Proposed Retirement for HEDIS®[1]
Comprehensive Diabetes Care (CDC)—Medical Attention for Nephropathy

Proposed New Measure for HEDIS MY 2020
Kidney Health Evaluation for Patients With Diabetes (KED)

NCQA seeks comments on the proposed retirement of the HEDIS *Comprehensive Diabetes Care—Medical Attention for Nephropathy* indicator as well as a proposed new measure for inclusion in HEDIS Measurement Year 2020:

- *Kidney Health Evaluation for Patients With Diabetes*: The percentage of members 18–75 years of age with diabetes (type 1 and type 2) who received a kidney health evaluation, defined by an estimated glomerular filtration rate (eGFR) ***and*** a urine albumin-creatinine ratio (uACR), during the measurement year.

The American Diabetes Association and the National Kidney Foundation (NKF) recommend annual kidney health evaluation for patients with diabetes, including both an eGFR and a uACR. Evaluation of kidney health is more accurate when both eGFR and uACR are completed, as eGFR assesses kidney function by testing for waste products (creatinine) in the blood and uACR assesses kidney damage by testing for proteins (albumin) in the urine. Having both results allows appropriate identification, staging, monitoring and treatment of diabetic kidney disease. However, despite the evidence and clinical practice guideline recommendations, kidney health evaluation is underperformed for patients with diabetes. NCQA advisory panels, as well as the NKF and its expert panel, provided feedback that the current HEDIS *Medical Attention for Nephropathy* indicator is not precise enough to meet the needs of kidney health evaluation as an aspect of diabetes management. To address this gap in care and measurement, NCQA proposes the new *Kidney Health Evaluation for Patients With Diabetes* measure.

Development of this HEIDS measure concept at the health-plan level aligns with work currently underway by the NKF focused on a clinician level measure. NCQA tested this measure concept in 2019 using claims data; testing demonstrated that more than half of Medicare Advantage and commercial members with diabetes did not receive annual kidney health evaluation. Overall variation in performance within and across product lines suggests significant room for improvement.

The NKF technical expert panel and the NCQA advisory panels support retirement of the *Medical Attention for Nephropathy* indicator because it does not align with clinical practice guideline recommendations and provides an unclear signal of quality related to care for kidney health. Stakeholders agree that the new stand-alone *Kidney Health Evaluation for Patients With Diabetes* measure would supersede the existing indicator and would provide more actionable information for health plans.

NCQA seeks general feedback on both measures and on the following question:

1. The proposed new measure assesses members 18–75 years of age. During development, advisory members suggested that NCQA consider raising the upper age limit. NCQA seeks feedback on the current age range and potential age limit above 75 years of age.

Supporting documents include the current and draft measure specifications and evidence workup.

NCQA acknowledges the contributions of the Diabetes Measurement Advisory Panel and the Technical Measurement Advisory Panel.

[1]HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

Kidney Health Evaluation for Patients With Diabetes (KED)

SUMMARY OF CHANGES TO HEDIS MEASUREMENT YEAR 2020

- First-year measure.

Description

The percentage of members 18–75 years of age with diabetes (type 1 and type 2) who received a kidney health evaluation, defined by an estimated glomerular filtration rate (eGFR) ***and*** a urine albumin-creatinine ratio (uACR), during the measurement year.

Eligible Population

Note: *Members in hospice are excluded from the eligible population. Refer to General Guideline 17: Members in Hospice.*

Product lines Commercial, Medicaid, Medicare (report each product line separately).

Ages 18–75 years as of December 31 of the measurement year.

Continuous enrollment The measurement year.

Allowable gap No more than one gap in enrollment of up to 45 days during the measurement year. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Anchor date December 31 of the measurement year.

Benefit Medical.

Step 1: **Event/diagnosis** There are two ways to identify members with diabetes: by claim/encounter data and by pharmacy data. The organization must use both methods to identify the eligible population, but a member only needs to be identified by one method to be included in the measure. Members may be identified as having diabetes during the measurement year or the year prior to the measurement year.

