoietin for treatment of anemia of chronic disease in children with Crohn's disease. J Pediatr. 1998;132:155-159.
20. Editorial Staff. Darbepoetin alfa (systemic). In: Klasko RK, ed. USP DI® Drug Information for the Healthcare Professional. Greenwood Village, CO: Thomson MICROMEDEX; 2004.
21. Editorial Staff. Epoetin (systemic). In: Klasko RK, ed. USP DI® Drug Information for the Healthcare Professional. Greenwood Village, CO: Thomson MICROMEDEX; 2004.
22. Epogen® Product Information. Amgen Inc. Thousand Oaks, CA. November 20011.
23. Fischl M, Galpin JE, Levine JD, et al. Recombinant human erythropoietin for patients with AIDS treated with zidovudine. N Engl J Med. 1990;322:1488-1493.
24. Fridge JL, Vichinsky EP. Correction of the anemia of epidermolysis bullosa with intravenous iron and erythropoietin. J Pediatr. 1998;132:871-873.
25. Gasche C, Dejaco C, Reinisch W, et al. Sequential treatment of anemia in ulcerative colitis with intravenous iron and erythropoietin. Digestion. 1999;60:262-267.
26. Glaspy JA, Jadeja JS, Justice G, et al. A randomized, active-control pilot trial of front-loaded dosing regimens of darbepoetin-alfa for the treatment of patients with anemia during chemotherapy for malignant disease. Cancer. 2003;97:1312-1320.
27. Glaspy JA, Jadeja JS, Justice G, et al. Darbepoietin alfa given every 1 or 2 weeks alleviates anemia associated with cancer chemotherapy. Br J Cancer. 2002;87:268-276.
28. Goldberg MA, Brugnara C, Dover GJ, et al. Treatment of sickle cell anemia with hydroxyurea and erythropoietin. N Engl J Med. 1990;323:366-372.
29. Goldberg MA, McCutchen JW. A safety and efficacy comparison study of two dosing regimens of epoetin alpha in patients undergoing major orthopedic surgery. Am J Orthoped. 1996;25(8):544-552.
30. Goodnough LT, Anderson KC, Kurtz S, et al. Indications and guidelines for the use of hematopoietic growth factors. Transfusion. 1993;33:944-959.
31. Goodnough LT, Rudnick S, Price TH, et al. Increased preoperative collection of autologous blood with recombinant human erythropoietin therapy. N Engl J Med. 1989;321:1163-1168
32. Grossman HA, Goon B, Leitz G, and the 010 Study Group. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV-infected patients. J Acquir Immune Defic Syndr. 2003;34(4):368-378.
33. Gudbjörnsson B, Hällgren R, Wide L, et al. Response of anaemia in rheumatoid arthritis to treatment with subcutaneous recombinant human erythropoietin. Ann Rheum Dis. 1992;51:747-752.
34. Hedenus M, Adriansson M, Miguel JS, et al. Efficacy and safety of darbepoetin alfa in anaemic patients with lymphoproliferative malignancies: a randomized, double-blind, placebo-controlled study. Br J Haematol. 2003;122:394-403.
35. Hellstrom-Lindberg E, Gulbrandsen N, Lindberg G, et al. A validated decision model for treating the anaemia of myelodysplastic syndromes with erythropoietin + granulocyte colony-stimulating factor: significant effects on quality of life. Br J Haematol. 2003;120(6):1037-1046.
36. Henry DH, Volberding PA, Leitz G. Epoetin alfa for treatment of anemia in HIV-infected patients: past, present, and future. J Acquir Immune Defic Syndr. 2004;37(2):1221-1227.

37. Henry DH. Epoetin alfa and high-dose chemotherapy. Semin Oncol. 1998;25(3 Suppl 7):54-57.
38. Hesketh PJ, Arena F, Patel D, et al. A randomized controlled trial of darbepoetin alfa administered as a fixed or weight-based dose using a front-loading schedule in patients with anemia who have nonmyeloid malignancies. Cancer. 2004;100(4):859-868.
