Measure Methodology Report: Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease and End Stage Renal Disease Measure

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Section 1: Introduction

Overview of Project

The Centers for Medicare & Medicaid Services (CMS), through the Center for Medicare and Medicaid Innovation (Innovation Center), has contracted Yale New Haven Health Services Corporation–Center for Outcomes Research and Evaluation (CORE) to develop a Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) Measure. This measure is intended for use in the Kidney Care Choices Model, a new voluntary payment model by the Innovation Center for nephrology practices and CKD-focused providers of care.

The Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure is a re-specification of the National Quality Forum (NQF)-endorsed #0369 Standardized Mortality Ratio for Dialysis Facilities Measure. This re-specification will assess the risk-standardized mortality ratio for patients with Stage 4 or 5 CKD or ESRD. CORE is re-specifying the detailed measure specifications consistent with the approach to outcomes measurement set forth in the NQF guidance for outcome measures[1] and aligning with CMS Measures Management System (MMS) Blueprint guidance[2].

Please see Section 5: Glossary for definitions of key terms used in this report.

Kidney Care Choices Model Background

The Kidney Care Choices Model is designed to test new ways of reimbursing care for Medicare patients with Late-Stage CKD and ESRD. The model will apply financial incentives for nephrology practices and affiliated health care providers that elect to participate in this Model (referred to as "Model participants" throughout). Model participants manage Medicare beneficiaries (referred to as "patients" throughout) with Late-Stage CKD (defined as Stage 4 and 5 CKD), or ESRD, or kidney transplants. More information on the Kidney Care Choices Model can be found on their website: https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model

The goals of the **Kidney Care Choices Model** are to:

- Delay and improve initiation of dialysis for patients with Late-Stage CKD;
- Improve coordination of care between providers caring for patients with Late-Stage CKD and ESRD, which may reduce total cost of care;
- Increase the number of patients receiving kidney transplants; and,
- Increase options for provider risk and payment to improve financial accountability.

The Model plans to implement the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure as part of a set of quality measures that assess the quality of care that Model participants deliver to their patients. This measure of mortality is being developed in conjunction with the development of a measure of progression, the Delay in Progression of CKD Measure. Although the cohort of the Delay in Progression of CKD Measure is a subset of the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure, both measures will likely assess the same Model participants in the Kidney Care Choices Model.

Measure Intent: Mortality as a Quality Indicator

The intent of the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure is to help incentivize the high-quality care of patients with Stage 4 or 5 CKD and ESRD by reducing preventable death related to quality of care. CORE anticipates some unavoidable and "expected" deaths among patients with Late-Stage CKD and ESRD given the severity of the disease and other possible comorbidities. However, better preventive measures, better care coordination, and increased support of effective self-management of CKD can extend life and reduce mortality rates[3].

Mortality is an unwanted outcome for most patients, providing a concrete signal of care quality. Moreover, though CKD is associated with an increase in mortality, evidence supports that access to quality care can reduce mortality[4]. CKD and ESRD often co-occur with other common conditions, including diabetes and heart failure. Interventions that apply appropriate care based on clinical guidelines have shown to have a positive impact on chronic conditions and renal outcomes[5]. Evidence has shown that good care coordination, timely monitoring, and intervention to manage chronic conditions associated with CKD progression such as hypertension, and efforts to support adequate disease self-management, and careful management during dialysis can prevent avoidable deaths[6]. CORE anticipates this mortality measure will promote providers to improve the quality of care for patients with CKD.

Feasibility

This measure uses Medicare claims data to identify beneficiaries with Stage 4 or 5 CKD to include in the cohort and the risk-adjustment variables. Information on ESRD for inclusion in the cohort, as well as the deaths assessed in the outcome, is obtained from the Medicare Enrollment Data Base (EDB). Additionally, the measure will not cause providers to incur additional costs or burden to report. Prior research has demonstrated that administrative claims can be used to assess the quality of care delivered by individual or small clinician groups (for example, use of claims-based Hospital-wide Readmission Measure in the Value Modifier)[7]. These models have demonstrated consistent performance across years of claims data.

Section 2: Methods & Measure Specifications

In the following section, we discuss the measure development process, including CORE's approach, the measure specifications, the data sources used, and methods used for testing.

Approach to Measure Development

CORE and the Innovation Center collaborated to develop this measure. The approach and specifications were informed by input from multiple clinical experts including nephrologists, as well as statistical and methodological experts.

Our goal was to develop measure specifications suitable for the Kidney Care Choices Model that could also be adapted beyond this model for use in other payment programs.

Measure Specifications

This outcome quality measure produces a risk-standardized score for nephrology practices and other kidney care providers treating patients with Stage 4 or 5 CKD, or ESRD.

- The **measure cohort** includes Medicare Fee-For-Service (FFS) patients aged 18 years and older who have received a diagnosis of Stage 4 CKD, Stage 5 CKD, or are enrolled in Medicare ESRD coverage.
- Patients who reach the **measure outcome** are those whose deaths occur during the measurement period.
- The **risk adjustment** model includes age and 70 additional clinical risk factors.
- The **performance score** for providers is a ratio of predicted number of outcome events (deaths) in the year, over the expected number of events.
    - The performance score calculation considers each patient's time eligible for the outcome, using a time-to-event Cox proportional hazard model with frailty.

Data Sources

The **Mortality Development Dataset** consists of Medicare FFS administrative claims and enrollment information from calendar years (CYs) 2017 through 2018 (January 1, 2017 – December 31, 2018) from CMS' Chronic Conditions Data Warehouse and CMS Virtual Research Data Center (CCW/VRDC) and the CMS integrated data repository (IDR). For risk adjustment model performance testing the Mortality Development Dataset is randomly split into a Mortality Development Sample and a Mortality Validation Sample.

To establish data element validity, or the accuracy of a diagnosis of Stage 4 CKD and Stage 5 CKD from International Classification of Diseases, 10th revision (ICD-10) codes in Medicare FFS claims, CORE used a dataset derived from electronic health records (EHR), referred to as **Mortality EHR Dataset**. CORE compared the accuracy of ICD-10 codes from claims with laboratory data (estimated glomerular filtration rate (eGFR) values) from the EHR (patient's medical records). The Mortality EHR Dataset was derived from a single health system and included all patients with any outpatient visit from 2013-2019 with Stage 4 or 5 CKD ICD diagnosis code or had an eGFR lab value under 30 during an outpatient visit. Data included demographics (such as age, sex, gender, race), creatinine/eGFR values, and claims history (comorbidities). Minor data cleaning steps included combining encounters on the same day, removing patients who only had one encounter, and applying the CKD-EPI 2009 equation for encounters where patients only had creatinine measured.[1]

Cohort Definition

The initial patient population was developed to align with the Kidney Care Choices Model, which includes patients with Stage 4 or 5 CKD, or ESRD. The intent was to capture the broadest possible cohort among this population who receive care from nephrology practices or other kidney care providers. Most inclusion criteria align with Kidney Care Choices Model requirements.

Inclusion

Patients are eligible for inclusion in the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure cohort if they are:

- Enrolled in Medicare FFS Parts A and B for one year prior to the performance year (calendar year) as well as the full performance year or until the date of death in the performance year.

[1] Equation can be accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2763564/

    - *Rationale*: Enrollment is required for the year prior to the performance year to ensure sufficient claims for the risk-adjustment model. Continuous enrollment during the performance year is required to ensure complete records for assessing patient outcomes.
- At least 18 years old at the start of the year prior to the performance year.
    - *Rationale*: Pediatric patients only receive Medicare coverage for ESRD requiring dialysis or due to transplantation.
- Patient has at least one of the following:
    - At least one occurrence of ICD-10 code N18.4 (CKD, Stage 4) or ICD-10 code N18.5 (CKD, Stage 5) in at least one claim during the performance year; or,
        - *Rationale*: This establishes a diagnosis of Stage 4 or 5 CKD.
    - Enrolled in ESRD Medicare coverage (either ESRD or ESRD for Dialysis) for at least one day in the measurement period.
        - *Rationale*: This establishes a diagnosis of ESRD.
- Patient is not enrolled in hospice at the time of their Stage 4 or 5 CKD diagnosis or at time of ESRD enrollment.
    - *Rationale*: Patients in hospice care have complex medical needs and have an outcome rate unrelated to Model Participant decision-making or quality of care. The care goals and decisions of patients enrolled in hospice care likely differ from those who are not enrolled in hospice care.
- If patient had a prior kidney transplant, they are not eligible for the measure until one-year post transplant.
    - *Rationale*: Patients are more vulnerable post-transplant to renal injury and have more variable disease staging due to early rejection and other issues related to the procedure rather than to the nephrology care provided.

Exclusion

The measure cohort excludes patients with:

- Metastatic and advanced cancers, defined as specific cancer-related ICD-10 codes from an inpatient encounter. Patients are excluded if coded with advanced or metastatic cancer within one year prior to the earlier date of being attributed to an nephrology practice or having Stage 4, 5 CKD or ERSD in the measurement year based on an inpatient claim with specific ICD-10 codes from the following Condition Categories: CC8, CC10, CC177, CC178 (for full list, refer to Appendix B).
    - *Rationale*: The measure excludes patients with metastatic and advanced cancers since the outcome (mortality) is not a reliable signal of care quality among these patients. Many patients in this population may be too ill for dialysis and have a high risk of mortality; thus, we find it inappropriate to attribute outcomes for these patients to their nephrologists' quality of care.

