Partnership for Quality Measurement
Powered by Battelle

Fall 2022 Cycle

Renal Final Technical Report

October 2023

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Executive Summary

Kidney disease is the fastest growing non-communicable condition in the United States, with 15% of adults currently being affected, and millions at risk.[1] It is in the top 10 causes of death and can also leads to other unwanted outcomes, such as high blood pressure, heart disease, and stroke.[2] Medicare spending for chronic kidney disease and end-stage renal disease (ESRD) exceeded $124 billion in 2019.[3] Improving patient outcomes and reducing expenditures could have a significant impact nationwide.

Quality measures are necessary tools for assessing improvements in renal health, as well as the extent to which health care stakeholders are using evidence-based strategies to advance the quality of care. To support this effort, Battelle endorses and maintains performance measures related to renal health through a standardized, consensus-based process.

For this project's measure review cycle, three measures were submitted for endorsement consideration (Table 1). The Renal standing committee did not recommend any of the three measures for endorsement. The Consensus Standards Approval Committee (CSAC) upheld the committee's endorsement recommendations.

Effective March 27, 2023, the National Quality Forum (NQF) is no longer the consensus-based entity (CBE) funded through the Centers for Medicare & Medicaid Services (CMS) National Consensus Development and Strategic Planning for Health Care Quality Measurement Contract. Battelle has been selected to oversee the endorsement & maintenance (E&M) of clinical quality and cost/resource use measures. Since the Fall 2022 cycle launched at NQF, measures submitted for Fall 2022 E&M cycle continued along the prior E&M protocols that were in place at time of the Fall 2022 "Intent to Submit." In addition, the Scientific Methods Panel review and the committee's measure evaluation meeting for the Fall 2022 cycle were conducted under NQF. Battelle took over the E&M work beginning with the public comment period to close out the Fall 2022 cycle. This included launching the Fall 2022 post-comment period, convening the E&M committees for the post-comment meeting, convening the CSAC to render a final endorsement decision, and executing the Appeals period.

Table 1. Measures Submitted for Endorsement Consideration

Measure Number	Measure Title	New/ Maintenance	Developer/Steward	Final Endorsement Decision
3719	Prevent Standardized Waitlist Ratio (PSWR)	New	University of Michigan Kidney Epidemiology and Cost Center/ Centers for Medicare & Medicaid Services	Not Endorsed
3722	Home Dialysis Rate	New	Kidney Care Quality Alliance	Not Endorsed
3725	Home Dialysis Retention	New	Kidney Care Quality Alliance	Not Endorsed

Summaries of the measure evaluation meetings are linked within the body of the report. Detailed summaries of the committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Kidney disease is one of the most prevalent conditions in the United States, with an estimated 37 million Americans having kidney disease, over 800,000 of whom have kidney failure.[1] In 2020 alone, 103,000 new diagnoses of kidney disease were made.[1] Once advanced, kidney disease can lead to other unwanted health outcomes, such as stroke and heart disease[4]. In 2022, Medicare spending for patients aged 66 years and older with kidney disease alone (not including ESRD) accounted for $75 billion.[4]

Quality measures are tools to measure or quantify health care processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health. Furthermore, quality measures can be powerful tools in helping identify substantial performance gaps in kidney disease care, affecting patient outcomes and overall cost.

Battelle, a CBE, convenes volunteer committees to evaluate and build consensus around measures for endorsement based on a standardized set of criteria. For the Fall 2022 cycle, the Renal standing committee reviewed measures focused on home dialysis and transplant waitlist rates.

Home Dialysis

The usage of home dialysis has increased over the past decade, with 13.3% of incident patients and 13.7% of prevalent patients utilizing home dialysis in 2020.[5] Research shows that up to 85% of patients may be eligible for home dialysis.[6] Home dialysis has been shown to improve quality of life and survival rates, although socially disadvantaged populations have reported less access to home dialysis.[7]

Transplant Waitlisting

There are currently over 100,000 patients on the waitlist to receive a donor kidney, with an average wait of 3.6 years. Every day, 3,000 people are added to the transplant waitlist, while thousands more become ineligible because the progression of their disease has become too severe.[8] Kidney transplants improve health outcomes and quality of life for patients, and recipients of a transplant have a 68% lower chance of death than eligible patients who remain solely on dialysis.[9]

Renal Measure Evaluation

For the Fall 2022 measure review cycle, the Renal standing committee (Appendix B) evaluated three new measures for initial endorsement review using standard measure evaluation criteria.

Table 2. Number of Fall 2022 Renal Measures Submitted and Reviewed

	Maintenance	New	Total
Number of measures submitted for endorsement review	0	3	3
Number of measures withdrawn from consideration *	0	0	0
Number of measures reviewed by the committee	0	3	3
Number of measures endorsed	0	0	0
Number of measures not endorsed	0	3	3

**Measure developers/stewards can withdraw a measure from measure endorsement review at any point before the CSAC meeting.*

Scientific Methods Panel Measure Evaluation

Prior to the committee's review, the Scientific Methods Panel (SMP) reviewed two measures (CBE #3722 and CBE #3725) in this topic area for scientific acceptability (i.e., reliability and validity). The SMP passed both measures on reliability and validity during its measure evaluation meeting.

