

These materials are offered as general educational guidelines to assist in the clinical decision-making of medical professionals care for patients on dialysis. They are not to be used as a substitute for independent medical judgment, professional training, or practice guidelines/protocols. Physicians should exercise their own medical judgment based on each patient's individual healthcare needs.

References: 1. EPOGEN® (Epoetin alfa) prescribing information, Amgen. 2. Roderick P, Jones C, Tomson C, Mason J. Late referral for dialysis: improving the management of chronic disease. *Q J Med.* 2002;95:363-370. 3. Obrador GT, Roberts T, St. Peter WL, Frazier E, Pereira BJG, Collins AJ. Trends in anemia at initiation of dialysis in the United States. *Kidney Int.* 2001;60:1875-1884. 4. Aiello J. Managing anemia using laboratory trend analysis: case study of the anemic patient. *ANNA.* 1999; 26:430-433. 5. Pisoni RL, Bragg-Gresham JL, Young EW, et al. Anemia management and outcomes from 12 countries in the dialysis outcomes and practice patterns study (DOPPS). *Am J Kidney Dis.* 2004;44:94-111. 6. Yaqub MS, Leiser J, Molitoris BA. Erythropoietin requirements increase following hospitalization in end-stage renal disease patient. *Am J Nephrol.* 2001;21:390-396. 7. Breiterman-White R. Infection and inflammation in patients on dialysis: An underlying contributor to anemia and epoetin alfa hyporesponse. *Nephrol Nurs J.* 2006;33:319-324. 8. Pagana KD, Pagana TJ. *Mosby's Manual of Diagnostic and Laboratory Tests.* 3rd ed. St. Louis, Mo: Mosby Elsevier; 2006:199-544. 9. Fishbane S. Hematologic abnormalities. In: Daugirdas JT, Blake TG, Ing TS, eds. *Handbook of dialysis.* 4th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2007:523-541. 10. Besarab A. Anemia and epoetin use: Anemia in patients with end-stage renal disease. In: Nissenson AR, Fine RN, eds. *Dialysis Therapy.* 3rd ed. Philadelphia, Pa: Hanley & Belfus, Inc; 2002:309-313. 11. National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis.* 2003;42(suppl 3):S7-S9. 12. Deziel SM. Anemia management in patients with chronic conditions that affect erythropoiesis. *Nephrol Nurs J.* 2002;29:582-585. 13. Hou S. The pregnant patient: Pregnancy in women on dialysis. In: Nissenson AR, Fine RN, eds. *Dialysis Therapy.* 3rd ed. Philadelphia, Pa: Hanley & Belfus, Inc; 2002:519-522. 14. Schrier SL. Chapter III: Anemia: Production defects. WebMD Corp:2001. 15. Ifudu O, Feldman J, Friedman EA. The intensity of hemodialysis and the response to erythropoietin in patients with end-stage renal disease. *N Engl J Med.* 1996;334:420-425. 16. National Kidney Foundation. K/DOQI clinical practice guidelines for hemodialysis adequacy, 2000. *Am J Kidney Dis.* 2001;37 (suppl 1):S7-S64. 17. Kalantar-Zadeh K, McAllister CJ, Lehn RS, Lee GH, Nissenson AR, Kopple JD. Effect of malnutrition-inflammation complex syndrome on EPO hyporesponsiveness in maintenance hemodialysis patients. *Am J Kidney Dis.* 2003;43:761-773. 18. Kalantar-Zadeh K, Ikizler TA, Block G, Avram MM, Kopple JD. Malnutrition-inflammation complex syndrome in dialysis patients; causes and consequences. *Am J Kidney Dis.* 2003; 42:761-773. 19. National Kidney Foundation. K/DOQI clinical practice guidelines for nutrition in chronic renal failure. *Am J Kidney Dis.* 2000; 35(suppl 2):S17-S104. 20. Traub SL, ed. *Basic Skills in Interpreting Laboratory Data.* 2nd ed. Bathesda, Md: American Society of Health-System Pharmacies, Inc; 1996. 21. Tietz NW, ed. *Clinical Guide to Laboratory Tests.* 3rd ed. Philadelphia, Pa: W.B. Saunders Company; 1995. 22. Sam R, Hariman A, Kjellstrand CM, Ing TX. Hemolysis during hemodialysis. In: Nissenson AR, Fine RN, eds. *Dialysis Therapy.* 3rd ed. Philadelphia, Pa: Hanley & Belfus, Inc; 2002:195-198.