Outcome Definition

The measure outcome is mortality within the measurement period. The goal of the Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure is to incentivize high quality care for Late-Stage CKD patients by assessing mortality. The measure does not capture CKD-specific mortality because the

cause of death may be unreliably recorded and therefore difficult to attribute as CKD-related or not. It is often difficult to assess whether deaths are related to or attributable to specific causes.

Events Not Counted in the Outcome

The outcome does not count the following event as an outcome of mortality for patients who:

- Enrolled in hospice prior to beginning ESRD enrollment.
    - *Rationale*: Patients in hospice care have complex medical needs and may have an outcome rate unrelated to Model Participant decision-making or quality of care. Hospice enrollment may be due to diseases unrelated to CKD such as a metastatic cancer. Appropriate referral to hospice care should be encouraged.

Attribution

This measure is developed across a national set of nephrology practices. CORE attributed patients to providers using similar methods as the Kidney Care Choices Model alignment. Patient alignment during measure implementation will be completed by the Kidney Care Choices Model. We represented the nephrology practice by their tax identification numbers. For measurement purposes, beneficiaries are attributed to the provider who has the highest number of evaluation and management (E&M) claims or MCP claims for visits with the beneficiary.

To identify the nephrology practice responsible for patient care, we attribute patients to providers based on having at least two encounters with that provider. Specifically, we first identified all the nephrology practices that provided any nephrology specialty services (with specialty code 39) during the performance year. We then identify the eligible patient visits with those nephrology practices by specific Healthcare Common Procedure Coding System (HCPCS) codes prescribed by the Kidney Care Choices Model, listed in Table 1 and Table 2. These tables include eligible Evaluation and Management Coding (E&M) services and/or received monthly capitation payments (MCP) for ESRD/dialysis services. Because the first three months of chronic dialysis entail a high risk of mortality, if a patient dies within that period, the outcome is attributed to the provider with the plurality of pre-dialysis E&M services. If a patient visited multiple practices that provide specialty care, the patient is attributed, 1) to the practice that provided most of the services to the patient; or if there is a tie, 2) to the practice that billed the most for those services; or there is still a tie, 3) the practice who provided the most recent service; or if there is still a tie, 4) a random selected practice.

Table 1. E&M and HCPCS Codes Identifying Providers Who Delivered Nephrology Specialty Services[8]

Service	**HCPCS Codes**
Office/Outpatient Visit E/M	99201-99205 99211-99215
Prolonged E/M	99354-99355
Transitional Care Management Services	99495-99496
Advance Care Planning	99497-99498
Welcome to Medicare and Annual Wellness Visits	G0402, G0438, G0439
Chronic Care Management Services	99490

Table 2. MCP HCPCS Codes Identifying Providers Who Delivered Nephrology Specialty Services

Service	CPT Codes
ESRD related services monthly, for patients 12-19	90957-90959
ESRD related services monthly, for patients 20 years of age and older	90960-90962
End-Stage Renal Disease Services	90965, 90966

Patients enter the cohort and begin being contributing at-risk time with the following parameters:

- The patient enters the measure at "t_0" or "time zero," which begins when the beneficiary is both attributed to a nephrology practice (See Attribution) and has a confirmed diagnosis of Stage 4 or 5 CKD or is enrolled in ESRD. Beneficiaries are required to have at least one CKD Stage 4 or 5 claim or ESRD enrollment during the measurement year. For attribution, beneficiaries are required to have two visits with the same nephrology practice with at least one occurring in the measurement year. So, the first nephrology visit can occur in the prior year. The t_0 is the last date among: 1) the start of the measurement year (if continuing care from the prior year); 2) the start of the attribution to the provider (two touches); or, 3) the start of the CKD Stage 4 or 5 (one or more claims) or one or more enrollment period for ESRD.

The patient will leave the cohort (stop contributing at-risk time) if they:

- Enroll in Medicare hospice during the measurement period
- Die (have an outcome event).

Approach to Risk Adjustment

In this section, we describe the conceptual basis for risk adjustment, our rationale for candidate variables including consideration of clinical and social risk factors, and our approach to selecting final variables from the candidate variables. CORE developed the risk model by using data from claims.

The goal of risk adjustment is to account for differences among nephrology practices in patient demographic and clinical characteristics. The measure incorporates risk adjustment to account for factors that are associated with the outcome, vary across providers, and are unrelated to quality of care so that measure scores reflect differences in care quality. Accounting for case-mix differences is important because it recognizes that some providers care for older, sicker patients who have higher mortality rates. Through the risk-adjustment modeling, a higher expected outcome rate is set for providers who care for patients with certain risk factors. We identified potential candidate risk factors using a focused literature search, clinical experts' input, and empirical analysis. We used logistic regression with a binary outcome to select risk variables for final models.

Candidate Clinical and Demographic Risk Variables

We considered age and medical history (comorbidities/frailty) as candidate variables.

- Comorbidities for inclusion in risk adjustment were identified through inpatient and outpatient administrative claims during the twelve months prior to entering the cohort.
- We used publicly available CMS condition categories (CMS-CCs) to group ICD-10 diagnosis codes into CMS-CCs, and selected comorbidities based on clinical relevance and statistical significance.

- We aligned with other CMS outcome measures by using the Yale-Modified FY20 v24 CC Map that contains 197 CMS-CCs.

Final Risk Variable Selection

Figure 1. Risk Variable Selection Flowchart for Late-Stage CKD and ESRD Mortality Measure

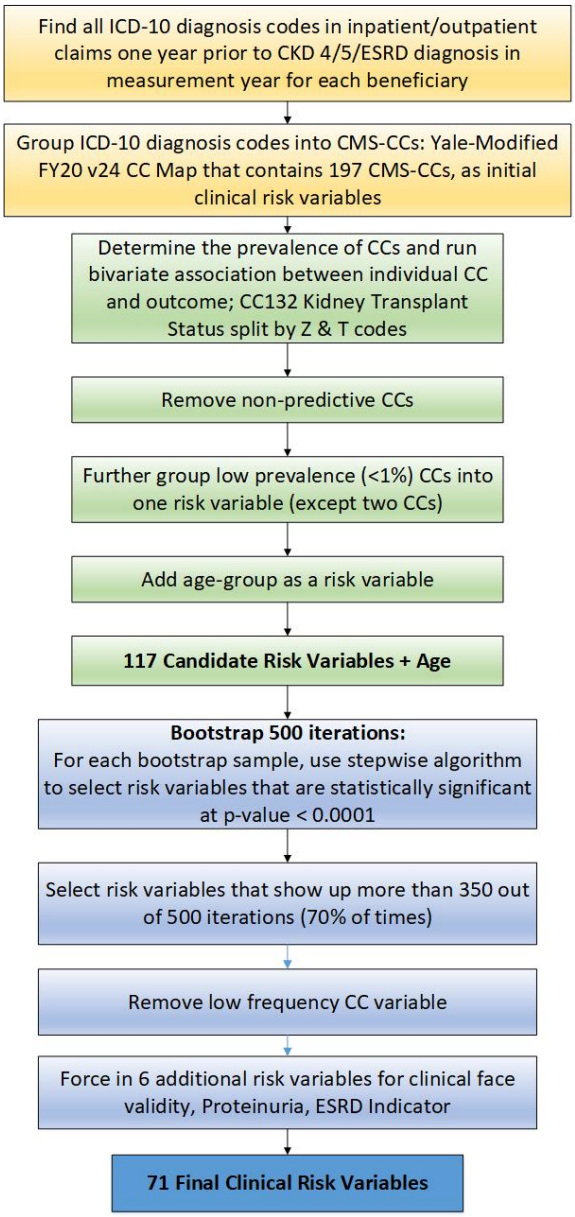


Figure 1 above is a flowchart depicting the process of selecting clinical risk variables for the model.

To select candidate clinical variables (yellow and green boxes in flowchart):

- We examined all condition categories (CMS-CCs).
- Examined frequencies and bivariate associations with outcome (including odds ratios) of all CMS-CCs.

- CC CMS-CCs that were not statistically significant were removed, unless deemed clinically relevant to the outcome by expert nephrologists (ex: diabetic-related CC). Statical significance was defined by having a p-value less than 0.05 (14 CC removed).
- CMS-CCs with low frequency (<1% of cohort), were grouped into one variable, except for CC1 HIV/AIDS and CC51 Dementia with Complications (48 CC grouped).
- CC132 Kidney Transplant Status was split into two: CC132Z ICD-10-CM codes beginning with 'Z' (codes indicating general aftercare or status); and CC132T ICD-10-CM codes beginning with 'T' (codes indicative of a kidney failure or complication).

This process resulted in 117 candidate risk variables shown in Appendix A.