Claim/encounter data. Members who met any of the following criteria during the measurement year or the year prior to the measurement year (count services that occur over both years):

- At least one acute inpatient encounter (Acute Inpatient Value Set) with a diagnosis of diabetes (Diabetes Value Set) ***without*** telehealth (Telehealth Modifier Value Set; Telehealth POS Value Set).
- At least one acute inpatient discharge with a diagnosis of diabetes (Diabetes Value Set) on the discharge claim. To identify an acute inpatient discharge:
  1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
  2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).
  3. Identify the discharge date for the stay.
- At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), telephone visits (Telephone Visits Value Set),

online assessments (Online Assessments Value Set), ED visits (ED Value Set), nonacute inpatient encounters (Nonacute Inpatient Value Set) or nonacute inpatient discharges (instructions below; the diagnosis must be on the discharge claim), on different dates of service, with a diagnosis of diabetes (Diabetes Value Set). Visit type need not be the same for the two encounters. To identify a nonacute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Confirm the stay was for nonacute care based on the presence of a nonacute code (Nonacute Inpatient Stay Value Set) on the claim.
3. Identify the discharge date for the stay.

Only include nonacute inpatient encounters (Nonacute Inpatient Value Set) ***without*** telehealth (Telehealth Modifier Value Set; Telehealth POS Value Set).

Only one of the two visits may be an outpatient telehealth visit, a telephone visit or an online assessment. Identify outpatient telehealth visits by the presence of a telehealth modifier (Telehealth Modifier Value Set) or the presence of a telehealth POS code (Telehealth POS Value Set) associated with the outpatient visit.

Pharmacy data. Members who were dispensed insulin or hypoglycemics/ antihyperglycemics on an ambulatory basis during the measurement year or the year prior to the measurement year (Diabetes Medications List).

Diabetes Medications

Description	Prescription		
Alpha-glucosidase inhibitors	• Acarbose	• Miglitol	
Amylin analogs	• Pramlinitide		
Antidiabetic combinations	• Alogliptin-metformin • Alogliptin-pioglitazone • Canagliflozin-metformin • Dapagliflozin-metformin • Empaglifozin-linagliptin	• Empagliflozin-metformin • Glimepiride-pioglitazone • Glipizide-metformin • Glyburide-metformin • Linagliptin-metformin	• Metformin-pioglitazone • Metformin-repaglinide • Metformin-rosiglitazone • Metformin-saxagliptin • Metformin-sitagliptin
Insulin	• Insulin aspart • Insulin aspart-insulin aspart protamine • Insulin degludec • Insulin detemir • Insulin glargine • Insulin glulisine	• Insulin isophane human • Insulin isophane-insulin regular • Insulin lispro • Insulin lispro-insulin lispro protamine • Insulin regular human • Insulin human inhaled	
Meglitinides	• Nateglinide	• Repaglinide	
Glucagon-like peptide-1 (GLP1) agonists	• Dulaglutide • Exenatide	• Albiglutide • Liraglutide	
Sodium glucose cotransporter 2 (SGLT2) inhibitor	• Canagliflozin	• Dapagliflozin	• Empagliflozin
Sulfonylureas	• Chlorpropamide • Glimepiride	• Glipizide • Glyburide	• Tolazamide • Tolbutamide

Description	Prescription	
Thiazolidinediones	• Pioglitazone	• Rosiglitazone
Dipeptidyl peptidase-4 (DDP-4) inhibitors	• Alogliptin • Linagliptin	• Saxagliptin • Sitagliptin

Note: *Glucophage/metformin as a solo agent is not included because it is used to treat conditions other than diabetes; members with diabetes on these medications are identified through diagnosis codes only.*

Step 2 Remove members who meet any of the following criteria:

- Members who do not have a diagnosis of diabetes (Diabetes Value Set), in any setting, during the measurement year or the year prior to the measurement year ***and*** who had a diagnosis of polycystic ovarian syndrome, gestational diabetes or steroid-induced diabetes (Diabetes Exclusions Value Set), in any setting, during the measurement year or the year prior to the measurement year.

  If the member was included in the measure based on claim or encounter data, as described in the event/ diagnosis criteria, this does not apply because the member had a diagnosis of diabetes.

