

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name	Anemia Management – Percentage of Patients with Hemoglobin >12 g/dL
Measure Description:	Hemodialysis and Peritoneal Dialysis patients, with ESRD \geq 3 months, who have a mean Hemoglobin >12 g/dL for a 12 month reporting period, treated with ESA. The last valid hemoglobin value reported for the end of each reporting month (end-of-month Hemoglobin) is used for the calculation.

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Outcome
 - quality of life

Body System:

Hematologic
Anemia

Kidney/urinary tract
ESRD

Variable Characteristics

Measure Care Setting

- Dialysis Facility

Unit of Measurement

- Facility

Consensus Endorsement Status

- NQF
Not endorsed by NQF.

Technical Specifications

Target Population

Age

NA

Gender

- Males and females

Anchor Date

NA

Effective Date

- 4/1/08

Effective date basis

NA

Payer Source

- Medicare

Measure result reported as

- Negative

Current Alignment with CMS

NA

CHI Compliant

- Yes

Method of Data collection

- Electronic only

Numerator statement

Number of eligible Medicare hemodialysis patients, treated with an erythropoiesis stimulating agent (ESA), specifically, the use of epoetin alfa or darbepoetin alfa, at the facility during the calendar year with a mean hemoglobin value greater than 12 g/dL.

Data source

- claim/encounter

Medicare outpatient dialysis claims, CMS Program Medical Management and Information System (PMMIS/REMIS), the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks

- Other
Codes

UB-92: Hemoglobin is reported monthly to CMS on Medicare dialysis claims (UB-92). For each patient, the average hemoglobin reported on the last valid monthly claims submitted by a facility during the calendar year is calculated. For claims that report hematocrit but not hemoglobin, hemoglobin is calculated as hematocrit divided by three. If a patient is treated at more than one facility during the year, the average hematocrit is calculated for him/her separately for each facility based on the claims from each facility only.

Numerator Time Window

One year

Denominator statement

Number of eligible dialysis patients at the facility during the calendar year.

- All dialysis patients who have had ESRD for at least 3 months (90 days)
- To be included in a facility's calculation, a patient must have 4 or more eligible claims from the facility. If a patient is treated at more than one facility during the year, the hemoglobin reported is calculated for him/her separately for each facility based on the claims from each facility only.

Data source

- claim/encounter

Denominator Time Window

One Year

Exclusion Criteria

Calculated on all Medicare hemodialysis claims submitted by the dialysis facility with the following three exclusions:

1. Claims which started before day 90 of ESRD for a patient;
2. Medicare dialysis claims that did not indicated ESA treatment;
3. Claims with invalid hemoglobin values (<5 or >20). We calculated hemoglobin as hematocrit divided by three for claims that report hematocrit but not hemoglobin.

Data source

- claim/encounter
 - Other
- Codes**
UB-92

Exclusion Criteria Time Window

One Year

History

Measure Status

Implemented

CMS Active Implementation Date

1/1/2001

Measure Developer

- CMS
- Contractor: Arbor Research/UM-KECC

Intellectual property status

- Public Domain

Measure Source

- Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)

Name of Original Measure:

ESRD 3.1 Anemia Management-Target Hemoglobin for Epoetin Therapy

CMS Final Approval Date

1/1/2001

CMS Implementation Use

- Dialysis Facility Compare

Attachments

The **Measure Justification** is a required attachment

Depending on the measure contract (development/maintenance/reevaluation) and, if the measure is risk adjusted, some of the listed Measures Management System forms may be required:

- Risk Adjustment
- Ad Hoc Measure Reevaluation
- Measure Maintenance Reevaluation
- Comprehensive Measure Reevaluation

Other attachments

Comments:

Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	Anemia Management - Percentage of Patients with Hemoglobin >12 g/dL
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	July 1, 2008
Date of Last Review	November 15, 2007

Section I: Importance/Relevance

Epidemiological relevance, Financial relevance, Policy relevance:

Epidemiological relevance

The kidneys are responsible for the production of the hormone erythropoietin, which stimulates the production of red blood cells in the bone marrow. Kidney disease frequently results in a deficiency in this hormone, leading to the development of anemia, particularly after reaching the reduced level of kidney function that requires dialysis. Hemodialysis also results in some blood loss during each treatment session. The benefit to patients of correcting anemia is primarily related to quality of life - increased vitality, less fatigue, less depression, and improved physical symptoms - and the avoidance of blood transfusions (KDOQI 2006). According to the USRDS, 45% of patients starting dialysis in 2006 had hemoglobin levels less than 10.0g/dL at initiation (USRDS 2006). The use of erythropoiesis-stimulating agents (ESAs) is an accepted and effective therapy for correcting anemia in people with chronic kidney disease and end-stage renal failure. Maintenance of hemoglobin above 10.0 g/dL has been shown to improve survival and avoid the need for blood transfusions (KDOQI 2006).

At the end of 2005, there were 485,012 patients being dialyzed, 106,912 of whom were new (incident) ESRD patients (USRDS 2006).

Financial relevance:

The Centers for Medicare and Medicaid Services (CMS) spent \$1.68 billion in 2005 for ESAs for anemia management and \$161 million on all laboratory testing in dialysis patients. At the end of 2005, total Medicare costs for the ESRD program were \$19 billion. This represents approximately 6% of the total Medicare annual budget (USRDS 2007 ADR, Chapter 11).

Policy relevance:

An anemia management measure has been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 2000 and on the Dialysis Facility Compare (DFC) web site (www.medicare.gov) since 2001, when the Balanced Budget Act (1997) required a system to measure and report the quality of dialysis services under Medicare.

The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. This anemia management measure in particular is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey. This measure is reported publicly on the DFC web site to assist patients in selecting dialysis facilities.

Section 2: Scientific Soundness

Explicit evidence base: Consider strength of recommendation and level of evidence that support the measure.

Complete one literature citation for each guideline or study on which the measure is based, stating level of evidence and rating scheme used. A suggested format is below; another format may be used.

Literature citation for clinical guideline

- (1) KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target, *American Journal of Kidney Diseases*, 50(3): Pages 471-530 (September 2007).
- A. The type of information: Clinical Guideline
 - B. Level of Evidence and Rating Scheme: Clinical Practice Recommendation and Moderately Strong Evidence
 - C. Web address http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/guide1.htm
 - D. Brief synopsis: Hemoglobin target recommendation of 11.0mg/dL to 12.0mg/dL, hemoglobin target should not be above 13.0mg/dL.

KDOQI Clinical Practice Guideline (CPG) and Recommendation (CPR): CPG AND CPR 2.1 HEMOGLOBIN TARGET

2.1.1 In the opinion of the Work Group, selection of the Hb target and selection of the Hb level at which ESA therapy is initiated in the individual patient should include consideration of potential benefits (including improvement in quality of life and avoidance of transfusion) and potential harms (including the risk of life threatening adverse events). (Clinical Practice RECOMMENDATION)

2.1.2 In the opinion of the Work Group, in dialysis and nondialysis patients with CKD receiving ESA therapy, the selected Hb target should generally be in the range of 11.0 to 12.0 g/dL. (Clinical Practice RECOMMENDATION)

2.1.3 In dialysis and nondialysis patients with CKD receiving ESA therapy, the Hb target should not be greater than 13.0 g/dL. (Clinical Practice GUIDELINE - MODERATELY STRONG EVIDENCE)

- (2) KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, *American Journal of Kidney Diseases*, 49(Supplement 3): S1-S146, May 2006.
- A. The type of information: Clinical Guideline
 - B. Level of Evidence and Rating Scheme: Expert opinion
 - C. Web address http://www.kidney.org/professionals/KDOQI/guidelines_anemia/cpr32.htm
 - D. Brief synopsis: Hemoglobin target recommendation of 11.0mg/dL to 12.0mg/dL, hemoglobin target should not be above 13.0mg/dL.