Comments Received Prior to Standing Committee Evaluation

For this evaluation cycle, pre-evaluation public commenting was conducted under NQF. Three pre-evaluation public comments for the measures under review were submitted and shared with the standing committee prior to the measure evaluation meeting on February 10, 2023. Two of the comments were supportive of CBE #3722 and CBE #3725, expressing home modalities are underutilized and can lead to favorable clinical and patient-reported outcomes. The last comment was for CBE #3719, which was not supportive. The comment raised concern with the measure's attribution and the measure's reliability and validity testing. A summary of comments for each measure reviewed is provided in Appendix A.

Comments Received After Standing Committee Evaluation

Following the standing committee's measure evaluation meeting, Battelle posted the committee endorsement recommendations to the PQM website for public comment. The commenting period opened on March 28, 2023, and closed on May 5, 2023. The committee received two comments pertaining to the three measures under review and the committee endorsement recommendations. One of the comments was submitted by the devleoper of CBE #3722 and

CBE #3725, which expressed support for both measures and disagreement with the standing committee's decision to not recommend the measures for endorsement. The developer further posited that the measures have considerable supportive evidence, been rigorously tested, and proven to be reliable and meaningful. The second commenter expressed agreement with the standing committee's recommendation to not endorse CBE #3725. Lastly, both comments agreed with the committee's recommendation to not endorse measure #3719, citing concerns with validity, attribution, reliability, and variability. Battelle convened the committee for the Fall 2022 post-comment web meeting on June 9, 2023, to review and respond to the full text of comments received. A summary of comments for each measure reviewed is provided in Appendix A.

Summary of Potential High-Priority Gaps

No potential high-priority measurement gap areas emerged during the standing committee's evaluation.

Summary of Major Concerns or Methodological Issues

Lack of Evidence Demonstrating Improved Outcomes

Two measures (CBE #3722 and #3725) did not receive endorsement due to lack of strong empirical evidence that the measure leads to improved outcomes. The committee recognized the importance of the area of kidney care, which the measures intended to capture, but expressed the need for more evidence to support them. Details of the standing committee's discussion and ratings of the criteria for each measure are included in Appendix A.

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Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Under NQF's process, quorum is 66% of active standing committee members minus any recused standing committee members. Due to the exclusion of recused standing committee members from the quorum calculation, the required quorum for live voting may vary among measures. Quorum (15 out of 22 standing committee members for CBE #3719 and 12 out of 17 standing committee members for CBE #3722 and CBE #3725) was reached and maintained throughout the full measure evaluation meeting on February 10, 2023. Vote totals may differ between measure criteria and between measures because standing committee members may have joined the meeting late, stepped away for a portion of the meeting, or had to leave the meeting before voting was complete. The vote totals listed below reflect the committee members present and eligible to vote at the time of the vote.

A measure is recommended for endorsement by the standing committee when greater than 60% of voting members select a passing vote option (i.e., Pass, High and Moderate, or Yes) on all must-pass criteria and overall suitability for endorsement. A measure is not recommended for endorsement when less than 40% of voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement.

A.1 Measures Not Endorsed

CBE #3719 Prevalent Standardized Waitlist Ratio (PSWR)

Staff Assessment | Specifications

Numerator Statement: Number of prevalent dialysis patients in the practitioner group listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within each calendar year.

Denominator Statement: The denominator for the PSWR is the expected number of waitlist or living donor transplant events in the practitioner group according to each patient's treatment history, adjusted for patient age, incident and prevalent comorbidities, previous waitlisting and transplant, dual eligibility, Area Deprivation Index (ADI), and transplant center characteristics, among patients under 75 years of age.

Exclusions: Patients with the below conditions are excluded from the measure:

• Patients were excluded when turning 75

• Patients who were admitted to a skilled nursing facility (SNF) were excluded from that period.

• Patients were excluded if determined to be in hospice in the prior 365 days

• Patients with dementia

The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data.

Patients who were attributed to dialysis practitioner groups with fewer than 11 patients or 2 expected events are not excluded from the measure. If a provider can not be matched to a TIN, patients will be grouped into a separate 'null' TIN and still included in the models, but are not summarized to any valid individual TINs. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician: Group/Practice

Setting of Care: Outpatient Services

Type of Measure: Outcome

Data Source: Claims; Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE EVALUATION

