Proposed New Measures for Diabetes Recognition Program in 2025: Statin Therapy Prescription (STP), Depression Screening and Follow-Up (DSD), and Continuous Glucose Monitoring Utilization (CGD)

NCQA seeks comments on three proposed clinician-level measures for inclusion in the Diabetes Recognition Program, alongside the existing measures:

- **Statin Therapy Prescription (DRP_STP):** Assesses the percentage of patients 40–75 years of age with diabetes and evidence of statin therapy during the measurement period.
- **Depression Screening and Follow-Up (DRP_DSD):** Assesses the percentage of patients 18–75 years of age with diabetes who received appropriate depression screening and follow-up during the measurement period. There are two indicators:
  - Individuals who were screened and had a negative result and no positive results for clinical depression during the measurement period, ***or***
  - Individuals who were screened, had a positive result for clinical depression during the measurement period and received follow-up.
- **Continuous Glucose Monitoring Utilization (DRP_CGD):** Assess the percentage of patients 18–75 years of age with diabetes who utilized continuous glucose monitoring (CGM) during the measurement period. There are two indicators:
  - Individuals with type 1 diabetes and evidence of CGM use during the measurement period.
  - Individuals in the initial population, *minus* denominator 1, with use of basal insulin, multiple daily injections or continuous insulin infusion and evidence of CGM use during the measurement period.

Diabetes Recognition Program

The Diabetes Recognition Program was launched in 1997 and recognizes clinicians who provide high-quality ambulatory care to adults with diabetes. Recognition is voluntary and requires applicants to meet criteria for a defined set of performance measures. NCQA highlights recognized clinicians on its public Report Card. Find information on the program and existing measures here: NCQA Diabetes Recognition Program.

In 2021, NCQA received a 4-year grant from the Helmsley Charitable Trust to refresh the program. As part of the refresh, NCQA released an interim update in 2023 that included measure updates and digital specifications for the existing measure set.

Subsequently, NCQA developed three new measures, with guidance and support from the Diabetes Expert Panel and the Diabetes Measurement Advisory Panel, to address gaps in the program. Measures are specified for submission by clinicians and are digitally specified to enable digital submission and align with NCQA's broader digital strategy.

Measure Importance

Statin Therapy Prescription: Individuals with diabetes are at increased risk of developing high blood pressure, high triglycerides and increased low-density lipoprotein (LDL) cholesterol.[1] High LDL cholesterol leads to a buildup of plaque in the walls of blood vessels and increases the risk of cardiovascular disease.

[1] Centers for Disease Control and Prevention. (2022, June 20). *Diabetes and Your Heart*. https://www.cdc.gov/diabetes/library/features/diabetes-and-heart.html

Statin therapies work to reduce LDL cholesterol, by blocking an enzyme in the liver that produces it, and thus reduce the risk of heart disease.[2] The approach to identifying evidence of statin therapy prescription in the Diabetes Recognition Program STP measure aligns with the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CMS347) eCQM stewarded by the Centers for Medicare & Medicaid Services (CMS).

Depression Screening and Follow-Up: Depression is 2–3 times more likely in individuals with diabetes, yet screening and treatment rates remain low.[3] Undiagnosed depression has been linked to an increased risk of diabetes-related complications.[3] Proper diagnosis and treatment of depression can improve mental health outcomes and reduce diabetes-related complications. The measure assesses new cases of depression and whether appropriate follow-up occurs, The Diabetes Recognition Program DSD measure aligns with NCQA's HEDIS®[4] *Depression Screening and Follow-Up for Adolescents and Adults* (DSF-E) measure.

Continuous Glucose Monitoring Utilization: Continuous glucose monitoring (CGM) devices provide real time glucose levels, enabling patients to monitor glucose level trends and take corrective action as needed.[5] The historical data gathered from the device allows individuals to make lifestyle changes to prevent glycemic events and better manage their diabetes. As a utilization measure, the Diabetes Recognition Program CGD measure will encourage data collection and provide insights into CGM utilization among people with diabetes.

NCQA seeks feedback on the proposed clinician-level measures for inclusion in the existing Diabetes Recognition Program measure set.

Supporting documents include the draft measure specifications and evidence workups.

