

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the [evaluation criteria](#) are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all **yellow highlighted** areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 1433	NQF Project: End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Use of Iron Therapy for Pediatric Patients	
De.2 Brief description of measure: Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom serum ferritin concentration was <100 ng/ml and TSAT<20% who received IV iron or were prescribed oral iron within the following three months.	
1.1-2 Type of Measure: Process	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure This measure is paired with Pediatric Anemia - Anemia Process Measure.	
De.4 National Priority Partners Priority Area: Population health	
De.5 IOM Quality Domain: Effectiveness	
De.6 Consumer Care Need: Living with illness	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</i></p> <p>A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	B

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public reporting, Internal quality improvement	C Y <input type="checkbox"/> N <input type="checkbox"/>
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1 Testing: No, testing will be completed within 12 months D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact	Eval Rating
(for NQF staff use) Specific NPP goal :	
1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure, High resource use, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 Summary of Evidence of High Impact: End Stage Renal Disease (ESRD) leads to a deficiency in the hormone erythropoietin, resulting in anemia. The use of erythropoiesis-stimulating agents (ESAs) and iron supplementation are effective therapies for correcting anemia in children with ESRD [1,2]. Anemia management requires the presence of sufficient iron stores. Iron deficiency is a leading cause of non-response to ESA therapy [3], and several studies demonstrate the effectiveness of oral or IV iron in correcting iron deficiency in the pediatric population [4,5]. With regards to defining iron deficiency, a TSAT less than 20% was shown to be predictive of iron deficiency in at least one study in the pediatric population [4]. Furthermore, in a clinical trial evaluating the impact of iron supplementation on improving iron stores, a TSAT less than 20% was used as indication for iron therapy [4]. A ferritin level of 100 ng/ml was used even though clinical studies are mixed with regards to the level of ferritin which is predictive of iron deficiency [5,6], since this cut-off was used in the Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines for the pediatric population. 1a.4 Citations for Evidence of High Impact: 1. Warady BA, Mazen AY, Lerner G, Nakanishi AM, Stehman-Breen C. Darbopoetin alfa for the treatment of anemia in pediatric patients with chronic kidney disease. Pediatr Nephrol 21: 1144-52, 2006.	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