Table A.1-1.1. Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	Total Votes-18; Pass-17; No Pass-1(17/18 – 94.4%, Pass)	• The standing committee recognized that this new measure, at the clinician group/practice-level, tracks the number of prevalent dialysis patients in a practitioner group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. For each practitioner group, the Prevalent Standardized Waitlist Ratio (PSWR) is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. • The developer provided a logic model that depicts a provider can impact if a patient is on the kidney-pancreas transplant list or receives a transplant by educating on transplantation, referring them to a transplant center, assisting with the transplant evaluation process, and optimizing patient's health and functional status. • The developer noted that two technical expert panels (TEPs) were convened to discuss potential measures directed at improving access to kidney transplantation. The developer noted broad support for the importance of waitlisting and formal voting by the TEP. • To further demonstrate the meaningfulness of the measure to the target population, the developer also cited a study published in the American Journal of Transplantation noting that patients with advanced chronic kidney disease find waitlisting and the ease of getting on a waitlist to be important. • The developer also provided several studies empirically demonstrating the association between processes under the dialysis practitioner's control that can improve the outcome of waitlisting. • While the standing committee agreed that the developer presented evidence highlighting the relationship between a provider's actions and waitlisting, the committee raised some concern that patients who are either unwilling or unable to receive a transplant will get waitlisted. • The developer clarified that most of the empirical evidence suggests that patients who could benefit from a transplant are not being added to the waitlist. • The standing committee did not raise any additional concerns or questions and passed the measure on evidence.

Criterion	Total Votes	Rationale

1b. Performance Gap	Total Votes-18; H-2; M-14; L-2; I-0 (16/18 – 88.9%, Pass)	• The standing committee recognized that the developer evaluated PSWR performance scores for all practitioner groups that had at least 11 patients and two expected events in the evaluation period between January 1, 2017 and December 31, 2019. This resulted in the inclusion of 2,022 groups totaling 362,093 patients.
		• The developer found that the mean value of the PSWR was 103% with an interquartile range of 63%.
		• The developer submitted PSWR scores by race, ethnicity, and sex for the sample.
		  ◦ Mean PSWR was highest for the categories Other (437%) and Asian Pacific Islander (424%) and lowest for White (121%).
		  ◦ Non-Hispanics had a lower PSWR (107%) than Hispanics (164%).
		  ◦ Females had a higher PSWR (118%) than males (98%).
		• The standing committee asked the developer to clarify how they should interpret the information provided in the submission in relation to gap and disparities. Particularly, the developer calculated PSWR performance among different strata of race, ethnicity, and sex, and the mean values for each of the strata are different than the median values.
		• The developer clarified that the medians show the most precise picture of gap and disparities. The standing committee noted that the PSWR for people who are Black, Native American /Alaska Native, Asian/Pacific Islander, and those who identified as “Other” was lower than for people who are White. Additionally, Hispanics and males had a lower PSWR than non-Hispanics and females.
		• The standing committee recognized that a gap in care and disparities do exist and passed the measure on performance gap.

Table A.1-1.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	Total Votes-18; H-0; M-14; L-3; I-1 (14/18 – 77.8%, Pass)	• The standing committee recognized that reliability testing was conducted at the accountable entity-level. The developer conducted testing using inter-unit reliability (IUR) with a bootstrap (n=100) approach.
		  • The developer calculated an IUR value of 0.56 for the measure, indicating that 56% of the variation in the measure can be attributed to the between-dialysis practitioner group practice differences and 44% to the within-dialysis practitioner group differences.
		  • Dialysis practitioner group practices with less than 11 eligible patients were excluded from this calculation.
		• The standing committee asked the developer to clarify how the measure is calculated, particularly if a patient were to move between provider groups but is waitlisted early on. The developer noted that the outcome is a one-time event. Therefore, if a patient is waitlisted by their first provider group and then subsequently moves to a new provider group, they would not be counted in that subsequent group's denominator because the first group has already waitlisted them.
		• The standing committee asked the developer to clarify the exclusion of 11 patients or less and specifically whether this applies to the 11 patients on dialysis and assigned to the practice or to the 11 waitlisted patients. The developer noted that the exclusion is for 11 total dialysis patients in the denominator.
		• The standing committee also asked the developer to clarify whether preemptively waitlisted patients are included in the measure. The developer noted that people who are preemptively waitlisted are not included in this measure's calculation.
		• The standing committee asked whether the developer looked at reliability for smaller practices and how many groups are smaller in size. The developer noted that they did not look at smaller practices but that they would expect reliability to be lower. The developer further noted that the exclusion of less than 11 eligible patients is to address the concern of reliability for smaller clinician groups.
		• The standing committee passed the measure on reliability.

2b. Validity	Total Votes-17; H-1; M-4; L-11; I-1 (5/17 – 29.4%, No Pass)	• The standing committee recognized that validity testing was conducted at the accountable entity-level. • The developer tested the validity of the measure by evaluating the association between the dialysis practitioner group level measure performance and subsequent mortality and overall transplant rates among all patients attributed to the practitioner groups. The developer hypothesized that for higher PSWR performance, transplant rates would be higher and for higher PSWR performance, mortality would be lower.

