

DRAFT

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

3b Measure Justification

Importance

- ◆ **High Impact Aspect of Health Care**

- **Demonstrated high impact aspect**

1a1.1 Select from the following all that apply:

- *Affects large numbers*
- *Frequently performed procedure*
- *High resource use*
- *Patient/societal consequences of poor quality*

- **Summary of evidence of high impact**

1a3. Provide epidemiological or resource use data

Erythropoiesis-stimulating agents are indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients 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. In the four large randomized controlled trials of ESA use in CKD, targeting a hemoglobin value greater than 13 g/dl was not associated with improved outcomes and in some studies was associated with increased risk of adverse cardiovascular outcomes.

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)

In June 2011, The U.S. Food and Drug Administration (FDA) recommended more conservative dosing of erythropoiesis-stimulating agents in patients with chronic kidney disease. The FDA made these recommendations in light of data showing increased risks of cardiovascular events with ESAs in this population. In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when ESAs were used to target a hemoglobin level of greater than 11 g/dL. It also recommended that the lowest ESA dose sufficient to reduce the need for red blood cell transfusions should be used. FDA guidelines indicate that for patients with CKD on dialysis the dose of ESA should be reduced or interrupted if the hemoglobin level approaches or exceeds 11 g/dl. There is a safety concern with hemoglobin greater than 12 g/dL and hence the proposed measure would be used to monitor the hemoglobin levels for ESA-treated patients at the facility level.

- **Citations**

1a.4. Provide citations for the evidence described above

- Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. *New England Journal of Medicine*, 355: 2085-2098, 2006.
- Drueke TB, Locatelli F, Clyne N, et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. *New England Journal of Medicine*, 355: 2071-2084, 2006.
- Besarab A, Bolton WK, Browne JK et al. The effects of normal as compared Besarab A, Bolton WK, Browne JK et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. *N Engl J Med* 1998; 339:584–590.
- Pfeffer MA, Burdmann EA, Chen CY et al. A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. *N Engl J Med* 2009; 361:2019–2032.
- 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
- KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease
http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

◆ **Opportunity for Improvement**

- **Briefly explain the benefits envisioned by use of this measure**

1b.1. (Quality improvement anticipated)

Using ESAs to target a hemoglobin level of greater than 12 g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit. This measure is intended to guard against risks associated with higher levels of hemoglobin for ESA-treated dialysis patients.

- **Summary of data demonstrating performance gap**

1b.2. (Variation or overall less than optimal performance across providers)

In the test calculation of the measure using the 1st quarter of 2011 claims data, the facility-level mean was 11.0% of patients at a facility with Hgb>12 g/dL (SD 10.1%) with the 25th percentile, median and 75th percentile being 4.3%, 8.9%, and 15.4%, respectively.

Year/Quarter	Number of Facilities	Mean %Hgb>12	Std Dev	25th Pctl	Median	75th Pctl
2010 Q1	5340	24.7%	13.9%	14.9%	24.3%	33.3%
2010 Q2	5383	21.7%	13.5%	12.0%	20.7%	29.6%
2010 Q3	5429	19.4%	12.8%	9.8%	18.0%	27.3%
2010 Q4	5457	16.8%	12.5%	7.3%	14.7%	24.4%
2011 Q1	5492	11.0%	10.1%	4.3%	8.9%	15.4%
2011 Q2	5535	8.8%	9.1%	2.9%	6.7%	12.2%
2011 Q3	5537	6.8%	8.2%	0.0%	4.8%	10.0%
2011 Q4	5545	4.3%	7.0%	0.0%	1.1%	6.7%

○ **Citations**

1b.3. Provide citations for the evidence described above

Unpublished analysis on draft Hgb > 12 measure based on Medicare claims done by Arbor Research Collaborative for Health and Kidney Epidemiology and Cost Center- University of Michigan.

○ **Summary of data on disparities by population group**

1b.4. Summarize evidence found that demonstrates any disparities. Describe groups in which disparities exist.

Investigations of the Hgb greater than 12 by race, sex, ethnicity, age indicated relatively little variation and no substantial disparities among these groups.

