NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 1666 **NQF Project:** Renal Endorsement Maintenance 2011
(for Endorsement Maintenance Review) **Original Endorsement Date:** **Most Recent Endorsement Date:**
BRIEF MEASURE INFORMATION
De.1 Measure Title: Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL
Co.1.1 Measure Steward: American Medical Association - Physician Consortium for Performance Improvement
De.2 Brief Description of Measure: Percentage of calendar months within a 12-month period during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy and have a Hemoglobin Level > 12.0 g/dL
2a1.1 Numerator Statement: Calendar months during which patients have a Hemoglobin level > 12.0 g/dL* *The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month
2a1.4 Denominator Statement: All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy Definitions: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation
2a1.8 Denominator Exclusions: None.
1.1 Measure Type: Outcome **2a1. 25-26 Data Source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records **2a1.33 Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Clinician : Team **1.2-1.4 Is this measure paired with another measure?** No **De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*): This measure is not a composite or paired measure.

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested? Yes☐ No☐ If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): 5. Similar/related endorsed or submitted measures (*check 5.1*): Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas (*Check all the areas that apply*): Renal, Renal : Chronic Kidney Disease (CKD), Renal : End Stage Renal Disease (ESRD)
De.5 Cross Cutting Areas (*Check all the areas that apply*): Overuse, Safety, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):
Chronic kidney disease (CKD), affects approximately 13.1% of United States adults and leads to end-stage renal disease (ESRD), cardiovascular disease (CVD), and premature death. (1)

CKD affects up to 5% of the population and 25% of those aged 70 years or older. An additional 6% of the population has signs of kidney damage, which may progress to ESRD. (2)

CKD is not recognized as a major public health concern. It is estimated that approximately 26.3 million adutls in the U.S. have non-dialysis dependent kidney disease and over 470,000 have ESRD, collectively representing over 13% of the US population. In the next 20 years, the burnden of CKD is expected to increase, with over 2 million individuals projected to be receiving renal replacement therapy (dialysis or kidney transplant) by 2030. (3)

Costs for CKD patients are now 23 percent of Medicare expenditures in the fee-for-service sector; when added to costs for ESRD patients, it appears that 31 percent of all Medicare expenditures are incurred by patients with a diagnosis of kidney disease. (4)

In 1993, costs for Medicare patients with CKD accounted for 3.8 percent of overall Medicare expenditures. By 2008, this had grown to 14.2 percent, in part reflecting growth in the number of recognized CKD patients. (4)

In 2008, 37-38 percent of prevalent dialysis patients had a hemoglobin of 11-12 g/dl, the target set by KDOQI; the mean monthly hemoglobin was 11.6 g/dl.(4)

Views of anemia treatment have evolved over the last several years, as safety concerns about targeting higher hemoglobin levels have emerged from clinical trials. The FDA´s recommended target - a range of 10-12 g/dl - is achieved by 68 percent of prevalent patients.(4)

Currently, patients with CKD are five to 10 times more likely to die than to reach ESRD. (4)

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Snyder JJ, Collins AJ. Association of Preventive Health Care with Atherosclerotic Heart Disease and Mortality in CKD. J Am Soc Nephrol. 2009 July; 20(7): 1614–1622.

2. Alves TP, Lewis J. Racial differences in chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States: a social and economic dilemma. Clinical Nephrology. 2010;74(1):S72-S77.

3. Choi AI, Rodriguez RA, Bacchetti P, Bertenthal D, et al. White/Black Racial Differences in Risk of End-Stage Renal Disease and Death. Am J Med. 2009 July;122(7):672-678.

4. US Renal Data System, USRDS 2010 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, 2010.

1b. Opportunity for Improvement: H☐ M☐ L☐ I☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Anemia is a common complication of chronic kidney disease (CKD). The prevalence of anemia varies with the degree of renal impairment in predialysis patients with CKD, but once end-stage kidney failure occurs, all patients are eventually affected. Anemia develops once renal function decreases to <50% because of a deficiency in endogenous erythropoietin (EPO) production by the kidney, decreased red cell survival, blood losses, and increased red blood cell destruction once the patient begins dialysis treatment, particular hemodialysis. Anemia reduces physical capacity, well-being, neurocognitive function, and energy level and worsens quality of life both in predialysis and dialysis patients. Anemia also induces adaptive cardiovascular mechanisms to maintain tissue oxygen supply. This leads to left ventricular hypertrophy, left ventricular dilation, and myocardial ischemia, which are risk factors for cardiovascular disease and death. It is plausible that reversing anemia may reduce this risk.

In clinical practice for CKD patients, determination of the frequency and size of sequential ESA dose adjustments in relationship to a threshold Hb or target Hb level; and an interpretation of previous therapeutic trends and responsiveness to ESA therapy is critical.(2)

Improvement in quality of life and avoidance of transfusion are treatment benefits from determining the appropriate hemoglobin level, and there is potential for harm when aiming for high Hb targets. The potential harms are based on evidence from RCT´s suggesting that assignment to Hb targets greater than 13.0 g/dL may increase the risk of life threatening adverse events. (2)

1. Strippoli GFM, Craig JC, Manno C, Schena FP. Hemoglobin Targets for the Anemia of Chronic Kidney Disease: A Meta-analysis of Randomized, Controlled Trials. J Am Soc Nephrol 15:3154-3165, 2004.

2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and CLinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1b.2 Summary of Data Demonstrating Performance Gap (*Variation or overall less than optimal performance across providers*):
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
Among incident dialysis patients receiving EPO in the first year of therapy, and with an initial hemoglobin of 10 g/dL or greater, the probability of reaching a hemoglobin of 13 g/dl or higher has fallen from 0.86 for 2005 incident patients to 0.79 for those beginning treatment in 2007.

This new measure encompasses patients with CKD and ESRD which is a combination of two previous measures. One of these measures, Plan of Care for ESRD Patients with Anemia, was used in the CMS Physician Quality Reporting Initiative, in the claims option for 2008.1

There is a gap in care as shown by this 2008 data; 63.5 % of patients reported on did not receive the optimal care.
10th percentile: 10.42 %
25th percentile: 38.17 %
50th percentile: 66.23 %
75th percentile: 84.04 %
90th percentile: 94.93 %

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
1. US Renal Data System, USRDS 2010 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, 2010.

2. Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]

Anemia, a common complication of CKD, is more prevalent and severe in African-American than Caucasian patients at each stage of the disease. Currently, African-Americans with CKD are less likely than Caucasian patients to receive anemia treatment before and after the onset of dialysis. Although African-Americans often require higher doses of erythropoiesis-stimulating agents, this may result from late treatment initiation, lower hemoglobin levels, or the presence of comorbidities such as diabetes and inflammation, although racial differences in response cannot be excluded.

Healthy and iron-replete African-Americans typically have lower average hemoglobin (Hb) levels than Caucasians, reflecting, among other factors, the effects of an alpha-thalassemia deletion allele (gene frequency 0.169). Iron deficiency anemia is also frequent in African- Americans, with prevalences ranging up to 19% in premenopausal black women.

In the general population as well as in all stages of CKD, anemia has been shown to be more prevalent in African-Americans than Caucasians , perhaps reflecting low Hb prior to CKD onset and/or higher prevalence of iron deficiency.

Once dialysis is initiated, African-Americans receive higher ESA doses; however, it is difficult to distinguish the effects of nutritional deficiency, lower pretreatment Hb levels, and delayed ESA initiation from possible racial-specific biological effects on ESA responsiveness.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

Lea JP. The role of anemia management in improving outcomes for african-americans. Am J Nephrol 2008;28:732–743

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐   **If not a health outcome**, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):

This measure captures the number of calendar months during which patients have a Hemoglobin level > 12.0 g/dL, which is a measurement of a Hemoglobin level greater than the target range, an intermediate clinical outcome. Identifying patients with a Hemoglobin level greater than the target range is linked to improved health outcomes such as decreasing the incidence of an associated illness and attaining the highest quality and quantity of life after onset of illness.

1c.2-3 Type of Evidence (*Check all that apply*):
Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
The guideline recommendation focuses on focuses on a specific patient population including dialysis and nondialysis patients with CKD receiving ESA therapy. This measure specifically focuses on patients with CKD (stage 4 or 5, not receiving Renal Replacement Therapy (RRT)) and patients with ESRD who are on hemodialysis or peritoneal dialysis. The measure development Work Group thought it would be most beneficial to focus on this subset of patients, as the kidney disease within this population is more severe. The guideline states that the Hemoglobin target should not be greater than 13.0 g/dL and also that the selected Hemoglobin target should generally be in the range of 11.0 to 12.0 g/dL. Therefore, the measure is written to capture all patients with a Hemoglobin level > 12.0, which will focus on all patients who have a Hemoglobin level greater than the target range.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: For systematic review topics, the literature searches yielded 2,756 citations. Of these, 137 articles were reviewed in full. An additional 19 were added by [NKF] Work Group members. A total of 83 were extracted and of these, 51 studies are included in Summary tables [within the guideline].

Evidence supporting the statement that 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 includes results from 14 RCTs in dialysis patients and 15 RCTs in nondialysis patients.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The evidence considered by the [NKF]Work Group to support the statement is confined to results of between-group comparisons generated by intention-to-treat trials that randomly assigned patients to distinct Hb targets, including trials that used ESAs in both treatment arms and trials that used ESAs in 1 treatment arm and either placebo or no treatment in the control arm.

The practitioner approaches the decision to select a Hb treatment goal with the intent to treat the individual patient and should expect that the achieved Hb level will vary considerably from the intended Hb target. To develop these guidelines and recommendations, we therefore appraised only evidence that was generated from intent-to-treat analyses of trials in patients randomly assigned to either higher or lower Hb targets.

In the statement the selected Hb target should generally be in the range of 11.0 to 12.0 g/dL, the word generally emphasizes the need to maintain flexibility in medical decision making given the breadth of variability between patients' individual needs, values, functional status, disease burden, prognosis, and responsiveness to ESA therapy (Rationale for CPR 2.1.1).

In the statement the selected Hb target should generally be in the range of 11.0 to 12.0 g/dL, the 2 specific values 11.0 g/dL and 12.0 g/dL define inclusively either a single Hb target range (11.0 to 12.0 g/dL) or a range of possible single-point Hb targets between 11.0 and 12.0 g/dL; entail unavoidable subjectivity in selecting Hb cutoff values; explicitly exclude reference to achieved Hb levels; and together reflect the efforts of the Work Group to balance the potential quality-of life benefits and avoidance of transfusion gained by ESA therapy against the potential harm suffered by patients with Hb targets greater than 13 g/dL.

Available RCTs illustrate the distinction between a Hb target range and a discrete Hb target.

The lack of information to support specific Hb cutoff values in defining an optimum Hb target renders [this] a CPR.