Criterion	Total Votes	Rationale
		• The dialysis practitioner group-level average mortality was 17.7, 17.5, and 18.1 deaths per 100 patient-years for each of the three tertiles (T1 to T3), respectively (trend test p=0.255). The Spearman correlation coefficient was not significant: -0.02 (p=0.264). • The dialysis practitioner group-level average transplant rate was 4.7, 3.8, and 2.6 transplants per 100 patient-years for each of the three tertiles (T1 to T3), respectively (trend test p<0.001). The Spearman correlation coefficient was significant: 0.41 (p<0.001). • The developer noted that higher PSWR performance correlated with higher transplant rates, and the relationship with mortality was also as expected by the developer, though not statistically significant, with the numerically highest mortality in the lowest performance tertile on the PSWR measure. • The standing committee recognized that the developers evaluated the exclusion criteria by comparing the differences in the number of patients with and without excluding age greater than or equal to 75, nursing home patients, hospice patients, and dementia patients. The developer noted that exclusions apply to all patients in the models regardless of whether the practitioner groups have fewer than 11 patients or two expected events. The developer reported that the overall measure scores were changed modestly by the exclusions. • The standing committee recognized that the developer conducted a statistical risk model with 24 variables. The developer considered social risk factors as well, but stated that while there are differences in waitlisting by sex, race, and ethnicity, these factors were not included in the final risk model because adjusting for these factors could create or reinforce disparities. • The standing committee posed several questions to the developer regarding concerns around exclusions, the nonsignificant association with mortality, the risk adjustment model, and the possibility of practices with high waitlisting rates not performing well on this measure. • The standing committee noted that the exclusions were insufficient, given that preemptively waitlisted patients are excluded, while pediatric patients weighing less than 10 kilograms and patients who choose not to be waitlisted are not excluded. The two patient advocates on the standing committee were particularly concerned by the lack of patient choice, and even physician choice, regarding this measure. The developer noted that in practice, there are difficulties in attributing the correct dialysis facility for preemptive waitlisting and that patient choice is difficult to capture accurately. Further, the developer reiterated that the focus of this measure is on transplants and the waitlisting that occurs after dialysis initiation. Regarding the pediatric patient exclusion, the developer noted that its approach was to exclude situations that can cause imbalances across groups. • The standing committee noted that while these numbers may appear to be small nationally, they would be significant for pediatric centers. Additionally, the exclusion of less than 11 patients may suppress some of these centers, but there are larger pediatric centers that may not be excluded.

Criterion	Total Votes	Rationale
		• As for the nonsignificant associations with mortality in the validity testing, the developer noted that it can be challenging to show a clearly demonstrable effect on mortality because it is inclusive of many factors. However, the developer did find a numerical trend that is consistent with what they hoped to see. • Regarding risk adjustment, the developer clarified that transplant center mortality and transplant rates were chosen as characteristics to account for variation in the model because they are proxies for the aggressiveness with which centers are willing to waitlist patients, particularly sicker ones; regional organ availability; and how aggressively they try to find living donors or convert patients to transplants. • As for the possibility of practices with high waitlisting rates not performing well on this measure, the developer noted that the measure adjusts for comorbidities on an ongoing basis, along with other adjustments, to continually update who is expected to be rapidly waitlisted in the denominator as the measurement period continues. • The standing committee asked whether the developer had performed any analyses on how high-performing groups performed on this measure to ensure that the developer's rationale is indeed how this scenario works. The developer replied that they had not. • The standing committee did not pass the measure on validity—a must-pass criterion. Therefore, it did not discuss or vote on any subsequent criteria nor the overall endorsement vote.

Table A.1-1.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Vote not taken	• The standing committee did not pass the measure on validity—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-1.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Vote not taken	• The standing committee did not pass the measure on validity—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.
4b. Usability	• Vote not taken	• The standing committee did not pass the measure on validity—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-1.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• CBE #3695 Percentage of Prevalent Patients Waitlisted (PPPW)	• Measure was not recommended for endorsement; therefore the related measure(s) were not discussed.

Table A.1-1.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Not Recommended for Endorsement	• Vote Not Taken	• The standing committee did not vote on overall suitability for endorsement because the measure did not pass on validity—a must-pass criterion.

Table A.1-1.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	• None
Non-supportive comments	• Three	Pre-evaluation comments *Disagreement that measure is attributed to physicians* • One comment was received for this measure prior to the measure evaluation meeting. The comment did not express support for the measure. The commenter disagreed with this measure being attributed to physicians because the decision to waitlist a patient is made by transplant centers. • The commenter also asserted that variation in transplant center waitlisting practices must be better accounted for the measure to be valid. Lastly, the commenter raised concern with the

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
		reliability statistics because they were not stratified by facility size; therefore, it is not possible to discern reliability for smaller units. The standing committee considered this comment in its evaluation of the measure. Post-evaluation comments *Support for standing committee's recommendation not to endorse* • One comment disagreed with the measure being attributed to physicians because the decision to waitlist a patient is made by transplant centers and the variation in their waitlisting practices must be better accounted for. There was also concern with reliability statistics not being stratified by facility size. • The second comment was also in agreement with the standing committee's recommendation, citing similar concerns around attribution, variation in transplant center eligibility, and the measure's reliability. • The standing committee considered the comments and maintained its decision not to endorse the measure.