Patient-level Demographics for 2011 Q1 (N=241,499)	
Strata	%Hgb > 12
Race	
American Indian/AK Native	13.5%
Asian/Pacific	10.6%
Black	10.4%
White	11.2%
Unknown	11.9%
Other/Multi-racial	10.4%
Sex	
Female	10.3%
Male	11.4%
Hispanic	
Yes	11.8%
No	10.8%
Unknown	10.5%
Age	
18-64	11.0%
65+	10.7%

○ **Citations**

1b.5. Provide citations for the evidence described above

Unpublished analysis on draft Hgb > 12 measure based on Medicare claims done by Arbor Research Collaborative for Health and Kidney Epidemiology and Cost Center- University of Michigan.

◆ **Evidence to Support Measure Focus**

○ **Structure-process-outcome relationship**

1c.1. Briefly state the measure focus (for example, health outcome, intermediate clinical outcome, process, structure) Then, identify the appropriate links (for example, structure-process-health outcome, process-health outcome, intermediate clinical outcome-health outcome)

Hemoglobin levels, an intermediate clinical outcome, are influenced by treatment at the dialysis facility such as through the administration of ESA. Multiple randomized controlled trials have found increased cardiovascular risk at high hemoglobin levels. Clinical guidelines and FDA guidance reflect this evidence. Maintaining appropriate hemoglobin levels may mitigate some of the increased cardiovascular risk demonstrated in randomized controlled trials.

○ **Type of evidence**

1c.2. Describe the type of evidence, selecting from the following list all that apply:

- *Clinical practice guideline*
- *Selected individual studies (rather than entire body of evidence)*
- *Systematic review of body of evidence (other than within guideline development)*
- *Other (state type of evidence) FDA Guidance*

○ **Directness of evidence to the specified measure**

1c.4. State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population.

This measure is focused on the population of all adult (>18 years old), ESA treated patients who are on dialysis for greater than 3 months using any type of modality. The randomized controlled trials studied the pre-dialysis chronic kidney disease population. The KDIGO Guidelines and the FDA Guidelines reviewed this evidence and made recommendations for the dialysis population.

○ **Quantity of studies in the body of evidence**

1c.5. Total number of studies, not articles

4 randomized controlled trials

○ **Quality of body of evidence**

1c.6. Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address:

- a) Study design/flaws*
- b) Directness/indirectness of the evidence to this measure (for example, interventions, comparisons, outcomes assessed, population included in the evidence)*
Imprecision/wide confidence intervals due to few patients or events)

Summary of Evidence from the ESA Package Inserts.

	Normal Hematocrit Study (NHS) (N = 1265)	CHOIR (N = 1432)	TREAT (N = 4038)
Time Period of Trial	1993 to 1996	2003 to 2006	2004 to 2009
Population	CKD patients on hemodialysis with coexisting CHF or CAD, hematocrit $30 \pm 3\%$ on epoetin alfa	CKD patients not on dialysis with hemoglobin < 11 g/dL not previously administered epoetin alfa	CKD patients not on dialysis with type II diabetes, hemoglobin ≤ 11 g/dL
Hemoglobin Target; Higher vs. Lower (g/dL)	14.0 vs. 10.0	13.5 vs. 11.3	13.0 vs. ≥ 9.0
Median (Q1, Q3) Achieved Hemoglobin level (g/dL)	12.6 (11.6, 13.3) vs. 10.3 (10.0, 10.7)	13.0 (12.2, 13.4) vs. 11.4 (11.1, 11.6)	12.5 (12.0, 12.8) vs. 10.6 (9.9, 11.3)
Primary Endpoint	All-cause mortality or non-fatal MI	All-cause mortality, MI, hospitalization for CHF, or stroke	All-cause mortality, MI, myocardial ischemia, heart failure, and stroke
Hazard Ratio or Relative Risk (95% CI)	1.28 (1.06 - 1.56)	1.34 (1.03 - 1.74)	1.05 (0.94 - 1.17)
Adverse Outcome for Higher Target Group	All-cause mortality	All-cause mortality	Stroke
Hazard Ratio or Relative Risk (95% CI)	1.27 (1.04 - 1.54)	1.48 (0.97 - 2.27)	1.92 (1.38 - 2.68)

KDIGO Summary of Clinical Trials Comparing High vs. Low ESA Targets and Clinical Outcomes