39. Hoeldtke RD, Streeten DHP. Treatment of orthostatic hypotension with erythropoietin. N Engl J Med. 1993;329:611-615.
40. Klaesson S. Clinical use of rHuEPO in bone marrow transplantation. Med Oncol. 1999;16:2-7.
41. Kornowski R, Schwartz D, Jaffe A, et al. Erythropoietin therapy obviates the need for recurrent transfusions in a patient with severe hemolysis due to prosthetic valves. CHEST. 1992;102:315-316.
42. Kotasek D, Steger G, Faught W, et al. Darbepoetin alfa administered every 3 weeks alleviates anaemia in patients with solid tumours receiving chemotherapy; results of a double-blind, placebo-controlled, randomized study. Eur J Cancer. 2003;39:2026-2034.
43. Locatelli F, Aljama P, Barany P, et al; European Best Practice Guidelines Working Group. Revised European Best Practice Guidelines for the management of anemia in patients with chronic renal failure. Nephrol Dial Transplant. 2004;19(Suppl 2):ii1-47.
44. Locatelli F, Aljama P, Barany P, et al; European Best Practice Guidelines Working Group. Revised European Best Practice Guidelines for the management of anemia in patients with chronic renal failure. Nephrol Dial Transplant. 2004;19(Suppl 2):ii1-47.
45. Locatelli F, Canaud B, Giacardy F, et al. Treatment of anaemia in dialysis patients with unit dosing of darbepoetin alfa at a reduce dose frequency relative to recombinant human erythropoietin (rHuEpo). Nephrol Dial Transplant. 2003;18:362-369.
46. Loukopoulos D. New therapies for the haemoglobinopathies. J Intern Med Suppl. 1997;740:43-48.
47. Low PA. Autonomic neuropathies. Curr Opin Neurol. 1998;11:531-537.
48. Ludwig H, Sundal E, Pecherstorfer M, et al. Recombinant human erythropoietin for the correction of cancer associated anemia with and without concomitant cytotoxic chemotherapy. Cancer. 1995;76(11):2319-2329.
49. Maeda H, Hitonu T, Hirata R, et al. Erythropoietin and autologous blood donation. Lancet. 1989;2:284.
50. Maeda H, Tohyama H. Erythropoietin and autologous blood donation: authors' reply. Lancet. 1989;2:1154.
51. Mancini DM, Katz SD, Lang CC, et al. Effect of erythropoietin on exercise capacity in patients with moderate to severe chronic heart failure. Circulation. 2003;107(2):294-299.
52. Mantovani L, Lentini G, Hentschel B, et al. Treatment of anemia in myelodysplastic syndromes with prolonged administration of recombinant human granulocyte colony-stimulating factor and erythropoietin. Br J Haematol. 2000;109(2):367-375.
53. Martínez AM, Sastre A, Muñoz A, et al. Recombinant human erythropoietin (rh-Epo) administration to normal child bone marrow donors. Bone Marrow Transplant. 1998;22:137-138.
54. McFarland JG. Perioperative blood transfusions. Indications and options. Chest. 1999;115(5):113S-121S.
55. Means RT Jr, Olsen NJ, Krantz SB, et al. Treatment of the anemia of rheumatoid arthritis with recombinant human erythropoietin: clinical and in vitro studies. Arthritis Rheum. 1989;32:638-642.
56. Mercuriali F, Zanella A, Barosi G, et al. Use of erythropoietin to increase the volume of autologous blood donated by orthopedic patients. Transfusion. 1993;33:55-60.
57. Murphy EA, Bell AL, Wojtulewski J, et al. Study of erythropoietin in treatment of anaemia in patients with rheumatoid arthritis. BMJ. 1994;309:1337-1338.
58. National Comprehensive Cancer Network (NCCN) clinical practice guidelines in oncology. Cancer and treatment-related anemia. Version 2.2004. Accessed on October 19, 2004 at http://www.nccn.org/professionals/physician_gls/PDF/anemia.pdf
59. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Cancer and treatment-related anemia. Version 2.2004. Accessed on 11/10/2004 at http://www.nccn.org/professionals/physician_gls/PDF/anemia.pdf

60. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myelodysplastic syndromes. Version 1.2005. Accessed on 11/10/2004 at http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf
61. National Kidney Foundation. K/DOQI clinical practice guidelines for anemia of chronic kidney disease, 2000. Am J Kidney Dis. 2001;37(suppl 1):S182-S238.