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-1.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Not Endorsed	• Total Votes-13; Accept-13; Do Not Accept-0 (13/13 – 100%, Not Endorsed)	• The Renal co-chairs noted that one challenge with this measure was the exclusion of the type of dialysis care could be a weakness for the measure, as this measure only focuses on waitlisting after dialysis initiation. • The CSAC had no major concerns and upheld the standing committee's decision to not endorse the measure.

APPEALS BOARD EVALUATION

Appeals:

- Based on the prior consensus-based entity's process, only endorsed measures are eligible for any appeal.

CBE #3722 Home Dialysis Rate

Staff Assessment | Specifications

Numerator Statement: Patient-months from the denominator in which the patient was dialyzing via a home modality (peritoneal dialysis and/or home hemodialysis) as of the final dialysis treatment of the given measurement month.

Denominator Statement: All dialysis patient-months (in-center and/or home) attributed to the dialysis facility (or aggregate HRR unit) during the measurement year.

Exclusions: The following exclusions are applied to the denominator:

1. Patient-months in which the patient was admitted to the facility to which they are attributed for <30 days as of the final day of the measurement month.
2. Patient-months in which the patient is receiving dialysis for AKI only at any time in the measurement month.
3. Patient-months in which the patient is enrolled in hospice at any time in the measurement month.
4. Patient-months in which the patient is residing in a nursing home or other LTCF at any time in the measurement month.
5. Patient-months in which the patient was discharged from the facility secondary to transplant, death, discontinuation of dialysis, and/or recovery of function at any time in the measurement month.

Adjustment/Stratification: Stratification by risk category/subgroup. Measure results are stratified by 5 risk factor groups: age, gender, race, ethnicity, dual-eligibility.

Level of Analysis: Facility; Other

Setting of Care: Ambulatory Care; Home Care; Outpatient Services; Post-Acute Care

Type of Measure: Process

Data Source: Electronic Health Data; Electronic Health Records

Measure Steward: Kidney Care Quality Alliance

STANDING COMMITTEE EVALUATION

Table A.1-2.1. Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-12; H-0; M-3; L-7; I-2 (3/12 – 25%, No Pass)	• The standing committee recognized that this new process measure examines the percentage of patients dialyzing via a home dialysis modality among patients assigned to a given dialysis facility and/or Hospital Referral Region (HRR) within a given measurement year. • The standing committee recognized the measure's intent to incentivize home modalities for all clinically appropriate patients. The standing committee reviewed the developer's logic model, which highlights potential outcomes of increased home dialysis, such as the reduced risk of cardiovascular disease, mortality, hospitalization, cost, and increased quality of life. • The developer noted that there are no relevant clinical practice guidelines, United States Preventive Services Task Force (USPSTF) recommendations, systematic reviews, or formal randomized controlled studies addressing home dialysis modalities uptake and provided evidence from observational studies.

Criterion	Total Votes	Rationale
		• During the evaluation of the evidence, the standing committee focused on determining whether there is strong enough evidence that home modalities provide better outcomes than in-center dialysis treatments. The standing committee acknowledged that home modalities can lead to reduced costs. However, several Standing committee members expressed that some patient subgroups tend to have varying health and quality-of-life outcomes due to other confounding factors. Specifically, patients who choose to go home and who report a higher quality of life are generally healthier, more motivated, and tend to have greater financial and social resources, as well as a more conducive home environment for home modalities. • The standing committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients. One member highlighted a post hoc analysis that resulted in worse mortality outcomes among patients at home versus in-center. Overall, members of the standing committee recognized that the observational studies presented by the developer suggest that there are some advantages to home therapies, but this is likely a reflection of the composition of those patients who choose to go home. • The developer mentioned that the evidentiary standard for measures regarding ESRD cannot be prospective trials. Specifically, the developer stated it would be unethical to suggest that a home dialysis measure cannot exist without having a randomized controlled trial. However, one Standing committee member noted that there are dialysis studies that are prospective randomized trials and that the current observational studies have significant vulnerabilities. • The standing committee expressed uncertainty about the developer's use of a nine-member panel to systematically assess the measure's importance. The developer emphasized in their response that patient groups as well as clinical experts from accredited nephrology associations and dialysis facilities drove the development of this measure. • Ultimately, the standing committee stated that the true benefits of home dialysis over in-center dialysis are not currently demonstrated in the literature and that there is no empirical evidence to suggest that the benefits of home modalities lead to better outcomes that outweigh undesirable effects for all patients. • The standing committee did not pass the measure on evidence—a must-pass criterion. Therefore, the standing committee did not discuss or vote on any subsequent criteria nor the overall endorsement vote.
1b. Performance Gap	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-2.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.
2b. Validity	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-2.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-2.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.
4b. Usability	• Total Votes- Vote not taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any subsequent criteria.

Table A.1-2.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• None	• N/A

Table A.1-2.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Not Recommended for Endorsement	• Vote Not Taken	• The standing committee did not vote on overall endorsement because the measure did not pass on validity—a must-pass criterion.