CMS Changes for ESA Reimbursement in the Dialysis Setting

In July 2008, the Centers for Medicare & Medicaid Services (CMS) changed its reimbursement policy for the use of erythropoiesis-stimulating agents (ESAs) in dialysis centers to reflect the FDA's recommendations that hemoglobin levels be maintained between 10-12g/dL.

CMS added a provision that reduces by 50% the reported ESA dosage used by the dialysis facility for which payment will be made if the facility reports that the beneficiary's hemoglobin has exceeded 13 g/dL for three consecutive months, including the current billed month. Under the previous policy, only a 25% reduction in ESA dosage was required when a patient's hemoglobin levels exceeded 13 g/dL, the CMS said.

In addition to the dose reduction requirements, reimbursement for the administration of monthly doses in excess of 400,000 IUs of Amgen's Epogen (epoetin) will be halted, as well as monthly doses in excess of 1,200 micrograms of Amgen's Aranesp (darbepoetin alfa).

ESRD Network 4, Inc.



: Working for you

Network-wide Quality Improvement Project

Anemia Management

Launch Date: September 1, 2009

BACKGROUND

Anemia develops in the majority of patients with chronic kidney disease (CKD) and is a risk factor for clinical complications and increased mortality. Anemia affects persons with prevalent symptoms such as fatigue, pallor, dyspnea, weakness, dizziness and impaired cognition. Hemodynamic changes can also occur, increasing the workload of the cardiovascular system, which can lead to left ventricular hypertrophy (LVH) and congestive heart failure (CHF). These cardiovascular impairments result in increased morbidity and mortality. The serum hemoglobin (Hgb) is one clinical marker for determining the level of anemia. Erythropoiesis stimulating agents (ESAs) are used to increase the level of hemoglobin in a CKD patient with anemia.

A Food and Drug Administration alert dated November 8, 2007 regarding ESAs revised the dosing recommendations for anemia patients with chronic kidney disease to maintain the hemoglobin within the range of 10 - 12 g/dL.

This alert was based on the data published in "The New England Journal of Medicine", November 2006, from the CHOIR and CREATE studies (Singh and Drueke, et al.) which indicated a higher risk for serious adverse cardiovascular events in CKD patients with Hgb \geq 13 g/dL. A "black box" warning was placed on ESA medications of increased risk of death with a Hgb >12 g/dL.

A National Kidney Foundation Kidney Disease Outcomes Quality Initiative work group revised the clinical practice recommendation in 2007 to target dialysis patients in the range of 11 - 12 g/dL hemoglobin and also suggested the target hemoglobin should not be greater than 13. The Centers for Medicare & Medicaid Services (CMS) also revised reimbursement for ESA medications when a Hgb is \geq 13 g/dL.

