

Quality Assessment & Performance Improvement Meeting Condition §494.110 Of CMS Conditions for Coverage

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CONDITIONS OVERVIEW

- Conditions for Coverage are minimum health and safety standards.
- They are the foundation for improving care and protecting beneficiaries.
- Facilities must meet the Conditions for Coverage in order to be paid by Medicare and Medicaid
- State Surveyors use these regulations to evaluate dialysis providers' compliance with the laws



EFFECTIVE DATE

October 14, 2008

Noteworthy Additions/Changes

- **Patient Care Technician Certification Required**

PCTs must be certified under a state or national certification program

For Current PCTs – 18 months from Oct. 14, 2008

For New PCTs – 18 months from date of hire.

- **Infection Control**

Must comply with the CDC's "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients".

Isolation Room required for all new facilities

Existing facilities must have ability to dialyze HBV patients

Additions/Changes Continued

- **Patient Assessment & Plan of Care**

Utilizes an Interdisciplinary Team (IDT) that works collaboratively and communicates regularly about patient status and the evolving Plan of Care.

>An initial individualized comprehensive Patient Assessment based on 14 “criteria”

>Plan of Care is based on the comprehensive assessment and must result in patient outcomes that meet minimum levels of defined standards

MEASURES ASSESSMENT TOOL (MAT)

Tag	Condition/Standard	Measure	Values	Reference	Source
494.40 Water and dialysate quality:					
V196 V196 V178 V180	Water quality	Max. chloramine (must determine) Max. total chlorine (may determine) Action / Max. bacteria – product water / dialysate Action / Max. endotoxin – product water / dialysate	≤0.1 mg/L daily/shift ≤0.5 mg/L daily/shift 50 CFU/mL / <200 CFU/mL 1 EU/mL / <2 EU/mL (endotoxin units)	AAMI RD52	Records
494.50 Reuse of hemodialyzers and blood lines (only applies to facilities that reuse dialyzers &/or bloodlines)					
V335	Dialyzer effectiveness	Total cell volume (hollow fiber dialyzers)	Measure original volume Discard if after reuse <80% of original	KDOQI HD Adequacy 2006; AAMI RD47	Records Interview
494.80 Patient assessment: The interdisciplinary team (IDT), patient/designee, RN, MSW, RD, physician must provide each patient with an individualized & comprehensive assessment of needs					
V502 V503 V504 V505 V506 V507 V508 V509 V510 V511 V512 V513 V514 V515	- Health status/comorbidities - Dialysis prescription - BP & fluid management - Lab profile - Immunization & meds history - Anemia (Hgb, Hct, iron stores, ESA need) - Renal bone disease - Nutritional status - Psychosocial needs - Dialysis access type & maintenance - Abilities, interests, preferences, goals, desired level of participation in care, preferred modality & setting, outcomes expectations - Suitability for transplant referral - Family & other support systems - Current physical activity level & referral to voc & physical rehab	Frequency: Evaluate: HD every mo; PD first mo & q 4 mo Monitor labs monthly & as needed Assess for fistula candidacy Initial assessments (new patient): within latter of 13 treatments or 30 calendar days of admission Re-assessment of patients within 3 months after initial assessment & annually (stable) or monthly (unstable)	Adult BP: 24 hr: ≤130/80; Day: ≤135/85; Sleep: ≤120/70; Pediatric BP: 90% of normal for age, gender, ht or 130/80 whichever is lower Euvolemic Refer to Plan of care & QAPI sections (below) for other values	Conditions for Coverage KDOQI Hypertension & Anti-Hypertensive Agents in CKD 2004 (BP) KDOQI HD Adequacy 2006 (volume)	Chart
494.90 Plan of care The IDT must develop & implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs as identified by the comprehensive assessment & changes in the patient's condition, & must include measurable & expected outcomes & estimated timetables to achieve outcomes. Outcomes must be consistent with current professionally accepted clinical practice standards.					
V543	(1) Dose of dialysis: volume	Management of volume status	Euvolemic & normotensive (see values for BP under Pt Assessment above)	KDOQI HD Adequacy 2006	Chart
V544	(1) Dose of dialysis (HD)	Adult HD <5 hours 3x/week Adult HD 2x/week, RKF <2 mL/min/1.73 m ² HD 4-6x/week	Kt/V ≥1.2; Min. time 3 hour Inadequate treatment frequency Min. Kt/V ≥2.0/week	KDOQI HD Adequacy 2006	Chart
V544	(1) Dose of dialysis (PD)	Adult PD patient <100 mL urine output/day Pediatric PD patients, low urine urea clearance	Min. delivered Kt/V _{urea} ≥1.7/week Min. delivered Kt/V _{urea} ≥1.8/week	KDOQI PD Adequacy 2006	Chart
V545	(2) Nutritional status Monitored monthly	Albumin Body weight Other parameters in Patient Assessment	≥4.0 g/dL bromocresol green (BCG) method % usual weight, % standard weight, BMI, estimated % body fat	KDOQI Nutrition 2000 KDOQI CKD 2003	Chart
V546	(3) Mineral metabolism & renal bone disease	Calcium Phosphorus Intact PTH q 3 months.	All: >8.4 mg/dL & <10.2 mg/dL All: 3.5-5.5 mg/dL Adult: 150-300 pg/mL (16.5-33.0 pmol/L) Pediatric 200-300 pg/mL.	KDOQI Bone Metabolism & Disease 2003	Chart
V547 V548	(4) Anemia Monitor Hgb/Hct monthly	Adult & pediatric Hgb on ESAs Adult & pediatric Hgb on ESAs Adult & pediatric Hgb off ESAs Adult & pediatric Hgb on ESAs	Hgb: <12.0 g/dL ³ Hgb: 10-12.0 g/dL ⁴ Hgb: >10 g/dL ⁴ Hgb: 10-12.0 g/dL, <13.0 g/dL ³	³ =FDA "black box" warning ⁴ =Medicare reimbursement policy ⁵ =KDOQI Anemia 2007 ⁶ =KDOQI Anemia 2006	Chart
V549	Monitor iron stores routinely	Adult & pediatric: transferrin saturation Adult & pediatric: serum ferritin	>20% (HD, PD), or Chr >29 pg/cell ⁶ HD: >200 ng/mL; PD: >100 ng/mL ⁶ HD/PD: <500 ng/mL or evaluate if indicated ⁶		