Literature citation for supporting evidence/study

- (1) 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.
- A. The type of information: Randomized Clinical Trial: CHOIR
 - B. Level of Evidence and Rating Scheme: B, subjects with CKD not on dialysis
 - C. Web address <http://content.nejm.org/cgi/reprint/355/20/2085.pdf>
 - D. Brief synopsis: Subjects randomized to a hemoglobin target of 13.5g/dL had fewer adverse events (death, hospitalization for chronic heart failure, myocardial infarction or stroke) than those randomized to a target of 11.3g/dL.

- (2) 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.
- The type of information: Randomized Clinical Trial: CREATE
 - Level of Evidence and Rating Scheme: B, subjects with CKD not on dialysis
 - Web address <http://content.nejm.org/cgi/reprint/355/20/2071.pdf>
 - Brief synopsis: Found no difference in adverse events and increased quality of life scores between a group randomized to a target of 13.0 to 15.0g/dL and a group randomized to a target of 10.5 to 11.5g/dL.
- (3) U.S. Food and Drug Administration. Information for health care professionals: erythropoiesis stimulating agents. Updated 11/8/2007, <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>
- The type of information: Determination by FDA's panel of experts' opinion
 - Level of Evidence and Rating Scheme: N/A, black box warning implemented
 - Web address <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>
 - Brief synopsis: FDA added a black box warning to ESAs prescriber information that hemoglobin for patients with chronic renal failure should be targeted at the 10.0 to 12.0g/dL.

Other aspects of scientific soundness:

Reliability, Validity, and Adequacy of risk adjustment:

In 1999, the Centers for Medicare & Medicaid Services (CMS) funded the development of dialysis facility-specific measures that could be released in reports to the public for their use in making dialysis treatment choices. An extensive public process was used to select the first set of measures to be publicly reported (Frederick 2002). See: Frederick PR, Maxey NL, Clauser SB, & Sugarman JR. Developing Dialysis Facility-Specific Performance Measures for Public Reporting. *Health Care Financing Review* 2002 Summer; 23(4) pp. 37-50.

Reliability

Hematocrit data from dialysis claims have been shown to be in good agreement with data from chart abstraction. Frankfield DL, Brier ME, Bedinger MR, Milam RA, Eggers PW, Cain JA, Aronoff GR, Frederick PR. Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Centers for Medicare and Medicaid Services and the Renal Network Inc. *Am J Kidney Dis*. 41, No 2. 2003: pp 443-441.

Validity

Hematocrit data from dialysis claims have been shown to be in good agreement with data from chart abstraction. Frankfield DL, Brier ME, Bedinger MR, Milam RA, Eggers PW, Cain JA, Aronoff GR, Frederick PR. Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Centers for Medicare and Medicaid Services and the Renal Network Inc. *Am J Kidney Dis*. 41, No 2. 2003: pp 443-441.

Adequacy of risk adjustment

Risk adjustment is not applicable for this measure

Section 3: Usability/Actionability

Provides actionable decision support, Message is clear to recipient, Operational relevance

- An anemia management measure has been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 2000 and on the Dialysis Facility Compare (DFC) web site (www.medicare.gov) since 2001, when the Balanced Budget Act (1997) required a system to measure and report the quality of dialysis services under Medicare. The measure is based on DOQI and KDOQI practice guidelines published in 1997 and 2000, respectively.

- The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. This anemia management measure in particular is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey. This measure is reported publicly on the DFC web site to assist patients in selecting dialysis facilities.

The previous language was consumer tested.

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).

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.

Section 4: Feasibility

Specifications are well-defined, Reasonable burden of data collection, Minimum distortion

Administrative and Medical Record data is used.

There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.

Burden is minimal for current data because it exists.

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	DFC Measures
Measure Name <i>(should be brief, concise):</i>	Anemia Management – Percentage of Patients with Hemoglobin >12 g/dL
Measure Description:	Hemodialysis and Peritoneal Dialysis patients, with ESRD \geq 3 months, who have a mean Hemoglobin >12 g/dL for a 12 month reporting period, treated with ESA. The last valid hemoglobin value reported for the end of each reporting month (end-of-month Hemoglobin) is used for the calculation.
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version:

The original DFC anemia management measure is reported as the percentage of epoetin or darbopoetin treated Medicare patients with a hematocrit level of 33 or higher in a calendar year among patients at that facility treated for epoetin or darbopoetin. In the current version, hemoglobin is used as the preferred measure for anemia, and is now reported as percent of patients with hemoglobin levels higher than the desired maximum value, a mean Hgb of greater than 12 g/dL.