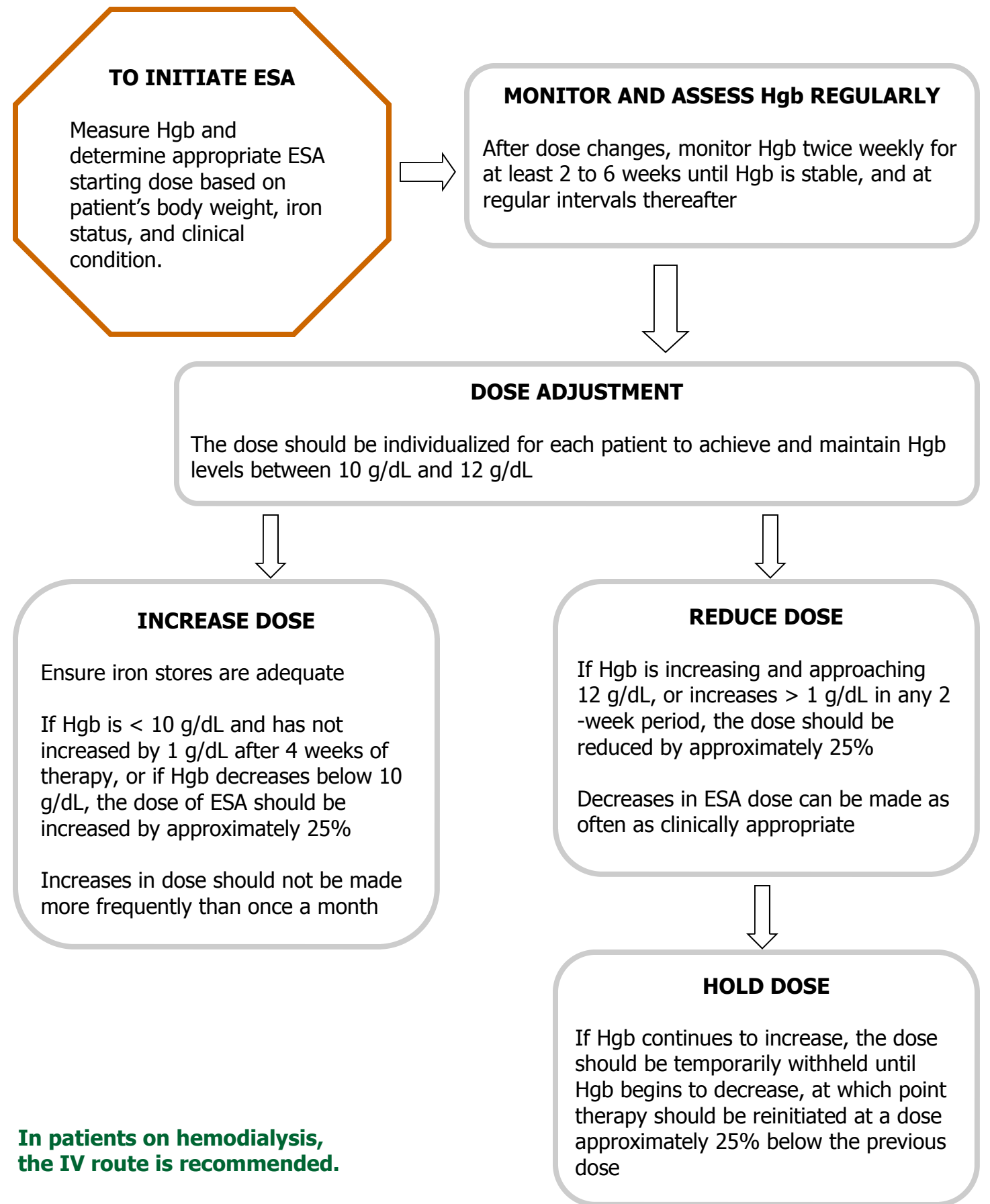
With the recent reduction in the Medicare payment formula for the ESA administration, the Medical Review Board of ESRD Network 4 is concerned about the possibility of an increase in patients with a hemoglobin < 10 g/dL as providers struggle to maintain hemoglobin within a narrow range.

According to the National Clinical Performance Measures 2009 Annual Data Report Preliminary Summary, Network 4's average anemia performance is slightly below the national average. This provides an opportunity to develop a focused intervention for facilities based on their specific needs.



Why should we look at Hemoglobin?

DOSING GUIDELINES



MANAGEMENT

EVALUATE Hgb over time	Monitor Hgb values regularly to determine Hgb trend; after dose changes, monitor Hgb at least weekly for at least 2 to 6 weeks until Hgb is stable, and at regular intervals thereafter
ANTICIPATE Hgb response	Evaluate Hgb trend
TAKE ACTION Proactively	Manage factors affecting Hgb response and determine appropriate ESA dose modifications

Recommendations

- ◆ Increases in ESA dose should not be made more frequently than once a month unless clinically indicated
- ◆ Decreases in ESA dose may be made as often as clinically appropriate
- ◆ In patients on hemodialysis, the IV route is recommended

What do we need to do?



PROJECT DETAILS

WHO

All dialysis facilities in Network 4 will be included in this project.

WHEN

Starting September 1, 2009 and continuing through March 31, 2010.

