ESA Documentation Requirements Necessary to Support an Appeal

Please see LCD L25211 @ CMS.gov, Per NGS for dates of services on or after December 1, 2007 thru 2014.

According to the local coverage determination, the main endpoint in studies for on-label indications has been avoidance or reduction in transfusions.

Covered indications include:

1. Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis;

2. Treatment of significant anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy;

3. Treatment of anemia induced by AZT and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) used in treatment of HIV/AIDS;

4. Treatment of selected patients with anemia related to myelodysplastic syndrome (MDS);

5. Perisurgical adjuvant therapy (Epoetin alfa only);

6. Treatment of anemia of selected chronic diseases: rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel diseases, and

7. Hepatitis C undergoing treatment.

To best approach outpatient denials for Erythropoietin Stimulating Agent (ESA) administration, we will require access to the following:

- UB-04 bills to validate appropriate ICD-9 diagnosis codes, CPT/HCPCS codes and administration codes that correspond to the ESA treatment for each denied date of service.
- Progress notes dating back previous to the first dosage/administration to validate the covered diagnosis indications, diagnosis-specific laboratory study minimum requirements (i.e.; Hgb, Hct, Cr, eGFR, CrCl), and documentation of the consideration and /or treatment of iron deficiency, underlying infection or inflammatory process, underlying hematologic disease, hemolysis, Vitamin deficiencies, blood loss and aluminum intoxication for any of the covered indications.
- Access to current (date/s of ESA administration) laboratory studies and progress notes that validate the continued use of ESA therapy, to assure the patient falls within the goal of therapy for continued administration (Hgb 10-12 and Hct 30-36%).
- Medication administration records that validate the drug, dose and ordering provider
- Access to the CPOE/physician orders for ESA therapy