- Medicare members 66 years of age and older as of December 31 of the measurement year who meet either of the following:

  Enrolled in an Institutional SNP (I-SNP) any time during the measurement year.

  Living long-term in an institution any time during the measurement year as identified by the LTI flag in the Monthly Membership Detail Data File. Use the run date of the file to determine if a member had an LTI flag during the measurement year.

- Members 66 years of age and older as of December 31 of the measurement year (all product lines) with frailty ***and*** advanced illness. Members must meet **BOTH** of the following frailty and advanced illness criteria to be excluded:

  1. At least one claim/encounter for frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) during the measurement year.
  2. Any of the following during the measurement year or the year prior to the measurement year (count services that occur over both years):

     At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), ED visits (ED Value Set), nonacute inpatient encounters (Nonacute Inpatient Value Set) or nonacute inpatient discharges (instructions below; the diagnosis must be on the discharge claim) on different dates of service, with an advanced illness diagnosis (Advanced Illness Value Set). Visit type need not be the same for the two visits. To identify a nonacute inpatient discharge:

     1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
     2. Confirm the stay was for nonacute care based on the presence of a nonacute code (Nonacute Inpatient Stay Value Set) on the claim.
     3. Identify the discharge date for the stay.

     At least one acute inpatient encounter (Acute Inpatient Value Set) with an advanced illness diagnosis (Advanced Illness Value Set).

At least one acute inpatient discharge with an advanced illness diagnosis (Advanced Illness Value Set) on the discharge claim. To identify an acute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).
3. Identify the discharge date for the stay.

A dispensed dementia medication (Dementia Medications List).

Dementia Medications

Description	Prescription
Cholinesterase inhibitors	• Donepezil • Galantamine • Rivastigmine
Miscellaneous central nervous system agents	• Memantine

***Step 3:* Required exclusions**

Exclude all members with evidence of end-stage renal disease (ESRD) (ESRD Diagnosis Value Set), dialysis (Dialysis Procedure Value Set), nephrectomy (Nephrectomy Value Set) or kidney transplant (Kidney Transplant Value Set; History of Kidney Transplant Value Set) any time during the member's history on or prior to December 31 of the measurement year.

Administrative Specification

Denominator

The eligible population.

Numerator

Kidney Health Evaluation for Patients With Diabetes

Members who received ***both*** of the following during the measurement year on the same or different dates of service:

- At least one eGFR (Estimated Glomerular Filtration Rate Lab Test Value Set).
- At least one uACR identified by ***both*** a quantitative urine albumin test (Quantitative Urine Albumin Lab Test Value Set) ***and*** a urine creatinine test (Urine Creatinine Lab Test Value Set) ***with*** dates of service four or fewer days apart.

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table KED-1/2/3: Data Elements for Kidney Health Evaluation for Patients With Diabetes

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Number of required exclusions	✓
Number of numerator events by administrative data	✓
Number of numerator events by supplemental data	✓
Reported rate	✓

Kidney Health Evaluation for Patients With Diabetes (KED)
Measure Workup

Topic Overview

Background

The current HEDIS *Comprehensive Diabetes Care (CDC)* measure was designed to evaluate if members diagnosed with diabetes are receiving the full scope of care needed to properly manage their disease. An important part of diabetic care is comprehensive chronic kidney disease (CKD) evaluation. The current CDC Medical Attention for Nephropathy indicator has limitations addressing this need and has been identified as problematic on multiple levels. Standard testing for CKD includes an estimated glomerular filtration rate (eGFR) blood test and a urine albumin-creatinine ration (uACR) test. Evaluation of kidney health is more accurate when both eGFR and uACR are assessed, and more effective when testing targets early detection in populations with diabetes (Vassalotti et al., 2016). However, the current nephropathy indicator allows urine screening alone to satisfy the numerator, and the eGFR test is not included. The numerator also allows treatment with ACE inhibitors or ARB medications to satisfy the numerator, but a recent study showed that ≤1% of these patients had the uACR test in the reporting year and 5 years prior. Furthermore, performance on the indicator is consistently high, which can lead to premature conclusion of care. Therefore, NCQA explored opportunities for improved measurement of comprehensive CKD evaluation for diabetes.