Table A.1-2.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• One	Pre-evaluation comment *Favorable outcomes* • The comment noted that home modalities lead to favorable clinical and patient-reported outcomes. The commenter further stated that home modalities are underutilized and that increasing utilization is a major objective of the ESRD Treatment Choices (ETC) Payment Model. • The standing committee considered the comment in its evaluation of the measure.
Non-supportive comments	• One	Post-evaluation comment One comment was submitted by the developer of CBE #3722 and CBE #3725, which raised several concerns with the committee's evaluation. These concerns are summarized by topic below. *Incorrect statement in measure evaluation meeting summary* • The developer expressed concern with the measure evaluation meeting summary incorrectly stating that both measures, CBE #3722 and CBE #3725, did not pass the validity criterion. • It was clarified during the post comment meeting that the meeting summary has been updated to accurately reflect that the measures did not pass the evidence criterion. The standing committee had no additional discussion for this topic. *Patient choice exclusion and process for evaluating paired measure submissions* • The developer's comment also provided justification to not incorporate a specific exclusion for patient preference into the measure specifications. The comment also noted that both measures were submitted as a pair to help address patient choice concerns but were evaluated by the standing committee independently.

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
		• It was clarified during the post comment meeting that according to the National Quality Forum (NQF) criteria, measures should be evaluated individually against a standard set of criteria rather than as a paired set. • Standing committee members noted the current unilateral focus on home dialysis will certainly lead to increased technique failure rates and may subject many patients to a treatment modality for which they have not received adequate education or training and may inadvertently infringe on patient choice. • The standing committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients. *Evidence algorithm not appropriately applied during review of the measures* • The developer's comment also focused on concerns that the evidence algorithm was not appropriately applied during the review of these measures, which were developed utilizing data from observational studies. The comment further stated that the committee was inappropriately treating randomized-controlled trials as the evidence standard, which is (1) not the standard as described in the NQF evaluation criteria and (2) infeasible, extraordinary, and inappropriate in this context. • During the discussion of this topic, standing committee members emphasized that their evaluation of the measures followed the evidence algorithm and that evidentiary concerns were based on methodological concerns in the evidence provided, not the lack of a randomized study design. During the February evaluation meeting, standing committee members agreed that it did not have high certainty that benefits clearly outweigh undesirable effects, and it did not find that the evidence was high-to-moderate quality. Additionally, the lack of evidence supporting the superiority of home versus in-center dialysis led standing committee members to not pass the measure on evidence. • The standing committee suggested methodological ways to strengthen the evidence. This may include future collaboration with a study methodologist and exploration of analytic techniques for non-randomized study designs to mitigate potential bias, such as propensity scoring and stratification. • The standing committee considered the developer's comment and maintained its decision to not endorse the measure.

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-2.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Not Endorsed	• Total Votes-13; Accept-13; Do Not Accept-0 (13/13 – 100%, Not Endorsed)	• The Renal co-chairs stressed that the committee did spend a lot of time discussing home peritoneal dialysis and in-center dialysis techniques and agreed that for some patients, home dialysis is not as good. • The CSAC chair noted that there is an assumption that having more people in home dialysis is clinically better so saying the evidence doesn't exist is saying the evidence is clinically better. If looking at this from a cost standpoint, home dialysis is a lot less than in-center. There may be instances where a measure is validated and may be included to assess value due to the cost savings. • One CSAC member noted that cost also includes the dialysis recipients' time and cost of transportation to dialysis centers so there are costs and outcomes beyond clinical care that are important to consider. • Another CSAC member noted a key issue here is patient preference and making decisions based on relative value and not purely economic. Also, there is an innate selection bias discussed by the Renal committee, as there are sub-populations who may have improved outcomes by going to a dialysis center versus home dialysis. The member challenged the developer to come up with ways to account for things like patient preferences and sub-populations. • The CSAC had no major concerns and upheld the standing committee's decision to not endorse the measure.

APPEALS BOARD EVALUATION

Appeals:

- Based on the prior consensus-based entity's process, only endorsed measures are eligible for any appeal.

CBE #3725 Home Dialysis Retention

Staff Assessment | Specifications

Numerator Statement: Patients from the denominator who achieved >=90 consecutive days of home dialysis in the measurement year.

Denominator Statement: The total number of eligible new home dialysis patients attributed to the dialysis facility during the measurement year.

Exclusions: Denominator patients who are discharged from the facility for any of the following events occurring <90 days after meeting the 30-day eligibility criterion are excluded:

• Transplant;
• Death;
• Discontinuation of dialysis;
• Recovery of function;
• Admission to hospice; and/or
• Admission to nursing home or other LTCF.

Adjustment/Stratification: Stratification by risk category/subgroup. We stratify the measure results by 5 risk factor groups: age, gender, race, ethnicity, dual-eligibility.