<p>2. Warady BA, et al. Iron therapy in the pediatric hemodialysis population. <i>Pediatr Nephrol</i> 19: 655-61, 2004.</p> <p>3. Seeherunvong W, Rubio L, Abitbol CL, et al. Identification of poor responders to erythropoietin among children undergoing hemodialysis. <i>J Pediatr</i> 138(5):710-714, 2001.</p> <p>4. Warady BA, Zobrist RH, Wu J, Finan E. Sodium ferric gluconate complex therapy in anemic children on hemodialysis. <i>Pediatr Nephrol</i> 20: 1320-7, 2005.</p> <p>5. Frankenfield DL, Neu AM, Warady BA, et al. Anemia in pediatric hemodialysis patients: results from the 2001 Clinical Performance Measures Project. <i>Kidney International</i> 64:1120-4, 2003.</p> <p>6. Morris KP, Watson S, Reid MM, Hamilton PJ, Coulthard MG. Assessing iron status in children with chronic renal failure on erythropoietin: which measurements should we use? <i>Pediatr Nephrol</i>. Feb;8(1):51-6, 1994.</p>	
<p>1b. Opportunity for Improvement</p> <p>1b.1 Benefits (improvements in quality) envisioned by use of this measure: End Stage Renal Disease (ESRD) leads to a deficiency in the hormone erythropoietin, resulting in anemia. The use of erythropoiesis-stimulating agents (ESAs) and iron supplementation are effective therapies for correcting anemia in children with ESRD.</p> <p>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: There is no current evidence demonstrating a performance gap in iron therapy for pediatric ESRD patients. However, the most commonly identified reason for poor responsiveness to ESA therapy in children is iron deficiency [1]. Furthermore, an analysis of Centers for Medicare & Medicaid Services (CMS) data suggests that hemoglobin levels in pediatric ESRD patients tended to be lower than among adult patients and that the use of IV iron therapy is less frequent in the pediatric as compared to the adult ESRD population [2].</p> <p>1b.3 Citations for data on performance gap:</p> <ol style="list-style-type: none"> 1. Seeherunvong W, Rubio L, Abitbol CL, et al: Identification of poor responders to erythropoietin among children undergoing hemodialysis. <i>J Pediatr</i> 138:710-714, 2001 2. Chavers BM, et al. Prevalence of anemia in erythropoietin-treated pediatric as compared to adult chronic dialysis patients. <i>Kidney International</i> (2004) 65, 266-273 <p>1b.4 Summary of Data on disparities by population group: The United States Renal Data System (USRDS) 2008 Annual Data Report (ADR) demonstrated that hemoglobin levels tended to vary by age group, and that hemoglobin levels are 0.5g/dL higher in white children as compared to African American children and other races [1].</p> <p>1b.5 Citations for data on Disparities:</p> <ol style="list-style-type: none"> 1. U.S. Renal Data System, USRDS 2008 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2008. 	<p>1b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Although large scale clinical trials have not been conducted in the pediatric population, smaller scale observational and cohort studies have shown an association between anemia and poor outcomes including poor quality of life, cardiovascular disease, morbidity, and mortality.</p> <p>1c.2-3. Type of Evidence: Observational study, Evidence-based guideline</p> <p>1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): The 2006 KDOQI Clinical Practice Recommendation (CPR) 3.2.1.2 for pediatrics recommends that iron status tests should be performed at least every three months during stable ESA treatment or in patients with hemodialysis-dependent Chronic Kidney Disease (HD-CKD) not treated with an ESA. CPR 3.2.2 recommends results of iron status tests, hemoglobin level, and ESA dose should be interpreted together to guide iron therapy. CPR 3.2.3.2 recommends iron administration at Serum Ferritin>100ng/mL and TSAT>20%.</p>	<p>1c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

ESRD leads to a deficiency in the hormone erythropoietin, resulting in anemia. The use of ESAs and iron supplementation are effective therapies for correcting anemia in children with ESRD [1,2]. However, erythropoietin therapy will not result in an increase in hemoglobin if iron stores are deficient. As such, assessment of iron stores is important to ensure success of anemia management.

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

The pediatric adequacy clinical Technical Expert Panel (TEP) rated the strength of this measure as high.

1c.6 Method for rating evidence: The clinical TEP followed similar methods of evidence assessment as that used by the KDOQI Clinical Practice Guidelines.

1c.7 Summary of Controversy/Contradictory Evidence: There are no controversial or contradictory evidence for this measure.

1c.8 Citations for Evidence (other than guidelines): 1. Warady BA, Mazen AY, Lerner G, Nakanishi AM, Stehman-Breen C. Darbopoetin alfa for the treatment of anemia in pediatric patients with chronic kidney disease. *Pediatr Nephrol* 21: 1144-52, 2006.

2. Warady BA, et al. Iron therapy in the pediatric hemodialysis population. *Pediatr Nephrol* 19: 655-61, 2004.

1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):
2006 KDOQI Clinical Practice Recommendations for Anemia in Chronic Kidney Disease in Children

CPR 3.2.1 Frequency of iron status tests (Fully Applicable to Children)

In the opinion of the Work Group, iron status tests should be performed as follows:

3.2.1.2 At least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an ESA

CPR 3.2.2 Interpretation of iron status tests: (FULLY APPLICABLE TO CHILDREN)

In the opinion of the Work Group, results of iron status tests, Hb level, and ESA dose should be interpreted together to guide iron therapy.