The National Kidney Foundation (NKF) and the members of its Technical Expert Panel recommended that NCQA improve upon the existing nephropathy indicator to focus on CKD evaluation. This effort aligns with the NKF's development of a clinician-level kidney health evaluation measure that aims to improve CKD testing for American adults with diabetes.

Importance and Prevalence

Diabetes is a complex group of diseases marked by high blood sugar due to the body's inability to make or use insulin. In 2015, diabetes affected 30.2 million American adults (12.2%). Of those, 7.2 million were newly diagnosed (CDC, 2017). Diabetes can lead to serious complications (NKF, 2014); having diabetes places adults at a significant risk for developing kidney disease due to vascular abnormalities that cause damage to kidneys (AHA, 2016).

CKD occurs when damage to kidneys increasingly hinders their ability to function. CKD is defined as abnormal albuminuria and abnormal eGFR (USRDS, 2018). It is common in the U.S., affecting approximately 15% (37 million) of the adult population (CDC, 2019). Other common causes of kidney disease are hypertension and genetic syndromes. The leading cause of kidney disease is diabetes (NKF, 2012). Diabetic kidney disease (DKD) is one of the most common adverse outcomes of diabetes, affecting 20%–40% of patients with diabetes (NKF, 2012).

Primary detection and management of kidney disease is an important aspect of diabetes management. Undiagnosed CKD can increase chances of related health problems, such as early death, heart disease, stroke, kidney failure and end-stage renal disease (ESRD) (CDC, 2019). Dialysis and kidney transplant are the only available treatments for ESRD and in 2016, diabetes accounted for approximately half of all Americans receiving dialysis. If a person is aware of their CKD, they can lower their risk for related health problems and kidney failure (CDC, 2019).

Supporting Evidence for Kidney Health Evaluation for Patients With Diabetes

American Diabetes Association (ADA) and NKF guidelines recommend annual kidney health evaluation for patients with diabetes. Kidney health evaluation includes screening for kidney disease and is defined by a measurement of serum creatinine to assess eGFR, and a measurement of uACR to assess albuminuria (USRDS, 2018). Recommendations are specific to the combination of both tests to better determine risk of CKD in this high-risk population. Despite clinical practice recommendations, the NKF states that fewer than 50% of adults with diabetes receive annual kidney health evaluation (NKF, 2016). Screening for kidney disease regularly is an important way to prevent kidney disease in the diabetic population or detect it early for appropriate management.

Financial importance and cost-effectiveness

In 2016, Medicare spending was approximately $79 billion for CKD patients and $35 billion for ESRD patients, exceeding $114 billion combined (USRDS, 2018). CDC simulation studies showed that uACR screening for early detection of CKD was cost-effective in patients with diabetes, at $50 thousand per quality-adjusted life-year (Hoerger et al., 2010).

Health care disparities

There are disparities in the prevalence of CKD by race, age, gender and socioeconomic status. CKD is more common in non-Hispanic Blacks. Based on CDC data in 2019, the percentage of CKD for adults ≥18, among non-Hispanic Blacks was 16%, 14% among Hispanics, 13% among non-Hispanic Whites and 12% among non-Hispanic Asians (CDC, 2019). CKD is more common in older adults. Approximately 38% of adults 65 and older have CKD, compared with 13% of adults 45–64 and 7% of adults 18–44 (CDC, 2019). Additionally, CKD is more common in women than in men: 15% compared with 12% (CDC, 2019). Among low-income participants, NHANES data between 2003–2008 showed that food insecurity is associated with prevalent CKD in patients with diabetes (Benjamin et al., 2019).

Awareness of CKD remains low, partly because diagnosis often occurs in the later stages of the disease. According to the 2017 CDC National Diabetes Statistics Report, overall awareness of CKD was 7.5%. Of patients with early-stage CKD, fewer than 7% were aware of their condition, while awareness among patients with CKD stage 3 was 10%–28% and with stage 4, approximately 50% (CDC, 2019).