The conclusion that the Hb target should not be greater than 13.0 g/dL is based on analysis of all-cause mortality and adverse cardiovascular events in patients with CKD assigned to Hb targets greater than 13.0 g/dL compared with lower Hb targets for ESA therapy (Tables 2, 4, 6 to 8, and 10 to 12). These trials evaluated whether a Hb target greater than 13.0 g/dL would prevent adverse cardiovascular events or mortality, testing the specific hypothesis that rates of fatal and nonfatal cardiovascular events or all-cause mortality in patients assigned to Hb targets greater than 13 g/dL differed from those in patients assigned to lower targets. None of the trials showed a benefit of higher Hb targets for these outcomes. Similarly, there is no evidence from the trials performed to date that higher Hb targets have a beneficial effect on left ventricular dimensions. With the exception of 1 small trial,6 RCTs also failed to

show a benefit of higher Hb targets in terms of reducing the progression of kidney disease.

In developing the statement that in dialysis and nondialysis patients with CKD receiving ESA therapy, the Hb target should not be greater than 13.0 g/dL, the Work Group considered a meta-analysis performed by the ERT. The meta-analysis included published trials that reported results of all-cause mortality and adverse cardiovascular events in patients assigned to higher compared with lower Hb targets.

In appraising the overall evidence, the Work Group considered mortality, cardiovascular events, and HRQoL as outcomes of high importance. TheWork Group rated the evidence showing a trend toward greater cardiovascular events in dialysis and nondialysis patients assigned to Hb targets greater than 13.0 g/dL to be of moderately high quality for showing harm and of high quality for showing lack of benefit. The Work Group considered the HRQoL benefits in patients assigned to higher Hb targets as low quality evidence based on the limitations of reported HRQoL evidence (see the following section, Limitations of Evidence). The conclusion that in dialysis and nondialysis patients with CKD receiving ESA therapy, the Hb target should not be greater than 13.0 g/dL reflects the Work Group's judgment that the possibility to cause harm weighs more heavily than the potential to improve quality of life and to decrease transfusions.

The appraisal of the Work Group that the evidence for harm is moderately high renders statement 2.1.3 a moderately strong evidence based CPG. As discussed in more detail elsewhere (Methods), the designation moderately strong acknowledges the possibility that further research may alter either the appraisal of the quality of the evidence or the estimate of the effect size and thus result in a change in the guideline. The designation moderately strong therefore does not impede continued investigation.

Limitations:
In general, a Hb target range suggests that ESA dose adjustment decisions are made by comparing the patient's achieved Hb with the selected Hb target. Although performance in managing to a Hb target can be expressed as the proportion of patients with Hb levels within the target range, in practice, only 30% of patients at any 1 time have an actual Hb level in the Hb target range of 11.0 and 12.0 g/dL when targeted to that range. The result of a single sampling in a single patient cannot be expected to lie within a narrow Hb target range (eg, Hb of 11.0 to 12.0 g/dL) or to equal a discrete point Hb target (eg, Hb of either 11.0, 11.5, or 12.0 g/dL). However, mean or median Hb levels of a group of patients or mean Hb levels of a single patient repeated over time would be expected to lie within a Hb target range or to approximate a discrete Hb target. In short, measures of clinical performance, to be clinically useful, must account for a high degree of within-patient and between patient variability.

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* [The NKF Work Group] compared both [their] methods and [their] results with those reported in another recent meta-analysis. [The NKF Work Group] included RCTs with 6 months or longer follow-up without restriction on study size, whereas the previous metaanalysis included RCTs with 12 weeks or longer follow-up and greater than 100 subjects; our statistical model was more conservative (random- effects model always versus fixed-effects model if no statistical heterogeneity), and unlike the previous report, we did not pool studies in dialysis patients with those from nondialysis patients given the dissimilarities between these 2 target populations in ESA administration, Hb monitoring, and the presence or absence of dialysis. Finally, for cardiovascular outcomes, the previous meta-analysis included only myocardial infarctions, whereas we combined all cardiovascular disease events, including all events from the primary composite outcome in both CHOIR and CREATE. Thus, our definition of cardiovascular disease as an outcome was less precise, but more inclusive, than that of the other meta-analysis.

For mortality, [the] meta-analysis, like the recently published meta-analysis, showed no statistically significant difference for assignment to higher versus lower Hb level in either subgroup of dialysis or nondialysis patients. In nondialysis patients with CKD, we showed a RR closer to 1.0 and a wider CI (RR, 1.01; CI, 0.63 to 1.61 versus 1.33; CI, 0.98 to 1.81) than that previously reported because our analysis included results from 4 studies not included in the other meta-analysis. These 4 studies added 441 patients and 18 deaths (5 in the upper Hb arms and 13 in the lower Hb arms). In patients with CKD on dialysis, the 2 meta-analyses included the same studies and yielded essentially identical results (RR, 1.12; CI, 0.91 to 1.37 versus 1.11; CI, 0.94 to 1.31, current versus previous meta-analysis).

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic

Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
In appraising the overall evidence, the [NKF] Work Group considered mortality, cardiovascular events, and HRQoL as outcomes of high importance. TheWork Group rated the evidence showing a trend toward greater cardiovascular events in dialysis and nondialysis patients assigned to Hb targets greater than 13.0 g/dL to be of moderately high quality for showing harm and of high quality for showing lack of benefit. The Work Group considered the HRQoL benefits in patients assigned to higher Hb targets as low quality evidence based on the limitations of reported HRQoL evidence (see the following section, Limitations of Evidence). The conclusion that in dialysis and nondialysis patients with CKD receiving ESA therapy, the Hb target should not be greater than 13.0 g/dL reflects the Work Group's judgment that the possibility to cause harm weighs more heavily than the potential to improve quality of life and to decrease transfusions.

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: John W. Adamson, MD
Consultant: Affymax; Fibrogen;Watson
Speaker:Watson
Grant/Research Support (no personal income): N/A
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Jeffrey S. Berns, MD
Consultant: Amgen; Neose
Speaker: N/A
Grant/Research Support (no personal income):
Advanced Magnetics; Hoffman LaRoche
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Kai-Uwe Eckardt, MD (Work Group Co- Chair
Consultant: Affymax; Amgen; Hoffman LaRoche; Ortho Biotech/Johnson & Johnson
Speaker: Amgen; Hoffman LaRoche; Ortho Biotech/Johnson & Johnson
Grant/Research Support (no personal income): Hoffman LaRoche; Ortho Biotech/Johnson & Johnson
Grant/Research Support (includes personal income):N/A
Part-Time Employee: N/A
Shares: N/A

Steven Fishbane, MD
Consultant: Abbott; Affymax; Amgen; Genzyme; Hoffman LaRoche; Renal Management Strategies;Watson
Speaker: Abbott; Genzyme; Ortho Biotech;Watson
Grant/Research Support (no personal income):
Abbott; Amgen; Genentech; Genzyme; Hoffman LaRoche; Ortho Biotech; Shire; Speedel;Watson
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Robert N. Foley, MD

Consultant: Amgen; Genzyme; Hoffman LaRoche; Ortho Biotech
Speaker: Amgen; Hoffman LaRoche; Ortho Biotech
Grant/Research Support (no personal income): Amgen; Hoffman LaRoche; Ortho Biotech
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Sana Ghaddar, PhD, RD
Dr. Ghaddar reported no relevant financial relationships.

John S. Gill, MD, MSConsultant: Hoffman LaRoche
Speaker: N/A
Grant/Research Support (no personal income): N/A
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Kathy Jabs, MDDr Jabs reported no relevant financial relationships.

Francesco Locatelli, MD, FRCP
Consultant: Amgen; Dompé Biotec; Hoffman LaRoche; Shire
Speaker: Abbott; Amgen; Bayer; Bellco; Bristol-Myers Squibb; Dompé Biotec; Fresenius; Gambro-Hospal; Hoffman LaRoche; Merck Sharp & Dohme; Novartis; Pfizer; Sanofi-Aventis;Shire
Grant/Research Support (no personal income):N/A
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Iain C. Macdougall, MD
Consultant: Affymax; Amgen; Hoffman La-Roche; Ortho Biotech; Shire
Speaker: Amgen; Hoffman LaRoche; Ortho Biotech; Shire Grant/Research Support (no personal income):
Affymax; Amgen; Hoffman LaRoche; Ortho Biotech;Shire
Grant/Research Support (includes personal income):N/A
Part-Time Employee: N/A
Shares: N/A

Patricia Bargo McCarley, RN, MSN, NP
Consultant: N/A
Speaker: Amgen
Grant/Research Support (no personal income): N/A
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Allen R. Nissenson, MD, FACP
Consultant: Advanced Magnetics; Affymax;Amgen; DaVita; Fibrogen; Hoffman LaRoche;Medgenics; Ortho Biotech; Prometic
Speaker:Watson
Grant/Research Support (no personal income):Amgen; Hoffman LaRoche; Ortho Biotech
Grant/Research Support (includes personal income):N/A
Part-Time Employee: N/A
Shares: Advanced Magnetics

Gregorio T. Obrador, MD, MPH
Dr Obrador reported no relevant financial relationships.

John C. Stivelman, MD
Consultant:Watson
Speaker:Watson
Grant/Research Support (no personal income):Amgen; Auxilium;Watson
Grant/Research Support (includes personal income):N/A
Part-Time Employee: N/A
Shares: N/A

David B. Van Wyck, MD (Work Group Co- Chair
Consultant: Affymax; American Regent; Amgen;DaVita; Ortho Biotech/Johnson & Johnson;Vifor
Speaker: American Regent; Amgen; DaVita;Ortho Biotech/Johnson & Johnson; Vifor
Grant/Research Support (no personal income):N/A
Grant/Research Support (includes personal income):American Regent
Part-Time Employee: DaVita
Shares:N/A

Colin T. White, MD
Consultant: Hoffman LaRoche
Speaker: N/A
Grant/Research Support (no personal income):Genzyme Canada
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

KDOQI Chair, Vice-Chair and ERT

Adeera Levin, MD, FACP
Consultant: Hoffman LaRoche
Speaker: Abbott; Amgen; Hoffman LaRoche;Merck Frosst; Ortho Biotech
Grant/Research Support (no personal income): Abbott; Genzyme; Merck Frosst; Ortho Biotech;Shire
Grant/Research Support (includes personal income):N/A
Part-Time Employee: N/A
Shares: N/A

Michael V. Rocco, MD, MSCE
Consultant: Amgen; DaVita; Hoffman La-Roche; Renaissance Health Care
Speaker: N/A
Grant/Research Support (no personal income): N/A
Grant/Research Support (includes personal income): N/A
Part-Time Employee: N/A
Shares: N/A

Joseph Lau, MD
Dr Lau reported no relevant financial relationships.

Katrin Uhlig, MD, MS
Dr Uhlig reported no relevant financial relationships.

Amy Earley, BS,
Ms Earley reported no relevant financial relationships.

1c.11 System Used for Grading the Body of Evidence: GRADE

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: In appraising the overall evidence, the [NKF] Work Group considered mortality, cardiovascular events, and HRQoL as outcomes of high importance. TheWork Group rated the evidence showing a trend toward greater cardiovascular events in dialysis and nondialysis patients assigned to Hb targets greater than 13.0 g/dL to be of moderately high quality for showing harm and of high quality for showing lack of benefit. The Work Group considered the HRQoL benefits in patients assigned to higher Hb targets as low quality evidence based on the limitations of reported HRQoL evidence .