For each patient, instead of using all eligible patient claims, the last claim of each month with a valid hemoglobin is used for the calculation.

Date of review (NQF approval date(s))
Not approved

I. Summary of Current Performance Data Analysis on Each Measure—(measure data as submitted to NQF).

Attach charts, graphs, or tables, as directed by CMS, that summarize the performance of the measure since it was initially used by CMS (ideally) or at least since it was last evaluated (either at measure inception or previous comprehensive evaluation).

Please see the 2006 ESRD CPM Annual Report and the Summary of Evidence Regarding Hemoglobin (HGB) Targets (links below):

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006AnnualReport.pdf>

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDAnemiaSummary05212008.pdf>

II. Summary of Analysis of the Comments and Questions Received Going into the TEP and during the NQF comment period:

- A. Importance
- B. Scientific Acceptability
- C. Feasibility
- D. Usability

Please see the ESRD CPM Development Process Final Report and ESRD TEP Final Report (links below).

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDDevelopmentProcessFinalReport.pdf>
<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDTEPFinalReport05212008.pdf>

III. Environmental scan to identify relevant scientific or other information published since the **last time the measure was evaluated.**

Document all relevant publications found, with a clear indication of:

- A. The type of information
 - B. The level of evidence
 - C. The relevant Web address (if the article is accessible via the Web)
 - D. A brief synopsis of the information and its relevance to the Comprehensive Reevaluation
- Example #1 (for new guidelines): "ACC HF guidelines now consider ARBs to be equivalent to ACEIs."
- Example #2 (for a study on antibiotics): "Study shows increase in inappropriate use of antibiotics in ER patients since measure was implemented."

(1) KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target, *American Journal of Kidney Diseases*, 50(3): Pages 471-530 (September 2007).

- A. Clinical Guideline
- B. Clinical Practice Recommendation and Moderately Strong Evidence
- C. http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/guide1.htm
- D. Hemoglobin target recommendation of 11.0mg/dL to 12.0mg/dL, hemoglobin target should not be above 13.0mg/dL.

(2) KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, *American Journal of Kidney Diseases*, 49(Supplement 3): S1-S146, May 2006.

- A. Clinical Guideline
- B. Expert opinion
- C. http://www.kidney.org/professionals/KDOQI/guidelines_anemia/cpr32.htm
- D. Iron stores should be evaluated every three months during stable ESA therapy and in those dialysis patients not treated with an ESA.

(3) 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.

- A. Randomized Clinical Trial: CHOIR
- B. B, subjects with CKD not on dialysis
- C. <http://content.nejm.org/cgi/reprint/355/20/2085.pdf>
- D. Subjects randomized to a hemoglobin target of 13.5g/dL had fewer adverse events (death, hospitalization for chronic heart failure, myocardial infarction or stroke) than those randomized to a target of 11.3g/dL.

(4) 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.

- A. Randomized Clinical Trial: CREATE
- B. B, subjects with CKD not on dialysis
- C. <http://content.nejm.org/cgi/reprint/355/20/2071.pdf>
- D. Found no difference in adverse events and increased quality of life scores between a group randomized to a target of 13.0 to 15.0g/dL and a group randomized to a target of 10.5 to 11.5g/dL.

(5) U.S. Food and Drug Administration. Information for health care professionals: erythropoiesis stimulating agents. Updated 11/8/2007, <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>

- A. Determination by FDA's panel of experts' opinion
- B. N/A, black box warning implemented
- C. <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>
- D. FDA added a black box warning to ESAs prescriber information that hemoglobin for patients with chronic renal failure should be targeted at the 10.0 to 12.0g/dL.

IV. A technical expert panel was convened: Yes No

If yes, date(s) of the meeting(s):

Clinical-TEP: September 18-19, 2006

Briefly summarize the TEP recommendations here.