We selected the final set of risk variables using bootstrap methods (blue boxes in flowchart, above) using logistic regression from the candidate variables:

- 500 random samples were generated with replacement.
- For each of the 500 samples, a logistic regression model (binary outcome) was selected by using backward selection approach.
- All variables significant at p<0.0001 were retained in each final bootstrap risk model. For each variable, we note its % retained in the 500 bootstrap models.
- We then selected all variables that were retained in the model which are above 70% threshold (cut-off). The threshold for cut-off was based on clinical and statistical evaluation to have a clinically meaningful, statistically robust, and parsimonious risk model.
    - Low frequency CC variable was removed. This group was very heterogeneous; removing aligns with many other measures that excluded prior to bootstrap results.
    - Six additional CCs were included that were below the 70% cut-off, for face validity, per our expert nephrologists (Diabetes with Chronic Complications [CC18], Diabetes without Complication [CC19], Unstable Angina and Other Acute Ischemic Heart Disease [CC87], Dialysis Status [CC134], Acute Renal Failure [CC135], Unspecified Renal Failure [CC 140])
    - Proteinuria identified by ICD-10 code (R80.9) was included as a risk variable (aligns with Progression Measure). We included the Proteinuria code as a separate variable based on input from nephrologists regarding its clinical relevance and importance for face validity.
- We then examined the impact of several variables interacting with others, and the impact of including ESRD coverage as a risk variable. Deeper investigation on variable interactions will be conducted during reevaluation.
    - ESRD coverage was added as a risk variable.

There are 71 final risk variables, shown in Table 4. We evaluated the performance of the model in Cox model with the selected risk factors.

Candidate Social Risk Variables

A patient's progression to mortality is likely influenced by their social risk factors (SRFs). Kidney care providers have the ability to address these SRFs and mitigate the impact on progression. We consider whether to adjust for SRF using a comprehensive approach that evaluates the following:

1. Conceptual influence of SRFs on measure outcome (and provider role)
2. Feasibility of utilizing meaningful SRFs in available data

3. Empiric testing of SRFs for inclusion in the measure risk models

As a starting principle, recent ASPE report recommends against SRF adjustment for outcome measures.

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of mortality are varied and complex. Some social risk factors may, for instance, influence the patient's ability to manage self-care such as following dietary recommendations. However, the best quality care should reduce mortality for all patient groups, especially if tailored to a particular patient's situation and preferences. Therefore, the conceptual rationale for risk-adjustment is limited.

We first compiled initial list of SRFs to consider, using the National Academies of Sciences, Engineering, and Medicine (NASEM) report framework which categorized social risk factors into the four domains:

- Socioeconomic status;
- Race, ethnicity (not social risk factors but proxy for the social risk factor of exposure to systemic racism), and cultural factors;
- Social relationships; and
- Residential and community context

Second, we identified candidate SRFs for analyses, based on:

- Internal hypotheses regarding the relationships between the SRF and mortality for patients with CKD and ESRD;
- Potential / perceived ability of a kidney care provider to mitigate the SRF; and
- Data availability and feasibility, including level of analysis (availability of patient-level or area-level data).

Among candidate SRFs, we identified the corresponding variable from different data sources and linked them to the test dataset based on the related beneficiary information. The candidate social risk variables considered are listed in Table 3, which includes social risk factors from Medicare FFS claims being dual eligibility for Medicare and Medicaid, Agency for Healthcare Research and Quality (ARHQ) socioeconomic status (SES) index, and being an urban resident.

Table 3. Candidate Social Risk Factors

Variable	Description	Data level
Dual-eligible	Dual-eligible for Medicare and Medicaid vs. Medicare-only (ref)	Beneficiary
Race	Each race vs. white race (ref). Note: Medicare administrative claims data are not a reliable source for accurate race information except for black race, as noted in the literature. Included here as above to explore general impact using available data	Beneficiary
AHRQ SES index	Socioeconomic status indicator (higher score = less social risk)	Zip code
Urban resident	Residence in metro area county (ref) vs. non-metro county (suburban and rural are considered non-urban)	County

Methods for testing each social risk factor included examining the distribution of SRFs, bivariate (unadjusted) relationships of SRFs with progression, risk adjusted relationships, and risk model performance when incorporating SRFs including impact on provider performance scores.

Risk Model Performance

CORE computed summary statistics to assess model performance: calibration (a measure of over-fitting), discrimination in terms of predictive ability, and discrimination in terms of c-statistic (see below).

Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and the outcome well in the Development Sample and does not produce valid predictions in new patients in the Validation Sample. A model without over-fitting is desirable. CORE calculates one set of statistics, with two parameters, for over-fitting using Validation Sample and models built with Development Sample: γ0 and γ1. If the γ0 in the validation sample is close to zero and the γ1 is close to 1, there is little evidence of over-fitting.

Discrimination in predictive ability measures the ability to distinguish high-risk patients from low-risk patients. It is desirable to see a big difference of observed outcome rates between the lowest decile and highest decile ranked by predicted probabilities.

The c-statistic is a summary score of how accurately a statistical model can distinguish between a patient with and without an outcome. For binary outcomes, the c-statistic is identical to the area under the Receiver Operator Curve (ROC). For time to event outcomes, we examined the Harrel's C-statistic, a concordance statistic that can be considered as a generalization of C-statistic for binary outcome.

A c-statistic of 0.50 indicates random prediction, implying all patient risk factors do not predict better then random change. A c-statistic of 1.0 indicates perfect prediction, implying patients' outcomes can be predicted completely by their risk factors. While higher c-statistic is desirable, we do not want to maximize it by adjusting for factors that should not be adjusted for because they are a signal of variation in quality of care.

Measure Score Calculation and Testing

The measure score is standardized mortality ratio, defined as the ratio of:

- The number of mortality events that predicted for eligible patients seen by provider given their case mix, provider quality, and length of time patients were observed in the cohort; over
- The number of mortality events that would be expected given the patient case mix in the cohort, an average providers' quality, and length of time patients were observed in the cohort.

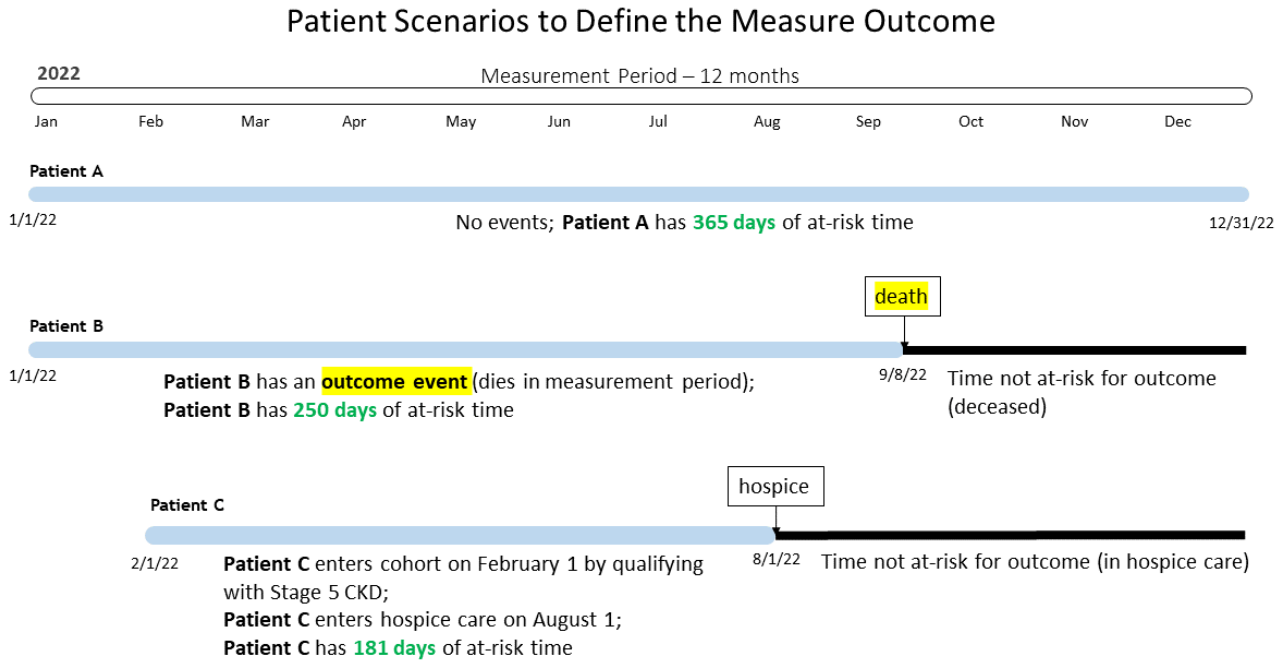
The Measure uses a time-to-event outcome, which includes the time to reach the outcome of mortality. Specifically, the start time (at-risk time) from each beneficiary is calculated from when beneficiary becomes eligible in the measurement period (see Attribution) until the earliest time of either: date of death (outcome); enrollment in Medicare hospice date; or end of measurement period. The event of interest is mortality during the measure year. This approach to assessing the outcome aligns with the current NQF-endorsed measure.

The outcome, or events in the numerator, are death events. Patients who enroll in hospice have their time included in the denominator from time zero (when they are eligible for cohort) until the time that

they enroll in hospice. Once enrolled in hospice they are 'censored' and stop contributing at-risk time to the denominator. The measure does not consider patient mortality while enrolled in hospice. Patients are not excluded from the cohort altogether because they should contribute at-risk time for the measure outcome (mortality) prior to their enrollment in hospice.