1c.14 Summary of Controversy/Contradictory Evidence: In the statement the selected Hb target should generally be in the range of 11.0 to 12.0 g/dL, the 2 specific values 11.0 g/dL and 12.0 g/dL define inclusively either a single Hb target range (11.0 to 12.0 g/dL) or a range of possible single-point Hb targets between 11.0 and 12.0 g/dL; entail unavoidable subjectivity in selecting Hb cutoff values; explicitly exclude reference to achieved Hb levels; and together reflect the efforts of the Work Group to balance the potential quality-of life benefits and avoidance of transfusion gained by ESA therapy against the potential harm suffered by patients with Hb targets greater than 13 g/dL.

The lack of information to support specific Hb cutoff values in defining an optimum Hb target renders [this] statement a CPR.

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
N/A

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:
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.

In dialysis and nondialysis patients with CKD receiving ESA therapy, the Hb target should not be greater than 13.0 g/dL.

1c.17 Clinical Practice Guideline Citation: National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Am J Kidney Dis 50, No 3 (September), 2007.

1c.18 National Guideline Clearinghouse or other URL:
http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/index.htm

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: NKF Anemia Update Work Group Membership: John W. Adamson, MD, has served as Executive Vice President for Research and Director of the Blood Research Institute of the Blood Center of Southeastern Wisconsin in Milwaukee since 1998. He holds the position of Professor of Medicine (Hematology) at the Medical College of Wisconsin. Before moving to Milwaukee, he was Director of the Lindsley F. Kimball Research Institute of the New York Blood Center since 1989 and President of the Center from 1989 to 1997. Dr Adamson received his MD from the University of California, Los Angeles, after which he trained at the University ofWashington in Seattle and the National Institutes of Health (NIH) in Bethesda, MD, in the fields of internal medicine and hematology. Before assuming his position in New York, Dr Adamson was professor of medicine and head of the Division of Hematology at the University of Washington. Dr Adamson is a past President of the American Society of Hematology and past Chairman of its committees on scientific affairs and transfusion medicine. Dr Adamson served as a member of the Advisory Council of the National Institute of Diabetes, Digestive and Kidney Diseases of the NIH. In 1988, he was designated clinical research professor by the American Cancer Society and elected a Fellow of the American Association for the Advancement of Science. Dr Adamson is past editor-in-chief of Blood, past editor of the Journal of Cellular Physiology, and founding editor of Current Opinion in Hematology. Altogether, he has authored or co-authored more than 400 scientific publications. Consultant: Affymax; Fibrogen;Watson Speaker:Watson Grant/Research Support (no personal income): N/A Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Jeffrey S. Berns, MD, earned his MD at Case Western Reserve

University, then completed his internship and residency in Internal Medicine at University Hospitals of Cleveland. He completed a fellowship in Nephrology and was anAssociate Research Scientist in the Department of Physiology at Yale University. Dr Berns was recently promoted to Professor of Medicine at the University of Pennsylvania School of Medicine, where he is Director of Clinical Nephrology and Director of the Renal Fellowship Program for the Renal, Electrolyte and Hypertension Division. He has published and lectured on topics related to CKD, anemia management in patients with CKD, and other areas in clinical nephrology. He is co-editor of Drug Prescribing in Renal Failure-Dosing Guidelines for Adults. He also serves on the editorial board of Seminars in Dialysis, American Journal of Kidney Diseases, and Clinical Journal of the American Society of Nephrology. He is an active investigator in clinical trials related to anemia treatment in patients with CKD. Consultant: Amgen; Neose Speaker: N/A Grant/Research Support (no personal income): Advanced Magnetics; Hoffman LaRoche Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Kai-Uwe Eckardt, MD (Work Group Co- Chair), is Professor of Medicine and Chief of Nephrology and Hypertension at the University of Erlangen–Nuremberg, Germany. He received his MD from theWestfälischeWilhelms-Universität Münster, Germany. In 1993, following postgraduate training in internal medicine, pathology, and physiology, he was appointed Assistant Professor of Physiology at the University of Regensburg, Germany. Subsequently, he continued his training in internal medicine and nephrology at the Charité, Humboldt University in Berlin, where he was appointed Associate Professor of Nephrology in 2000. His major scientific interests are in the molecular mechanisms and physiological/pathophysiological relevance of oxygen sensing and the management of anemia. Professor Eckardt is Subject Editor of Nephrology, Dialysis and Transplantation and serves on the editorial board of several other journals. He contributed to the development of the European Best Practice Guidelines for Anemia. Management and is a member of the executive committee of Kidney Disease: Improving Global Outcomes (KDIGO). Dr Eckardt is associated with the CREATE and TREAT studies. Consultant: Affymax; Amgen; Hoffman LaRoche; Ortho Biotech/Johnson & Johnson Speaker: Amgen; Hoffman LaRoche; Ortho Biotech/Johnson & Johnson Grant/Research Support (no personal income): Hoffman LaRoche; Ortho Biotech/Johnson & Johnson Grant/Research Support (includes personal income):N/A Part-Time Employee: N/A Shares: N/A Steven Fishbane, MD, currently is Chief of Nephrology and Associate Chair of the Department of Medicine atWinthrop-University Hospital (WUH) in Mineola, NY, as well as Professor of Medicine at SUNY Stony Brook School of Medicine. He is the Medical Director of WUH Dialysis Network, which includes 4 outpatient dialysis units and 3 hospital units. Dr Fishbane serves as the Chairman of the Long Island Health Network Quality Council; Chairman of the Department of Medicine Quality Improvement Program, WUH; Chairman of Clinical Guidelines Committee, WUH; Co-Chairman of WUH Patient Care Committee; and Associate Chairman of the Department of Medicine, WUH. Dr Fishbane is a member of the Network 2 Medical Review Board. Consultant: Abbott; Affymax; Amgen; Genzyme; Hoffman LaRoche; Renal Management Strategies;Watson Speaker: Abbott; Genzyme; Ortho Biotech;Watson Grant/Research Support (no personal income): Abbott; Amgen; Genentech; Genzyme; Hoffman LaRoche; Ortho Biotech; Shire; Speedel;Watson Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Robert N. Foley, MD, was born in Ireland and received his undergraduateMDfrom University College Cork. He completed Internal Medicine training in Cork, later moving to Saint John's, Newfoundland, Canada, where he completed a residency in nephrology, as well as a Masters in Clinical Epidemiology. From 1999 to 2002, Dr Foley worked at Hope Hospital, Salford, UK, and has been Director of the Chronic Disease Research Group since September of 2002. Dr Foley was also a Co-Editor of the American Journal of Kidney Diseases. His major interest is in outcomes research, especially the interplay of cardiovascular and renal disease. Dr Foley is active in anemia correction trials, as well as in the US Renal Data System Cardiovascular Special Study Center. Consultant: Amgen; Genzyme; Hoffman LaRoche; Ortho Biotech Speaker: Amgen; Hoffman LaRoche; Ortho Biotech Grant/Research Support (no personal income): Amgen; Hoffman LaRoche; Ortho Biotech Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Sana Ghaddar, PhD, RD, is an Assistant professor at the American University of Beirut, Lebanon. She has more than 10 years of experience in the renal and clinical dietetics field. She was a renal dietitian and researcher at Peninsula Nephrology Inc in San Mateo, currently a division of Satellite Healthcare. She has served as a principal investigator for anemia management studies that examined the response of heme-iron polypeptide to ESAs in patients with CKD, in addition to other studies that examined patient perceptions, beliefs, and compliance with hemodialysis and nutritional therapy. She has presented her studies at national conferences, including the NKF, American Dietetic Association, and Gerontological Society of America. Dr. Ghaddar reported no relevant financial relationships. John S. Gill, MD, MS, obtained his MD from the University of British Columbia (UBC) in 1995. He completed his internal medicine training at the University of Western Ontario in 1998 and his nephrology training in 2000 at UBC. He then completed his transplantation training at Tufts–New England Medical Center in Boston, MA, and obtained a Masters in Clinical Care Research from Tufts in 2002. Dr Gill currently is assistant professor of medicine in the Division of Nephrology at UBC and has a cross appointment at Tufts–New England Medical Center. Dr Gill's research interests focus on clinical outcomes in kidney transplant recipients. He is the principal investigator and co-investigator on current Canadian Institutes of Health Research, Kidney Foundation, and Michael Smith funded studies. Dr Gill is Chair of the Canadian Society of Transplantation Work Group for Pan-Canadian database development, member of the Canadian Organ Replacement Register Advisory Board, and member of a number of NKF Committees. Consultant: Hoffman LaRoche Speaker: N/A Grant/Research