Level of Analysis: Facility; Other

Setting of Care: Ambulatory Care; Home Care; Outpatient Services; Post-Acute Care

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Electronic Health Data; Electronic Health Records

Measure Steward: Kidney Care Quality Alliance

STANDING COMMITTEE EVALUATION

Table A.1-3.1. Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-13; H-0; M-4; L-7; I-2 (4/13 – 30.7%, No Pass)	• The standing committee recognized that this is a new intermediate clinical outcome measure at the facility level that measures the percentage of all new home dialysis patients in the measurement year for whom greater than or equal to 90 consecutive days or more of home dialysis was achieved. • The standing committee considered the developer's logic model depicting the relationship between the individual measure components, process interventions, and the desired health outcomes, which include lowering patient mortality, hospitalization, and cardiovascular risks, while improving patients' quality of life, and reducing the cost of care. Specifically, adoption of the home dialysis measure will incentivize the facility to implement process interventions such as effective modality education, and appropriate patient preparation, training, and support to

Criterion	Total Votes	Rationale
		improve home dialysis retention among patients who have selected and commenced a home modality. • The developer noted that there are no relevant clinical practice guidelines, USPSTF recommendations, systematic reviews, or formal randomized controlled studies addressing home dialysis modalities uptake or retention. • The developer cited observational studies and convened a Technical Home Dialysis Expert Workgroup in summer 2021 to conceptualize and develop the Home Dialysis Measures. • During the discussion on evidence, the standing committee observed that much of the evidence for CBE #3725 was similar to the evidence provided for CBE #3722. The standing committee stated that home dialysis could reduce costs for patients who choose home dialysis. However, it disagreed with the developer that there was evidence to support improved outcomes for home dialysis over in-center treatment regarding cardiovascular disease, mortality, or hospitalizations, as was noted in the conversation for CBE #3722. • The standing committee further expressed concern that the measure may not be able to accurately identify whether people who drop out of home dialysis prior to 90 days do so due to clinical reasons, such as infection or decrease in renal function. The developer noted that it had to practically consider what is achievable and can be reported. The developer also emphasized that benchmarks built into programs will be able to identify patients who are unable to stay on home dialysis for a clinical reason. • The standing committee expressed concern regarding the evidence provided to justify the 90-day time period for the measure. Specifically, the evidence submitted does not point to 90 days as a definitive time frame for success on home dialysis. The developer noted that 90 days was chosen based on the consensus reached by the TEP. • The standing committee further raised concern with the potential for unintended consequences, such as limiting access to therapy, due to the 90-day time period. Specifically, access to therapy could be limited because providers may be disincentivized from having patients try home therapy when they are unconvinced that the patient could maintain home dialysis for the full 90-day period. A standing committee member did note that the measure has an already built-in 30-day escape mechanism, where patients are not counted if they stop home dialysis before the 30-day mark to try to address this concern. • Ultimately, due to the evidence concerns, the standing committee did not pass the measure on evidence—a must-pass criterion. Therefore, the standing committee did not discuss or vote on any subsequent criteria nor the overall endorsement vote.
1b. Performance Gap	Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.

Table A.1-3.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.
2b. Validity	• Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.

Table A.1-3.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.

Table A.1-3.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.
4b. Usability	• Total Votes- Vote Not Taken	• The standing committee did not pass the measure on evidence—a must-pass criterion; therefore, the standing committee did not discuss or vote on any subsequent criteria.

Table A.1-3.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• None	• N/A

Table A.1-3.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Not Recommended for Endorsement	• Vote Not Taken	• The standing committee did not vote on overall endorsement because the measure did not pass on evidence—a must-pass criterion.

Table A.1-3.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• One	Pre-evaluation comment *Favorable outcomes* • The commenter expressed support noting that home modalities lead to favorable clinical and patient-reported outcomes. The commenter further stated that home modalities are underutilized and that increasing utilization is a major objective of the ETC Payment Model. • The standing committee considered the comment in its evaluation of the measure.
Non-supportive comments	• Two	Post-evaluation comments One comment agreed with the standing committee's recommendation to not endorse the measure. A second comment was submitted by the developer of CBE #3722 and CBE #3725, which raised several concerns with the committee's evaluation. These concerns are summarized by topic below. *Incorrect statement in measure evaluation meeting summary* • The developer expressed concern with the measure evaluation meeting summary incorrectly stating that both measures, CBE #3722 and CBE #3725, did not pass the validity criterion. • It was clarified during the post comment meeting that the meeting summary has been updated to accurately reflect that the measures did not pass the evidence criterion. The standing committee had no additional discussion for this topic. *Patient choice exclusion and process for evaluating paired measure submissions* • The developer's comment also provided justification to not incorporate a specific exclusion for patient preference into the measure specifications. The comment also noted that both measures

