

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name	ESRD- PD Adequacy CPM II: Calculate Weekly Kt/V Urea in a Standard Way
Measure Description:	Percentage of all adult (≥ 18 years old) peritoneal dialysis patients with weekly Kt/V urea (endogenous residual renal urea clearance & dialytic) calculated in a standard way.

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Process

Body System:

- Kidney/urinary tract
ESRD

Variable Characteristics

Measure Care Setting

- Dialysis Facility

Unit of Measurement

- Facility

Consensus Endorsement Status

- NQF (National Quality Forum)

Consensus Endorsement Process Status

- Endorsed

Endorsed Status Date

November 15, 2007

Technical Specifications

Target Population

Age

Lower limit

- 18

Lower Span

-Years

Gender

- Both Males and Females

Continuous Enrollment

NA

Anchor Date

NA

Effective Date

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

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

Effective date basis

NA

Payer Source

- Medicare

Measure result reported as

- Positive

Current Alignment with CMS

NA

CHI Compliant

- Yes

Method of Data collection

- Electronic supplemented by medical record review

Numerator statement

Patients with:

- Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance
- Residual renal function (unless negligible [< 100 mL urine in 24 hours]) is assessed by measuring the renal component of Kt/Vurea and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance
- Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method or the Haycock method of using actual body weight, during the four month study period

Data source

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

Numerator Time Window

Four months

Data collected for this ESRD CPM is for the four month time period for peritoneal dialysis patients. Facilities implementing this measure may choose any time period.

Denominator statement

All adult (\geq 18 years old) peritoneal dialysis patients.

Data source

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

Denominator Time Window

Four months

Exclusion Criteria

None

Data source

NA

Exclusion Criteria Time Window

NA

History**Measure Status**

- Implemented/approved by CMS

CMS Active Implementation Date

- 2/1/09

Measure Developer

- CMS
Contractor: Arbor Research/UM-KECC

Intellectual property status

- Public Domain

Measure Source

- Adapted from the original Peritoneal Adequacy measure

CMS Final Approval Date

- 4/1/08

CMS Implementation Use

- ESRD Disease Management

- ESRD Network Program
- Other
Quality Improvement and Public Reporting

Attachments

The **Measure Justification** is a required attachment

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

- Comprehensive Measure Reevaluation

Other attachments

Comments:

Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	ESRD- PD Adequacy CPM II: Calculate Weekly Kt/V Urea in a Standard Way
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	February 1, 2009
Date of Last Review	November 15, 2007

Section I: Importance/Relevance

Epidemiological relevance, Financial relevance, Policy relevance:

Epidemiological Relevance: There were 25,892 ESRD patients (21,067 aged 20+) being treated with peritoneal dialysis at the end of 2003 with approximately 6,979 incident ESRD patients (6,647 aged 20+) starting peritoneal dialysis each year. (USRDS 2005 ADR, Tables D.1, D.4, D.8). K/DOQI and other PD guidelines have set minimum standards for periodic assessment of dialysis adequacy. Both peritoneal clearance and residual renal function need to be assessed. Recent evidence has emphasized the importance of peritoneal clearance.

Financial Relevance: In 2003, total Medicare costs for the ESRD program were \$18.1 billion, an increase of 7.2 percent over costs in 2002. Peritoneal dialysis patients represented 8% of the ESRD dialysis population at the end of 2003.

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

Section 2: Scientific Soundness

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

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

Literature citation for clinical guideline

Author Last Name/Organization: Peritoneal Dialysis Adequacy Work Group

Author First Name:

Title of Chapter or Article: NKF-K/DOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2006.

Title of Book or Journal: American Journal of Kidney Disease

Publication Date: July 2006

Journal Volume and Number: 48 (1 Suppl 1)

Pages:

Web link: http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm

KDOQI Guidelines (2006) Relevant to PD Adequacy CPM II:

- I: Clinical Practice Guidelines for Peritoneal Dialysis Adequacy
 - [Guideline 1](#). Initiation of Dialysis
 - [Guideline 2](#). Peritoneal Dialysis Solute Clearance Targets and Measurements
 - [Guideline 3](#). Preservation of Residual Kidney Function
 - [Guideline 4](#). Maintenance of Euvolemia
 - [Guideline 5](#). Quality Improvement Programs
 - [Guideline 6](#). Pediatric Peritoneal Dialysis
- II. Clinical Practice Recommendations for Peritoneal Dialysis Adequacy
 - [Clinical Practice Recommendation for Guideline 1](#): Initiation of Dialysis
 - [Clinical Practice Recommendations for Guideline 2](#): Peritoneal Dialysis Prescription Targets and Measurements
 - [Clinical Practice Recommendations 3](#): Recommended Laboratory Measurements for Peritoneal Membrane Function and Ultrafiltration Volume
 - [Clinical Practice Recommendations 4](#): Writing the Peritoneal Dialysis Prescription
 - [Clinical Practice Recommendations for Guideline 6](#): Pediatric Peritoneal Dialysis
- [III. Research Recommendations](#)