Support (no personal income): N/A Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Kathy Jabs, MD, is a Pediatric Nephrologist who was trained at Babies Hospital, NY, and Children's Hospital, Boston, MA. She was a faculty member at Children's Hospital in Boston (1988 to 1996) and served as Director of Dialysis and Renal Transplantation at Children's Hospital of Philadelphia (1996 to 2000). She currently is the Director of Pediatric Nephrology at Vanderbilt Children's Hospital and an Associate Professor of Pediatrics at Vanderbilt University School of Medicine, Nashville, TN. Dr Jabs has had a long-standing interest in the care of children with chronic kidney disease. Dr Jabs is associated with the CKid and FSGS studies sponsored by the NIH. Dr Jabs reported no relevant financial relationships. Francesco Locatelli, MD, FRCP, is Head of the Department of Nephrology and Dialysis at A. Manzoni Hospital, Lecco, Italy, and postgraduate Professor of Nephrology at the Universities of Brescia and Milan. He is Past President of the European Renal Association–European Dialysis and Transplant Association, the International Society of Blood Purification, and the Italian Society of Nephrology. He is an Honorary Member of the Czech, Hungarian, Polish, Romanian, and Turkish Societies of Nephrology and an International Distinguished Medalist and recipient of the Garabed Eknoyan Award of the NKF, United States (2006). He is also an honorary fellow of the Royal College of Physicians of London, UK (FRCP). He has been Chairman of the Lombardy Regional Dialysis and Transplantation Registry since 1982. He also serves as Chairman of the board of European Best Practice Guidelines and is on the board of the NKF-Dialysis Outcomes Quality Initiative and the executive board of directors of KDIGO. Dr Locatelli is President- Elect of the World Congress of Nephrology (2009), Subject Editor of Nephrology Dialysis Transplantation, Associate Editor of the Journal of Nephrology, member of the Editorial Board of Journal of the American Society of Nephrology, past Associate Editor of the American Journal of Kidney Diseases (2001 to 2004), and serves as reviewer for a number of journals (including the New England Journal of Medicine and The Lancet). He has authored more than 600 papers in the fields of hypertension, nutrition, and CKD progression; adequacy in dialysis; sodium and other electrolyte balance, immunoglobulin A nephropathy, and anemia. Consultant: Amgen; Dompé Biotec; Hoffman LaRoche; Shire Speaker: Abbott; Amgen; Bayer; Bellco; Bristol-Myers Squibb; Dompé Biotec; Fresenius; Gambro-Hospal; Hoffman LaRoche; Merck Sharp & Dohme; Novartis; Pfizer; Sanofi-Aventis;Shire Grant/Research Support (no personal income):N/A Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Iain C. Macdougall, MD, is a combined medical and science graduate of Glasgow University, Scotland, from which he was awarded a First Class Honours BSc in Pharmacology in 1980. For the last 11 years, he has been Consultant Nephrologist and Honorary Senior Lecturer at King's College Hospital in London, UK. He developed both a clinical and a basic science research interest in factors affecting responsiveness to ESAs. He has served on the Working Parties responsible for both the 1999 and the 2004 versions of the European Best Practice Guidelines on Renal Anaemia Management, as well as the KDOQI Anemia Guidelines Work Group. He is a current Council member of the European Renal Association and a past member of the KDIGO Board of Directors. He has coauthored the section on renal anemia for the last 2 editions of the Oxford Textbook of Clinical Nephrology and the current edition of Comprehensive Clinical Nephrology and is a Subject Editor of Nephrology Dialysis Transplantation. Consultant: Affymax; Amgen; Hoffman La-Roche; Ortho Biotech; Shire Speaker: Amgen; Hoffman LaRoche; Ortho Biotech; Shire Grant/Research Support (no personal income): Affymax; Amgen; Hoffman LaRoche; Ortho Biotech;Shire Grant/Research Support (includes personal income):N/A Part-Time Employee: N/A Shares: N/A Patricia Bargo McCarley, RN, MSN, NP, is a nephrology nurse practitioner at Diablo Nephrology Medical Group in Walnut Creek, CA. Ms McCarley received her BSN and MSN from Vanderbilt University. She is active in the American Nephrology Nurses Association (ANNA), having served on local, regional, and national committees. She is currently a member of the Nephrology Nursing Journal Board. Ms McCarley has authored many publications, including most recently chapters in the 2005 ANNA Nephrology Nursing Standards of Practice and Guidelines for Care and the Contemporary Nephrology Nursing: Principles and Practice (2nd edition). Consultant: N/A Speaker: Amgen Grant/Research Support (no personal income): N/A Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Allen R. Nissenson, MD, FACP, is Professor of Medicine and Director of the Dialysis Program at the David Geffen School of Medicine at University of California at Los Angeles (UCLA), where he has developed a comprehensive dialysis program. He is President of the National Anemia Action Council and recently chaired a Chancellor's committee at UCLA on Financial Conflicts of Interest in Clinical Research. He is currently serving on a University of California Task Force on Institutional Conflicts of Interest in Research. Dr Nissenson is Chair of the Faculty Executive Council for the David Geffen School of Medicine at UCLA. He has served as Chair of the Southern California End-Stage Renal Disease (ESRD) Network during its organizational years in the early 1980s and is its recent President- Elect. He is Chair of the Medical Review Board. Dr Nissenson served as a Robert Wood Johnson Health Policy Fellow of the Institute of Medicine from 1994 to 1995. He is Immediate Past President of the Renal Physicians Association and has served as a member of the Advisory Group overseeing the entire NKF-Dialysis Outcomes Quality Initiative. Dr Nissenson's major research interests focus on the quality of care for patients with CKD. His research has included extensive clinical trials of new devices and drugs related to renal disease. Dr Nissenson is co-principal investigator on a recently obtained NIH Center Grant looking at issues of disparities in health care delivery for patients with CKD. He is the author of 2 dialysis textbooks, both in their fourth editions, and was the founding Editor-in-Chief of Advances in Renal Replacement Therapy (currently, Advances in Chronic Kidney Disease), an official journal of the NKF. He currently is Editorin- Chief of Hemodialysis International, the official journal of the

International Society for Hemodialysis. He has more than 340 publications in the field of nephrology, dialysis, anemia management, and health care delivery and policy.Among his numerous honors is the President's Award of the NKF. Consultant: Advanced Magnetics; Affymax;Amgen; DaVita; Fibrogen; Hoffman LaRoche;Medgenics; Ortho Biotech; Prometic Speaker:Watson Grant/Research Support (no personal income):Amgen; Hoffman LaRoche; Ortho Biotech Grant/Research Support (includes personal income):N/A Part-Time Employee: N/A Shares: Advanced Magnetics Gregorio T. Obrador, MD, MPH, is Professor of Medicine and Dean at the Universidad Panamericana School of Medicine in Mexico City. He also serves as Adjunct Staff at the Division of Nephrology of the Tufts–New England Medical Center and Assistant Professor of Medicine at the Tufts University School of Medicine in Boston, MA. While doing a clinical research fellowship at the Tufts–New England Medical Center and a Master of Public Health at Harvard University, he began a line of investigation in the area of CKD. Through several publications, he and others showed that the pre-ESRD management of patients with CKD is suboptimal, and that this is an important factor for the high morbidity and mortality observed in these patients. A particular area of interest has been anemia management before the initiation of dialysis therapy. By using population registry data, he and his colleagues have reported trends in anemia and iron management. Dr Obrador has served as reviewer for several journals, including Kidney International, the Journal of the American Society of Nephrology, and the American Journal of Kidney Diseases. He also has been a member of the Advisory Board of the NKFKDOQI. Dr Obrador reported no relevant financial relationships. John C. Stivelman, MD, is Chief Medical Officer of the Northwest Kidney Centers and Associate Professor of Medicine in the Division of Nephrology, Department of Medicine, at the University ofWashington School of Medicine in Seattle. Dr Stivelman obtained his MD from the University of Pennsylvania, completed his residency in Internal Medicine at Harbor-UCLA Medical Center, and nephrology training at Brigham and Women's Hospital. Dr Stivelman has been involved in investigative efforts to optimize hematopoietic therapy for dialysis patients since the phase III recombinant erythropoietin trials in 1986. His major interests and literature contributions center on iron utilization, mechanisms of resistance of erythropoietin therapy, improved dialytic survival in disadvantaged populations, and the interaction of regulatory issues with optimization of care. Dr Stivelman has served as the Chair of the Network 6 Medical Review Board and a member of the Forum of ESRD Networks Board of Directors. He currently serves as medical director of one of Northwest Kidney Centers' free-standing facilities and as a member of the Boards of Directors of the Renal Physicians' Association and the Northwest Renal Network (Network 16). Consultant:Watson Speaker:Watson Grant/Research Support (no personal income):Amgen; Auxilium;Watson Grant/Research Support (includes personal income):N/A Part-Time Employee: N/A Shares: N/A David B. Van Wyck, MD (Work Group Co- Chair), is Professor of Medicine and Surgery at the University of Arizona College of Medicine in Tucson. After completing his undergraduate studies at Washington University, St Louis, Dr Van Wyck earned his MD at the University of Arizona College of Medicine. There, he undertook a research fellowship in Surgical Biology and completed his residency in Internal Medicine and fellowship in Nephrology. Dr Van Wyck has written or contributed to books, book chapters, articles, and abstracts on basic iron metabolism and reticuloendothelial function and on clinical aspects of iron and anemia in patients with CKD. On the subject of anemia and kidney disease, he pursues research, provides consultation to industry including American Regent, Amgen, and DaVita, Inc, and reviews manuscripts for the major nephrology journals. Dr Van Wyck served on the original KDOQI AnemiaWork Group and assumed Co-Chair responsibilities in 2002. Frequently invited to speak, Dr Van Wyck has lectured on the molecular and cellular control of erythropoiesis and iron homeostasis, diagnostic and treatment issues in anemia and iron management, protocol development in the treatment of dialysis-associated anemia, and new approaches to iron and erythropoietin replacement therapy. Consultant: Affymax; American Regent; Amgen;DaVita; Ortho Biotech/Johnson & Johnson;Vifor Speaker: American Regent; Amgen; DaVita;Ortho Biotech/Johnson & Johnson; Vifor Grant/Research Support (no personal income):N/A Grant/Research Support (includes personal income):American Regent Part-Time Employee: DaVita Shares:N/A Colin T. White, MD, is a pediatric nephrologist at British Columbia (BC) Children's Hospital in Vancouver and clinical assistant professor at the University of BC in Canada. He completed medical school in Ottawa and Pediatrics in London, Ontario. There, he finished 3 years of pediatric nephrology training before moving to Vancouver to complete 3 more years. He has been on staff as a Pediatric Nephrologist since 2003 and is currently the Director of Dialysis at BC Children's Hospital. He has a number of research interests, including medical education, optimizing dialysis care in children, estimation of glomerular filtration rate, and CKD and its complications. Dr White's interest in anemia management is geared towards children. He is presently completing a Masters degree in Medical Education. Dr White is associated with the CKid study and various NAPRTC protocols. Consultant: Hoffman LaRoche Speaker: N/A Grant/Research Support (no personal income):Genzyme Canada Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A KDOQI Chair, Vice-Chair and ERT Adeera Levin, MD, FACP, is Professor of Medicine and the Co-Chair of the Clinical Investigator Program at the University of British Columbia (UBC). She received her medical degree from McMaster University and nephrology training at the University of Toronto. Dr Levin currently serves as the Director of the Kidney Function Clinic at St Paul's Hospital in Vancouver, Executive Director of the British Columbia Provincial Renal Agency, Curriculum Chair of the Kidney Research Scientist Core Education and National Training program, and KDOQI Chair at the NKF. In addition, she is a member of the KDIGO Executive Committee, International Society of Nephrology Council, and ROFAR Board of Trustees. Her research interests include early kidney disease, anemia, mineral metabolism

disorders, cardiovascular diseases, and CKD progression and health outcomes. Dr. Levin is also the recipient of the UBC Martin Hoffman Award for research excellence and the Dean Whitlaw Award for Outstanding Grand Rounds. She is presently on the editorial board of the American Journal of Kidney Diseases and Nephrology Dialysis and Transplantation. Consultant: Hoffman LaRoche Speaker: Abbott; Amgen; Hoffman LaRoche;Merck Frosst; Ortho Biotech Grant/Research Support (no personal income): Abbott; Genzyme; Merck Frosst; Ortho Biotech;Shire Grant/Research Support (includes personal income):N/A Part-Time Employee: N/A Shares: N/A Michael V. Rocco, MD, MSCE, is Professor of Medicine at Wake Forest University in Winston- Salem, NC. He received his MD degree from Vanderbilt University in Nashville, TN, and also served his Internal Medicine residency at Vanderbilt. He completed a nephrology fellowship at the University of Pennsylvania in Philadelphia, PA, and received a master's degree in epidemiology at Wake Forest University. He has been on the faculty of the Wake Forest University School of Medicine since 1991 and currently holds the Vardaman M. Buckalew Jr Chair in Nephrology. He has more than 100 manuscripts and book chapters in the areas of hemodialysis, peritoneal dialysis, nutrition, chronic renal failure, and epidemiology. He has served as the clinical center Principal Investigator at Wake Forest for several NIH trials, including the HEMO Study, the Acute Renal Failure Trial Network, the Dialysis Access Consortium, and the Frequent Hemodialysis Network. Dr. Rocco has served as the Vice-Chair for KDOQI since 2003 and was the Vice-Chair for the NKF-KDOQI Hypertension Work Group. He was also a workgroup member of the Centers for Medicare & Medicaid Services (CMS) ESRD Clinical Performance Measures Quality Improvement Committee and served as the Chair of the peritoneal dialysis subcommittee. Consultant: Amgen; DaVita; Hoffman La-Roche; Renaissance Health Care Speaker: N/A Grant/Research Support (no personal income): N/A Grant/Research Support (includes personal income): N/A Part-Time Employee: N/A Shares: N/A Joseph Lau, MD, is a Professor of Medicine at Tufts University and Program Director, Evidence- based Medicine, NKF Center for CPG Development and Implementation at Tufts New England Medical Center in Boston, MA. Dr Lau completed a fellowship in Clinical Decision Making and Medical Computer Science and he holds a joint appointment as Physician and Clinical Investigator at Tufts. He is also a recipient of the Tufts School of Medicine Distinguished Faculty Award (2003) and an Agency for Healthcare Research and Quality Evidence-Based Practice Center contract. His primary research focus is evidence-based medicine and meta-analyses. Dr Lau reported no relevant financial relationships. Katrin Uhlig, MD, MS, is an Assistant Professor of Medicine at Tufts University and Program Director, Nephrology, NKF Center for CPG Development and Implementation at Tufts-New England Medical Center in Boston, MA. She completed a rheumatology fellowship at Policlinic, Munich University in Germany and a nephrology fellowship at Tufts, where she is currently a Staff Physician, Division of Nephrology. She is Co-Editor of the American Journal of Kidney Diseases. She is a recipient of the German National Merit Foundation scholarship. Her research interests include developing evidence-based CPGs, conducting systematic reviews, performing critical literature appraisal, and teaching evidence-based medicine. Dr Uhlig reported no relevant financial relationships. Amy Earley, BS, is a Research Assistant at the NKF Center for CPG Development and Implementation at Tufts–New England Medical Center in Boston, MA. She assists in the development of evidence-based clinical guidelines and conducts systematic reviews and critical literature appraisals. Ms Earley reported no relevant financial relationships