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
		were submitted as a pair to help address patient choice concerns but were evaluated by the standing committee independently. • It was clarified during the post comment meeting that according to the NQF criteria, measures should be evaluated individually against a standard set of criteria rather than as a paired set. • Standing committee members noted that the current unilateral focus on home dialysis will certainly lead to increased technique failure rates and may subject many patients to a treatment modality for which they have not received adequate education or training and may inadvertently infringe on patient choice. • The standing committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients. *Evidence algorithm not appropriately applied during review of the measures* • The developer's comment also focused on concerns that the evidence algorithm was not appropriately applied during the review of these measures, which were developed utilizing data from observational studies. The comment further stated that the committee was inappropriately treating randomized-controlled trials as the evidence standard, which is (1) not the standard as described in the NQF evaluation criteria and (2) infeasible, extraordinary, and inappropriate in this context. • During the discussion of this topic, standing committee members emphasized that their evaluation of the measures followed the evidence algorithm and that evidentiary concerns were based on methodological concerns in the evidence provided, not the lack of a randomized study design. During the February evaluation meeting, standing committee members agreed that it did not have high certainty that benefits clearly outweigh undesirable effects, and it did not find that the evidence was high-to-moderate quality. Additionally, the lack of evidence supporting the superiority of home versus in-center dialysis led standing committee members to not pass the measure on evidence. • The standing committee suggested methodological ways to strengthen the evidence. This may include future collaboration with a study methodologist and exploration of analytic techniques for non-randomized study designs to mitigate potential bias, such as propensity scoring and stratification. *Clarifying how the measure importance was assessed* • The developer's comment also attempted to clarify how measure importance was assessed with expert input and provided justification for the 90-day timeframe in the measure. • The standing committee agreed that these issues were discussed at length during the measure evaluation meeting and maintained its decision to not endorse the measure.

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-3.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Not Endorsed	• Total Votes-13; Accept-13; Do Not Accept-0 (13/13 – 100%, Not Endorsed)	• The Renal co-chairs stressed that the committee did spend a lot of time discussing home peritoneal dialysis and in-center dialysis techniques and agreed that for some patients, home dialysis is not as good. • The CSAC chair noted that there is an assumption that having more people in home dialysis is clinically better so saying the evidence doesn't exist is saying the evidence is clinically better. If looking at this from a cost standpoint, home dialysis is a lot less than in-center. There may be instances where a measure is validated and may be included to assess value due to the cost savings. • One CSAC member noted that cost also includes the dialysis recipients' time and cost of transportation to dialysis centers, so there are costs and outcomes beyond clinical care that are important to consider. • Another CSAC member noted a key issue here is patient preference and making decisions based on relative value and not purely economic. Also, there is an innate selection bias discussed by the Renal committee, as there are sub-populations who may have improved outcomes by going to a dialysis center versus home dialysis. The member challenged the developer to come up with ways to account for things like patient preferences and sub-populations. • The CSAC had no major concerns and upheld the standing committee's decision to not endorse the measure.

APPEALS BOARD EVALUATION

Appeals:

- Based on the prior consensus-based entity's process, only endorsed measures are eligible for any appeal.

Appendix B: Prevention and Population Health Standing Committee and Battelle Staff

STANDING COMMITTEE

Lorien Dalrymple, MD, MPH, (Co-Chair)
Vice President, Epidemiology & Research, Fresenius Medical Care North America

Renee Garrick, MD, FACP (Co-Chair)
Professor of Clinical Medicine, Vice Dean, and Renal Section Chief, Westchester Medical Center, New York Medical College

Andrew Chin, MD
Health Science Clinical Professor, University of California, Davis Medical Center

Annabelle Chua, MD
Medical Director of Pediatric Dialysis, Duke University

Rajesh Davda, MD, MBA, CPE
National Medical Director, Senior Medical Director, Network Performance Evaluation and Improvement, Cigna Healthcare

Gail Dewald, BS, RN, CNN
Nephrology Nurse, Gail Dewald & Associates LLC

Stuart Greenstein, MD
Professor of Surgery, Montefiore Medical Center

Mike Guffey (Patient/Caregiver Perspective) (*Inactive*)
Business Continuity Manager, UMB Bank (Board of Directors Treasurer, Dialysis Patient Citizens)

Lori Hartwell (Patient/Caregiver Perspective)
President/Founder, Renal Support Network

Frederick Kaskel, MD, PhD
Chief of Pediatric Nephrology, Vice Chair of Pediatrics, Children's Hospital at Montefiore

Myra Kleinpeter, MD, MPH
Associate Professor of Clinical Medicine, Tulane University School of Medicine

Alan Kliger, MD
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Vice President, Medical Director Clinical Integration and Population Health, Yale New Haven Health System

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Karilynne Lenning, MHA, LBSW
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Precious McCowan (Patient/Caregiver Perspective)
National Advocate, ESRD Network

Andrew Narva, MD, FASN
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Jessie Pavlinac, MS, RDN-AP, CSR, LD, FAND
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Jeffrey Silberzweig, MD
Chief Medical Officer, The Rogosin Institute (New York Presbyterian)

Michael Somers, MD
Associate Professor in Pediatrics/Director, Renal Dialysis Unit, Associate Chief Division of Nephrology, American Society of Pediatric Nephrology/Harvard Medical School/Boston Children's Hospital

Cher Thomas, RDH (Patient/Caregiver Perspective)
Patient Advocate

Jennifer Vavrinchik, MSN, RN, CNN
Chief Operating Officer, National Dialysis Accreditation Commission

Bobbi Wager, MSN, RN (Patient/Caregiver Perspective)
Renal Care Coordinator, American Association of Kidney Patients

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