Gaps in care

Healthy People 2020, which provides science-based, 10-year national objectives for improving the health of all Americans, recommends increasing the percentage of adults with diabetes and CKD who receive recommended health evaluation (Healthy People, 2020). However, performance of the eGFR and uACR tests among patients with diabetes remains low. In 2016, the USRDS Annual Data Report showed that testing for uACR was performed for fewer than half of Medicare and commercial patients with diabetes (41.8% and 49.0%, respectively) (USRDS, 2018).

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Specific Guideline Recommendations

Clinical Practice Guidelines: Kidney Health Evaluation for Patients With Diabetes

Organization, Year	Population	Recommendation	Grade
American Diabetes Association, 2019	Patients with type 1 diabetes with duration of ≥5 years, patients with type 2 diabetes, and patients with comorbid hypertension.	At least once a year, assess urinary albumin (e.g., spot urinary albumin-to-creatinine ratio) and estimated glomerular filtration rate in patients with type 1 diabetes with duration of ≥5 years, in all patients with type 2 diabetes, and in all patients with comorbid hypertension.	B
Endocrine Society, 2019	Patients aged 65 years and older with diabetes who are not on dialysis.	We recommend annual screening for chronic kidney disease with an estimated glomerular filtration rate and urine albumin-to-creatinine ratio.	1| ++++
	Patients aged 65 years and older with diabetes who have poor health and have a previous albumin-to-creatinine ratio of, 30 mg/g.	We suggest against additional annual albumin-to-creatinine ratio measurements.	2| ++00
	Patients aged 65 years and older with diabetes and decreased estimated glomerular filtration rate.	We recommend limiting the use or dosage of many classes of diabetes medications to minimize the side effects and complications associated with chronic kidney disease.	1| ++00
National Kidney Foundation, 2007, updated 2012	Patients with diabetes, 5 years after the diagnosis of type 1 diabetes or from diagnosis of type 2 diabetes.	Patients with diabetes should be screened annually for DKD. Initial screening should commence: • 5 years after the diagnosis of type 1 diabetes; or • From diagnosis of type 2 diabetes.	 A B
		Screening should include: • Measurements of urinary albumin-creatinine ratio (ACR) in a spot urine sample; • Measurement of serum creatinine and estimation of GFR.	 B B

Grading System Key

National Kidney Foundation: Rating the Strength of Guideline and CPR Statements

Grade	Recommendation
A	It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.
B	It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.
C (CPR)	It is recommended that clinicians consider following the CPR (clinical practice recommendation) for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

Endocrine Society: GRADE Classification of Guideline Recommendations

Quality of Evidence		High Quality	Moderate Quality	Low Quality	Very Low Quality
Description of Evidence		• *Well-performed RCTs* • *Very strong evidence from unbiased observational studies*	• *RCTs with some limitations* • *Strong evidence from unbiased observational studies*	• *RCTs with serious flaws* • *Some evidence from observational studies*	• *Unsystematic clinical observations* • *Very indirect evidence from observational studies*
Strength of Recommendation	**Strong (1): "We recommend…"** *Benefits clearly outweigh harms and burdens or vice versa*	1| ++++	1| +++0	1| ++00	1| +000
	Conditional (2): "We suggest…" *Benefits closely balanced with harms and burdens*	2| ++++	2| +++0	2| ++00	2| +000

American Diabetes Association: ADA Evidence-Grading System

Level of Evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted multicenter trial. • Evidence from a meta-analysis that incorporated quality ratings in the analysis. Compelling nonexperimental evidence. • "All or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford. Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions. • Evidence from a meta-analysis that incorporated quality ratings in the analysis.
B	Supportive evidence from well-conducted cohort studies: • Evidence from a well-conducted prospective cohort study or registry. • Evidence from a well-conducted meta-analysis of cohort studies.

Level of Evidence	Description
	Supportive evidence from a well-conducted case-control study.
C	Supportive evidence from poorly controlled or uncontrolled studies: • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results. • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls). • Evidence from case series or case reports. Conflicting evidence with the weight of evidence supporting the recommendation.
E	Expert consensus or clinical experience.