Hospice rationale: Enrollment in hospice is an indicator of terminal illness, whether due to CKD or not, and by not counting deaths that occur after a patient is enrolled in hospice this measure will encourage thoughtful end-of-life decision-making. This approach risks that some providers may use hospice enrollment to avoid having a poor-quality score, but CORE believes this in unlikely to undermine overall assessment of quality.

Figure 2. Time-to-Event Outcome Examples



Measure Score Calculation Details

Assume that the hazard function of an event for patient *i* serviced by provider *j*, with a vector of risk factors $\boldsymbol{X}_{ij}$ is defined as a frailty model under the proportional hazard framework:

$$h_{ij}(t_{ij}) = w_j h_0(t_{ij}) \exp(\boldsymbol{X_{ij}\beta}),$$

where w_j is the frailty (exponential of a random effect) for each provider *j*.

So, for the patient *ij*, the predicted probability of mortality at time t as cumulative hazard at the time t_{ij}[9]

is

$$P_{ij} = H_{ij}(t_{ij}) = \int_0^{t_{ij}} w_j h_0(t) \exp(X_{ij}\beta)\, dt = w_j \exp(X_{ij}\beta) \int_0^{t_{ij}} h_0(t) dt = w_j \exp(X_{ij}\beta) H_0(t_{ij})$$

Correspondingly, the expected probability of mortality, the probability of death is the patient taken care by an average provider, is calculated by setting w_j=1 :

$$E_{ij} = \exp(X_{ij}\beta) H_0(t_{ij})$$

The measure score, the risk standardized chronic kidney disease mortality ratio (RSCKDMR), in a frailty model for provider j will be the frailty estimation w_j, since

$$\text{RSCKDMR}_j = \frac{predicted\ number\ of events}{expected\ number\ of\ events} = \frac{\sum_{i=1}^{n_j} P_{ij}}{\sum_{i=1}^{n_j} E_{ij}} = \frac{w_j \sum_{i=1}^{n_j} \exp(X_{ij}\beta) H_0(t_{ij})}{\sum_{i=1}^{n_j} \exp(X_{ij}\beta) H_0(t_{ij})} = w_j$$

Where n_j is the number of patients seeing provider j.

For frailty, we used a lognormal distribution, or log(w_j)~ N(0,θ), where median (w_j)=1.

The confidence interval for the ratio of the *RSCKDMR* (in other words, the frailty) is a direct output from the estimation software.

The final measure score, Risk Standardized Incidence Rate (RSIR), is calculated as RSIR = RSCKDPR * IR,

where *IR* is the national incidence rate calculated as number of mortality events in the measurement year divided by total patient years times 100.

Measure Score Variation

CORE examined the extent of RSCKDMR variation across providers using summary statistics: mean, standard deviation (SD), median, interquartile ranges (IQR).

Reliability

For **data element reliability**, this measure will use routinely submitted claims data to identify the measure's cohort, risk-adjustment variables, and outcome. Using claims data imposes no costs on providers and eliminates provider burden, which is important since providers have limited time to dedicate to reporting. Prior research has demonstrated that administrative claims for comorbidity history can be used to assess the quality of care delivered by individual or small clinician groups (for example, use of claims-based Hospital-Wide Readmission Measure in the Value Modifier). These models have demonstrated consistent performance across years of claims data and using administrative claims for risk model purposes has historically performed well. CMS claims (not specific to the KCC Model) are regularly audited, which further supports their validity in measure development. For more information on the audit process, please refer to the following resource: https://www.cms.gov/files/document/2020-program-audit-process-overview.pdf.

For **measure score reliability**, we calculated signal-to-noise reliability scores for nephrology practices. We used the formula for signal-to-noise reliability presented by Adams et al. to calculate individual clinician-level and TIN-level reliability scores[10]. To estimate the overall signal and noise, we first

calculated the ICC for the Model Participant, j, using the estimates of between-entity variance τ^2 and the formula for intraclass correlation coefficient (ICC) presented by Shrout and Fleiss[11]. Specifically, the signal-to-noise reliability score for Model Participant, *j*, R_j, is calculated as:

$$R_j = \frac{n_j ICC}{1 + (n_j - 1)ICC}$$

where

$$ICC = \frac{\tau^2}{\tau^2 + \pi^2/6\gamma^2}$$

n_j is the number of beneficiaries for the nephrology practice j, τ^2 is the between agency variance in a Weibull model with lognormal frailty that used to approximate the Cox model with lognormal frailty specified above. The τ^2 represents the signal variance, and $\pi^2/6\gamma^2$ represents the noise variance and γ is the shape parameter of the Weibull distribution.

So, R_j ranges from 0 to 1.0. The higher the score, the higher the reliability. Also, we can see that the reliability of agency measure score will vary depending on the number of beneficiaries (volume) attributed to a practice. Entities with higher volume will tend to have more reliable scores, while those with lower volume will tend to have less reliable scores.

Validity

For **data element validity**, an EHR Dataset was used to compare the accuracy of ICD-10 claims diagnoses of Stage 4 and 5 CKD with laboratory results (eGFR values) from patient's medical records. For each encounter with a Stage 4 or 5 CKD diagnosis (claim), we defined a positive 'match' if the patient had an eGFR of 15-29 (Stage 4) or an eGFR under 15 (Stage 5) within 6-month (180 days) prior, or 30-days after diagnosis. Timeframe based on clinical guidelines that a stable patient with Stage 4 CKD should see their provider every 3-6 months. Matching looks forward to account for labs ordered during the patient visit but drawn and resulted weeks later.

For **measure score validity**, we assessed how the standard mortality ratio measure correlated with other quality measures among providers also caring for patients with ESRD. There were no other outcome or quality measures for patients with Stage 4 or 5 CKD. Assessment of measure validity was conducted through comparison to external measures from the CMS Merit-based Incentive Payment System (MIPS) program.

CORE identified suitable measures through a multi-step process which ensured that the measures have performance score data available among a number of providers included in the Late-Stage CKD and ESRD Mortality Measure. We developed a priori hypotheses about the potential relationship between each measure and the Mortality Measure. We selected three measures from the MIPS program for comparison (Validity Results section below).

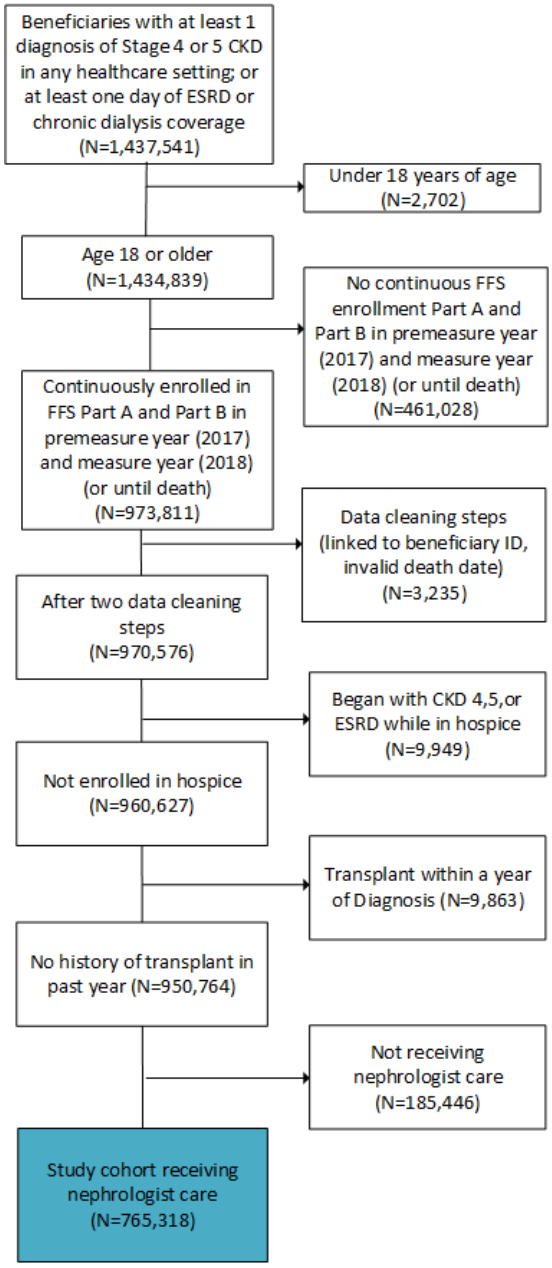
Section 3: Results

Details on data sources results are outlined in Data Sources Section above, and each analysis is labeled by dataset, below.

Measure Cohort

Figure 3 below shows the cohort flowchart, with the number of patients remaining in the cohort and the number being excluded. The cohort began with over one million patients with either a Stage 4 or CKD claim, or at least one day of ESRD (or ESRD for dialysis) enrollment in the measurement period (2018), then were restricted to those 18 years of age and older, enrolled in Medicare FFS Part A and Part B, leaving 973,811 patients. After cleaning the data to ensure dates of death were valid, the cohort excluded patients who were enrolled in hospice at the time of their first CKD Stage 4 or 5 code, or ESRD from enrollment data, or received a transplant within a year of their CKD Stage 4 or 5 code, or ESRD enrollment, leaving 950,764 patients. Patients who were coded with advanced or metastatic cancer in an inpatient setting in the year prior to the measurement year were also excluded. Finally, the cohort was narrowed to those patients receiving nephrologist care, so that patients could be attributed to a provider. The final cohort in **Mortality Development Dataset** contained 758,162 patients.