Level of Evidence and Rating Scheme: A

Author Last Name/Organization: EBPG Expert Group on Peritoneal Dialysis

Author First Name: Dombros N. Dratwa M. Feriani M. Gokal R. Heimbürger O. Krediet R. Plum J. Rodrigues A. Selgas R. Struijk D. Verger C.

Title of Chapter or Article: European best practice guidelines for peritoneal dialysis. 7 Adequacy of peritoneal dialysis.

Title of Book or Journal: Nephrology Dialysis Transplantation

Publication Date: 2005 Dec.

Journal Volume and Number: 20 Suppl 9

Pages: ix24-ix27

Web link:

Level of Evidence and Rating Scheme: B

Author Last Name/Organization:

Author First Name: Lo W-K. Bargman JM. Burkart J. Krediet RT. Pollock C. Kawanishi H.Blake P.

Title of Chapter or Article: ISPD Guidelines / Recommendations: Guideline on targets for solute and fluid removal in adult patients on chronic peritoneal dialysis.

Title of Book or Journal: Peritoneal Dialysis International

Publication Date: 2006 Sep.

Journal Volume and Number: 26(5)

Pages: 520–522

Web link:

Level of Evidence and Rating Scheme: B

Literature citation for supporting evidence/study

Author Last Name/Organization:

Author First Name: Paniagua R, Amato D, Vonesh E, et al

Title of Chapter or Article: Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial

Title of Book or Journal: J Am Soc Nephrol

Publication Date: 2002

Journal Volume and Number:13

Pages:1307-1320

Web link:

Level of Evidence and Rating Scheme: A

Author Last Name/Organization:

Author First Name: Lo WK, Ho YW, Li CS, et al

Title of Chapter or Article: Effect of Kt/V on survival and clinical outcome in CAPD patients in a randomized prospective study

Title of Book or Journal: Kidney Int

Publication Date: 2003

Journal Volume and Number:64

Pages:649-656

Web link:

Level of Evidence and Rating Scheme: A

Author Last Name/Organization: NECOSAD Study Group

Author First Name: Jansen MA. Termorshuizen F. Korevaar JC. Dekker FW. Boeschoten E. Krediet RT

Title of Chapter or Article: Predictors of survival in anuric peritoneal dialysis patients

Title of Book or Journal: Kidney Int

Publication Date: 2005 Sep.

Journal Volume and Number: 68 (3)

Pages:1199-205

Web link:

Level of Evidence and Rating Scheme: B

Author Last Name/Organization:

Author First Name: Lam MF. Tang C. Wong AK. Tong KL. Yu AW. Li CS. Cheung KO. Lai KN

Title of Chapter or Article: ASPD: A prospective study of adequacy in Asian patients on long term, small volume, continuous ambulatory peritoneal dialysis

Title of Book or Journal: *Peritoneal Dialysis International*

Publication Date: 2006 Jul - Aug

Journal Volume and Number: 26 (40)

Pages:466 - 74

Web link:

Level of Evidence and Rating Scheme: B

Other aspects of scientific soundness:

Reliability, Validity, and Adequacy of risk adjustment:

Please see below link for the Reliability Report:

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

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

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

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

Risk adjustment is not applicable for this measure.

Section 3: Usability/Actionability

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

Please see below link for the Annual Report.

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

Section 4: Feasibility

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

Administrative and Medical Record data is used.

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

Approximate time for data collection,

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

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

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	Peritoneal Dialysis Adequacy
Measure Name (<i>should be brief, concise</i>):	ESRD- PD Adequacy CPM II: Calculate Weekly Kt/V Urea in a Standard Way
Measure Description:	Percentage of all adult (≥ 18 years old) peritoneal dialysis patients with weekly Kt/V urea (endogenous residual renal urea clearance & dialytic) calculated in a standard way.
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version?

No major changes in this version.

Date of review (NQF approval date(s))

November 15, 2007

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

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

Please see the 2006 ESRD CPM Annual Report (link below)

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

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

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

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

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

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

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

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

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

Please see attached Measure Justification Form (Section 2: Scientific Soundness) and Appendix F “Publications List for PD Adequacy CPMs.”

