

DRAFT

Anemia of chronic kidney disease: Patient informed consent for ESA treatment

3a Measure Information Form (MIF)

Data Source

- ◆ Electronic administrative data/claims
- ◆ CROWNWeb attestation

Measure Set ID

- ◆ N/A

Version Number and effective date

- ◆ V. 1.3, 3/8/2013

CMS approval date

- ◆ Pending

NQF ID

- ◆ N/A

Date Endorsed

- ◆ N/A

Care Setting

- ◆ Dialysis Facility

Unit of Measurement

- ◆ Facility level

Measurement Duration

- ◆ Patient year

Measurement Period

- ◆ Calendar year

Measure Type

- ◆ Process

Measure Scoring

- ◆ Rate/proportion

Payer source

- ◆ Medicare

Improvement notation

- ◆ Better quality = higher score

Measure steward

- ◆ CMS

Copyright / Disclaimer

- ◆ N/A

Measure description

- ◆ A measure of the percentage of the facility's ESA-treated patients who were provided information regarding risks, potential benefits, and alternative treatment options for anemia and consented to the anemia treatment provided by the facility.

Rationale

- ◆ The risks associated with aggressive treatment of anemia of CKD with ESAs have been documented with increased frequency over the last several years. Recently published KDIGO Anemia Management Guidelines as well as updated FDA package insert information for ESAs highlight this evolving understanding of these risks.
- ◆ Given the highlighted risks associated with aggressive anemia management with ESAs, the net benefit of ESA treatment of anemia of CKD has been questioned, particularly in patients identified as being at higher risk for development of complications (ESA resistant, high risk for thromboembolic events, active malignancy).
- ◆ Careful evaluation of the risks and potential benefits of ESA treatment of anemia in patients with CKD should be made prior to initiation of ESAs or if dose escalation is contemplated.

Clinical Recommendation Statement

- ◆ Epogen and Aranesp are indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion. The FDA recommends that therapy of ESAs should be individualized to the patient and the lowest possible ESA dose given to reduce the need for transfusions.
- ◆ From the package insert for Epogen (epoetin alfa), For patients with CKD on dialysis: "Use the lowest Epogen dose sufficient to reduce the need for red blood cell (RBC) transfusions."
- ◆ From the package insert for Aranesp (darbepoetin alfa). For patients with CKD on dialysis: "Use the lowest Aranesp dose sufficient to reduce the need for red blood cell (RBC) transfusions."
- ◆ KDIGO Anemia Guidelines 2012: Guideline 3.2: In initiating and maintaining ESA therapy, we recommend balancing the potential benefits of reducing blood transfusions and anemia-related symptoms against the risks of harm in individual patients (e.g., stroke, vascular access loss, hypertension). (1B)
- ◆ KDIGO Anemia Guidelines 2012: Guideline 3.3: We recommend using ESA therapy with great caution, if at all, in CKD patients with active malignancy—in particular when cure is the anticipated outcome— (1B), a history of stroke (1B), or a history of malignancy (2C)

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>
- ◆ Highlights of prescribing information: Epogen (epoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103234Orig1s5166_103234Orig1s5266lbl.pdf

- ◆ Highlights of prescribing information: Aranesp (darbepoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103951Orig1s5173_103951Orig1s5258lbl.pdf
- ◆ Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney inter., Suppl.* 2012; 2: 279–335.

Release Notes / Summary of Changes

- ◆ Updated measure title.

Technical Specifications

- ◆ Target Population
Dialysis-requiring chronic kidney disease patients with concomitant anemia.

Denominator

- ◆ Denominator Statement
All patients treated in the dialysis facility in the calendar year.
- ◆ Denominator Details
TBD
- ◆ Denominator Exceptions and Exclusions
None
- ◆ Denominator Exceptions and Exclusions Details
Details: Definitions and instructions as needed.
N/A

Numerator

- ◆ Numerator Statement
Number of patients in the denominator with attestation by the treating dialysis facility that they have provided information regarding risks, potential benefits, and alternative treatment options for anemia to the patient and informed consent was obtained from the patient for the anemia treatment strategy used.

Numerator Details
TBD

Stratification or Risk Adjustment

- ◆ None

Sampling

- ◆ N/A

Calculation Algorithm

Calculation Algorithm/Measure logic: 2a1.20, 2a1.21. Describe the calculation of the measure as a flow chart or series of steps.