1c.21 **System Used for Grading the Strength of Guideline Recommendation:** Other

1c.22 **If other, identify and describe the grading scale with definitions:** A modified version of the GRADE criteria was used to grade the strength of the guideline recommendations. The modified language is below.

Strong – It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is high-quality evidence that the practice results in net medical benefit to the patient.
• Moderately strong – It is recommended that clinicians routinely follow this guideline for eligible patients. There is at least moderately high-quality evidence that the practice results in net medical benefit to the patient.
• Clinical Practice Recommendation (CPRs) – Based on consensus of the [NKF] Work Group that following the recommendations might improve health outcomes.

1c.23 **Grade Assigned to the Recommendation:** Clinical Practice Guideline, Moderately Strong Evidence

1c.24 **Rationale for Using this Guideline Over Others:** It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

KDOQI was founded on the principles of structured review of the literature, with data abstraction of pertinent articles. All of the KDOQI guidelines were developed in this manner. Since the first guideline was published, additional refinement and maturation of

this process has occurred. This rigorous process of guideline development has been well received as both credible and transparent. National Kidney Foundation. KDOQI Guideline Processed. http://www.kidney.org/professionals/KDOQI/guidelines_process.cfm. Accessed: May 19, 2011.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: Moderate   1c.26 Quality: Moderate 1c.27 Consistency: Moderate

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*)   Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, underline specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (underline evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 **Measure Web Page** *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for underline this measure can be obtained? Yes

S.2 **If yes, provide web page URL:** www.physicianconsortium.org

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 **Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Calendar months during which patients have a Hemoglobin level > 12.0 g/dL*

*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month

2a1.2 **Numerator Time Window** *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Once during the measurement period.

2a1.3 **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
See attached for EHR specifications.

For Claims/Administrative:
Report CPT Category II 3XXXF: Hemoglobin level > 12.0 g/dL

2a1.4 **Denominator Statement** *(Brief, narrative description of the target population being measured)*:
All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy

Definitions:

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney

transplantation

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
12 Consecutive months

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
See attached for EHR specifications.

For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)

AND

CPT® Category II Code: 4171F - Patient receiving erythropoiesis-stimulating agent (ESA) therapy OR HCPCS codes to identify erythropoietin therapy: J0881, J0885

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
None.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
N/A

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification   **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
This measure is not risk adjusted.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed**:**

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Lower score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:

Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. 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):
This measure does not require sampling or a survey.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested)*. If other, please describe:
Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): N/A

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
Attachment
AMA-PCPI_AKID-7_ESA Therapy Hgb greater than 12.0.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other:, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
•   Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures
o   The number of physicians per site ranged from 5-62 physicians
o   The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
o   Patient visit volume ranged from 240-2,800 ESRD patients seen per month
•   Sample size per physician organization ranged from 24-30 (as shown below) for a total of 169 ESRD patients on Peritoneal Dialysis (PD), or Hemodialysis (HD)
o   Site 1: 27 ESRD patients (3 PD patients, 24 HD patients)
o   Site 2 :40 ESRD patients (10 PD patients, 30 HD patients)
o   Site 3 :42 ESRD patients (19 PD patients, 23 HD patients)
o   Site 4 : 60 ESRD patients (30 PD patients, 30 HD patients)
•   Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
•   Data abstraction was completed for multiple patient visits per patient for a total of 2012 patient visits.
•   Data abstraction was performed in 2008

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Data abstracted from patient records were used to calculate inter-rater reliability for the measure.

Patients were randomly selected from visits for chronic kidney disease
Data analysis included:
- Percent agreement
- Kappa statistic to adjust for chance agreement

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
This measure is highly reliable.

Plan of Care for Anemia Measure (N, % Agreement, Kappa (95% Confidence Interval))
2012, 99.45% Agreement, Kappa 0.9860 (0.9943 – 0.9778)

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:   H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c***) and identify any differences from the evidence:**
The guideline recommendation focuses on focuses on a specific patient population including dialysis and nondialysis patients with CKD receiving ESA therapy. This measure specifically focuses on patients with CKD (stage 4 or 5, not receiving Renal Replacement Therapy (RRT)) and patients with ESRD who are on hemodialysis or peritoneal dialysis. The measure development Work Group thought it would be most beneficial to focus on this subset of patients, as the kidney disease within this population is more severe. The guideline states that the Hemoglobin target should not be greater than 13.0 g/dL and also that the selected Hemoglobin target should generally be in the range of 11.0 to 12.0 g/dL. Therefore, the measure is written to capture all patients with a Hemoglobin level > 12.0, which will focus on all patients who have a Hemoglobin level greater than the target range.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD
Barbara Fivush, MD (Work Group Co-Chair) (Nephrology - Pediatrics) Professor of Pediatrics, Division Chief of Pediatric Nephrology, Johns Hopkins University, Baltimore, MD
Paul M. Palevsky, MD, FACP, FCCD, FASN (Work Group Co-Chair) (Nephrology - Adult) Professor of Medicine, University of Pittsburgh School of Medicine, Chief, Renal Section, VA Pittsburgh Healthcare System, Pittsburgh, PA
Eileen D. Brewer, MD (Nephrology - Pediatrics) Professor and Head, Pediatric Renal Section, Baylor College of Medicine Chief, Renal Service, Texas Children´s Hospital, Houston, TX
John W. Foreman, MD (Nephrology - Pediatrics) Department of Pediatrics, Professor of Pediatrics, Duke University, Durham, NC
Richard S. Goldman, MD (Nephrology - Adult, Methodology) Nephrology and Internal Medicine, Albuquerque, NM
Stuart L. Goldstein, MD (Nephrology - Pediatrics) Director, Center for Acute Care Nephrology, Cincinnati Children´s Hospital Medical Center; Medical Director, Pheresis Service, Professor of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
John Hartman, MD (Nephrology - Adult) CEO, Visonex, LLC, Treasurer, Wisconsin Medical Society, Green Bay, WI
Richard Hellman, MD, FACP, FACE (Endocrinology, Methodology) Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, Private Practice, Diabetes & Endocrinology, North Kansas City, MO
Jean L. Holley, MD, FACP (Nephrology - Adult) Clinical Professor of Medicine, University of Illinois, Urban-Champaign and Carle Physician Group, Urbana, IL
Edward R. Jones, MD (Nephrology - Adult) Self-Employed, Delaware Valley Nephrology Associates, Philadelphia, PA
Karen M. Kolbusz, RN, BSN, MBA, (Nursing, Joint Commission Liaison) Associate Project Director, The Joint Commission, Oakbrook Terrace, IL
Craig B. Langman, MD (Nephrology - Pediatrics) The Isaac A. Abt MD Professor of Kidney Diseases and Head, Kidney Diseases, Feinberg School of Medicine, Northwestern University, and Children´s Memorial Hospital, Chicago, IL
Rajnish Mehrotra, MD (Nephrology - Adult) Professor of Medicine at David Geffen School of Medicine at UCLA and Associate Chief, Div of Nephrology and Hypertension, Harbor-UCLA Medical Center, Torrance, CA

Alvin H. Moss, MD (Nephrology - Adult) Professor of Medicine, West Virginia University, Morgantown, WV

Sharon A. Perlman, MD (Nephrology - Pediatrics) USF Pediatric Nephrology, All Children´s Hospital, St. Petersburg, FL

Paul D. Rockswold, MD, MPH (Preventive Medicine and Family Medicine) Physician Epidemiologist, Head of Health Analysis, Navy and Marine Corps Public Health Center, Suffolk, VA

Candace C. Walworth, MD (Nephrology - Adult) Nephrology and Internal Medicine, Lewiston, ME

Bradley Warady, MD (Nephrology - Pediatrics) Chief, Pediatric Nephrology, Children´s Mercy Hospitals and Clinics, Kansas City, MO

Steven J. Wassner, MD, FAAP (Nephrology - Pediatrics) Professor of Pediatrics, Vice-Chair for Education, Chief, Division of Nephrology & Hypertension, Hershey, PA

Jerry Yee, MD (Nephrology - Adult) Division Head, Nephrology and Hypertension, Henry Ford Hospital, Detroit, MI

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Face validity of the measure score as an indicator of quality was systematically assessed as follows:

After the measure was fully specified, the expert panel (workgroup membership) was asked to rate their agreement with the following statement:

Please rate your agreement with the following statement for each measure:

The scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
The results of the expert panel rating of the validity statement were as follows: N = 19; Mean rating = 4.37
Frequency Distribution of Ratings
1 - 0 (Strongly Disagree)
2 - 1
3 - 1 (Neither Disagree nor Agree)
4 - 7
5 - 10 (Strongly Agree)

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
•   At the time of testing, this measure did not have exclusions.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):
•   At the time of testing, this measure did not have exclusions.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses)*:
•   At the time of testing, this measure did not have exclusions.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
This measure is not risk adjusted.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):
This measure is not risk adjusted.

2b4.3 Testing Results (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*):
This measure is not risk adjusted.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: This measure focuses on an intermediate outcome. Since this measure focuses on a specific outcome, measure exceptions would be used to risk adjust. This measure has no exceptions, therefore, there is no risk adjustment.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
PCPI Testing Project:
• Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures
o The number of physicians per site ranged from 5-62 physicians
o The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
o Patient visit volume ranged from 240-2,800 ESRD patients seen per month
• Sample size per physician organization ranged from 24-30 (as shown below) for a total of 169 ESRD patients on Peritoneal Dialysis (PD), or Hemodialysis (HD)
o Site 1: 27 ESRD patients (3 PD patients, 24 HD patients)
o Site 2 :40 ESRD patients (10 PD patients, 30 HD patients)
o Site 3 :42 ESRD patients (19 PD patients, 23 HD patients)
o Site 4 : 60 ESRD patients (30 PD patients, 30 HD patients)
• Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
• Data abstraction was completed for multiple patient visits per patient for a total of 2012 patient visits.
• Data abstraction was performed in 2008

CMS Physician Quality Reporting Initiative:
For the measure, Plan of Care for ESRD Patients with Anemia, 179,197 patient visit were reported on for the 2008 program, the most recent year for which data are available.