62. Nissenson AR, Swan SK, Lindberg JS, et al. Randomized, controlled trial of darbepoetin alfa for the treatment of anemia in hemodialysis patients. Am J Kidney Dis. 2002;40(1):110-118.
63. Ohls RK, Ehrenkranz RA, Wright LL, et al. Effects of early erythropoietin therapy on the transfusion requirements of preterm infants below 1250 grams birth weight: a multicenter, randomized, controlled trial. Pediatrics. 2001;108(4):934-942.
64. Ohls RK, Harcum J, Schibler KR, Christensen RD. The effect of erythropoietin on the transfusion requirements of preterm infants weighing 750 grams or less: a randomized, double-blind, placebo-controlled study. J Pediatr. 1997;131(5):661-665.
65. Peeters HRM, Jongen-Lavrencic M, Bakker CH, et al. Recombinant human erythropoietin improves health-related quality of life in patients with rheumatoid arthritis and anaemia of chronic disease; utility measures correlate strongly with disease activity measures. Rheumatol Int. 1999;18:201-206.
66. Pincus T, Olsen NJ, Russell IJ, et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. Am J Med. 1990;89:161-168.
67. Pirker R. Darbepoetin alfa for the treatment of cancer-related anemia: an update. Expert Rev Anticancer Ther. 2004;4(5):735-744.
68. Procrit® Product Information. Amgen Inc. Thousand Oaks, CA. January 2011.
69. Quirt I, Robeson C, Lau CY, et al. Epoetin alfa therapy increases hemoglobin levels and improves quality of life in patients with cancer-related anemia who are not receiving chemotherapy and patients with anemia who are receiving chemotherapy. J Clin Oncol. 2001;19(21):4126-4134.
70. Rachmilewitz EA, Aker M. The role of recombinant human erythropoietin in the treatment of thalassemia. Ann NY Acad Sci. 1998;850:129-138.
71. Rarick MU, Espina BM, Colley DT, et al. Treatment of a unique anemia in patients with IDDM with epoetin alfa. Diabetes Care. 1998;21:423-426.
72. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother. 2000;34:433-439.
73. Rizzo JD, Lichtin AE, Woolf SH, et al. Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. J Clin Oncol. 2002;20:4083-4107.
74. Salvati F, Liani M. Erythropoietin and thrombotic events. Lancet. 1998;352:1471.
75. Sawka MN, Joyner MJ, Miles DS, et al. American college of sports medicine position stand. The use of blood doping as an ergogenic aid. Med Sci Sports Exerc. 1996;28:i-viii.
76. Schreiber S, Howaldt S, Schnoor M, et al. Recombinant erythropoietin for the treatment of anemia in inflammatory bowel disease. N Engl J Med. 1996;334:619-623.
77. Scott WC. The abuse of erythropoietin to enhance athletic performance. JAMA. 1990; 264:1660.
78. Silverberg DS, Wexler D, Blum M, et al. The effect of correction of anemia in diabetics and non-diabetics with severe resistant congestive heart failure and chronic renal failure by subcutaneous erythropoietin and intravenous iron. Nephrol Dial Transplant. 2003;18(1):141-146.
79. Silverberg DS, Wexler D, Blum M, et al. The use of subcutaneous erythropoietin and intravenous iron for the treatment of anemia of severe, resistant congestive heart failure improves cardiac and renal function and functional cardiac class, and markedly reduces hospitalizations. J Am Coll Cardiol. 2000;35(7):1737-1744.
80. Silverberg DS, Wexler D, Iaina A. The importance of anemia and its correction in the management of severe congestive heart failure. Eur J Heart Fail. 2002;4(6):681-686.
81. Silverberg DS, Wexler D, Sheps D, et al. The effect of correction of mild anemia in severe, resistant congestive heart failure using subcutaneous erythropoietin and intravenous iron: a randomized controlled study. J Am Coll Cardiol. 2001;37(7):1775-1780.