3.2.3 Targets of iron therapy: (APPLICABLE TO CHILDREN, BUT NEEDS MODIFICATION)

In the opinion of the Work Group, sufficient iron should be administered to generally maintain the following indices of iron status during ESA treatment:

3.2.3.1 ADULT CPR HD-CKD:

- Serum ferritin > 200 ng/mL, AND
- TSAT > 20%, or CHr > 29 pg/cell.

PEDIATRIC CPR

HD-CKD:

- Serum ferritin > 100 ng/mL; AND
- TSAT > 20%.

3.2.3.2 ND-CKD and PD-CKD:

- Serum ferritin > 100 ng/mL AND
- TSAT > 20%.

Please note that these are clinical practice recommendations and are therefore defined in the KDOQI document as "expert opinion" based recommendations.

1c.10 Clinical Practice Guideline Citation: Clinical Practice Recommendation for Anemia in Chronic Kidney Disease in Children 3.2: Using Iron Agents; KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2006.

1c.11 National Guideline Clearinghouse or other URL: N/A

1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):

The KDOQI CPRs were based on Work Group Consensus.

<p>1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF): The method used is the same as was used in developing the 2006 KDOQI guidelines, in which experts decided which recommendations were supported by evidence and which were supported by consensus of Work Group opinion. Evidence-based guideline recommendations were graded as strong or moderate or weak. This approach is consistent with the United States Preventive Services Task Force (USPSTF) grading method.</p> <p>1c.14 Rationale for using this guideline over others: There are no other known clinical practice guidelines for the use of iron agents in the management of anemia in the pediatric ESRD patient. The KDOQI clinical practice guidelines and recommendations are widely utilized by the nephrology community.</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	1
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
<p>Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	Eval Rating
2a. MEASURE SPECIFICATIONS	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p>	
<p>2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome): Number of patients in the denominator who received IV iron or were prescribed oral iron within three months following the first occurrence of serum ferritin <100 ng/mL and transferrin saturation (TSAT) <20% during the study period.</p> <p>2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): Three months following the first occurrence of serum ferritin <100 ng/mL and transferrin saturation (TSAT) <20%.</p> <p>2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions): The numerator will be determined by counting all patients in the denominator and "Intravenous IV Iron Prescribed" is populated OR "Oral Iron Prescribed" is populated.</p>	
<p>2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured): All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin <11 g/dL and in whom serum ferritin was <100 ng/mL and TSAT<20% during the three month study period.</p>	
<p>2a.5 Target population gender: Female, Male 2a.6 Target population age range: Pediatric patients less than 18 years old.</p>	2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator): Three months from the start of the reporting period.</p>	

<p>2a.8 Denominator Details (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>): Patients are counted as being in the facility for the entire three-month reporting period if “Admit Date” to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged (“Discharge Date” is null or blank), OR “Discharge Date” from the facility is greater than or equal to the last day of the study period. The patient’s age will be determined by subtracting the patient’s date of birth from the first day of the reporting month. Patients who are in the facility for the entire three-month study period with age <18 years will be included in the denominator if “Hemoglobin” <11 g/dl in any of the reporting months AND “Serum Ferritin” <100 ng/ml AND “TSAT” <20%, recorded in the same month (“Serum Ferritin Collection Date” = “Iron Saturation (TSAT) Percentage Collection Date”) in any of the reporting months.</p>
<p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): Patients who are not in the facility for the entire three-month study period.</p>
<p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): See denominator exclusions.</p>
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): No stratification is required for this measure.</p>
<p>2a.12-13 Risk Adjustment Type: No risk adjustment necessary</p>
<p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): N/A</p>
<p>2a.15-17 Detailed risk model available Web page URL or attachment:</p>
<p>2a.18-19 Type of Score: Rate/proportion 2a.20 Interpretation of Score: Better quality = Higher score 2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): Patients are counted as being in the facility for the entire three-month reporting period if “Admit Date” to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged (“Discharge Date” is null or blank), OR “Discharge Date” from the facility is greater than or equal to the last day of the study period. The patient’s age will be determined by subtracting the patient’s date of birth from the first day of the reporting month. Patients who are in the facility for the entire three-month study period with age <18 years will be included in the denominator if “Hemoglobin” <11 g/dl in any of the reporting months AND “Serum Ferritin” <100 ng/ml, AND “TSAT” <20% recorded in the same reporting month (“Serum Ferritin Collection Date” = “Iron Saturation (TSAT) Percentage Collection Date”) in any of the reporting months. The numerator will be determined by counting all patients in the denominator and “Intravenous IV Iron Prescribed” is populated OR “Oral Iron Prescribed” is populated.</p>
<p>2a.22 Describe the method for discriminating performance (<i>e.g., significance testing</i>): The performance of the facility will be compared to state, Network and national performance.</p>
<p>2a.23 Sampling (Survey) Methodology <i>If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):</i> N/A</p>
<p>2a.24 Data Source (<i>Check the source(s) for which the measure is specified and tested</i>) Electronic clinical data</p>
<p>2a.25 Data source/data collection instrument (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)</p>
<p>2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.projectcrownweb.org/crown/index.php</p>

