

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name:	ESRD- Anemia Management CPM Ia: Hemoglobin Control for ESA Therapy
Measure Description:	Percentage of Adult (>= 18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >= 3 months, who have received ESA therapy at any time during a 3 month study period AND who had Hb values reported for at least 2 of the 3 study months AND who achieved a mean hemoglobin of 10.0-12.0 g/dL for the 3 month study period. The hemoglobin value reported for the end of each reporting month (end-of-month Hemoglobin) is used for the calculation of the mean.

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

- Not endorsed by NQF

Technical Specifications

Target Population

Age

Lower limit

- 18

Lower Span

-Years

Gender

- Both males and females

Anchor Date

NA

Effective Date

- 4/1/08- Please see Phase III ESRD Clinical Performance Measures (link below):

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDPhaseIIICPM04012008Final.pdf>

Payer Source

- Medicare

Measure result reported as

- Positive

CHI Compliant

- Yes

Method of Data collection

- Electronic supplemented by medical record review

Numerator statement

Adult hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have received ESA therapy at any time during a 3 month study period AND have achieved a mean hemoglobin of 10.0-12.0 g/dL for the 3 month study period. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for the calculation.

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

Numerator Time Window

Data collected for this ESRD CPM are for the three-month time period (Oct-Dec) for the in-center hemodialysis patients and a six-month time period for peritoneal dialysis and home hemodialysis patients.

Denominator statement

All adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients with ESRD ≥ 3 months, and who have been prescribed an ESA at any time during the 3 month study period, and who had Hb values reported for at least 2 of the 3 study months.

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

Denominator Time Window

Same as numerator

Exclusion Criteria

Patients on dialysis <3 months at the start of study period, acute HD, transient dialysis patients, home hemodialysis patients, and kidney transplant patients are excluded from the calculation of this CPM.

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

History**Measure Status**

- Implemented/approved by CMS

CMS Active Implementation Date

- 2/1/09

Measure Developer

- CMS
Contractor: Arbor Research/UM-KECC

Intellectual property status

- Public Domain

Measure Source

- Adapted from original measure (ESRD-10 Anemia Management CPM I: Hemoglobin Control for ESA) with submitted status date of 8/15/2005

CMS Final Approval Date

- 4/1/08

CMS Implementation Use

- ESRD Disease Management
- ESRD Network Program
- Other
Quality Improvement and Public Reporting

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 (*please attach these forms to this MIF as required*)

Other attachments

Comments:

Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	ESRD- Anemia Management CPM Ia: Hemoglobin Control for ESA Therapy
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	February 1, 2009
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. There is recent evidence that hemoglobin levels near 12.5 g/dL or higher are associated with adverse events, including mortality, particularly among patients with co-morbid cardiovascular disease (KDOQI 2006). This evidence supports an upper hemoglobin target of 12.0 g/dL.

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:

In 1998, CMS developed ESRD Clinical Performance Measures (CPMs) based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines, in response to the Balanced Budget Act of 1997. Sixteen CPMs were developed to measure and report the quality of dialysis services provided under Medicare in the areas of adequacy of hemodialysis and peritoneal dialysis, anemia management, and vascular access management. Section 4558 (b) of the Balanced Budget Act (BBA) requires CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, CMS decided to fund the development of CPMs based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines.

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).
- The type of information: Clinical Guideline
 - Level of Evidence and Rating Scheme: Clinical Practice Recommendation and Moderately Strong Evidence
 - Web address http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/guide1.htm
 - 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.
- The type of information: Clinical Guideline
 - Level of Evidence and Rating Scheme: Expert opinion
 - Web address http://www.kidney.org/professionals/KDOQI/guidelines_anemia/cpr32.htm
 - 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.
- The type of information: Randomized Clinical Trial: CHOIR
 - Level of Evidence and Rating Scheme: B, subjects with CKD not on dialysis
 - Web address <http://content.nejm.org/cgi/reprint/355/20/2085.pdf>
 - 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) Druke 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. The type of information: Randomized Clinical Trial: CREATE
 - B. Level of Evidence and Rating Scheme: B, subjects with CKD not on dialysis
 - C. Web address <http://content.nejm.org/cgi/reprint/355/20/2071.pdf>
 - D. 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>
- A. The type of information: Determination by FDA's panel of experts' opinion
 - B. Level of Evidence and Rating Scheme: N/A, black box warning implemented
 - C. Web address <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>
 - D. 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:

Please see below link for the Reliability Report:

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf>

Please see the following reports on the validity of the CPM data:

Wolfe RA, Brunton C, Ashby VB, Hulbert-Shearon TE, Port FK, Saran R, Kari J: The Association between Dialysis Practice Patterns, Patient Mortality, and State Surveyor Findings. [Abstract] *Journal of the American Society of Nephrology* 2002; 13:627A.

Appendix D - MV Rocco, MD, DL Frankenfield, DrPH, SD Hopson, MSPH, et al. "Relationship between Clinical Performance Measures and Outcomes among Patients Receiving Long-Term Hemodialysis." *Ann Intern Med* 2006; 145:512-519.