82. Smith RE, Tchekmedyian NS, Chan D, et al. A dose-and schedule-finding study of darbepoetin alpha for the treatment of chronic anaemia of cancer. Br J Cancer. 2003;88:1851-1858.
83. Stasi R, Pagano A, Terzoli E, Amadori S. Recombinant human granulocyte-macrophage colony-stimulating factor plus erythropoietin for the treatment of cytopenias in patients with myelodysplastic syndromes. Br J Haematol. 1999;105(1):141-148.
84. Suranyi MG, Lindberg JS, Navarro J, et al. Treatment of anemia with darbepoetin alfa administered de novo once every other week in chronic kidney disease. Am J Nephrol. 2003;23:106-111.
85. Terpos E, Mougiou A, Kouraklis A, et al. Prolonged administration of erythropoietin increases erythroid response rate in myelodysplastic syndromes: a phase II trial in 281 patients. Br J Haematol. 2002;118:174-180.
86. Thomas MJG, Desmond M, Gillon J. Preoperative autologous donation: what was the impact of the 1995
1. consensus statement? Transfus Med. 1999;9:241-257.
87. Toto RD, Pichette V, Navarro J, et al. Darbepoetin alfa effectively treats anemia in patients with chronic kidney disease with de novo every-other-week administration. Am J Nephrol. 2004;24(4):453-460.
88. Toy PTCY, Beattie C, Gould SA, et al. Transfusion alert: use of autologous blood. National Heart, Lung, and Blood Institute Expert Panel on the use of Autologous Blood. Transfusion. 1995;35:703-711. Also, accessed on October 20, 2004 at http://www.nhlbi.nih.gov/health/prof/blood/transfusion/logo.htm#expert
89. Utilization Management Criteria for Aranesp®. CuraScript Pharmacy, Inc. October 2002.
90. Utilization Management Criteria for Erythropoietin (Procrit®, Epogen®). CuraScript Pharmacy, Inc. October 2002.
91. Vanrenterghem Y, Barany P, Mann JFE, et al. Randomized trial of darbepoetin alfa for treatment of renal anemia at a reduce dose frequency compared with rHuEPO in dialysis patients. Kidney Int. 2002;62:2167-2175.
92. Vansteenkiste J, Pirker R, Massuti B, et al. Double-blind, placebo-controlled, randomized phase III trial of darbepoetin alfa in lung cancer patients receiving chemotherapy. J Natl Cancer Inst. 2002;94:1211-1220.
93. Volberding PA, Levine AM, Dieterich D, et al, for the anemia in HIV working group. Anemia in HIV infection: clinical impact and evidence-based management strategies. Clin Infect Dis. 2004;38(10):1454-1463.
94. Winkler AS, Marsden J, Chaudhuri KR, et al. Erythropoietin depletion and anaemia in diabetes mellitus. Diabet Med. 1999;16:813-819.
95. Ghany MG, Nelson DR, Strader DB, et al. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American association for the study of liver diseases. *Hepatology* 2011;54(4);1433-1444
96. Cash WJ, Patterson K, Callender ME, et al. Adjuvant therapy used in conjunction with combination therapy for chronic hepatitis C improves sustained virus response rates in genotype 1 patients. *Journal of Viral Hepatitis* 2010;17;269-273
97. Bertino E, Ardiri A, Boemi PM, et al. Epoetin alpha improves the response to antiviral treatment in HCV-related chronic hepatitis. *Eur J Clin Pharmacol* 2010;66;1055-1063.
98. AMCP Format for Formulary Submissions Version 3.0 Dossier for OMONTYS® (peginesatide) Injection. Palo Alto, CA and Deerfield, IL: Affymax, Inc and Takeda Pharmaceuticals, Inc.; 2012.
99. 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;50(3):471-530.
100. National Institute for Health and Clinical Excellence. Quick reference guide: anaemia management in people with chronic kidney disease. February 2011. Available at: http://www.nice.org.uk/nicemedia/live/13329/52857/52857.pdf. Accessed June 8, 2012.
101. Mircera [prescribing information]. South San Francisco, CA: Hoffman-La Roche Inc. October 2014.

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16,02/17, 02/18*
Preferred Product Update	*12/18*