Figure 3. Measure Cohort Flowchart, Mortality Development Dataset



Details on patient demographics of the Mortality Development Dataset in Table 4 shows the mean age at 70.1 years old with a standard deviation (SD) of 13.8 years (minimum of 18, and maximum of 109), with a slight majority male. The majority of patients are White at 66.7%, and 22.4% are Black. Twenty-five percent are dual-enrolled in both Medicare and Medicaid. This is in part due to the inclusion of Medicare patients between 18 and 65, who are frequently enrolled in both Medicare and Medicaid.

Table 4. Patient Characteristics, Mortality Development Dataset (N=758,162)

Total Patients	**N**	**%**
Age in the pre-measure year (2017)	-	-
Mean (SD)	70.14	13.8
Minimum, Maximum	18	109.0
P1, P99	31	94.0
Q1, Q3	63	80.0
Q2 (QR)	72	17.0
Gender	-	-
Male	391,058	51.6
Female	367,104	48.4
Race	-	-
Unknown	7,739	1.0
White	505,872	66.7
Black	169,736	22.4
Other	15,159	2.00
Asian	20,416	2.7
Hispanic	30,698	4.1
North America Native	8,542	1.1
Dual in 2018	-	-
Missing	6	0.0
No	565,854	74.6
Yes	192,302	25.4

Final Risk Variable Selection

The final 70 risk variables with frequencies, estimates, and hazard ratios (HR) with 95% confidence interval (similar interpretation to odds ratio) using Cox Proportional Hazard Model with Frailty Regression Model are listed in Table 5, below.

Table 5. Parameter Estimates for Final Risk Variables Using Cox Proportional Hazard Model with Frailty Regression Model (N= 758,162 Patients)

Description (CC#)	**%**	**Estimate (Standard Error)**	**Hazard Ratio (LHR-UHR)**
Age (mean (standard deviation))	70.14 (13.76)	0.02 (0)	1.018 (1.017-1.019)
Proteinuria: DX Code of R80.9	16.05	-0.09 (0.01)	0.911 (0.887-0.936)
ESRD-Dialysis Enrollment	39.28	-0.15 (0.02)	0.856 (0.823-0.892)
Metastatic Cancer and Acute Leukemia (CC 8)	1.62	0.48 (0.03)	1.612 (1.523-1.706)
Lung and Other Severe Cancers (CC 9)	3.61	0.21 (0.02)	1.231 (1.184-1.28)

Description (CC#)	%	Estimate (Standard Error)	Hazard Ratio (LHR-UHR)
Lymphoma and Other Cancers (CC 10)	2.72	0.15 (0.02)	1.163 (1.110-1.218)
Colorectal, Bladder, and Other Cancers (CC 11)	6.09	0.01 (0.02)	1.012 (0.977-1.048)
Other Digestive and Urinary Neoplasms (CC 14)	10.04	-0.10 (0.01)	0.902 (0.878-0.927)
Diabetes with Acute Complications (CC 17)	2.62	0.12 (0.02)	1.129 (1.084-1.177)
Diabetes with Chronic Complications (CC 18)	59.76	0.11 (0.01)	1.118 (1.089-1.148)
Diabetes without Complication (CC 19)	58.15	0.04 (0.01)	1.039 (1.013-1.066)
Protein-Calorie Malnutrition (CC 21)	9.39	0.11 (0.01)	1.114 (1.088-1.14)
Morbid Obesity (CC 22)	14.12	-0.10 (0.01)	0.902 (0.881-0.924)
Disorders of Fluid/Electrolyte/Acid-Base Balance (CC 24)	57.29	0.10 (0.01)	1.104 (1.081-1.127)
Disorders of Lipoid Metabolism (CC 25)	80.52	-0.17 (0.01)	0.844 (0.824-0.863)
End-Stage Liver Disease (CC 27)	1.94	0.25 (0.03)	1.286 (1.224-1.351)
Cirrhosis of Liver (CC 28)	3.27	0.31 (0.02)	1.365 (1.312-1.421)
Disorders of the Vertebrae and Spinal Discs (CC 41)	23.67	-0.09 (0.01)	0.918 (0.900-0.936)
Osteoporosis and Other Bone/Cartilage Disorders (CC 43)	25.81	-0.09 (0.01)	0.910 (0.893-0.927)
Severe Hematological Disorders (CC 46)	2.71	0.17 (0.02)	1.181 (1.134-1.23)
Coagulation Defects and Other Specified Hematological Disorders (CC 48)	17.63	0.09 (0.01)	1.09 (1.068-1.111)
Iron Deficiency and Other/Unspecified Anemias and Blood Disease (CC 49)	81.54	0.12 (0.02)	1.127 (1.094-1.162)
Delirium and Encephalopathy (CC 50)	11.39	0.10 (0.01)	1.104 (1.079-1.13)
Dementia With Complications (CC 51)	2.28	0.13 (0.02)	1.140 (1.090-1.193)
Dementia Without Complication (CC 52)	10.96	0.11 (0.01)	1.121 (1.094-1.149)
Depression (CC 61)	18.38	0.00 (0.01)	0.999 (0.978-1.019)
Parkinson's and Huntington's Diseases (CC 78)	1.88	0.02 (0.03)	1.016 (0.963-1.072)
Seizure Disorders and Convulsions (CC 79)	5.71	0.05 (0.02)	1.056 (1.025-1.088)
Cardio-Respiratory Failure and Shock (CC 84)	18.28	0.18 (0.01)	1.193 (1.167-1.22)
Congestive Heart Failure (CC 85)	49.53	0.36 (0.01)	1.427 (1.396-1.458)
Acute Myocardial Infarction (CC 86)	8.88	0.18 (0.01)	1.202 (1.174-1.231)
Unstable Angina and Other Acute Ischemic Heart Disease (CC 87)	7.69	0.03 (0.01)	1.026 (1-1.053)
Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease (CC 89)	48.43	0.15 (0.01)	1.160 (1.137-1.183)
Valvular and Rheumatic Heart Disease (CC 91)	32.03	0.12 (0.01)	1.131 (1.111-1.152)
Hypertension (CC 95)	91.62	-0.22 (0.02)	0.805 (0.779-0.832)
Specified Heart Arrhythmias (CC 96)	33.16	0.22 (0.01)	1.252 (1.229-1.275)

Description (CC#)	%	Estimate (Standard Error)	Hazard Ratio (LHR-UHR)
Atherosclerosis of the Extremities with Ulceration or Gangrene (CC 106)	4.12	0.07 (0.02)	1.073 (1.036-1.111)
Vascular Disease (CC 108)	43.41	0.08 (0.01)	1.086 (1.066-1.106)
Other Circulatory Disease (CC 109)	37.61	0.08 (0.01)	1.081 (1.062-1.101)
Chronic Obstructive Pulmonary Disease (CC 111)	25.81	0.16 (0.01)	1.173 (1.151-1.196)
Fibrosis of Lung and Other Chronic Lung Disorders (CC 112)	5.40	0.08 (0.02)	1.087 (1.055-1.121)
Asthma (CC 113)	11.18	-0.10 (0.01)	0.902 (0.880-0.924)
Viral and Unspecified Pneumonia, Pleurisy (CC 116)	23.04	0.09 (0.01)	1.097 (1.074-1.12)
Pleural Effusion/Pneumothorax (CC 117)	18.25	0.24 (0.01)	1.270 (1.244-1.297)
Other Respiratory Disorders (CC 118)	43.32	-0.04 (0.01)	0.963 (0.945-0.981)
Other Ear, Nose, Throat, and Mouth Disorders (CC 131)	37.88	-0.09 (0.01)	0.911 (0.895-0.926)
Kidney Transplant Status: ICD-10-CM codes beginning with 'Z' (CC 132Z) (Z4822 Encounter for aftercare following kidney transplant; and Z940 Kidney transplant status)	6.98	-0.26 (0.02)	0.769 (0.739-0.801)
Dialysis Status (CC 134)	39.74	0.19 (0.02)	1.214 (1.165-1.265)
Acute Renal Failure (CC 135)	35.29	0.13 (0.01)	1.137 (1.114-1.16)
Chronic Kidney Disease, Stage 5 (CC 136)	49.74	0.06 (0.02)	1.066 (1.034-1.099)
Chronic Kidney Disease, Severe (Stage 4) (CC 137)	61.70	-0.46 (0.01)	0.630 (0.615-0.644)
Chronic Kidney Disease, Moderate (Stage 3) (CC 138)	48.60	-0.13 (0.01)	0.877 (0.857-0.897)
Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified) (CC 139)	72.26	-0.08 (0.01)	0.928 (0.909-0.947)
Unspecified Renal Failure (CC 140)	16.19	0.01 (0.01)	1.008 (0.987-1.028)
Nephritis (CC 141)	6.51	-0.10 (0.02)	0.904 (0.873-0.936)
Other Urinary Tract Disorders (CC 145)	42.04	-0.07 (0.01)	0.930 (0.914-0.947)
Pressure Ulcer of Skin with Full Thickness Skin Loss (CC 158)	2.83	0.11 (0.02)	1.114 (1.072-1.157)
Pressure Ulcer of Skin with Partial Thickness Skin Loss (CC 159)	3.02	0.12 (0.02)	1.130 (1.089-1.171)
Pressure Pre-Ulcer Skin Changes or Unspecified Stage (CC 160)	3.82	0.14 (0.02)	1.151 (1.112-1.19)
Chronic Ulcer of Skin, Except Pressure (CC 161)	11.62	0.21 (0.01)	1.235 (1.203-1.267)
Cellulitis, Local Skin Infection (CC 164)	19.28	0.10 (0.01)	1.101 (1.078-1.124)
Vertebral Fractures without Spinal Cord Injury (CC 169)	2.27	0.15 (0.02)	1.167 (1.116-1.221)