<p>2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents</p> <p>2a.32-35 Level of Measurement/Analysis (<i>Check the level(s) for which the measure is specified and tested</i>) Facility/Agency</p> <p>2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Dialysis Facility</p> <p>2a.38-41 Clinical Services (<i>Healthcare services being measured, check all that apply</i>) Dialysis</p>	
TESTING/ANALYSIS	
<p>2b. Reliability testing</p> <p>2b.1 Data/sample (<i>description of data/sample and size</i>): For the 2008 ESRD Clinical Performance Measures (CPM) project, inter-rater reliability was assessed using facility abstracted and Network re-abstracted data. A total of 301 randomly selected medical records from both adult and pediatric patients were included in the analysis.</p> <p>2b.2 Analytic Method (<i>type of reliability & rationale, method for testing</i>): To analyze the inter-rater reliability of the ESRD CPM data agreement rates, levels of concurrence, and kappa statistics were computed. Agreement rates were calculated for continuous data, and kappa statistics and levels of concurrence were jointly used to analyze categorical data. For measures based on target values, (e.g. hemoglobin<11 g/dL), non-missing reliability estimates are assessed. Missing vs. non-missing reliability estimates are assessed for variables in which the presence/absence is evaluated for the measure (e.g. TSAT and serum ferritin). ESA use was not evaluated in this reliability report.</p> <p>2b.3 Testing Results (<i>reliability statistics, assessment of adequacy in the context of norms for the test conducted</i>): Reliability statistics were calculated separately for hemodialysis and peritoneal dialysis patients. Among hemodialysis patients, the average kappa statistic for Hemoglobin<11 g/dL (non-missing data) was 0.95. The average level of concurrence was 99%. The missing vs. non-missing average kappa statistic for serum ferritin was 0.94 and for TSAT was 0.91. The average level of concurrence was 98% for both for serum ferritin and TSAT. Among peritoneal dialysis patients, the average kappa statistic (non-missing data) for Hemoglobin<11 g/dL was 0.96. The missing vs. non-missing average kappa statistic for serum ferritin was 0.80 and for TSAT was 0.75. The average level of concurrence was 92% for serum ferritin and 91% for TSAT.</p>	<p>2b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2c. Validity testing</p> <p>2c.1 Data/sample (<i>description of data/sample and size</i>): This measure was established on the basis of face validity. All clinical TEP members agreed that this measure will improve quality of care for pediatric hemodialysis and peritoneal patients.</p> <p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): Face validity is the only validity assessed as there is no gold standard for iron therapy in anemic pediatric ESRD patients. All clinical TEP members agreed that this measure will improve quality of care for pediatric hemodialysis and peritoneal dialysis patients.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): N/A</p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s):</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/></p>

