

	DIAGNOSIS	Hgb/Hct LEVELS AT INITIATION OF THERAPY		THERAPY GOAL		Required Epogen Dosage	REQUIRED Hgb/Hct DOCUMENTATION FOR CLAIMS PROCESSING	OTHER DOCUMENTATION REQUIREMENTS	COVERAGE LIMITATION	OTHER COVERAGE REQUIREMENTS
		Hgb g/dl	Hct %	Hgb g/dl	Hct %					
1	Anemia of ESRD (on dialysis)	<10	<30	10-12	30-36	Dependent on ff. factors: 1. baseline Hgb/Hct 2. availability of iron stores 3. presence of concurrent medical problems	Hgb/Hct immediately prior to billing period.	1. Diagnosis 2. Physician's (or NPP) Order 3. Dialysis Schedule 4. Patient's weight in kilogram. 5. Epogen units administered /kg of body weight, and route of administration. 6. Medical justification for administration of Epo exceeding usual doses. 7. Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Adequate iron stores.		Diagnosis of End Stage Renal Disease (ESRD)
2	Anemia of ESRD (not on dialysis)	<10	<30	10-12	30-36	Dependent on ff. factors: 1. baseline Hgb/Hct 2. availability of iron stores 3. presence of concurrent medical problems	Most recent Hgb/Hct reading	1. Diagnosis 2. Physician's (or NPP) order. 3. Date and results of the most recent Hgb/Hct within 1 week prior to initiation of therapy. 4. Patient's weight in kilograms and adequate iron stores. 5. Date of initiation of Epogen therapy and expected duration of treatment. 6. Epogen units administered /kg of body weight and route of administration. 7. Response to Epogen Administration (change in Hgb/Hct and or transfusion requirements). Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Medical justification for administration of Epo exceeding usual doses.		1. Serum creatinine \geq 3 2. Creatinine clearance < 60 mL/min, or glomerular filtration rate (GFR) < 60 mL/min/1.73 m2
3	Anemia related to chemotherapy for non-myeloid malignancies	<10	<30	maintain 10	maintain 30	*Refer to listed requirements on bottom of page 2.	Most recent Hgb/Hct reading	1. Diagnosis 2. Physician's (or NPP) order. 3. Date and results of the most recent Hgb/Hct within 1 week prior to initiation of therapy. 4. Patient's weight in kilograms and adequate iron stores. 5. Date of initiation of Epogen therapy and expected duration of treatment. 6. Epogen units administered /kg of body weight and route of administration. 7. Response to Epogen Administration (change in Hgb/Hct and or transfusion requirements). Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Medical justification for administration of Epo exceeding usual doses.	1. ESA is covered for 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy program. 2. ESA will not be reimbursed if Hgb/Hct is > than 10/30	
4	Anemia related to AZT and/or other NRTI therapy for HIV disease	<10	<30	10-12	30-36	Dependent on ff. factors: 1. baseline Hb/Hct 2. availability of iron stores 3. presence of concurrent medical problems	Most recent Hgb/Hct reading	1. Diagnosis 2. Physician's (or NPP) order. 3. Date and results of the most recent Hgb/Hct within 1 week prior to initiation of therapy. 4. Patient's weight in kilograms and adequate iron stores. 5. Date of initiation of Epogen therapy and expected duration of treatment. 6. Epogen units administered /kg of body weight and route of administration. 7. Response to Epogen Administration (change in Hgb/Hct and or transfusion requirements). Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Medical justification for administration of Epo exceeding usual doses.		
6	Preoperative use in patients undergoing hip or knee surgery.	10-13				Dependent on ff. factors: 1. baseline Hgb/Hct 2. availability of iron stores 3. presence of concurrent medical problems	Most recent Hgb/Hct reading	1. Diagnosis 2. Physician's (or NPP) order. 3. Date and results of the most recent Hgb/Hct within 1 week prior to initiation of therapy. 4. Patient's weight in kilograms and adequate iron stores. 5. Date of initiation of Epogen therapy and expected duration of treatment. 6. Epogen units administered /kg of body weight and route of administration. 7. Response to Epogen Administration (change in Hgb/Hct and or transfusion requirements). Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Medical justification for administration of Epo exceeding usual doses.	Preoperative use in specified patients.	1. Patient is undergoing hip or knee surgery. 2. Patient is not a candidate for autologous blood transfusion. 3. Expected to lose > 2units of blood. 4. Anemia is due to chronic disease.
7	Anemia of chronic inflammatory disease and Hepatitis C with anemia due to the medication therapy.	<10	<30	10-12	30-36	Lowest dose to gradually increase Hgb to the lowest level sufficient to avoid transfusion.	Most recent Hgb/Hct reading	1. Diagnosis 2. Physician's (or NPP) order. 3. Date and results of the most recent Hgb/Hct within 1 week prior to initiation of therapy. 4. Patient's weight in kilograms and adequate iron stores. 5. Date of initiation of Epogen therapy and expected duration of treatment. 6. Epogen units administered /kg of body weight and route of administration. 7. Response to Epogen Administration (change in Hgb/Hct and or transfusion requirements). Regular reporting of Hgb/Hct to show monitoring of ESA dose. 8. Medical justification for administration of Epo exceeding usual doses.	Coverage is limited to anemia due to ff. chronic conditions: 1. Rheumatoid Arthritis 2. Crohn's disease 3. ulcerative colitis 4. Hepatitis C w/anemia due to medication therapy.	

*Dosage requirements for patients with anemia due to chemotherapy for treatment of non-myeloid malignancies
START: No more than 150 U/kg/3 x weekly
MAINTENANCE: 1. SAME as starting dose if the Hgb/Hct remains <10/30 4 weeks after initiation of therapy and the rise in Hgb/Hct is >1/3. 2. INCREASE the starting dose by 25% if the Hgb/Hct rises <1/3 compared to baseline after 4 weeks of therapy and Hgb/Hct level remains <10/3
NOT REASONABLE AND NECESSARY (R & N): Continued use of Epogen is not R&N; 1. If the Hgb/Hct rises <1/3 after 8 weeks of treatment. 2. If there is a rapid rise in Hb/Hct >1/3 over 2 weeks of treatment unless the Hgb/Hct remains below or subsequently falls to <10/30. Continuation and reinstitution of ESA therapy must include a reduction of 25% from previously administered dos
COVERAGE LIMITATION: 1. ESA is covered for 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. 2. ESA therapy will not be reimbursed when the Hgb/Hct is greater than 10/3

NOTE: 1. Refer to "Guidelines for Reporting Administration of Epogen" for detailed instructions. 2. ESAs in dialysis patients are covered by separate Federal regulations under which there is a unique ESA/ESRD payment structure: see Benefit Policy Manual Chapter 15, 50.5.2. Any mention here of ESA use in ESRD on dialysis is only to show distinction in use of ESA
REFERENCES: NGS, LCD 25211 01-01-08; SIAA44399 01-01-08 and 02-01-08; CMS CR 5569 01/11/08; NHIC, LCD 31146 01-17-08
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