The following information is for the 2009 program, the only year for which such data are available.
Clinical Condition and Measure: #123 Plan of Care: Elevated Hemoglobin for Patients Receiving ESAs
Eligible Professionals: 45,994
Professionals Reporting >=1 Valid QDC: 604
% Professionals Reporting >=1 Valid QDC: 1.31%
# Professionals Satisfactorily Reporting: 192
% Professionals Satisfactorily Reporting: 31.79%

2b5.2 Analytic Method (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):
The inter-quartile range (IQR) was calculated, which provides a measure of the dispersion of performance.

2b5.3 Results (*Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance*):
 PCPI Testing Project Results:

Scores on this measure: N = 2012 Mean = 74 % Range (61%-94%)

CMS Physician Quality Reporting Initiative:
This new measure encompasses patients with CKD and ESRD which is a combination of two previous measures. One of these measures, Plan of Care for ESRD Patients with Anemia, was used in the CMS Physician Quality Reporting Initiative, in the claims option for 2008.

63.5 % of patients reported on did not receive the optimal care. There is significant variation in performance on this measure in the PQRI program as shown by the 2008 data, the most recent available1.
10th percentile: 10.42 %
25th percentile: 38.17 %
50th percentile: 66.23 %
75th percentile: 84.04 %
90th percentile: 94.93 %

The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 45.87, and indicates that 50% of physicians have performance on this measure ranging from 38.17% to 84.04%. A quarter of reporting physicians have performance on this measure which is greater than 84.04%, while a quarter have performance on this measure less than 38.17%.

Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
PCPI Testing Project:
•	Two nephrology practice sites representing various types, locations and sizes which participated in the CMS PQRI Project in 2007 were identified to participate in testing the measures
•	Sample size across the two physician offices as 314 patient visits
•	Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
•	Data abstraction was performed in 2008

2b6.2 Analytic Method (*Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
Data abstracted from patient records were used to calculate parallel-forms reliability for the measure.
Patients were randomly selected from visits for ESRD
Data analysis included:
•	Percent agreement
•	Kappa statistic to adjust for chance agreement

2b6.3 Testing Results (*Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
Plan of Care for Anemia Measure (N, % Agreement)
314, 58.3% Agreement

It should be noted that there were instances where the wrong quality data code was inserted on the claim based on the documented laboratory results available. This was likely due to the process of some dialysis facilities' practice of routine billing the first of every month. This would cause a June bill to refer to laboratory results from May. This test was run in the first year of the program implementation which may have affected results as well.

2c. Disparities in Care: H☐ M☐ L☐ I☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results (*Scores by stratified categories/cohorts)*: We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as

recommended data elements to be collected.

2c.2 **If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:**
The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45
practices including stratification by the aforementioned variables.(1) A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."(2)

References:
(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/research/iomracereport. Accessed May 25, 2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes ☐ No ☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

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**)

C.1 **Intended Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended)*:   Professional Certification or Recognition Program, Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 **Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Professional Certification or Recognition Program, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H ☐ M ☐ L ☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. **Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
This measure is currently being used in the CMS Physician Quality Reporting SYstem for 2011, and will provide information about clinician participation to the public. This measure was also used in the 2009 and 2010 CMS PQRI programs.

The results from the 2009 and 2010 programs can be found on the CMS website:

http://www.cms.gov/PQRS/01_Overview.asp#TopOfPage

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The PCPI, RPA, and ASPN believe that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure may be used in a Maintenance of Certification program and/or included in the Centers for Medicare and Medicaid Services´ (CMS) Final ESRD Prospective Payment System (PPS). Under the new "bundled payment system, effective January 1, 2011, Medicare will provide a single payment that covers all renal dialysis services-including drugs and diagnostic laboratory tests-to dialysis facilities for each dialysis treatment. Simultaneously, CMS issued a proposed rule that will establish a new quality incentive program (QIP) for facilities that provide renal dialysis services. The QIP is the first pay-for-performance program in a Medicare fee-for-service program. Currently, facilities only report on whether they have complied with quality measures. Beginning in 2012, the extent to which dialysis facilities meet established performance standards will be reflected in their payment rates, with reductions of up to 2 percent. (American Society of Nephrology, ASN Kidney News, Volume 2, Number 8, Washing, DC: August 2010.)

3b. **Usefulness for Quality Improvement:** H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
The PCPI, RPA and ASPN believe that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. **Data Generated as a Byproduct of Care Processes:** H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
We are not aware of any unintended consequences related to this measurement.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (*e.g., fees for use of proprietary measures*):
This measure previously was for ESRD patients only and now includes CKD patients as well. CKD patients were tested for this measure in the CKD Plan of Care (Anemia) measure. There is no reason to believe that the combination of the two data elements is more difficult than finding each data element separately. Additionally, the cut-off level has changed from 11g/dL to 12 g/dL but there is no reason to believe that this affects the validity of the testing data.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (*either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

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

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (*e.g., a more valid or efficient way to measure quality); OR* provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:
We are unaware of any competing measures.

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):** American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654

Co.2 **Point of Contact:** Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-

Co.3 **Measure Developer if different from Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654

Co.4 **Point of Contact:** Katherine, Ast, MSW, LCSW, katherine.ast@ama-assn.org, 312-464-4920-

Co.5 **Submitter:** Diedra, Joseph, MPH, diedra.joseph@ama-assn.org, 312-464-4904-, American Medical Association - Physician Consortium for Performance Improvement

Co.6 **Additional organizations that sponsored/participated in measure development:**
Renal Physicians Association, American Society of Pediatric Nephrology

Co.7 **Public Contact:** Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD
Barbara Fivush, MD (Work Group Co-Chair) (Nephrology - Pediatrics) Professor of Pediatrics, Division Chief of Pediatric Nephrology, Johns Hopkins University, Baltimore, MD
Paul M. Palevsky, MD, FACP, FCCD, FASN (Work Group Co-Chair) (Nephrology - Adult) Professor of Medicine, University of Pittsburgh School of Medicine, Chief, Renal Section, VA Pittsburgh Healthcare System, Pittsburgh, PA
Eileen D. Brewer, MD (Nephrology - Pediatrics) Professor and Head, Pediatric Renal Section, Baylor College of Medicine Chief, Renal Service, Texas Children´s Hospital, Houston, TX
John W. Foreman, MD (Nephrology - Pediatrics) Department of Pediatrics, Professor of Pediatrics, Duke University, Durham, NC
Richard S. Goldman, MD (Nephrology - Adult, Methodology) Nephrology and Internal Medicine, Albuquerque, NM
Stuart L. Goldstein, MD (Nephrology - Pediatrics) Director, Center for Acute Care Nephrology, Cincinnati Children's Hospital Medical Center; Medical Director, Pheresis Service, Professor of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
John Hartman, MD (Nephrology - Adult) CEO, Visonex, LLC, Treasurer, Wisconsin Medical Society, Green Bay, WI
Richard Hellman, MD, FACP, FACE (Endocrinology, Methodology) Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, Private Practice, Diabetes & Endocrinology, North Kansas City, MO
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Craig B. Langman, MD (Nephrology - Pediatrics) The Isaac A. Abt MD Professor of Kidney Diseases and Head, Kidney Diseases, Feinberg School of Medicine, Northwestern University, and Children´s Memorial Hospital, Chicago, IL
Rajnish Mehrotra, MD (Nephrology - Adult) Professor of Medicine at David Geffen School of Medicine at UCLA and Associate Chief, Div of Nephrology and Hypertension, Harbor-UCLA Medical Center, Torrance, CA
Alvin H. Moss, MD (Nephrology - Adult) Professor of Medicine, West Virginia University, Morgantown, WV
Sharon A. Perlman, MD (Nephrology - Pediatrics) USF Pediatric Nephrology, All Children´s Hospital, St. Petersburg, FL
Paul D. Rockswold, MD, MPH (Preventive Medicine and Family Medicine) Physician Epidemiologist, Head of Health Analysis, Navy and Marine Corps Public Health Center, Suffolk, VA
Candace C. Walworth, MD (Nephrology - Adult) Nephrology and Internal Medicine, Lewiston, ME
Bradley Warady, MD (Nephrology - Pediatrics) Chief, Pediatric Nephrology, Children´s Mercy Hospitals and Clinics, Kansas City,

MO

Steven J. Wassner, MD, FAAP (Nephrology - Pediatrics) Professor of Pediatrics, Vice-Chair for Education, Chief, Division of Nephrology & Hypertension, Hershey, PA

Jerry Yee, MD (Nephrology - Adult) Division Head, Nephrology and Hypertension, Henry Ford Hospital, Detroit, MI

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: This is a new measure submission.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2007

Ad.4 Month and Year of most recent revision: 06, 2011

Ad.5 What is your frequency for review/update of this measure? Every 3 years or as new evidence becomes available that materially affects the measures.

Ad.6 When is the next scheduled review/update for this measure?

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Ad.8 Additional Information/Comments: The next scheduled review/update for this measure will be in 2014.

Date of Submission (*MM/DD/YY*): 06/08/2011

PCPI eSpecification

Clinical Topic	Adult Kidney Disease
Measure Title	**Patients on Erythropoiesis Stimulating Agent (ESA)—Hgb Level > 12.0 g/dL**
Measure #	**AKID-7**

Measure Description	Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy have a hemoglobin (Hgb) level > 12.0 g/dL Note: For this measure, a lower score indicates higher quality
Measurement Period	Twelve consecutive months

Initial Patient Population	IPP Option 1 Patient Age: Patient aged 18 years and older starts before the start of the measurement period Diagnosis Active: Patient has a diagnosis of CKD (stage 4 or 5, not receiving RRT) starts before or during encounter during measurement period Encounter: At least two visits with the physician, physician's assistant, or nurse practitioner during the measurement period	IPP Option 2 Patient Age: Patient aged 18 years and older starts before the start of the measurement period Diagnosis Active: Patient has a diagnosis of ESRD starts before or during the measurement period Procedure Performed: Patients receiving hemodialysis or peritoneal dialysis during the measurement period

Denominator Statement	All calendar months during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy Definition: RRT (Renal Replacement Therapy): For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation
Numerator Statement	Calendar months during which patients' most recent hemoglobin (Hgb) level is > 12.0 g/dL* *The hemoglobin result used for this measure should be the most recent (last) hemoglobin result recorded for each calendar month
Denominator Exceptions	None

Adult Kidney Disease
DRAFT Data Elements for PCPI eSpecification

Measure 7--Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > 12.0 g/dL

QDM* Standard Category	QDM* Data Type	Standard Terminology	Constraints	Value Set Name	Value of Data Element	Data Source	Comments/Rationale
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement Start Date			
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement End Date			
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Gender		• Electronic Administrative Claims • Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Race		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Ethnicity		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Primary Language		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	LN	starts before the start of measurement period	Date of Birth		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Individual Characteristic	Patient Characteristic	Calculated	starts before the start of measurement period	Age	≥ 18	• Electronic Administrative Claims • Electronic Health Record (EHR)	Measurement start date minus Date of Birth must be greater than or equal to 18 years.
Condition / Diagnosis / Problem	Diagnosis, Active	I9, I10, SNM	starts before or during encounter	Chronic Kidney Disease, Stage IV		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Condition / Diagnosis / Problem	Diagnosis, Active	I9, I10, SNM	starts before or during encounter	Chronic Kidney Disease, Stage V		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Encounter	Encounter, Performed	CPT	during measurement period	Encounter, Outpatient		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Condition / Diagnosis / Problem	Diagnosis, Active	I9, I10, SNM	during measurement period	End Stage Renal Disease (ESRD)		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Procedure	Procedure, Performed	SNM, CPT	during measurement period	Hemodialysis		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Procedure	Procedure, Performed	SNM, CPT	during measurement period	Peritoneal Dialysis		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Medication	Medication, Active	CPT II, RxNorm	during measurement period	Erythropoiesis Stimulating Agent (ESA)		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Laboratory Test	Laboratory Test, Performed	LN, CPT	during calendar month/ during measurement period	Hemoglobin		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Laboratory Test	Laboratory Test, Result	LN, CPT	most recent (last) result during calendar month	Hemoglobin	> 12.0 g/dL	• Electronic Administrative Claims • Electronic Health Record (EHR)	
No Valid Exceptions							

**For this measure, a lower score indicates a higher quality.

*The Quality Data Model (QDM), Version 2.1, was developed by National Quality Forum (NQF).