<p>Exclusions are not supported by evidence. However, they are limited to those with a compelling clinical rationale and are precisely defined.</p> <p>2d.2 Citations for Evidence: N/A</p> <p>2d.3 Data/sample (description of data/sample and size): N/A</p> <p>2d.4 Analytic Method (type analysis & rationale): N/A</p> <p>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): N/A</p>	<p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (description of data/sample and size): No risk adjustments are necessary for this measure.</p> <p>2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): N/A</p> <p>2e.3 Testing Results (risk model performance metrics): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A</p>	<p>2e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (description of data/sample and size): Data from the ESRD CPM Project were used to perform analyses on determining differences in performance in facilities with pediatric hemodialysis and peritoneal dialysis patients. In the 2008 study, CPM data were collected on all pediatric hemodialysis patients from October 2007 through December 2007 from a total of 317 facilities.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale): Patient and facility level performance was evaluated by the calculation of percentages.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): A total of 31 pediatric patients from 26 facilities had hemoglobin <11 g/dL and had simultaneous values of serum ferritin <100 ng/mL and TSAT<20% during the three-month study period. Five patients (16%) did meet the criteria for this measure (no record of iron prescribed over the three-month study period). At the facility level, 5 facilities (19%) did not have any patients who met the criteria for this proposed measure.</p>	<p>2f</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (description of data/sample and size): CROWNWeb. Phase 1 and 2 CROWNWeb Beta Testing Data: Data are based on the 18 facilities participating in Phase 1 and the 180 facilities participating in Phase 2 plus about 3000 additional batch-submission facilities in CROWNWeb. These data include about 60% of dialysis facilities and 75% of dialysis patients and are heavily weighted towards large dialysis organization facilities.</p> <p>2g.2 Analytic Method (type of analysis & rationale): Multiple data sources are not allowed for this measure, and therefore testing is not needed.</p> <p>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): N/A</p>	<p>2g</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>

<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: Stratification by age group, race, gender may be considered given disparities observed in hemoglobin levels as described above.</p>	<p>2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>3. USABILITY</p>	
<p>Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: Testing not yet completed</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years</i>): This measure is currently not in use for pediatric patients, but a similar measure is in use for the adult population and can be found in the CPM Project 2008 Annual Report. URL: www.cms.hhs.gov/CPMProject.</p> <p>3a.3 If used in other programs/initiatives (<i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years</i>): An analysis of patients <18 years of age in the North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) found that 68% of patients were anemic. A total of 77.3% of patients not anemic were receiving oral and/or intravenous iron, while 72.9% of anemic patients were receiving iron (P<0.05). Additionally, results showed anemia was associated with a 52% higher risk of death (Warady B Ho M. Morbidity and mortality in children with anemia at initiation of dialysis. <i>Pediatr Nephrol</i> 18:1055-1062, 2003).</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>)</p> <p>3a.4 Data/sample (<i>description of data/sample and size</i>): Testing of interpretability has not been performed.</p> <p>3a.5 Methods (<i>e.g., focus group, survey, QI project</i>): N/A</p> <p>3a.6 Results (<i>qualitative and/or quantitative results and conclusions</i>): N/A</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: 0252 Adult ESRD- Anemia Management CPM IIa- Assessment of Iron Stores</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population):</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/></p>

<p>3b.2 Are the measure specifications harmonized? If not, why? This measure is based on a topic which similar to the National Quality Forum (NQF) endorsed Adult ESRD Anemia Management CPM IIa and is partially harmonized with the adult measure. This measure uses similar but not identical language to the adult CPM IIa for two reasons; (1) The use of reticulocyte hemoglobin content (CHr) as a measure of iron stores has not been adequately tested in the pediatric population and should be excluded from the measure description and (2) The measurement period of 3 months applies to both hemodialysis and peritoneal dialysis pediatric patients whereas in the adult measure, 3 months is used as the reporting period for hemodialysis patients and 6 months for peritoneal dialysis patients. Additionally, this measure is partially harmonized with the proposed adult Anemia Management CPM II: Use of Iron Therapy When Indicated. Both measures require assessment of iron therapy based on TSAT and serum ferritin levels. However, the proposed adult measure does not require hemoglobin levels to be below 11 g/dL, has a higher TSAT limit (TSAT<50%), and only assesses IV iron use.</p>	<p>M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: This measure is for pediatric (<18 years) patients only. The NQF endorsed measure is for patients >=18 years.</p> <p>5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: This measure is for pediatric (<18 years) patients only. The NQF endorsed measure is for patients >=18 years.</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4. FEASIBILITY</p>	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>4a. Data Generated as a Byproduct of Care Processes 4a.1-2 How are the data elements that are needed to compute measure scores generated? Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition)</p>	<p>4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources 4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4c. Exclusions 4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p>	<p>4d C <input type="checkbox"/></p>