IV. A technical expert panel was convened: Yes No

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

Clinical-TEP: September 18-19, 2006

Data-TEP: October 11-12, 2006

Briefly summarize the TEP recommendations here.

C-TEP Recommendations:

The TEP recommended the following revisions to the current Clinical Performance Measures in order to make them consistent with the 2006 K/DOQI Clinical Practice Guidelines (CPG) and Recommendations (CPR).

- 1) Include tidal dialysis patients in all three measures (CPG 2)
- 2) Estimate total body water (V) using Watson or Hume method using *ideal* or *standard* (rather than *actual*) body weight (CPR 2.6)
- 3) Define negligible residual renal function as $\leq 100\text{mL}$ urine in 24 hours (rather than $<200\text{mL}$) (CPG 2.2)
- 4) No minimum target for creatinine clearance (CPG 2)
- 5) Minimum delivered dose of dialysis is total Kt/V_{urea} of at least 1.7 for all peritoneal dialysis patients (CPG 2.1.1)

Although the 2006 K/DOQI Guidelines state that total solute clearance should be measured at least once every four months (CPG 2.1.2), the TEP decided against recommending a change to the frequency of measurement required by PD CPM I. There were two reasons for this recommendation. First, the frequency of measurement in the 2006 K/DOQI Guidelines was not evidence based. It was selected because that was the frequency used in one of the key studies cited. However, another key study used a 6 month interval. Second, K/DOQI recommends that this measurement be done only on clinically stable patients and at least 1 month after resolution of an episode of peritonitis, because the test is unreliable in those with peritonitis or other acute illnesses (CPR 2.4). The 6 month time frame in this CPM will allow for some flexibility in the time of the measurement in cases where the patient condition could cause the measurement to be unreliable at the 4 month time point.

The TEP recommended removing the creatinine clearance target values from CPM III as described above, however, the TEP decided, after much deliberation, against recommending that creatinine clearance measures be removed from PD CPM I and II. The reasons for this recommendation were that (a) creatinine is an index of muscle mass generation (CPR 2.7), (b) creatinine clearance may be used as

a surrogate of larger molecule substance removal, and (c) the ISPD and CARI Guidelines continue to recommend (based on weak evidence) minimum targets for creatinine clearance.

Proposed Revised PD Adequacy Clinical Performance Measures

The resulting revised CPMs proposed by the TEP are listed below.

II: Calculate weekly Kt/V_{urea} and creatinine clearance in a standard way

Numerator: The number of patients in the denominator with all of the following:

- a. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; and
- b. Total body water (V) estimated by either the Watson or Hume method using ideal or standard body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the study period; and
- c. Total weekly Kt/V_{urea} and weekly creatinine clearance normalized to 1.73m^2 body surface area (BSA) used to measure delivered PD dose.

* negligible is $\leq 100\text{mL}$ urine in 24 hours

Denominator: All adult (≥ 18 years old) PD patients in sample for analysis.

D-TEP Recommendations:

Current CPM II:

Numerator: The number of patients in the denominator with all of the following:

- a. Weekly creatinine clearance normalized to 1.73m^2 body surface area (BSA) and total weekly Kt/V_{urea} used to measure delivered PD dose
- b. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance
- c. Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the study period.

* negligible = $< 200\text{mL}$ urine in 24 hours

Denominator: All adults (≥ 18 years old) PD patients in the sample for analysis, excluding tidal dialysis patients

Proposed CPM II Revisions: Include tidal dialysis patients, estimate total body water (V) using Watson or Hume method using ideal or standard (rather than actual) body weight, and define negligible residual renal function as $\leq 100\text{mL}$ urine in 24 hours (rather than $<200\text{mL}$).

Comments:

The panel discussed ideal or standard body weight. If ideal body weight was calculated, information on patient amputations would need to be collected. As with the previous measure, the D-TEP consensus was to keep the value if it was needed and there was enough evidence to support it. The D-TEP and CMS suggested that Arbor Research confer with the members from the C-TEP on this issue, as well.

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

NA

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

Yes No

If yes, indicate the results of the testing.

Measure Contractor Recommended Disposition			
Measure contractor recommended disposition of the measure	<input checked="" type="checkbox"/> Retain		
			Effective Date of Action
	<input type="checkbox"/> Revise (as described above)		2/09, pending CROWNWeb implementation
	<input type="checkbox"/> Replace		
	<input type="checkbox"/> Rotate		
<input type="checkbox"/> Retire			
Rationale for recommendation			
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date <input type="checkbox"/> Other:
Recommended by	Name: Date:		

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

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

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