Current Measure

The anemia management measure is reported as the percentage of epotein or darboepotein treated Medicare patients with a hematocrit level of 33 or higher in a calendar year among patients at that facility treated for epotein or darboepotein. Hematocrit is reported monthly to CMS on Medicare dialysis claims (UB-92). For each patient, the average hematocrit reported on these claims is calculated. Medicare dialysis claims that did not indicate epotein or darboepotein treatment, claims starting before day 90 of ESRD, and claims with hematocrit values less than 14 or greater than 60 were excluded from the calculation. In order to be included in a facility's calculation, a patient must have 4 or more such eligible claims from the facility. If a patient is treated at more than one facility during the year, the average hematocrit is calculated for him/her separately for each facility based on the claims from each facility only.

Clinical-TEP Recommendations for Changes to Measure

1. Hemoglobin is the preferred measure for anemia management rather than hematocrit.
2. Inclusion criteria should include all ESAs because new products have been developed (ex. Darboepotein). The definition for drug therapy should be based on type of drug activity rather than upon drug name.
3. The measure should be as consistent as possible with the Clinical Performance Measures, subject to constraints of the claims data.

Measure Specifications (changes from current specifications in bold)

NUMERATOR: number of eligible **ESA-treated** Medicare dialysis patients at the facility during the calendar year with an **average hemoglobin greater than 12g/dL**

DENOMINATOR: number of eligible **ESA-treated** Medicare dialysis patients at the facility during the calendar year

ELIGIBILITY: Calculated on **the last** Medicare hemodialysis **claim of the month with a valid hemoglobin** submitted by the dialysis facility, with the following exclusions: (1) Medicare dialysis claims that did not indicate **ESA** treatment; (2) claims starting before day 90 of ESRD; and (3) **claims with hemoglobin values less than 5 or greater than 20**. In order to be included in a facility's calculation, a patient must have 4 or more such eligible claims from the facility. For each patient, the average **hemoglobin** reported on these claims is calculated. If a patient is treated at more than one facility during the year, the average **hemoglobin** is calculated for him/her separately for each facility based on ≥ 4 claims from each facility only.

V. If any of the codes used in the technical specifications have changed since the last measure update or comprehensive reevaluation, specify the change(s) with an explanation of its impact on the measure.

N/A

VI. If material¹ changes to the measure have occurred — i.e., wording, data elements, time periods, abstraction instructions, etc. – document them here. If material changes were made to the measure, was the measure tested?

Yes No

If yes, indicate the results of the testing.

Measure Contractor Recommended Disposition				
Measure contractor recommended disposition of the measure	<input type="checkbox"/> Retain		Effective Date of Action	
	<input checked="" type="checkbox"/> Revise (as described above)			
	<input type="checkbox"/> Replace			
	<input type="checkbox"/> Rotate			
	<input type="checkbox"/> Retire			
Rationale for recommendation	<i>This is an important measure for the health of dialysis patients and the above changes are needed to accommodate new prescribing information from the FDA.</i>			
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date	<input type="checkbox"/> Other:
Recommended by	Name: Date:			

CMS Role	
CMS decision for measure disposition	<input type="checkbox"/> Retain
	Effective Date of Action
	<input type="checkbox"/> Revise
	<input type="checkbox"/> Replace
	<input type="checkbox"/> Rotate
<input type="checkbox"/> Retire	
<input type="checkbox"/> Approved as recommended.	
Comments about decision	
Approved by	Name: Date:

¹ A **material change** is one that changes the intended meaning of the measure or the strength of the measure in terms of measure evaluation criteria. NQF's process for an ad hoc expedited review will be triggered at any point when the measure developer make material changes to the measure construct (including the numerator, denominator, and exclusions) or measure logic. The timing of the ad hoc review will depend on whether there is an accompanying safety concern. If changes to the measure are deemed appropriate:

- Would a change in the measure result in statistical discontinuity from the current measurement baseline?
- Would a change in the measure significantly impact current processes and the burden for data collection, analysis, and reporting?
- Would the proposed change unintentionally result in the modification of a current clinical or administrative practice?