Description (CC#)	%	Estimate (Standard Error)	Hazard Ratio (LHR-UHR)
Other Injuries (CC 174)	35.56	0.09 (0.01)	1.094 (1.074-1.114)
Major Symptoms, Abnormalities (CC 178)	82.78	0.15 (0.02)	1.158 (1.123-1.195)
Amputation Status, Lower Limb/Amputation Complications (CC 189)	5.45	0.18 (0.02)	1.200 (1.163-1.237)
Chemotherapy (CC 193)	5.17	0.02 (0.02)	1.016 (0.977-1.057)
Screening/Observation/Special Exams (CC 195)	90.69	-0.25 (0.01)	0.782 (0.759-0.805)
Supplemental Oxygen (CC 197)	6.54	0.24 (0.01)	1.266 (1.233-1.299)
Wheelchairs, Commodes (CC 200)	1.57	0.16 (0.02)	1.179 (1.126-1.235)
Alcohol/Cannabis Use or Use Disorder, Mild or Uncomplicated; Non-Psychoactive Substance Abuse; Nicotine Dependence (CC 203)	12.70	0.11 (0.01)	1.114 (1.089-1.14)

CC = condition category (groups of ICD-10 codes); LHR = lower hazard ratio; UHR = upper hazard ratio

Risk Model Performance

The Harrel's C-statistic, evaluating the risk model using Cox proportional hazard model, is 0.751.

Results in Table 6 include summary statistics to assess model performance used logistic regression: calibration (a measure of over-fitting), discrimination in terms of predictive ability, discrimination in terms of c-statistic.

The c-statistic indicated strong model discrimination across the development and validation models. There was good calibration of the model between development and validation datasets. We observed a wide range between lowest decile and highest decile of patient risk.

Table 6. Risk Model Performance, Mortality Development Dataset (N=758,162)

Model Performance Statistic	Derivation Dataset	Validation Dataset
Number of Patients	379,081	379,081
Mortality Rate	7.92%	7.98%
C-statistic	0.734	0.734
Calibration (γ0, γ1)	(0, 1)	(-0.001, 0.996)
Discrimination- Predictive ability (lowest decile %- highest decile %)	(1.2%, 22.9%)	(1.2%, 23.1%)

Measure Score Calculation Results

Below, measure score variation, reliability, and validity are presented and discussed.

Measure Score Variation

Examination of provider-level risk-standardized ratio results in Table 7 below, including measure scores for all nephrology practices and those with at least 25 patients, along with their summary statistics such as mean (SD), median (IQR), and the minimum (min) and maximum (max). We are using 25 as an example minimum case count.

As shown by these distributions of the performance score, there was a substantial gap in performance, with the mortality risk standardized ratio varying across providers.

Table 7. Measure Performance Statistics (Risk-Standardized Ratio) for All Providers and Providers with 25 or More Patients, Mortality Development Dataset

Statistics	**All Nephrology Practices (N=3,009)**	**Nephrology Practices with 25 + Patients (N=2,403)**
Mean (SD)	1.01 (0.11)	1.00 (0.12)
Median (IQR)	1.00 (.95-1.05)	0.99 (.93- 1.07)
Range (min-max)	(0.68- 1.65)	(0.68- 1.65)

Reliability

Table 8 below has the signal-to-noise reliability statistic among all providers and those with 25 or more cases, showing the mean, standard deviation, and median, quartiles, minimum and maximum. We are using 25 as an example minimum case count.

The variation between entities ('signal') comprises the total variation ('noise' and 'signal') in the outcome; signal-to-noise is a statistic from 0-1, where closer to one is interpreted as having more of a quality signal than noise. Looking at the median, even among all nephrology practices, at least half of the providers have a reliability over 0.7 and those with at least 25 cases at least half have reliability of 0.8.

Table 8. Signal-To-Noise Reliability Statistics Among All Nephrology Practices and Those With At Least 25 Cases, Mortality Development Dataset

Description	**N Providers**	**Mean (SD)**	**Median**	**Q1 (Q3)**	**Min – Max**
Among All Nephrology Practices	3009	0.623 (0.286)	0.703	0.430 (0.867)	0.021-0.990
Among Nephrology Practices with at least 25 cases	2403	0.742 (0.173)	0.783	0.608 (0.891)	0.344-0.990

Validity

Data element validity using the Mortality EHR Dataset, which included 7,599 patients, described further below in Table 9. This dataset did not contain identifying provider information, so analyses were at the patient-level.

Table 9. Patient Demographics, Mortality EHR Dataset Cohort, 7,599 Patients (2013-2019)

Total patients – EHR dataset	**N**	**%**
All	7,599	100.00
Age (from DOB to 06/01/2021)	-	-
Mean, Standard Deviation	72.81	15.40
Minimum, Maximum	20	109
P1, P99	31	101

Total patients – EHR dataset	N	%
Q1, Q3	63	85
Median, QR	74	21
Gender	-	-
Male	3,858	50.77
Female	3,741	49.23
Race	-	-
American Indian or Alaska Native	19	0.25
Asian	119	1.57
Black or African American	1,796	23.63
Native Hawaiian	2	0.03
Native Hawaiian or Other Pacific Islander	11	0.14
Patient Refused	68	0.89
White or Caucasian	5,073	66.76
Other	135	1.78
Other Pacific Islander	2	0.03
Other/Not Listed	351	4.62
Unknown	22	0.29
Ethnicity	-	-
Hispanic or Latino	656	8.63
Non-Hispanic	6,897	90.76
Patient Refused	18	0.24
Unknown	27	0.36

The match rate for Stage 4 CKD, which was if the patient had an eGFR of 15-29 within 6-months (180 days) prior, or 30-days after diagnosis, was 82%. Additional analysis showed the match rate within 15-days prior (or +30 days) to be 78.5%.

The match rate for Stage 5 CKD corresponding to an eGFR of under 15 within 6-months (180 days) prior, or 30-days after diagnosis, was 85.3%. Additional analysis showed the match rate within 15-days prior (or +30 days) to be 83.6%.

We interpret these match rates to show adequate data element validity. There were many limitations with this dataset. Some laboratory data may be captured outside of this EHR system. Additionally, patients often fluctuate between stages, so eGFR in the clinical chart and codes from administrative claims are not expected to be perfectly matched. Despite these limitations, this analysis shows that for most patients identified as Stage 4 and Stage 5 CKD in claims/condition coding, a relevant and timely measure of eGFR confirmed this staging to be correct. The data element for ESRD is derived from Medicare enrollment status which is audited by CMS and considered to be reliable and valid.

The **measure score validity** is supported first by these considerations:

- Mortality, in patients with CKD and ERSD, has inherent face validity as a quality measure; we have provided evidence of data element validity to demonstrate capture of patients with CKD and ERSD in claims.
- The CKD and ESRD Mortality Measure was originally based on the Standardized Mortality Ratio for Dialysis Facilities (NQF#0369) measure that has been deemed valid and is currently NQF-endorsed.

In order to provide assurance that the measure performs well in reference to an independent standard, we tested the calibration of the patient-level risk model for the patients in the expanded cohort (compared to NQF#0369, which primarily includes patients with ESRD only). Using a patient-level logistic regression model to obtain predicted death risk for two subgroups: (1) ESRD patients and (2) Stage 4/Stage 5 CKD patients (using the same model coefficients from the entire combined cohort), we compared to the observed mortality across deciles of the predicted values as shown in Figures 4 and 5. The overall mortality risk was 11.0% among the ESRD subgroup and 6.0% among the Stage 4/Stage 5 CKD subgroup. The bottom-decile predicted risk was 2.7% for ESRD and 1.7% for CKD; the top-decile predicted risk was 30.1% for ESRD and 17.5% for CKD.

