

Erythropoiesis Stimulating Agent Orders and Flow Sheet

Date: _____ Patient Name: _____ Age: _____ Weight: _____

Diagnosis: _____ Most recent chemotherapy date: _____ Regimen: _____

Hemoglobin or Hematocrit measurement: _____ g/dL Initial Iron: _____

INITIAL SYMPTOMS: _____

Special Announcement (Updated August 5, 2008): Effective July 31, 2008, the United States Food and Drug Administration (FDA) mandated the following changes to the labels for the erythropoiesis stimulating agents, epoetin alfa and darbepoetin: 1) ESAs are no longer indicated for patients receiving myelosuppressive chemotherapy if the anticipated treatment outcome is cure. They remain indicated when myelosuppressive chemotherapy is intended for palliation. 2) ESAs should not be initiated if the patient's hemoglobin is above 10 g/dL. Further, the label change: a.) specifies that ESA treatment should target the lowest hemoglobin concentration that will avoid transfusion, b.) removes "...or exceeds 12 g/dL" as an upper range for ESA use, and c.) removes language that allowed earlier initiation of ESAs, or treatment to higher hemoglobin targets, if the patient cannot tolerate anemia due to a co-morbid condition.

The labels' Boxed Warnings now read: "ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers." The warning is no longer focused on studies with hemoglobin targets at or above 12 g/dL.

JUSTIFICATION FOR USE:

<input type="checkbox"/> Hemoglobin concentration is approaching or has fallen below 10 g/dL	<input type="checkbox"/> Patient has low-risk myelodysplasia	<input type="checkbox"/> Patient has chemotherapy-associated anemia
<input type="checkbox"/> Other causes of anemia considered	<input type="checkbox"/> No contraindications	

<input type="checkbox"/> Patient has a hemoglobin concentration greater than 10 and but below 12 g/dL and I have documented the clinical necessity				
Clinical Considerations	<input type="checkbox"/> Symptomatic angina	<input type="checkbox"/> Limited cardiopulmonary reserve	<input type="checkbox"/> Reduction in ADL's	<input type="checkbox"/> Coronary Artery Disease
Clinical necessity: _____				

CONTRAINDICATIONS - WARNING: If patient has contraindications to ESAs do not administer or use only with extreme caution - *use caution †Do not use

<input type="checkbox"/> Patient has previous history of thromboembolic events*	<input type="checkbox"/> Prolonged periods of immobilization or limited activity*
<input type="checkbox"/> Just about to have or recently has had surgery (perioperative)*	<input type="checkbox"/> Patient has multiple myeloma and is receiving thalidomide or lenalidomide*
<input type="checkbox"/> Anemia of cancer not receiving concurrent chemotherapy†	<input type="checkbox"/> Patient with anemic myeloma, NHL, CLL not receiving concurrent chemotherapy*

Monitoring

	Date	Measurement	Date	Measurement	Date	Measurement	Date	Measurement
Iron								
Total iron-binding capacity								
Transferring saturation %								
Ferritin								

PLAN:

ESA	Dose and Modifications	Dose/basis	Dose	Route	Schedule
Epoetin alfa	Initial dose – 3 Times Weekly	150 units/kg		Subcut	Until reduction in transfusion requirement or rise in Hb after 8 weeks. If not, increase dose. If Hb approaches 12 g/dL or Hb increases more than 1 g/dL in 2 weeks, decrease dose.
	Dose increase – 3 Times Weekly	300 units/kg		Subcut	If Hb approaches 12 g/dL or Hb increases more than 1 g/dL in 2 weeks, then decrease dose.
	Initial dose – Weekly	40,000 units weekly		Subcut	Assess at 4 weeks. If Hb approaches 12 g/dL or Hb increases more than 1 g/dL in 2 weeks, then decrease dose. If no increase greater than or equal to 1 g/dL in that time and in the absence of a RBC transfusion, increase dose.
	Dose increase – Weekly	60,000 units		Subcut	If Hb approaches 12 g/dL or Hb increases more than 1 g/dL in 2 weeks, then decrease dose.
	Dose reduction – for both Initial Doses	Decrease dose by 25%		Subcut	
	Dose withholding	If Hb exceeds 12 g/dL	-	-	Until Hb is less than 11 g/dL, then restart 25% below previous dose.
	Dose restarting	25% below previous dose		Subcut	
Darbepoetin alfa	Initial dose – Weekly	2.25 mcg/kg		Subcut	Assess at 2 and 6 weeks. If Hb increases by greater than 1 in 2 weeks, decrease. If Hb exceeds 11 g/dL, decrease dose. If less than 1 g/dL increase after 6 weeks, then increase.
	Dose increase – Weekly	4.5 mc/kg		Subcut	If Hb increases by greater than 1 in 2 weeks, decrease. If Hb exceeds 11 g/dL, decrease.
	Initial dose – Every 3 Weeks	500 mcg		Subcut	Assess at 2 weeks. If Hb increases by greater than 1 in 2 weeks, decrease. If Hb exceeds 11 g/dL, decrease dose.
	Dose reduction – for both Initial Doses	40% of previous dose		Subcut	
	Dose withholding	If Hb exceeds 12 g/dL	-	-	Until Hb = 11 g/dL, then restart at 40% below previous dose.
	Dose restarting	40% below previous dose		Subcut	

Write dose to be given in appropriate box. After it is administered, write in site and your initials.

Cycle #	Day of cycle	Date to be given	Dose to be given	MD Initials	Dose given	Site	RN Initials

Reviewed by _____ on _____

This flow sheet is derived from recommendations in the Use Of Epoetin And Darbepoetin in Patients With Cancer: 2007 ASCO/ASH Clinical Practice Guideline Update. This flow sheet is a practice tool based on ASCO® practice guidelines and is not intended to substitute for the independent professional judgment of the treating physician. Practice guidelines do not account for individual variation among patients. This tool does not purport to suggest any particular course of medical treatment. Use of the practice guidelines and this flow sheet are voluntary. The practice guidelines and additional information are available at <http://www.asco.org/guidelines/epo>. Copyright © 2007 by the American Society of Clinical Oncology. All rights reserved.