Outcome	# of studies & study design	Total N of patients randomized	Methodologic quality of studies	Consistency across studies	Directness of the evidence, including applicability	Other considerations	Summary of findings		
							Quality of evidence for outcome	Qualitative description of effect	Importance of outcome
Mortality	7 RCTs [5 H vs. L; 3 ESA vs. P] (High)	2790	No limitations (0)	No important inconsistencies (0)	Some uncertainty (-1)	None (0)	High for patients with CVD Moderate for others	Possible harm in Besarab study with higher risk CVD at Hb 14 g/dL vs. 10 g/dL. No benefit in other studies with other patients.	Critical
Non-fatal CV events	4 RCTs [3 H vs. L; 1 ESA vs. P] (High)	2104	Some limitations (-1)	No important inconsistencies (0)	Direct (0)	None (0)	Moderate	Overall, no benefit. Possible harm for CVA in the Parfrey study of 13.5-14.5 g/dL vs. 9.5-11.5 g/dL.	Critical
QoL	5 RCTs [4 H vs. L; 2 ESA vs. P] (High)	2518	Some limitations (-1)	No important inconsistencies (0)	Direct (0)	None (0)	Moderate	Possible benefit with higher Hb target	High
Transfusion requirement	5 RCTs [3 H vs. L; 3 ESA vs. P] (High)	2228	No limitations (0)	No important inconsistencies (0)	Some uncertainty ³¹ (-1)	None (0)	Moderate	Benefit with higher Hb target	High
Adverse events	6 RCTs [4 H vs. L; 2 ESA vs. P] (High)	2741						Significantly increased incidence of access thrombosis in Besarab study with higher risk CVD. Insufficient evidence for AEs in other studies.	Moderate
Total N	7 RCTs (High)	2790							
Balance of benefit and harms							Quality of overall evidence Moderate		
Trade off									
Improvement in QoL and transfusion requirements. Possible harm for mortality, cardiovascular events, and adverse events.									

- 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
- KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease Supplemental Tables
http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia-GL-Suppl-Tables-August-2012.pdf

◦ **Consistency of results across studies**

1c7. Summarize the consistency of the magnitude and direction of the effect across studies

The randomized controlled trials found generally consistent results (see above).

◦ **Net benefit**

1c8. Provide estimates of effect for benefit/outcome, identify harms addressed and estimates of effect, and net benefit---benefit over harms across studies. Please include results of business/social/economic case for the measure.

Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit and no clinical trial to date has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks. In addition KIDIGO guidelines states that ESAs not be used to maintain Hgb concentration above 11.5 g/dl (115 g/l) in adult patients with CKD. This measure is important as it will act as a useful monitoring tool for facilities' successful adherence to the guidelines and also ensure the safety of the patients.

◦ **Grading of strength/quality of the body of evidence**

1c9, 1c10, 1c11, 1c13, 1c14. Please address:

- *Indicate if the body of evidence has been graded: No*
- *If the body of evidence was graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias*
- *System used for grading the body of evidence*
- *Grade assigned to the body of evidence*
- *Summary of controversy/contradictory evidence*

◦ **Citation**

1c15. Provide citations for the evidence described above

See citations in 1a.4

◦ **Guideline recommendation**

1c16. Quote verbatim, the specific guideline recommendation (Including guideline number and/or page number)

3.5.1: In general, we suggest that ESAs not be used to maintain Hb concentration above 11.5 g/dl (115 g/l) in adult patients with CKD.

◦ **Citation**

1c17. Provide citations for the clinical practice guideline quoted above

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.

◦ **URL**

1c18. National Guideline Clearinghouse or other URL

http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

◦ **Grading of strength of recommendation**

1c191 1c21, 1c23. Please address:

- *Has the recommendation been graded?*
- *System used for grading the strength of guideline recommendation (USPSTF, GRADE, etc.) Grade assigned to the recommendation*

The above recommendation was graded using the GRADE system as level “2C”.

◦ **Rationale for using this guideline over others**

1c24. If multiple guidelines exist, describe why the guideline cited was chosen. Factors may include rigor of guideline development, widespread acceptance and use, etc.

The guideline cited above is more current compared to the prior KDOQI guidelines that recommended a higher Hgb target of between 10-12 g/dl.

◦ **Overall assessment of the body of evidence**

1c25, 1c26, 1c27. Based on the NQF descriptions for rating the evidence, what was your assessment of the following attributes of the body of evidence?

- *Quantity: Moderate*
- *Quality: High*
- *Consistency: High*

Reliability and Validity – Scientific Acceptability of Measure Properties

◆ **Reliability Testing**

◦ **Data sample**

2a2.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Reliability of the measure was assessed using data on ESRD patients over a one year period in 2011.

