ASCO Erythropoiesis Stimulating Agent Orders and Flow Sheet for Adult Patients with Cancer

COVER SHEET

Note: The FDA-approved package inserts (the "labels") limit the indication for use of Erythropoiesis Stimulating Agents (ESAs) in patients with cancer and anemia to those being treated with chemotherapy for palliation, and excludes those undergoing chemotherapy with curative intent. In addition, the FDA has mandated a Risk Evaluation and Mitigation Strategy (REMS) for all ESAs: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200297.htm

Before using this flowsheet, please complete the following items from the REMS:

- ☐ Verify that the health care provider has enrolled in the ESA APPRISE program and completed all of its requirements
- ☐ Sign the Health Professional Acknowledgment form
- ☐ Have the patient sign the Patient Acknowledgement form
- ☐ Provide the patient with the ESA Medication Guide

Erythropoiesis Stimulating Agent Orders and Flow Sheet – For Adult Patients with Cancer

Boxed Warnings : "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."

FDA required patient/healthcare professional acknowledgment form signed (see cover sheet for this form) ☐ Patient ☐ Healthcare professional

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

- ☐ Patient has previous history of thromboembolic events*
- ☐ Just about to have or recently has had surgery (perioperative)*
- ☐ Anemia of cancer not receiving concurrent chemotherapy‡
- ☐ Prolonged periods of immobilization or limited activity*
- ☐ Patient has multiple myeloma and is receiving thalidomide or lenalidomide*
- ☐ Patient with myeloma, NHL or CLL not receiving concurrent chemotherapy‡

Patient Name:_____ DOB/MRN:_____ Age:_____ Weight: _____

Diagnosis:_____ Regimen: _____

Pre-treatment Labs: Hemoglobin or Hematocrit:_____g/dL Initial Iron: _____ Date:_____

INITIAL ANEMIA SYMPTOMS:_____

PURPOSE OF CHEMOTHERAPY: ☐palliative – ESAs not indicated when chemotherapy is for curative intent

JUSTIFICATION FOR USE:

- ☐ Hemoglobin concentration has fallen below 10 g/dL
- ☐ Patient has chemotherapy-associated anemia
- ☐ Patient has low-risk myelodysplasia
- ☐ Other causes of anemia considered
- ☐ No contraindications
- ☐ Patient without contraindications wants to avoid transfusion and accept risk of ESAs

LABORATORY VALUES

	Date	Result	Date	Result	Date	Result
Iron						
Total iron-binding capacity						
Transferrin saturation %						
Ferritin						

PLAN:

Cycle #	Day of cycle	Date given	Dose ordered	MD Initials	Dose given	Site	RN/NP Initials

ESA DOSING* [*based on 2/16/2010 FDA-approved labels]

Epoetin

TIW Schedule:
Starting dose
150 Units/kg SC TIW

Evaluate at 2 & 8 weeks

- No reduction in transfusion or if increase of Hb @ 4 weeks, increase dose to 300 Units/Kg
- If Hb increases > 1 g/dL or enough to avoid transfusion at 2 weeks, decrease dose by 25%
- If Hb > level needed to avoid transfusion, hold until Hb reduced, then restart at 25% dose reduction

WKY Schedule:
Starting dose
40,000 Units SC WKY

Evaluate at 4 weeks

- No reduction in transfusion or increase of Hb ≥ 1 g/dL @ 2 weeks, increase dose to 60,000 Units
- If Hb increases > 1 g/dL or enough to avoid transfusion, decrease dose by 25%
- If Hb > level needed to avoid transfusion, hold until Hb approaches need for transfusion, then restart at 40% dose reduction

Darbepoetin

Q3W Schedule:
Starting dose
500 mcg/kg SC Q3W

Evaluate at 2 weeks

- If Hb increases enough to avoid transfusion or if increase Hb > 1g/dL @ 2 weeks, decrease by 40%
- If Hb > level needed to avoid transfusion, hold until Hb approaches need for transfusion, then restart at 40% dose reduction

WKY Schedule:
Starting dose
2.25 mcg/kg SC WKY

Evaluate at 2 & 6 weeks

- If < 1 g/dL increase @ 6 weeks, increase dose to 4.5 mcg/kg
- If Hb increases enough to avoid transfusion or if increase of HB ≥ 1 g/dL @ 2 weeks, decrease dose by 40%
- If Hb > level needed to avoid transfusion, hold until Hb approaches need for transfusion, then restart at 40% dose reduction