MEASURES ASSESSMENT TOOL (MAT)

Tag	Condition/Standard	Measure	Values	Reference	Source
V550 V551	(5) Vascular access	Fistula Graft Central Venous Catheter	Preferred ^{1,2} Acceptable if fistula not possible ^{1,2} Avoid, unless bridge to fistula/graft or to PD, if transplant imminent, or in small adult/peds pt ¹	¹ =KDOQI Vascular Access 2006 ² =Fistula First	Chart Interview CW
V552	(6) Psychosocial status	Survey physical & mental functioning annually KDQOL-36 survey annually	Achieve & sustain appropriate status	Conditions for Coverage CMS CPM	Chart Interview
V553 V554	(7) Modality	Home dialysis referral Transplantation referral	Candidacy or reason for non-referral	Conditions for Coverage	Chart Interview
V555	(8) Rehabilitation status	Productive activity desired by patient Pediatric: formal education needs met Vocational & physical rehab referrals as indicated	Achieve & sustain appropriate level, unspecified	Conditions for Coverage	Chart Interview
V562	(d) Patient education & training	Dialysis experience, treatment options, self-care, QOL, infection prevention, rehabilitation	Documentation of education in record	Conditions for Coverage CMS CPM 4/1/2008	Records Interview
494.110 Quality assessment & performance improvement (QAPI): The dialysis facility must develop, implement, maintain, & evaluate an effective, data-driven QAPI program with participation by the professional members of the IDT. The program must reflect the complexity of the organization & services (including those under arrangement), & must focus on indicators related to improved health outcomes & the prevention & reduction of medical errors. The dialysis facility must maintain & demonstrate evidence of its QAPI program including continuous monitoring for CMS review.					
V629	(i) HD adequacy (monthly) (i) PD adequacy (rolling average each patient tested ≤4 months)	HD: Adult (patient with ESRD ≥3 mo) PD: Adult	% with spKt/V ≥1.2 or URR ≥65% (conventional 3 times/week dialysis) % with weekly Kt/V _{urea} ≥1.7 (dialysis+RKF)	Conditions for Coverage CMS CPM 4/1/2008 (all)	DFR Records
V630	(ii) Nutritional status	Unspecified in Conditions for Coverage & CPMs Refer to parameters in Patient Assessment	↑ % within target range	Conditions for Coverage	DFR Records
V631	(iii) Mineral metabolism/renal bone disease	Calcium & phosphorus	↑ % in target range monthly	Conditions for Coverage CMS CPM 4/1/2008	DFR Records
V632	(iv) Anemia management Patients taking ESAs &/or Patients not taking ESAs	Mean hemoglobin (patient with ESRD ≥3 mo) Mean hematocrit Serum ferritin & transferrin saturation or CHR	↑ % with mean 10-12 g/dL ↑ % with mean 30-36% Evaluate if indicated	Conditions for Coverage CMS CPM 4/1/2008 (all)	DFR Records
V633	(v) Vascular access (VA) Evaluation of VA problems, causes, solutions	Cuffed catheters > 90 days AV fistulas for dialysis using 2 needles Thrombosis episodes Infections per use-life of accesses VA patency	↓ to <10% ¹ ↑ to ≥65% ¹ or ≥66% ² ↓ to <0.25/p/yr (graft) or 0.50/p/yr (fistula) ↓ to <1% (fistula), <10% (graft) ↑ % with fistula >3 yrs & graft >2 yrs	¹ =KDOQI 2006 ² =Fistula First CMS CPM 4/1/2008	DFR Records CW 2/09
V634	(vi) Medical injuries & medical errors identification	Medical injuries & medical errors reporting	↓ frequency through prevention, early identification & root cause analysis	Conditions for Coverage	Records
V365	(vii) Reuse	Evaluation of reuse program including evaluation & reporting of adverse outcomes	↓ adverse outcomes	Conditions for Coverage	DFR Records
V636	(viii) Patient satisfaction & grievances	Report & analyze grievances for trends CAHPS In-Center Hemodialysis Survey available Other surveys for pediatric & home patients	Prompt resolution of patient grievances ↑ % of patients satisfied with care	Conditions for Coverage CMS CPM 4/1/2008	Records Interview
V637	(ix) Infection control	Analyze & document incidence for baselines & trends	Minimize infections & transmission of same Promote immunizations	Conditions for Coverage	Records
V637	Vaccinations	Hepatitis B, influenza, & pneumococcal vaccines Influenza vaccination	↑ % of patients vaccinated on schedule ↑ % of patients receiving flu shots 10/1-3/31	Conditions for Coverage CMS CPM 4/1/2008	Records
V627	Health outcomes: Physical & mental functioning	Survey adult/pediatric patients KDQOL-36 survey annually	Achieve & sustain appropriate status ↑ % completing survey	Conditions for Coverage CMS CPM 4/1/2008	Interview
V627	Health outcomes: Patient survival	Standardized mortality ratio (1.0 is average, >1.0 is worse than average, <1.0 is better than average)	↓ mortality	Conditions for Coverage CMS CPM 4/1/08	DFR Records