Figure 4. Comparison of Observed Mortality Risk Across Deciles of Predicted Values for ESRD subgroup (n=297,787)

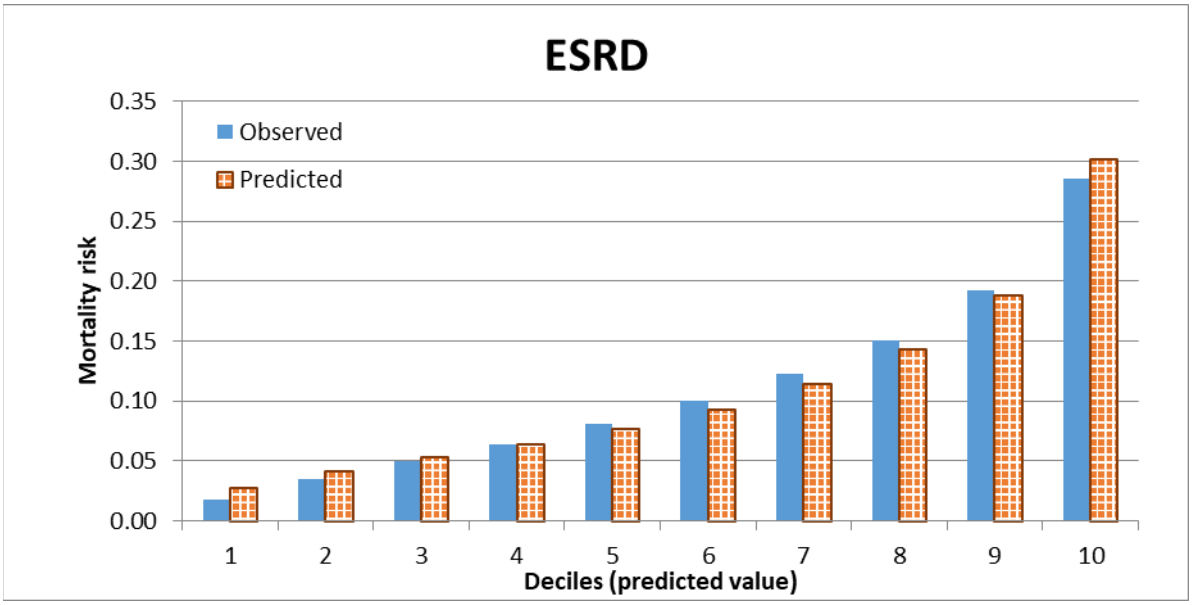
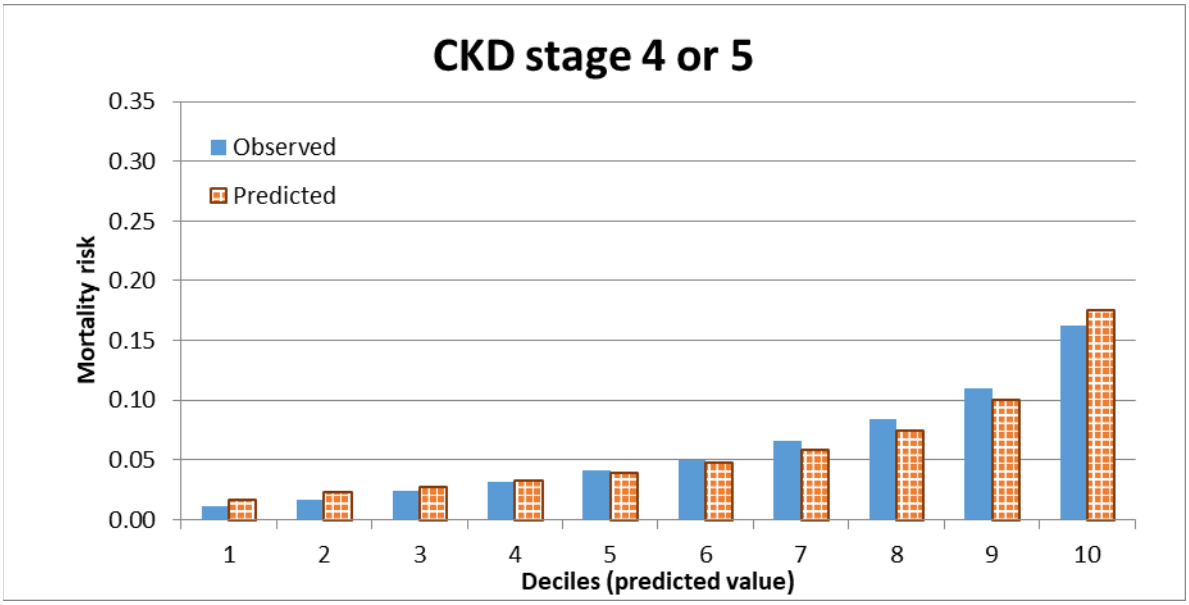


Figure 5. Comparison of Observed Mortality Risk Across Deciles of Predicted Values for CKD Stage 4 / Stage 5 subgroup (n=460,375)



Our internal validity results show that as expected, the subgroup of patients with CKD have overall lower mortality compared to patients with ERSD. Additionally, the model validation results show good calibration for both CKD and ERSD patients, which supports the expanded cohort of both CKD and ESRD patients.

The subgroup analysis revealed a few important findings about the measure methodology that support its use in an expanded context from the original NQF#0369 measure. First, the risk adjustment model has a clear predictive ability to differentiate outcomes in clinically distinct subgroups, ranging from 2.7%-30.1% from the bottom to top deciles in the ESRD subgroup and 1.6%-17.5% in the CKD subgroup. Second, the overall mortality is much lower among the CKD subgroup (6.0%, compared to 11.0% among the ESRD subgroup), which aligns with the expectation that ESRD patients are generally at higher risk for death. Finally, the predicted and observed deaths align closely within each subgroup, demonstrating that the common risk model is well-calibrated both in the original NQF#0369 cohort of ESRD patients and in the expanded cohort of stage 4/5 CKD patients.

Section 4: Summary

CORE respecified and tested an outcome measure for assessing the risk-standardized mortality ratio for patients with Stage 4 or 5 CKD or ESRD. CORE respecified the measure specifications to be consistent with the approach to outcome measurement as per NQF guidance for outcome measures and MMS Blueprint guidance. The primary goal of the Late-Stage CKD and ESRD Mortality Measure is to incentivize high quality care for patients with Stage 4 or 5 CKD or ESRD through the reduction of preventable deaths related to quality of care. CORE collaborated with the Innovation Center, clinical experts, and statistical and methodological experts for the development of this measure. The measure was respecified using Medicare claims data for identification of the cohort and the risk-adjustment variables.

The final measure risk adjustment model included 71 risk variables. The c-statistic from the risk model was 0.751, and indicated strong model discrimination. Results also showed a strong median signal-to-noise reliability statistic, with at least half of providers having a reliability of over 0.7 and providers with at least 25 cases having a reliability of 0.8.

The Stage 4 and 5 CKD variables (ICD-10 code N18.4 and N18.5) were validated using an EHR dataset containing laboratory data, resulting in high matching rates. Data element validity match rate for Stage 4 CKD was 82%, and for Stage 5 CKD was 85.3%. CORE interprets these match rates to show adequate data element validity, despite limitations to the datasets. Measure score validity showed correlated predictably to other quality measures in the MIPS program, also despite limitations.

The data element validity and measure score validity results demonstrate the robustness of the measure and its ability to discern a signal of quality nephrology care. CORE supports use of the Late-Stage CKD and ESRD Mortality Measure for implementation.

Section 5: Glossary

Beneficiary Enrollment (Coverage) Data: A dataset that is used for determination of the outcome of mortality.

Chronic Dialysis/Renal Replacement Therapy: When your kidneys are no longer cleaning the blood adequately, chronic dialysis involves a machine that cleans the blood on behalf of the kidneys. Dialysis helps remove waste, salt, and extra water; keeps a safe level of certain chemicals and nutrients in your blood; and helps control blood pressure. Although dialysis does some of the work of healthy kidneys, it does not cure CKD. Without a kidney transplant, people with ESRD need to have dialysis treatments permanently to survive.

Chronic Kidney Disease (CKD): Gradual loss of kidney function over many years. If left untreated, CKD can lead to ESRD.

Cohort: Group of patients included in the measure, eligible for the outcome.

End-Stage Renal Disease (ESRD): ESRD is the most severe stage of CKD, requiring either chronic dialysis or a kidney transplant for the patient to survive. Some patients may also choose more conservative, palliative care, and enroll in hospice.

Kidney Care Choices Model: Uses financial incentives to encourage providers to better manage care of Medicare patients with Stage 4 or 5 CKD and ESRD.

Outcome: Result of care, or endpoint in care (in other words, what happens to the patient) specific to this quality measure. In this measure, the outcome is defined as all-cause mortality.

Medicare Fee-for-Service (FFS): A system of health care payment in which a provider is paid for each service they perform. These individuals have Medicare Part A and Part B healthcare coverage.

Mortality Development Dataset: The data that is being used to develop the measure, based on claims from CY 2017-2018.

Mortality EHR Dataset: Data used specifically to test the Stage 4 and 5 CKD data elements used to define the measure cohort. Data obtained from single health system, using CY 2013-2019.

Risk Adjustment: Statistical model within a measure that accounts for how sick patients are so that providers can be fairly compared to each other, even if one provider takes care of patients who are sicker. The risk-adjustment model intends to “adjust for” factors so that differences in performance on the measure are due to quality of care, rather than patient and provider characteristics. The goal of risk adjustment is to make the comparison of providers fairer and more meaningful.

