Anemia Management Protocol

Steps		Parameters	Clinical Notes
1 **Select a target hemoglobin (hematocrit) range.**	Define target Hb (Hct):	Hb____ to____ g/dL Hct____% to____%	• The NKF-K/DOQI guidelines recommend a target Hb range of 11 to 12 g/dL (Hct of 33% to 36%) • The EPOGEN® package insert recommends a target Hb (Hct) range of 10 to 12 g/dL (30% to 36%)
2 **Define parameters for use of EPOGEN® (Epoetin alfa).**	A. Start dose at:_____ TIW)	_____(U/kg	• Dose EPOGEN® by weight: recommended starting dose is 50 to 100 U/kg three times a week (TIW) • Maintenance doses may range from 12.5 to 525 U/kg TIW, and must be individualized
	B. Monitor Hb (Hct) to measure outcomes every:		• Twice a week for 2 to 6 weeks following any dose adjustment • Monthly when the EPOGEN® dose has stabilized
	C. Increase dose by ____% when Hb (Hct) approaches:		• Increase the dose in increments of 10% to 25% • Increase the dose when the Hb (Hct) approaches the lower end of the facility's target range • When initiating therapy, increase the dose if the Hb (Hct) does not increase 1.7 to 2 g/dL (5 to 6 points) after 8 weeks, and the Hb (Hct) is below the suggested target range • Unless clinically indicated, dose adjustments should not be made more frequently than once every 4 weeks
	D. Decrease dose by ____% when Hb (Hct) approaches:		• Decrease the dose in decrements of 10% to 25% • Decrease the dose when the Hb (Hct) approaches 12 g/dL/36%, or the upper end of the facility's target range • If the Hb (Hct) rises more than 1.3 g/dL (4 pts) in any 2 week period, decrease the dose • Unless clinically indicated, dose adjustments should not be made more frequently than once every 4 weeks

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	E. Hold the dose when Hb (Hct) is:		• Hold the dose of EPOGEN® (Epoetin alfa) when the Hb (Hct) is > 12 g/dL (36%) AND a 10% to 25% decrease in the dose does not slow the rate of rise in the Hb (Hct) • Holding the EPOGEN® dose can lead to a dramatic decrease in the Hb (Hct). In some cases, Hb (Hct) levels > 12 g/dL may be appropriate on the basis of individual patient clinical characteristics, and the discretion of the physician.
	F. If the dose is held, check Hb (Hct) every: _____ Restart EPOGEN® at a reduced dose when Hb (Hct) is:		• Check the Hb (Hct) weekly to determine trends • Restart EPOGEN® at a 10% to 25% reduction in dose when the Hb (Hct) has decreased to within the facility's target range
3 **Define the parameters for use of iron.**[1-8]	A. Select TSAT and ferritin target range:	TSAT ____% to ____% Ferritin ____ng/mL to ____ng/mL	
	B. Monitor	TSAT _____ Ferritin _____ TIBC _____	• The EPOGEN® package insert recommends regular evaluation of iron status for all patients receiving therapy. A TSAT ≥20% and a ferritin ≥100 ng/mL are recommended to support erythropoiesis. • The NKF-K/DOQI guidelines recommend evaluating iron parameters at least every 3 months
	C. Start oral iron at ____; when:		• Iron deficiency is defined as TSAT < 20% and ferritin < 100 ng/mL • Many dialysis patients will require higher levels • Oral iron supplements are safe and inexpensive, but reduced intestinal absorption and poor patient compliance limit their effectiveness • Oral iron may be sufficient for peritoneal dialysis patients • Hemodialysis patients may require IV iron supplements • Recommended dosing for oral iron = 200 mg of elemental iron per day