Quality Assessment & Performance Improvement (QAPI)

§494.110 Condition: QAPI

- Facilities must develop, implement, maintain and evaluate an effective, data-driven, quality assessment and performance improvement program.
- All professional members of the interdisciplinary team must participate.
- Program must reflect the complexity of the facility's organization & services(including services provided under arrangement)

QAPI-continued

- Must focus on indicators related to improved health outcomes & the prevention and reduction of medical errors.
- Each facility must maintain & demonstrate evidence of its quality and performance improvement program for review by the surveyors for CMS.
- The facility must measure, analyze, and track the quality indicators it adopts or develops that reflect processes of care and facility operations.

Show Me The Progress!!!

(V629) Adequacy	Kt/V, URR
(V630) Nutrition	Albumin, body weight
(V631) Bone disease	PTH, Ca+, Phos
(V632) Anemia	Hgb, Ferritin
(V633) Vascular access	↑Fistula, ↓catheter rate
(V634) Medical errors	↓Frequency of specific errors
(V635) Reuse	↓Adverse outcomes
(V636) Pt satisfaction	↑Survey scores
(V637) Infection control	↓Infections, ↑vaccination status

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Show Me The Progress!!!

The facility must:

- Continuously monitor its performance
- Take actions that result in performance improvement
- Track to assure improvements are sustained over time

QAPI Templates

Developed by The Renal Network, Inc. to assist dialysis facilities in meeting § 494.110

- It is not mandatory for facilities to use these QAPI templates (unless participating in a Network project)
- Facilities may use these templates or adapt them to better fit their specific needs.
- Templates will be posted on The Renal Network website www.therenalnetwork.org as they are completed.

QAPI Template Objectives

- To help facility staff understand and meet the requirements of §494.110 condition.
- Provide tools necessary for an evidence-based quality improvement program.
- Provide tools to assist facilities in sustaining improvements.
- Provide an appropriate format for a facility to demonstrate evidence of its quality assessment and performance improvement program.

Vascular Access Template

Components Of This Template Include:

- CQI Action Plans
- Barriers Questionnaire
- Data Collection Tool which includes facility, nephrologist and surgeon reports.
- Needs Assessment Tool

Adequacy Template

Components Of This Template Include:

- Adequacy CQI Action Plan
- Barriers Questionnaire
- Data Collection Tool With Report

Quality Assessment and Performance Improvement

Questions?