PCPI eSpecification

Measure Logic for Adult Kidney Disease : Patients on Erythropoiesis Stimulating Agent (ESA)—Hgb Level > 12.0 g/dL

Measure Description: Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (Stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy have a hemoglobin (Hgb) level > 12.0 g/dL

Measurement Period: 12 Consecutive Months

PCPI Measure #: AKID-7

●*For this measure, a lower score indicates a higher quality.*

	Identify Patients in Initial Patient Population (IPP)	Identify Patients in Denominator (D)	Identify Patients in Numerator (N)	Identify Patients who have valid Denominator Exceptions * (E)

Page 1

Identify Patients in Initial Patient Population (IPP):

PATIENT AGE [1] — 18 and older

And

(a)

DIAGNOSIS Active [2] — Chronic Kidney Disease, Stage IV — Value Set 000285

OR

DIAGNOSIS Active [3] — Chronic Kidney Disease, Stage V — Value Set 000286

OR

ENCOUNTER [5] — Outpatient Value Set 000002

(b)

DIAGNOSIS Active [4] — End Stage Renal Disease (ESRD) — Value Set 000287

And

PROCEDURE Performed [6] — Hemodialysis — Value Set 000308

OR

PROCEDURE Performed [7] — Peritoneal Dialysis — Value Set 000311

Identify Patients in Denominator (D): See Page 2 for Denominator

Identify Patients in Numerator (N): See Page 2 for Numerator

Identify Patients who have valid Denominator Exceptions * (E): See Page 2 for Denominator Exceptions
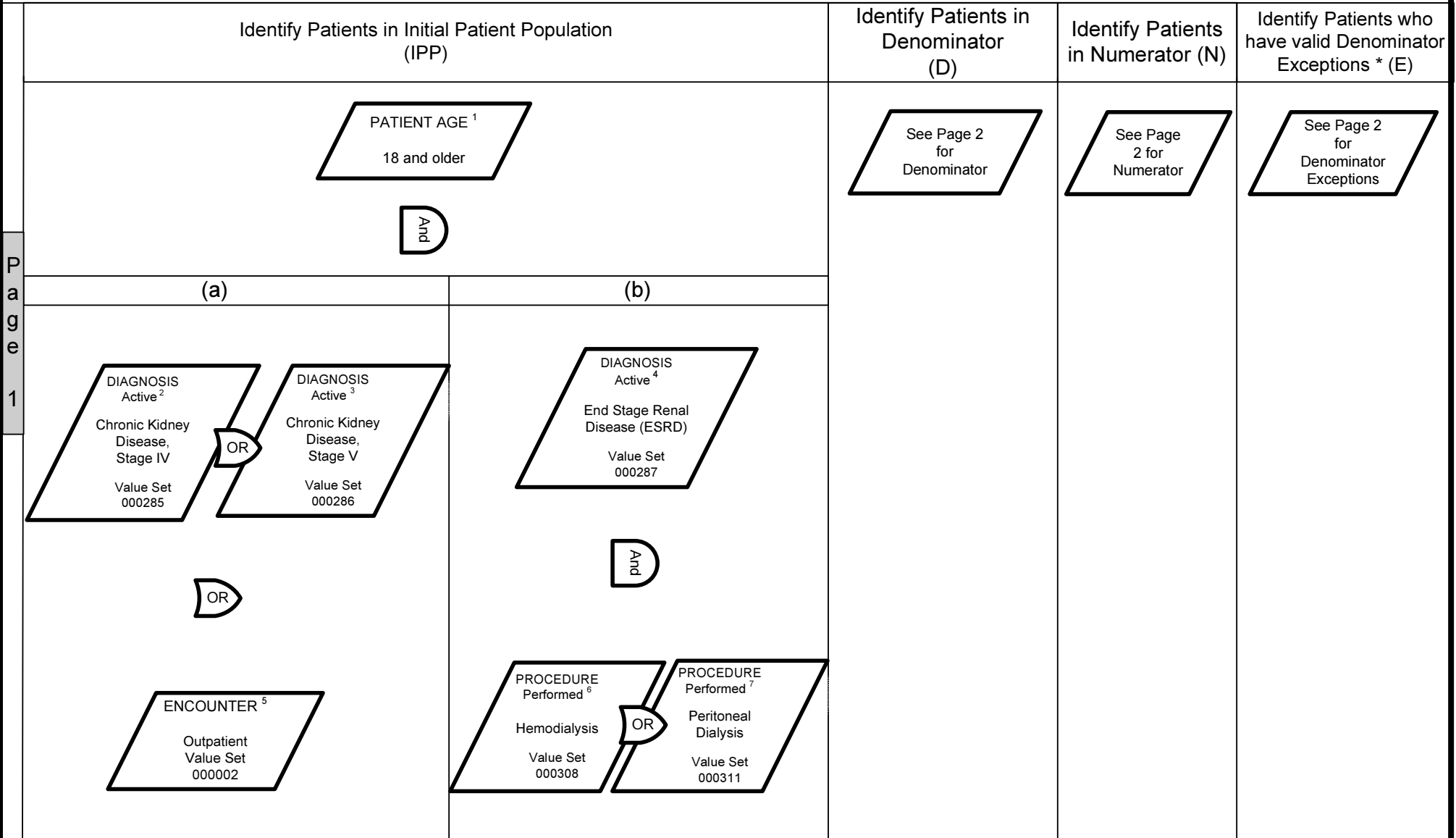
PARAMETER SPECIFICATIONS (Value Sets are found in the Coding Appendices):

IPP: In (IPP) follow pathway, (a) **or** (b), based on applicable diagnosis; [1] Patient Age: measurement start date minus birth date (value set 000307) ≥ 18 years starts before the start of measurement period; [2][3] Diagnosis, Active: starts before or during encounter during measurement period; [4] Diagnosis, Active: starts before or during measurement period; [5] Encounter: count ≥ 2 during measurement period; [6][7] Procedure, Performed: during measurement period;

PCPI eSpecification

Measure Logic for Adult Kidney Disease : Patients on Erythropoiesis Stimulating Agent (ESA)—Hgb Level > 12.0 g/dL

Measure Description: Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (Stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy have a hemoglobin (Hgb) level > 12.0 g/dL

Measurement Period: 12 Consecutive Months

PCPI Measure #: AKID-7

● *For this measure, a lower score indicates a higher quality.*

Identify Patients in Initial Patient Population (IPP)	Identify Patients in Denominator (D)	Identify Patients in Numerator (N)	Identify Patients who have valid Denominator Exceptions * (E)
See Page 2 for Initial Patient Population	All Patients Identified within the Initial Patient Population And MEDICATION Active [8] Erythropoietin Stimulating Agent (ESA) Value Set 000319 And LABORATORY TEST Performed [9] Hemoglobin Value Set 000318	All Patients Identified within the Denominator And LABORATORY TEST Result [10] Hemoglobin Level > 12.0 g/dL	No Valid Denominator Exceptions for this Measure

(Page 2)

PARAMETER SPECIFICATIONS (Value Sets are found in the Coding Appendices):
D: [8] Medication, Active: during measurement period; [9] Laboratory Test, Performed: during a calendar month during measurement period;
N: [10] Laboratory Test, Result: result > 12.0 g/dL during the calendar month during measurement period;

Basic Measure Calculation:

$$\frac{(N)}{(D) - (E)} = \%$$

The PCPI strongly recommends that exception rates also be computed and reported alongside performance rates as follows:

Exception Calculation:

$$\frac{(E)}{(D)} = \%$$

Exception Types:

E= E1 (Medical Exceptions) + E2 (Patient Exceptions) + E3 (System Exceptions)

For patients who have more than one valid exception, only one exception should be be counted when calculating the exception rate

Initial Patient Population (IPP)	Denominator (D)	Numerator (N)	Denominator Exceptions (E)
Definition: The initial patient population identifies the general group of patients that the performance measureis designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CADwho has at least 2 Visits during the measurement period.	**Definition:** The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be I dentical to the initial patient population.	**Definition:** The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).	**Definition:** Denominator exceptions are the valid reasons why patients who are included in the denominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for medical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient declined flu vaccine); or system reasons (e.g., patient did not receive flu Vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exception reporting population – patients for whom the numerator was not achieved and a there is a valid Denominator Exception.
Find the patients who meet the Initial Patient Population criteria (IPP)	Find the patients who qualify for the denominator (D): ○ From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria. (In some cases the IPP and D are identical).	Find the patients who qualify for the Numerator (N): ○ From the patients within the Denominator (D) criteria, select those people who meet Numerator selection criteria. ○ Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator	From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.

