

DRAFT

Anemia of chronic kidney disease: Hemoglobin < 10 g/dL

3a Measure Information Form (MIF)

Data Source

- ◆ Electronic administrative data/claims

Measure Set ID

- ◆ N/A

Version Number and effective date

- ◆ V. 1.4 06/21/2013

CMS approval date

- ◆ Pending

NQF ID

- ◆ N/A

Date Endorsed

- ◆ N/A

Care Setting

- ◆ Dialysis Facility

Unit of Measurement

- ◆ Facility-level

Measurement Duration

- ◆ Three months

Measurement Period

- ◆ Three months

Measure Type

- ◆ Outcome

Measure Scoring

- ◆ Rate/proportion

Payer source

- ◆ Medicare

Improvement notation

- ◆ Better quality = lower score

Measure steward

- ◆ CMS

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- ◆ N/A

Measure description

- ◆ Adult dialysis patients with hemoglobin (Hgb) values reported for at least 2 of the 3 study months who have a mean Hemoglobin <10.0 g/dL in the 3 month reporting period.

Rationale

- ◆ Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive ESA use, expansion of the ESRD Prospective Payment System bundled payment, and the development of the ESRD Quality Incentive Program. There are concerns that these changes could result in underutilization of ESAs, with lower achieved hemoglobin values that may impact quality of life or increase the frequency of red blood cell transfusion in the US chronic dialysis population.
- ◆ Monitoring the proportion of patients with a low achieved hemoglobin level may help facilities with quality assurance activities in anemia management. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for under treatment of anemia that could place patients at risk of needing blood transfusions.

Clinical Recommendation Statement

- ◆ FDA-approved ESA labels now recommend:
 - For patients with CKD, consider starting ESA treatment when the hemoglobin level is less than 10 g/dL. This advice does not recommend that the goal is to achieve hemoglobin of 10 g/dL or hemoglobin above 10 g/dL.
- ◆ KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease
 - 3.4.3: For adult CKD 5D patients, we suggest that ESA therapy be used to avoid having the Hgb concentration fall below 9.0 g/dl (90 g/l) by starting ESA therapy when the hemoglobin is between 9.0–10.0 g/dl (90–100 g/l). (2B)
 - 3.4.4: Individualization of therapy is reasonable as some patients may have improvements in quality of life at higher Hb concentration and ESA therapy may be started above 10.0 g/dl (100 g/l). (Not Graded)
- ◆ KHA-CARI guideline
 - Suggest that in dialysis patients with anemia due to CKD, an erythropoiesis-stimulating agent (ESA) can be used to prevent the hemoglobin falling below 95 g/L in order to avoid the need for blood transfusion and to improve quality of life.
- ◆ NICE UK Anaemia Management in Chronic Kidney Disease Guidelines
 - Typically maintain the aspirational Hb range between 10 and 12 g/dl for adults, young people and children aged 2 years and older, and between 9.5 and 11.5 g/dl for children younger than 2 years of age, reflecting the lower normal range in that age group.
 - To keep the Hb level within the aspirational range, do not wait until Hb levels are outside the aspirational range before adjusting treatment (for example, take action when Hb levels are within 0.5 g/dl of the range's limits). [NICE 2011]

- Consider investigating and managing anaemia in people with CKD if:
 - their Hb level falls to 11 g/dl or less (or 10.5 g/dl or less if younger than 2 years) or,
 - they develop symptoms attributable to anaemia (such as tiredness, shortness of breath, lethargy and palpitations). [NICE 2011]

References

- ◆ FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease.
<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>
- ◆ KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease
http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf
- ◆ KHA-CARI guideline
<http://onlinelibrary.wiley.com/doi/10.1111/j.1440-1797.2011.01535.x/full>
- ◆ NICE 2011 Guideline
<http://www.ncbi.nlm.nih.gov/books/NBK65530/>

Release Notes / Summary of Changes

- ◆ Changes were made to the unit of measurement, measurement duration, numerator, and denominator exclusions sections to provide additional clarity.

Technical Specifications

- ◆ Target Population

Adult patients (≥ 18 years old) with 90+ days on dialysis with exclusions for patients with comorbid conditions that may lead to transfusions unrelated to dialysis facility anemia management practice.

Denominator

- ◆ Denominator Statement

Total number of patients at the dialysis facility with Hgb values reported for at least two of the three months in the reporting period.

- ◆ Denominator Details

All adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients with ESRD ≥ 3 months and who had Hgb values reported for at least 2 of the 3 months in the reporting period.

- ◆ Denominator Exceptions and Exclusions

The denominator excludes patients who are receiving dialysis for fewer than 90 days, or had only one Hgb value in the three month period, or who were less than 18 years of age at the beginning of the month. In addition, patients with the following comorbidities identified from Medicare claims within one year prior to the observation period.

- Hemolytic and Aplastic Anemia
- Solid Organ Cancer (Breast, Prostate, Lung, Digestive tract and others)
- Lymphoma
- Carcinoma in situ

- Coagulation Disorders
- Multiple myeloma, Myelodysplastic Syndrome, and Myelofibrosis
- Leukemia
- Head and Neck Cancer
- Other Cancers (connective tissue, skin, and others)
- Metastatic Cancer
- Sickle cell anemia

Numerator

◆ Numerator Statement

Number of patients in the dialysis facility who have a mean Hgb <10.0 g/dL for at least two of the three months in the reporting period.

◆ Numerator Details

The average hemoglobin is calculated from the two or three months of values available for each patient over the period, irrespective of ESA use. For records reporting Hematocrit, hematocrit divided by three is substituted for hemoglobin. A patient can be included in the numerator only once during this three month period.

Stratification or Risk Adjustment

None

Sampling

None

Calculation Algorithm

The measure is calculated by dividing the numerator by the denominator. .