Appendix E - DL Frankenfield, DrPH, ME Brier, PhD, MR Bedinger, BA, et al. "Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Centers for Medicare & Medicaid Services and The Renal Network Inc." *Am J of Kidney Dis*, Vol 41, No 2 (February), 2003: pp 433-441.

Risk adjustment is not applicable for this measure.

Section 3: Usability/Actionability

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

Please see below link for the Annual Report.

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

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.

Approximate time for data collection,

FOR ALL MEASURES TOTAL IN THE ESRD DIALYSIS FACILITY MEASURES SET: Approximately 30 minutes for data abstraction, less if the patient's medical record has not been sent to offsite storage. This is the time estimate if all of the data elements are manually abstracted. However, for those facilities that are owned by Large Dialysis Organizations (LDO's), a majority of the data elements are submitted electronically from the LDO's corporate database to CMS. Only a few if any elements are abstracted manually by facility staff, so their time for data abstraction is reduced considerably.

CMS is in the process of implementing a web-based data collection system called **CrownWeb** for the measures; however, at this time CMS has not assessed the cost and administrative burden of using CrownWeb by dialysis facilities. CrownWeb is scheduled to be implemented early 2009.

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	Anemia Management
Measure Name:	ESRD- Anemia Management CPM Ia: Hemoglobin Control for ESA Therapy
Measure Description:	Percentage of Adult (>= 18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >= 3 months, who have received ESA therapy at any time during a 3 month study period AND who had Hb values reported for at least 2 of the 3 study months AND have achieved a mean hemoglobin of 10.0-12.0 g/dL for the 3 month study period. The hemoglobin value reported for the end of each reporting month (end-of-month Hemoglobin) is used for the calculation of the mean.
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version?

Due to the FDA issuing a black box warning for erythropoiesis stimulating agents (ESAs) to not target hemoglobin levels above 12.0g/dL, the lower end of the target range was lowered to 10.0g/dL to reduce the likelihood of a hemoglobin higher than 12.0g/dL. Patients just starting dialysis (ESRD<3 months) are excluded and the last hemoglobin of the month is used to calculate the measure, for months where the patient had hemoglobin measured more than one time.

Date of review

November 15, 2007 – Not Endorsed by NQF.

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 (link below):

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

Data-TEP: October 11-12, 2006

Briefly summarize the TEP recommendations here.

Even though additional research is still required to understand adverse outcomes for some patients with CKD when targeting Hb levels > 13.5 g/dl, we recommend annual reporting to monitor the percent of ESA-treated patients with a Hb > 13.0 g/dl. This will be useful for determining if the percent of ESA-treated patients with a Hb > 13 g/dl changes over time, and thus would also be in agreement with KDOQI which had recommended that patients should not be routinely maintained at a Hb concentration > 13 g/dl. Although there is evidence from some RCTs that maintaining some ESA-treated patients at a Hb > 13 g/dl can be associated with adverse outcomes, there is a lack of evidence whether there is any risk for patients to occasionally have a Hb > 13 g/dl for short periods of time. Furthermore, it is well recognized that in trying to keep a patient's Hb level > 11 g/dl that there is wide variation in response by hemodialysis patients within the population such that a standard deviation of ~1.2 g/dl has been observed. As a result of this variation in response to anemia management protocols, it is not uncommon for some patients to occasionally exceed 13 g/dl as part of the effort of dialysis units to maintain patient Hb levels above 11.0 g/dl. Even though it is difficult at the present time to determine an acceptable percentage of ESA-treated patients to have a Hb > 13 g/dl, there is value associated with monitoring this practice and determine time trends. However, due to insufficient generalizable evidence regarding the risks and benefits associated with Hb > 13 g/dl, and the need for further discussions and review by expert panels as additional data are published, the C-TEP is reluctant to recommend a CPM for > 13 g/dl for ESA-treated patients at the present time. Since Hb levels and ESA prescription are expected to be collected each month in the near future, another possible measure for consideration would be the percent of ESA-treated patients with an end of the month Hb > 13 g/dl for 3 or 4 consecutive months as this would provide an indication of whether certain ESA-treated patients are routinely being maintained at this higher Hb concentration. It is noteworthy that some patients such as those with polycystic kidney disease are able to spontaneously maintain Hb levels > 13 g/dl without receiving exogenous ESAs. The recommendation that annual reporting of Hb levels > 13 g/dl be restricted to patients receiving ESA therapy is based on lack of any evidence for worse outcomes for patients such as polycystic kidney disease patients who are able to maintain higher Hb levels without use of exogenous ESAs. In fact, in observational studies, polycystic kidney disease patients show lower relative risks of mortality even after adjusting for differences in numerous patient characteristics.

The C-TEP recommended that patients on dialysis < 90 days should be excluded from the calculation of the CPM for anemia management. Arbor Research recommends that this exclusion be changed to "< 3 months" instead of "< 90 days" to fit more closely with how the data would be collected and analyzed.

It is also recommended that the data collection form be designed to address use of all different forms of ESAs – those known presently, and those entering into the market in the future.

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.

NA

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?