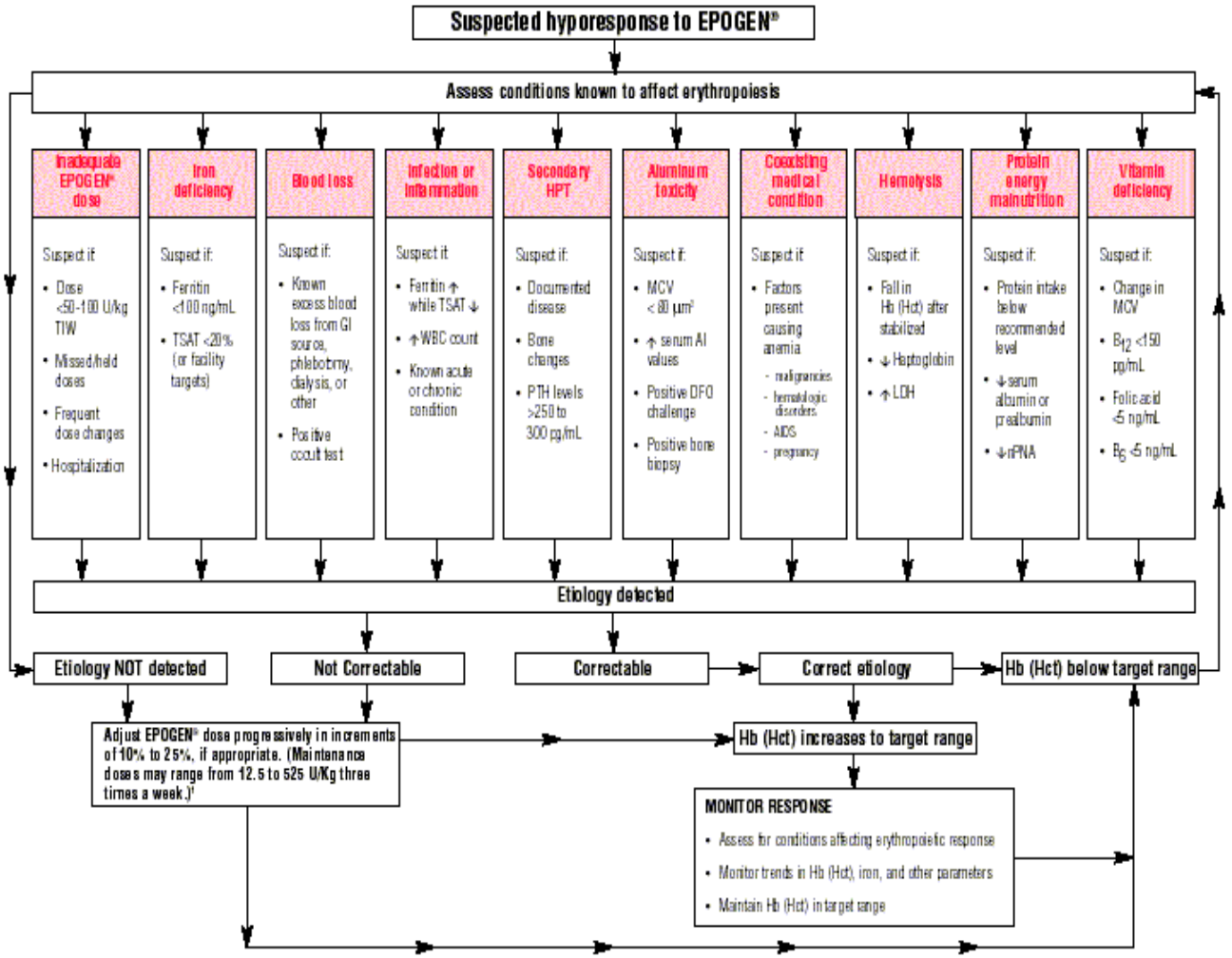
Steps	Parameters	Clinical Notes
D. Stop oral iron and start IV iron when:		• Consider IV iron if oral iron is ineffective, or the patient cannot tolerate oral iron and TSAT and ferritin are below the facility's target levels • Rule out other causes of hyporesponse that may affect iron levels (see step 4)
E. Calculate the total dose of IV iron required to treat anemia and to replace iron stores/ ongoing blood loss.		• Calculate iron needs on the basis of actual iron deficiency and blood loss (see specific IV Iron Package Insert) • For patients with poor dietary intake, add the calculation for replacing obligatory iron loss (average 1 mg/day = 365 mg/year) • If necessary, administer a test dose before the initial dose. Administration of subsequent test doses during therapy should be considered.
F. Discontinue IV iron and use oral iron when:		• The patient has an allergic reaction • Use caution when administering IV iron to a patient who has an infection/inflammation
G. Discontinue all iron supplements when:		• Safe upper limits for iron parameters in dialysis patients remain controversial • The NKF-K/DOQI Anemia Work Group recommends maximum levels of 50% for TSAT and 800 ng/mL for serum ferritin • In a subsequent analysis of safety considerations, Fishbane recommended that ferritin levels not exceed 500 ng/mL[4]

Steps

4

Monitor outcomes and assess for causes of hyporesponse if the target Hb (Hct) is not achieved.

EPOGEN® (Epoetin alfa) Hyporesponse and Dosing Algorithm



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Steps	Parameters	Clinical Notes
5 **Document anemia management to achieve target Hb (Hct).**	Does your medical record include the following?	• Most Recent Hb (Hct) (include date) • Target Hb (Hct) • Rationale for target Hb (Hct) • Current EPOGEN® (Epoetin alfa) Dose (if change required) • New EPOGEN® Dose (if change required) • Rationale for new EPOGEN® dose • Physician signature and date

References

1. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000. *Am J Kidney Dis*. 2001;37:S182-S238.

2. Fishbane S, Maesaka JK. Iron management in end-stage renal disease. *Am J Kidney Dis*. 1997;29:319-333.

3. Fishbane S, Mittal SK, Maesaka JK. Beneficial effects of iron therapy in renal failure patients on hemodialysis. *Kidney Int*. 1999;55:S67-S70.

4. Fishbane S. Intravenous iron therapy: reweighing risk and reward. *Semin Dial*. 1999;12:5-8.

5. EPOGEN® (Epoetin alfa) [package insert] Thousand Oaks, Calif: Amgen Inc; 1999.

6. Eschbach JW, Abdulhadi MH, Browne JK, et al. Recombinant human erythropoietin in anemic patients with end-stage renal disease: results of a phase III multicenter clinical trial. *Ann Intern Med*. 1989;111:992-1000.