<p>4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. The clinical TEP described the fact that oral iron is an over the counter preparation and may not necessarily be recorded as a prescription. However, the clinical TEP believes that a patient's oral iron use should still be recorded by the clinical care team. There is a possibility, however, that the use of oral iron is underdetected.</p>	P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>4e. Data Collection Strategy/Implementation</p> <p>4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: The clinical TEP described the fact that oral iron is an over the counter preparation and may not necessarily be recorded as a prescription. However, the clinical TEP believes that a patient's oral iron use should still be recorded by the clinical care team. There is a possibility, however, that the use of oral iron is underdetected.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): The estimated data collection burden and associated cost estimate is presented in Tables 1-3 in the Federal Register. Vol. 73, No. 73 page 20469. URL:http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf.</p> <p>4e.3 Evidence for costs: See above reference to Federal Register.</p> <p>4e.4 Business case documentation: No formal studies evaluating the cost-effectiveness of maintaining adequate iron stores in the pediatric ESRD population have been published. However, anemia has been associated with increased hospitalization rates in this population. Given that hospitalization is associated with increased costs of care, it is possible that efforts to reduce the prevalence of anemia in the pediatric ESRD population (including the maintenance of adequate iron stores) may potentially reduce hospitalization rates, and may therefore be cost-effective.</p>	4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	4
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
RECOMMENDATION	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	Time-limited <input type="checkbox"/>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
CONTACT INFORMATION	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244</p> <p>Co.2 Point of Contact Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-</p>	

<p>Measure Developer If different from Measure Steward</p> <p>Co.3 Organization Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103</p> <p>Co.4 Point of Contact Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-</p>
<p>Co.5 Submitter If different from Measure Steward POC Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>
<p>ADDITIONAL INFORMATION</p>
<p>Workgroup/Expert Panel involved in measure development</p> <p>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. Dr. Bradley Warady, panel chair (University of Missouri, Kansas City School of Medicine, Kansas City, MO) Dr. Carolyn Abitbol (University of Miami, Holtz Children's Hospital, Miami, FL) Dr. Eileen Brewer (Baylor College of Medicine/Texas Children's Hospital, Houston, TX) Dr. Stuart Goldstein (Baylor College of Medicine/Texas Children's Hospital, Houston, TX) Dr. Alicia Neu (Johns Hopkins Medical Institution, Baltimore, MD) Dr. Irene Restaino (Children's Hospital of The King Daughters, Norfolk, VA) Dr. Douglas Silverstein (Children's National Medical Center, Washington, D.C.) Dr. Sylvia Ramirez, Moderator (Arbor Research Collaborative for Health) Alissa Kapke, Analyst (Arbor Research Collaborative for Health) Jeffrey Pearson, Analytic Manager, (Arbor Research Collaborative for Health)</p>
<p>Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>Measure Developer/Steward Updates and Ongoing Maintenance</p> <p>Ad.6 Year the measure was first released: Ad.7 Month and Year of most recent revision: Ad.8 What is your frequency for review/update of this measure? Three years Ad.9 When is the next scheduled review/update for this measure? 2013</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment:</p>
<p>Date of Submission (MM/DD/YY): 03/03/2011</p>