We evaluated hgb > 12 measure from data on all 2011 claims data for ESA treated dialysis patients. These data represent 241,499 patients at 5492 facilities in the first quarter of 2011. Overall, there were 302,534 patients and

5675 facilities in 2011. Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

- **Analytic methods**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

This measure is a simple average across individuals in the facility and hence the NQF-recommended approach for determining measure reliability by doing a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined, is appropriate. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance.

- **Testing Results**

2a2.3. Provide reliability statistics and assessment of adequacy in the context of norms for the test conducted

Overall, we found that IUR = 0.71, which indicates that about 71% of the variation in the hgb>12 can be attributed to the between facility differences and 29% to within facility variation.

- ◆ **Validity Testing**

- **Data sample**

2b2.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

- **Analytic method**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

In May 2012 there was an assessment of face validity based on polling of a CMS Technical Expert Panel (TEP). TEP members were asked if they recommend development of a facility-level quality measure for achieved hemoglobin level to avoid adverse outcomes

- **Testing results**

2b2.3. (Provide statistical results and assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)

6/6 voting members of the Technical Expert Panel (TEP) voted to recommend development of a facility-level quality measure for an achieved hemoglobin level to avoid adverse outcomes. Although there was not consensus among TEP members between a Hgb threshold of 12 g/dL vs. 13 g/dL, a Hgb greater than 12 was ultimately selected because it is a more conservative value with regards to the safety concerns, it is difficult to demonstrate

an incremental benefit for hgb beyond 12 g/dl, and was useful for creating harmonization with already endorsed measures.

Exclusions

◦ **Data sample for analysis of exclusions**

2b3.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients

◦ **Analytic method**

2b3.2. Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference

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.

◦ **Results**

2b3.3. Provide statistical results for analysis of exclusions (for example, frequency, variability, sensitivity analyses)

N/A

◆ **Risk Adjustment Strategy**

◦ **Rationale for no adjustment**

2b4.4. If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment. The three rows above may be deleted if this field is used. Delete row if measure is risk adjusted or if this is a process measure.

This measure focuses on a specific intermediate clinical outcome. Analyses of the Hg > 12 measure by race, sex, age and ethnicity indicate relatively little variation and hence no risk adjustment was done. Refer to 1b.4 for details.

◆ **Identification of Meaningful Differences in Performance**

○ **Data/ sample**

2b5.1 Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

○ **Analytic method**

2b5.2. Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance

To quantify the level of variation, the distribution of the measure was reported using the mean, SD, 25th, 50th, and 75th percentile.

○ **Testing Results**

2b5.3. Results-Provide measure performance results/scores (for example, distribution by quartile, mean, median, SD, etc.); identification of statistically significant and meaningfully differences in performance

In the first quarter of 2011, a quantifiable variation is observed from the measure distribution. Half of the facilities have performance on this measure ranging from 4.3% to 15.4% (An IQR of 11.1).

Year/Quarter	Number of Facilities	Mean %Hgb>12	Std Dev	25th Pctl	Median	75th Pctl
2010 Q1	5340	24.7%	13.9%	14.9%	24.3%	33.3%
2010 Q2	5383	21.7%	13.5%	12.0%	20.7%	29.6%
2010 Q3	5429	19.4%	12.8%	9.8%	18.0%	27.3%
2010 Q4	5457	16.8%	12.5%	7.3%	14.7%	24.4%
2011 Q1	5492	11.0%	10.1%	4.3%	8.9%	15.4%
2011 Q2	5535	8.8%	9.1%	2.9%	6.7%	12.2%
2011 Q3	5537	6.8%	8.2%	0.0%	4.8%	10.0%
2011 Q4	5545	4.3%	7.0%	0.0%	1.1%	6.7%

◆ **Comparability of Multiple Data Sources/Methods**

○ **Data/ sample**

2b6.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

- **Analytic method**

2b6.2. Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure

N/A

- **Testing results**

2b6.3. Provide statistical results (for example, correlation statistics, and comparison of rankings) and assessment of adequacy in the context of norms for the test conducted

N/A

- ◆ **Disparities in Care**

- **Stratification**

2c.1. If measure is stratified for disparities, provide stratified results (scores by stratified categories/cohorts)

N/A

- **Rationale for no stratification**

2c.2. If disparities have been reported/identified, but measure is not specified to detect disparities, please explain.