ADULT KIDNEY DISEASE
Coding Spreadsheet for PCPI eSpecification
AKID-7 : Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > 12.0 g/dL

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000307	AKID	7	IPP	Birth Date	Individual Characteristic	LN	21112-8	Birth date: TmStp:Pt:^Patient:Qn:
000285	AKID	7	IPP (a)	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	I9	585.4	Chronic Kidney Disease, Stage IV (Severe)
000285	AKID	7	IPP (a)	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	I10	N18.4	Chronic Kidney Disease, Stage IV (severe)
000285	AKID	7	IPP (a)	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	SNM	431857002	Chronic kidney disease stage 4 (disorder)
000286	AKID	7	IPP (a)	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	I9	585.5	Chronic Kidney Disease, Stage V
000286	AKID	7	IPP (a)	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	I10	N18.5	Chronic Kidney Disease, Stage V
000286	AKID	7	IPP (a)	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	SNM	433146000	Chronic kidney disease stage 5 (disorder)
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99201	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99202	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99203	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99204	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99205	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99212	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99213	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99214	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99215	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99241	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99242	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99243	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99244	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99245	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99304	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99305	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99306	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99307	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99308	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99309	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99310	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99324	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99325	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99326	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99327	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99328	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99334	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99335	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99336	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99337	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99341	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99342	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99343	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99344	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99345	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99347	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99348	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99349	
000002	AKID	7	IPP (a)	Encounter	Encounter	CPT	99350	
000287	AKID	7	IPP (b)	End Stage Renal Disease (ESRD)	Condition / Diagnosis / Problem	I9	585.6	End Stage Renal Disease [Chronic Kidney Disease, Stage V (requiring chronic dialysis)]
000287	AKID	7	IPP (b)	End Stage Renal Disease (ESRD)	Condition / Diagnosis / Problem	I10	N18.6	End Stage Renal Disease (chronic kidney disease requiring chronic dialysis)
000287	AKID	7	IPP (b)	End Stage Renal Disease (ESRD)	Condition / Diagnosis / Problem	SNM	46177005	end stage renal disease
000287	AKID	7	IPP (b)	End Stage Renal Disease (ESRD)	Condition / Diagnosis / Problem	SNM	236435004	end stage renal failure on dialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90957	

ADULT KIDNEY DISEASE
Coding Spreadsheet for PCPI eSpecification
AKID-7 : Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > 12.0 g/dL

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90958	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90959	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90960	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90961	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90962	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90965	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90966	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90969	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90970	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	CPT	90989	
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	302497006	Hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233578004	Continuous hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233579007	Continuous arteriovenous hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233580005	Continuous venovenous hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	427053002	Extracorporeal albumin hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	67970008	Hemodialysis, maintenance at home
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	68341005	Hemodialysis, supervision at home
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	57274006	Initial hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233575001	Intermittent hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233576000	Intermittent hemodialysis with sequential ultrafiltration
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233577009	Intermittent hemodialysis with continuous ultrafiltration
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	11932001	Stabilizing hemodialysis
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233589006	continuous arteriovenous hemodiafiltration
000308	AKID	7	IPP (b)	Hemodialysis	Procedure	SNM	233590002	continuous venovenous hemodiafiltration
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90945	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90947	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90957	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90958	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90959	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90960	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90961	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90962	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90965	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90966	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90969	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90970	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	CPT	90989	
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	71192002	peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	428648006	automated peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	225230008	chronic peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	238318009	continuous ambulatory peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	238319001	continuous cycling peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	238321006	intermittent peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	238323009	night-time intermittent peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	73257006	peritoneal dialysis catheter maintenance
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	14684005	peritoneal dialysis excluding cannulation
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	676002	peritoneal dialysis including cannulation
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	225231007	stab peritoneal dialysis
000311	AKID	7	IPP (b)	Peritoneal Dialysis	Procedure	SNM	238322004	tidal peritoneal dialysis
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753413	Methoxy polyethylene glycol-epoetin beta 1 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753423	Methoxy polyethylene glycol-epoetin beta 0.1 MG/ML Injectable Solution

ADULT KIDNEY DISEASE
Coding Spreadsheet for PCPI eSpecification
AKID-7 : Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > 12.0 g/dL

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758160	0.3 ML Methoxy polyethylene glycol-epoetin beta 0.5 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758162	0.3 ML Methoxy polyethylene glycol-epoetin beta 0.667 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753427	Methoxy polyethylene glycol-epoetin beta 0.2 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758164	0.3 ML Methoxy polyethylene glycol-epoetin beta 0.833 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753401	Methoxy polyethylene glycol-epoetin beta 0.3 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758165	0.6 ML Methoxy polyethylene glycol-epoetin beta 0.667 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753407	Methoxy polyethylene glycol-epoetin beta 0.4 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758169	0.3 ML Methoxy polyethylene glycol-epoetin beta 0.167 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753411	Methoxy polyethylene glycol-epoetin beta 0.05 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753415	Methoxy polyethylene glycol-epoetin beta 0.6 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	753415	Methoxy polyethylene glycol-epoetin beta 0.6 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	804171	0.3 ML Methoxy polyethylene glycol-epoetin beta 0.25 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	758179	0.6 ML Methoxy polyethylene glycol-epoetin beta 1.33 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	349273	darbepoetin alfa 0.025 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	349274	darbepoetin alfa 0.04 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	349275	darbepoetin alfa 0.06 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	730044	0.5 ML darbepoetin alfa 0.2 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	349276	darbepoetin alfa 0.1 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731171	|0.3 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731174	0.4 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	349277	darbepoetin alfa 0.2 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731179	0.6 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731184	1 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	403943	darbepoetin alfa 0.5 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	351247	darbepoetin alfa 0.3 MG/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731181	0.4 ML darbepoetin alfa 0.1 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731167	0.3 ML darbepoetin alfa 0.2 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731176	0.42 ML darbepoetin alfa 0.06 MG/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352044	darbepoetin alfa 0.025 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352045	darbepoetin alfa 0.04 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352046	darbepoetin alfa 0.06 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	730046	0.5 ML darbepoetin alfa 0.2 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352047	darbepoetin alfa 0.1 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731231	0.3 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731235	|0.4 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352048	darbepoetin alfa 0.2 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731229	0.6 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	352262	darbepoetin alfa 0.3 MG/ML Injectable Solution [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731241	1 ML darbepoetin alfa 0.5 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	404686	darbepoetin alfa 0.5 MG/ML Injectable Solution [Aranesp]

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Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731245	0.42 ML darbepoetin alfa 0.06 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731227	0.4 ML darbepoetin alfa 0.1 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	731250	0.3 ML darbepoetin alfa 0.2 MG/ML Prefilled Syringe [Aranesp]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	242706	Epoetin Alfa 40000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	727870	0.5 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	727868	0.6 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	727868	0.6 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792693	0.8 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792696	0.9 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	239999	Epoetin Alfa 4000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792686	0.4 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	240377	Epoetin Alfa 3000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792683	0.3 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	241999	Epoetin Alfa 20000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	239998	Epoetin Alfa 2000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792715	0.5 ML Epoetin Alfa 4000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792740	0.6 ML Epoetin Alfa 20000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	240000	Epoetin Alfa 10000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	727850	0.5 ML Epoetin Alfa 2000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	792710	1 ML Epoetin Alfa 10000 UNT/ML Prefilled Syringe
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	213475	Epoetin Alfa 40000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205924	Epoetin Alfa 4000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205922	Epoetin Alfa 3000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	212219	Epoetin Alfa 20000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205918	Epoetin Alfa 2000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205913	Epoetin Alfa 10000 UNT/ML Injectable Solution [Procrit]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	150915	Epoetin Alfa 2000 UNT/ML Injectable Solution [Eprex]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205923	Epoetin Alfa 4000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	213474	Epoetin Alfa 40000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205921	Epoetin Alfa 3000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	212218	Epoetin Alfa 20000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205917	Epoetin Alfa 2000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	205912	Epoetin Alfa 10000 UNT/ML Injectable Solution [Epogen]
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	153633	epoetin beta 10000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	153630	epoetin beta 20000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	153629	epoetin beta 5000 UNT/ML Injectable Solution
000319	AKID	7	D	Erythropoietin Stimulating Agent (ESA) Therapy	Medication	RxNorm	387037	Epoetin beta 60000 UNT/ML Injectable Solution
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	10346-5	Hemoglobin A
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	14775-1	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	20509-6	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30313-1	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30350-3	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30351-1	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30352-9	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30353-7	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	30354-5	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	33025-8	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	33026-6	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	33509-1	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	35183-3	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	40719-7	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	43113-0	Hemoglobin panel
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	42810-2	Hemoglobin

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Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4588-0	Hemoglobin H/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	44920-7	Hemoglobin C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	44921-5	Hemoglobin D/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	44922-3	Hemoglobin E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	44923-1	Hemoglobin S/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4534-4	Cyanmethemoglobin/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4683-9	Sulfhemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4536-9	Deoxyhemoglobin/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4546-8	Hemoglobin A/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4547-6	Hemoglobin A1/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4550-0	Hemoglobin A2
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4551-8	Hemoglobin A2/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4552-6	Hemoglobin A2/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4553-4	Hemoglobin A2/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4554-2	Hemoglobin A2/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4555-9	Hemoglobin A3/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4561-7	Hemoglobin C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4562-5	Hemoglobin C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4563-3	Hemoglobin C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4569-0	Hemoglobin D/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4571-6	Hemoglobin D-Punjab
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4580-7	Hemoglobin F1/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4573-2	Hemoglobin E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4574-0	Hemoglobin E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4575-7	Hemoglobin E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4576-5	Hemoglobin F/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4578-1	Hemoglobin F-Texas
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4582-3	Hemoglobin G-Coushatta
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4587-2	Hemoglobin H/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4625-0	Hemoglobin S/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4633-4	Hemoglobin F/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4635-9	Hemoglobin.free
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4636-7	Hemoglobin.free
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4638-3	Hemoglobin.thermolabile/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	46423-0	Hemoglobin distribution width
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	4685-4	Sulfhemoglobin/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	48343-8	Hemoglobin.other/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	47278-7	Erythrocyte mean corpuscular hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	47279-5	Erythrocyte mean corpuscular hemoglobin concentration
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	48711-6	Hemoglobin.free^post transfusion reaction
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	48725-6	Hemoglobin^pre therapeutic phlebotomy
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	49137-3	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	50559-4	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	50765-7	Hemoglobin Hasharon/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	51196-4	Hemoglobin A1/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	51613-8	Hemoglobin J/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	51614-6	Hemoglobin M/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	51615-3	Hemoglobin A2+C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	51616-1	Hemoglobin A2+E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	53223-4	Hemoglobin G/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	53553-4	Estimated average glucose
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	53857-9	Hemoglobin F
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54068-2	Hemoglobin O-Arab/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54069-0	Hemoglobin Barts/Hemoglobin.total

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Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54070-8	Hemoglobin D/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54071-6	Hemoglobin E/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54072-4	Hemoglobin A/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54073-2	Hemoglobin C/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54074-0	Hemoglobin F/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54209-2	Hemoglobin C-Harlem/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	54289-4	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55370-1	Hemoglobin A2+C+E+O/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55371-9	Hemoglobin A2+E+O/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55372-7	Hemoglobin Constant Spring/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55373-5	Hemoglobin D+G/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55374-3	Hemoglobin N+I/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55782-7	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	55942-7	Methemoglobin/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	56040-9	Methemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	56476-5	Hemoglobin S/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	58453-2	Hemoglobin.gastrointestinal
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	5913-9	Hemoglobin F/Hemoglobin.total
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	59260-0	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	59467-1	Erythrocyte mean corpuscular hemoglobin concentration
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	59468-9	Erythrocyte mean corpuscular hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	61180-6	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	62243-1	Erythrocyte mean corpuscular hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	62246-4	Erythrocyte mean corpuscular hemoglobin concentration
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	718-7	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	719-5	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	721-1	Hemoglobin.free
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	722-9	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	723-7	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	724-5	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	726-0	Hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	727-8	Hemoglobin distribution width
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	785-6	Erythrocyte mean corpuscular hemoglobin
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	786-4	Erythrocyte mean corpuscular hemoglobin concentration
000318	AKID	7	D	Hemoglobin	Laboratory Test	LN	9749-3	Hemoglobin F