

DRAFT

Anemia Management of Chronic Kidney Disease: Hemoglobin >12 g/dL

3a Measure Information Form (MIF)

Data Source

- ◆ Electronic administrative data/claims

Measure Set ID

- ◆ N/A

Version Number and effective date

- ◆ V. 1.5, 6/21/2013

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 (Intermediate outcome)

Measure Scoring

- ◆ Rate/proportion

Payer source

- ◆ Medicare

Improvement notation

- ◆ Better quality = lower score

Measure steward

- ◆ CMS

Copyright / Disclaimer

- ◆ N/A

Measure description

- ◆ Percent of ESA-treated chronic dialysis patients in the facility, who have a mean Hemoglobin greater than 12 g/dL for a three month period.

Rationale

- ◆ In controlled trials of patients with chronic kidney disease using ESAs to treat anemia, targeting hemoglobin values above 12gm/dl has been associated with poorer patient outcomes. FDA guidelines, updated in 2011, recommended that for patients with CKD on dialysis the dose of ESA should be reduced or interrupted if the achieved hemoglobin level approaches or exceeds 11 g/dl. This proposed measure is intended to allow monitoring of variation in dialysis facility anemia treatment, using ESAs, monitoring for overtreatment that could result in increased patient morbidity and mortality.
- ◆ A 3 month time frame was selected as it is more sensitive in detecting elevated hemoglobin values when compared to using a 12 month time frame. While public reporting on Dialysis Facility Compare has used 12-month measures of anemia management since its inception in 2001, anemia management practices have changed over time and now few patients have a 12-month mean hemoglobin greater than 12 g/dL.

Clinical Recommendation Statement

- ◆ KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease
 - 3.5.1: In general, we suggest that ESAs not be used to maintain Hgb concentration above 11.5 g/dl (115 g/l) in adult patients with CKD. (2C)
 - 3.6: In all adult patients, we recommend that ESAs not be used to intentionally increase the Hgb concentration above 13 g/dl (130 g/l). (1A)

NOMENCLATURE AND DESCRIPTION FOR RATING GUIDELINE RECOMMENDATIONS

Within each recommendation, the strength of recommendation is indicated as **Level 1**, **Level 2**, or **Not Graded**, and the quality of the supporting evidence is shown as **A**, **B**, **C**, or **D**.

Grade*	Implications		
	Patients	Clinicians	Policy
Level 1 'We recommend'	Most people in your situation would want the recommended course of action and only a small proportion would not.	Most patients should receive the recommended course of action.	The recommendation can be evaluated as a candidate for developing a policy or a performance measure.
Level 2 'We suggest'	The majority of people in your situation would want the recommended course of action, but many would not.	Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with her or his values and preferences.	The recommendation is likely to require substantial debate and involvement of stakeholders before policy can be determined.

*The additional category 'Not Graded' was used, typically, to provide guidance based on common sense or where the topic does not allow adequate application of evidence. The most common examples include recommendations regarding monitoring intervals, counseling, and referral to other clinical specialists. The ungraded recommendations are generally written as simple declarative statements, but are not meant to be interpreted as being stronger recommendations than Level 1 or 2 recommendations.

Grade	Quality of evidence	Meaning
A	High	We are confident that the true effect lies close to that of the estimate of the effect.
B	Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
C	Low	The true effect may be substantially different from the estimate of the effect.
D	Very Low	The estimate of effect is very uncertain, and often will be far from the truth.

References

- ◆ 2012 Anemia Management TEP Summary Report
<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html>
- ◆ KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease
http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

Release Notes / Summary of Changes

- ◆ This version includes changes to the rationale, denominator details, and numerator details.

Technical Specifications

- ◆ Target Population
ESA-treated adult patients (≥ 18 years old) with 90+ days on chronic dialysis

Denominator

- ◆ Denominator Statement
Total number of eligible ESA-treated patients under the care of a dialysis facility during the three month period.
- ◆ Denominator Details

In order to be included in a facility's calculation, a patient must have at least 2 months with a valid non-missing hemoglobin value from the facility during the three month period. ESA refers to epoetin alfa, darbepoetin alfa, or peginesatide* and hemoglobin values are taken from the last claim during the month.

* Note peginesatide was recalled in February 2013 and is not presently available.

◆ Denominator Exceptions and Exclusions

Claims are excluded if (1) the patient is less than 18 years of age at the start of the claim period; (2) the patient was on chronic dialysis for less than 90 days at the start of the claim period; (3) the hemoglobin value was implausible, defined as less than 5 g/dL or greater than 20 g/dL; (4) the hemoglobin value is missing or reported as 99.99; (5) no ESA was administered during the claim period.

Patients are excluded if they had only one month of otherwise valid claims data at the facility in the three month period.

Numerator

◆ Numerator Statement

Number of eligible ESA-treated patients at a dialysis facility with average hemoglobin during the three month period greater than 12 g/dL.

◆ Numerator Details

The average hemoglobin calculation uses monthly values within the three month period. Patient averages must be calculated from at least two months with eligible claims. If patient average exceeds 12g/dl then a patient is counted in the numerator. 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. If hemoglobin is missing or out of range, hematocrit divided by three is substituted for hemoglobin.