Section 6: Appendix A

Table 10 (Appendix A). Clinical Candidate Risk Adjustment Variables

CC Description	CC
HIV/AIDS	1
Opportunistic Infections	6
Other Infectious Diseases	7
Metastatic Cancer and Acute Leukemia	8
Lung and Other Severe Cancers	9
Lymphoma and Other Cancers	10
Colorectal, Bladder, and Other Cancers	11
Breast, Prostate, and Other Cancers and Tumors	12
Other Digestive and Urinary Neoplasms	14
Other Neoplasms	15
Benign Neoplasms of Skin, Breast, Eye	16
Diabetes with Acute Complications	17
Diabetes with Chronic Complications	18
Diabetes without Complication	19
Protein-Calorie Malnutrition	21
Morbid Obesity	22
Other Significant Endocrine and Metabolic Disorders	23
Disorders of Fluid/Electrolyte/Acid-Base Balance	24
Disorders of Lipoid Metabolism	25
Other Endocrine/Metabolic/Nutritional Disorders	26
End-Stage Liver Disease	27
Cirrhosis of Liver	28
Chronic Hepatitis	29
Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	36
Other Gastrointestinal Disorders	38
Bone/Joint/Muscle Infections/Necrosis	39
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	40
Disorders of the Vertebrae and Spinal Discs	41
Osteoarthritis of Hip or Knee	42
Osteoporosis and Other Bone/Cartilage Disorders	43
Other Musculoskeletal and Connective Tissue Disorders	45
Severe Hematological Disorders	46
Disorders of Immunity	47
Coagulation Defects and Other Specified Hematological Disorders	48
Iron Deficiency and Other/Unspecified Anemias and Blood Disease	49
Delirium and Encephalopathy	50
Dementia With Complications	51

CC Description	CC
Dementia Without Complication	52
Nonpsychotic Organic Brain Syndromes/Conditions	53
Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	55
Major Depressive, Bipolar, and Paranoid Disorders	59
Depression	61
Anxiety Disorders	62
Other Psychiatric Disorders	63
Parkinson's and Huntington's Diseases	78
Seizure Disorders and Convulsions	79
Polyneuropathy, Mononeuropathy, and Other Neurological Conditions/Injuries	81
Cardio-Respiratory Failure and Shock	84
Congestive Heart Failure	85
Acute Myocardial Infarction	86
Unstable Angina and Other Acute Ischemic Heart Disease	87
Angina Pectoris	88
Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease	89
Heart Infection/Inflammation, Except Rheumatic	90
Valvular and Rheumatic Heart Disease	91
Hypertension	95
Specified Heart Arrhythmias	96
Other Heart Rhythm and Conduction Disorders	97
Other and Unspecified Heart Disease	98
Ischemic or Unspecified Stroke	100
Precerebral Arterial Occlusion and Transient Cerebral Ischemia	101
Cerebrovascular Atherosclerosis, Aneurysm, and Other Disease	102
Hemiplegia/Hemiparesis	103
Late Effects of Cerebrovascular Disease, Except Paralysis	105
Atherosclerosis of the Extremities with Ulceration or Gangrene	106
Vascular Disease with Complications	107
Vascular Disease	108
Other Circulatory Disease	109
Chronic Obstructive Pulmonary Disease	111
Fibrosis of Lung and Other Chronic Lung Disorders	112
Asthma	113
Aspiration and Specified Bacterial Pneumonias	114
Viral and Unspecified Pneumonia, Pleurisy	116
Pleural Effusion/Pneumothorax	117
Other Respiratory Disorders	118
Legally Blind	119
Glaucoma	126

CC Description	CC
Other Ear, Nose, Throat, and Mouth Disorders	131
Dialysis Status	134
Acute Renal Failure	135
Chronic Kidney Disease, Stage 5	136
Chronic Kidney Disease, Severe (Stage 4)	137
Chronic Kidney Disease, Moderate (Stage 3)	138
Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	139
Unspecified Renal Failure	140
Nephritis	141
Urinary Obstruction and Retention	142
Urinary Incontinence	143
Urinary Tract Infection	144
Other Urinary Tract Disorders	145
Pelvic Inflammatory Disease and Other Specified Female Genital Disorders	147
Other Female Genital Disorders	148
Pressure Ulcer of Skin with Full Thickness Skin Loss	158
Pressure Ulcer of Skin with Partial Thickness Skin Loss	159
Pressure Pre-Ulcer Skin Changes or Unspecified Stage	160
Chronic Ulcer of Skin, Except Pressure	161
Cellulitis, Local Skin Infection	164
Other Dermatological Disorders	165
Concussion or Unspecified Head Injury	168
Vertebral Fractures without Spinal Cord Injury	169
Hip Fracture/Dislocation	170
Other Injuries	174
Poisonings and Allergic and Inflammatory Reactions	175
Complications of Specified Implanted Device or Graft	176
Major Symptoms, Abnormalities	178
Minor Symptoms, Signs, Findings, modified	179
Other Organ Transplant Status/Replacement	187
Artificial Openings for Feeding or Elimination	188
Amputation Status, Lower Limb/Amputation Complications	189
Chemotherapy	193
Screening/Observation/Special Exams	195
History of Disease	196
Supplemental Oxygen	197
Wheelchairs, Commodes	200
Alcohol/Cannabis Use or Use Disorder, Mild or Uncomplicated; Non-Psychoactive Substance Abuse; Nicotine Dependence	203
Kidney Transplant Status: ICD-10-CM codes beginning with 'T'	132A
Kidney Transplant Status: ICD-10-CM codes beginning with 'Z'	132B

CC Description	CC
Age	NA

Section 7: Appendix B

Table 11 (Appendix B). ICD Codes for Advanced and Metastatic Cancer Exclusions

Description	ICD Codes	Condition Category (CC) #	CC Name
Secondary malignant neoplasm of bone	C7951	CC8	Metastatic Cancer and Acute Leukemia
Secondary malig neoplasm of liver and intrahepatic bile duct	C787	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified lung	C7800	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of other specified sites	C7989	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of retroperiton and peritoneum	C786	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of right lung	C7801	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified site	C799	CC8	Metastatic Cancer and Acute Leukemia
Secondary and unsp malignant neoplasm of intra-abd nodes	C772	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of left lung	C7802	CC8	Metastatic Cancer and Acute Leukemia
Malignant pleural effusion	J910	CC177	Pleural Effusion/Pneumothorax
Secondary malignant neoplasm of brain	C7931	CC8	Metastatic Cancer and Acute Leukemia
Secondary and unsp malignant neoplasm of lymph node, unsp	C779	CC10	Lymphoma and Other Cancers
Secondary malignant neoplasm of bladder	C7911	CC8	Metastatic Cancer and Acute Leukemia
Secondary and unsp malignant neoplasm of intrathorac nodes	C771	CC9	Metastatic Cancer and Acute Leukemia
Sec and unsp malig neoplasm of nodes of head, face and neck	C770	CC10	Metastatic Cancer and Acute Leukemia
Secondary and unsp malignant neoplasm of intrapelv nodes	C775	CC11	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of other digestive organs	C7889	CC12	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of genital organs	C7982	CC10	Lymphoma and Other Cancers
Secondary malignant neoplasm of large intestine and rectum	C785	CC8	Metastatic Cancer and Acute Leukemia
Malignant ascites	R180	CC178	Major Symptoms, Abnormalities
Sec and unsp malig neoplasm of axilla and upper limb nodes	C773	CC10	Lymphoma and Other Cancers

Description	ICD Codes	Condition Category (CC) #	CC Name
Secondary malignant neoplasm of pleura	C782	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of other urinary organs	C7919	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of left adrenal gland	C7972	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified adrenal gland	C7970	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of skin	C792	CC10	Lymphoma and Other Cancers
Secondary carcinoid tumors of liver	C7B02	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of small intestine	C784	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unsp kidney and renal pelvis	C7900	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of right adrenal gland	C7971	CC8	Metastatic Cancer and Acute Leukemia
Other secondary neuroendocrine tumors	C7B8	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of left kidney and renal pelvis	C7902	CC8	Metastatic Cancer and Acute Leukemia
Sec and unsp malig neoplasm of inguinal and lower limb nodes	C774	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of r kidney and renal pelvis	C7901	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of mediastinum	C781	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of oth parts of nervous system	C7949	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of bone marrow	C7952	CC8	Metastatic Cancer and Acute Leukemia
Sec and unsp malig neoplasm of nodes of multiple regions	C778	CC8	Metastatic Cancer and Acute Leukemia
Malignant carcinoid tumor of unspecified site	C7A00	CC12	Breast, Prostate, and Other Cancers and Tumors
Disseminated malignant neoplasm, unspecified	C800	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of breast	C7981	CC10	Lymphoma and Other Cancers
Secondary carcinoid tumors of peritoneum	C7B04	CC8	Metastatic Cancer and Acute Leukemia
Secondary carcinoid tumors of other sites	C7B09	CC8	Metastatic Cancer and Acute Leukemia

Description	ICD Codes	Condition Category (CC) #	CC Name
Secondary malignant neoplasm of other respiratory organs	C7839	CC8	Metastatic Cancer and Acute Leukemia
Secondary carcinoid tumors, unspecified site	C7B00	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of right ovary	C7961	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified ovary	C7960	CC8	Metastatic Cancer and Acute Leukemia
Secondary carcinoid tumors of distant lymph nodes	C7B01	CC8	Metastatic Cancer and Acute Leukemia
Secondary Merkel cell carcinoma	C7B1	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of left ovary	C7962	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of cerebral meninges	C7932	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified digestive organ	C7880	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unspecified urinary organs	C7910	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unsp respiratory organ	C7830	CC8	Metastatic Cancer and Acute Leukemia
Secondary carcinoid tumors of bone	C7B03	CC8	Metastatic Cancer and Acute Leukemia
Secondary malignant neoplasm of unsp part of nervous system	C7940	CC8	Metastatic Cancer and Acute Leukemia

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