Investigations of the Hgb greater than 12 by race, sex, ethnicity, age indicated relatively little variation and no substantial disparities among these groups. Refer to 1b.4 for details. Hence, stratification was not necessary.

- **Supplemental information**

2.1. Supplemental testing methodology information: If additional information is available, please indicate where this information can be found: appendix, attachment, or URL

N/A

Usability

- ◆ **Public Reporting**

- **Meaningful, understandable and useful**

3a.1. Use in public reporting---disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s). If not publicly reported in a national or community program, state the reason and plans to achieve public reporting, potential reporting programs or commitments, and timeline, for example, within 3 years of endorsement)

Currently, the 12-month average Hgb >12 is reported on <http://www.medicare.gov/> Dialysis Facility Compare.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (for example, focus, group, cognitive testing) describe the data, method and results.

Similar language has been consumer tested. Please see: Trisolini M, Roussel A, Harris S, Bandel K, Salib P, Schatell D, Cell J, Klicko K. Evaluation of the Content of the Dialysis Facility Compare Website: Final Report. Prepared for the Centers for Medicare & Medicaid Services under Contract No. 500-00-0024. Waltham, Massachusetts: RTI International, 2004. The web site has been tested with focus group(s). Please see: Trisolini M, Zerhusen E, Bandel K, Roussel A, Frederick P, Schatell D, Harris S. Evaluation of the Dialysis Facility Compare Website Tool on Medicare.gov. Dialysis & Transplantation 2006 April: pp 1-8.

◆ **Quality Improvement**

○ **Meaningful, understandable and useful**

3b.1. Use in QI (If used in quality improvement program, provide name of program(s), locations, Web page URL(s))

The 12-month and 3-month average Hgb>12 are reported to facilities in the Dialysis Facility Report and Dialysis Facility Compare preview report on <http://www.dialysisreports.org/>.

3b.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (for example, QI, initiative) describe the data, method and results

N/A

○ **Other accountability uses**

3.2. Use for other accountability functions (payment, certification, accreditation) (If used in a public accountability program, provide name of program(s), locations, Web page URL(s)). This row may be deleted if not applicable.

The 12-month average Hgb>12 has been used by CMS's ESRD Quality Incentive Program.

Feasibility

◆ **How the data elements needed to compute measure score are generated**

4a.1. How are the data elements needed to compute measure scores generated? State all that apply. Data used in the measure are:

- Generated by and used by health care personnel during the provision of care (for example, blood pressure, lab value, medical condition)

◆ **Electronic availability**

4b.1. Are the data elements needed for the measure as specified available electronically (elements that are needed to compute measure scores are in defined, computer-readable fields)?

- ALL data elements in electronic claims

◆ **Susceptibility to inaccuracies, errors, or unintended consequences**

4c.1. Identify susceptibility to inaccuracies, errors, or unintended consequences of measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results.

N/A

◆ **Data collection strategy**

4d.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (for example fees for use of proprietary measures)

N/A

Related Measures

◆ **Harmonization**

5a.1. If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? If so, describe.

The proposed intermediate clinical outcome measure is closely harmonized with an already endorsed physician-level measure with the same measure focus:

- NQF #1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL

The proposed measure is also closely harmonized with a similar measure used for public reporting on Dialysis Facility Compare which is not currently NQF-endorsed, with the exception of using a 3-month time period as opposed to a 12-month time period.

◆ **Similar measures**

5b.1. If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s) or other measures in current use, describe why this measure is superior to existing measures (for example, a more valid or efficient way to measure quality); OR, provide a rationale for the additive value of developing and endorsing an additional measure. (Provide analyses when possible.)

Many features of this measure are harmonized with the similar NQF measure #1666 maintained by the AMA/PCPI. The key differences are the level of measurement (physician versus facility) and time period (year versus quarter). Hirth et al found more variation in anemia management quality measure results across facilities versus physicians.

Compared to a 12-month measure as has been used for public reporting on Dialysis Facility Compare, a 3 month time frame was selected as it is more sensitive in detecting elevated hemoglobin values. 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.

○ **Citation**

Hirth RA, Turenne MN, Wheeler JRC, Ma Y, Messana JM. **Do resource utilization and clinical measures still vary across dialysis chains after controlling for the local practices of facilities and physicians?**. *Med Care*. 2010;48(8):726–732

Sample Dialysis Facility Compare Preview Report and Guide including measure calculation:
<http://www.dialysisreports.org/Methodology.aspx>