Why

Low Hgb levels are associated with a wide range of potential risks, including an increased risk of cardiovascular complication and mortality.

HOW

Utilize the information enclosed with this document to help your unit track and improve Hemoglobin levels for your patients as part of your Quality Assessment and Performance Improvement (QAPI) work.

No tracking sheets or special data elements are required to be submitted to the Network office for this project.

NEXT STEPS

The Network office will evaluate the success of your improvement in Hemoglobin levels by checking the results from our Lab Data Collection project, which will conclude in the second quarter of 2010.

We will also ask for you to complete a Facility Assessment Scan, so the Network can gauge the level of practice changes you implemented in order to successfully roll-out this project to your unit.

GOT QUESTIONS

You may contact either Suzanne Kirschbaum, RN, Director of Quality Improvement, or Dave Moskovitz, RN, Quality Improvement/Community Outreach Coordinator at (412) 325-2250.

ASSESSMENT

Individualize the dose to achieve and maintain Hgb levels of **10 to 12 g/dL**.

Common causes of low Hemoglobin (Hgb)

Initiation of dialysis or ESA therapy

Suspect if:

- Starting dose < 50-100 U/kg three times weekly (TTW)¹
- Delayed initiation of ESA therapy²
- Anemia untreated or undertreated prior to dialysis³
- Late referral to nephrologist²

ESA dose

Suspect if:

- Low ESA dose based on body weight¹
- Inappropriate dose changes⁴
- Nonadherence⁵
- Hgb not tested 2x/week to establish appropriate maintenance dose¹

Hospitalization⁶

Suspect if:

- Blood loss during hospitalization (including repeated blood drawings)⁸
- Missed ESA doses in hospital⁶
- Not identified for more frequent Hgb monitoring after discharge⁶
- Received blood transfusion⁶
- Had surgery⁶

Iron deficiency¹

Suspect if:

- Ferritin < 100 ng/mL (or facility-established target)¹
- TSAT < 20% (or facility-established target)¹

Infection or Inflammation⁷

Suspect if:

- ↑ Ferritin with ↓ TSAT⁷
- ↑ WBC count⁸
- ↑ CRP⁷

Blood loss¹

Suspect if:

- Known occult blood loss⁹
- ↑ Reticulocyte count⁸
- Low TSAT (or facility-established target)⁸
- Clotted dialyzers¹⁰

Secondary HPT⁹

Suspect if:

- iPTH > 300 pg/mL^{9,11}
- Osteitis fibrosis¹²

Concomitant medical condition/therapy

Suspect if:

- Conditions include:
 - Hematologic disorders¹
 - HIV/AIDS¹²
 - Pregnancy¹³
 - Malignant processes¹
- Medications/therapies include:
 - Certain analgesics⁸
 - Certain antibiotics⁸
- Aluminum toxicity¹
 - Certain phosphate binders¹⁴
 - Dialysis fluid contamination¹⁴
 - Long dialysis vintage⁹
 - High plasma aluminum levels¹⁴

Inadequate dialysis¹⁵

Suspect if:

- Dialysis missed/shortened¹⁵
- URR < 65%¹⁵
- Kt/V < 1.2¹⁶

Protein energy malnutrition¹⁷

Suspect if:

- Protein intake below recommended level¹⁸
- ↓ Serum albumin or prealbumin¹⁷
- ↓ nPNA¹⁹

Vitamin deficiency¹

Suspect if:

- ↑ mcv⁸
- B₁₂ < 140 pg/mL²⁰
- Folic Acid < 3 ng/mL²¹
- B₆ < 5 ng/mL²¹

Hemolysis¹

Suspect if:

- ↑ Bilirubin²²
- Abnormal Coombs' test²²
- ↓ Serum haptoglobin⁹
- ↑ Reticulocyte count⁸
- ↑ TSAT⁸
- ↑ Ferritin⁸
- Cherry-red to port-wine-colored blood²²
- On medication that can cause hemolysis²²
- Problems with water supply, dialysate, or dialysis equipment (especially if more than one patient is suspected of hemolysis)²²

If no other cause of low Hgb is found, consider screening for PRCA.