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

[2] Mayo Clinic. *Statin side effects: Weigh the benefits and risks*. (2023, May 27). https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013

[3] Li, C., Ford, E. S., Zhao, G., Ahluwalia, I. B., Pearson, W. S., & Mokdad, A. H. (2009). Prevalence and correlates of undiagnosed depression among U.S. adults with diabetes: The Behavioral Risk Factor Surveillance System, 2006. *Diabetes Research and Clinical Practice*, *83*(2), 268–279. https://doi.org/10.1016/j.diabres.2008.11.006

[4] HEDIS is a registered trademark of the National Committee for Quality Assurance.

[5] Fierce Biotech & Medpace. (2022, November). Benefits and Challenges of Continuous Glucose Monitoring (CGM) in Clinical Development. https://www.medpace.com/wp-content/uploads/2023/03/Whitepaper-Benefits-and-Challenges-of-Continuous-Glucose-Monitoring-in-Clinical-Trials.pdf

Measure title	Statin Therapy Prescription	Measure ID	DRP_STP
Description	The percentage of patients 40–75 years of age with diabetes with evidence of statin therapy during the measurement period.		
Measurement period	January 1–December 31.		
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Clinical recommendation statement	American Diabetes Association (2024) • For people with diabetes aged 40–75 years without ASCVD. use moderate-intensity statin therapy in addition to lifestyle therapy. Level of evidence: A • For people with diabetes aged 40–75 at higher cardiovascular risk, including those with one or more ASCVD risk factors, it is recommended to use high-intensity statin therapy to reduce LDL cholesterol by ≥50% of baseline and to target an LDL cholesterol goal of <70mg/dL. Level of evidence: A • For people of all ages with diabetes and ASCVD, high-intensity statin therapy should be added to lifestyle therapy. Level of evidence: A US Preventive Services Task Force (2022) • Adults ages 40–75 years who have 1 or more cardiovascular risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year cardiovascular risk of 10% or greater–Initiate a statin. Grade: B American College of Cardiology (2018) • In adults 40 to 75 years of age with diabetes mellitus, regardless of estimated 10-year ASCVD risk, moderate statin therapy is indicated. Class I. Level of evidence: A
Citations	American Diabetes Association Professional Practice Committee. 2023. "10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes—2024." *Diabetes Care* 47(Supplement_1), S179–S218. https://doi.org/10.2337/dc24-S010 Grundy, S.M., N.J. Stone, A.L. Bailey, C. Beam, K.K. Birtcher, R.S. Blumenthal, L.T. Braun, et al. 2019. "2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol." *Journal of the American College of Cardiology* 73 (24): e285–350. https://doi.org/10.1016/j.jacc.2018.11.003 US Preventive Services Task Force. 2022. "Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement." *JAMA* 328(8), 746–53. https://doi.org/10.1001/jama.2022.13044
Characteristics	
Scoring	Proportion.
Type	Process.
Product line	NA.
Stratification	None.
Risk adjustment	None.
Improvement notation	Increased score indicates improvement.
Guidance	None.

Definitions	
Initial population	Patients 40–75 years of age by the end of the measurement period who had a qualifying visit (Qualifying Visit Value Set) during the measurement period and had an ongoing or a new diagnosis of diabetes (Diabetes Value Set) during the first 6 months of the measurement period.
Exclusions	Exclude patients who meet any of the following criteria: • Patients who die any time during the measurement period. • Patients in hospice or using hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) any time during the measurement period. This can include: – Patients discharged from hospital (Acute Inpatient Value Set) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107). – Patients with a completed hospice care Minimum Data Set (LOINC code 45755-6; SNOMEDCT code 373066001). • Patients 66 and older by the end of the measurement period whose housing status (LOINC code 71802-3) indicates they are living in a nursing home (SNOMEDCT code 373066001) any time on or before the end of the measurement period. • Patients 66 and older by the end of the measurement period, with an indication of frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set; LOINC code 98181-1) for any part of the measurement period, who also meet any of the following advanced illness criteria: – Advanced illness (Advanced Illness Value Set) during a qualifying encounter (Outpatient Value Set; Emergency Department Visit Value Set; Acute Inpatient Value Set; Nonacute Inpatient Value Set) during the measurement period or the year prior to the measurement period, ***or*** – Prescribed dementia medications (Dementia Medications List) during the measurement period or the year prior to the measurement period. • Patients receiving palliative care (Palliative Care Encounter Value Set; Palliative Care Intervention Value Set; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period. • Patients with a diagnosis of pregnancy (Pregnancy Value Set) during the measurement period or the year prior to the measurement period. • Patients undergoing in vitro fertilization (IVF Value Set) in the measurement period or the year prior to the measurement period. • At least one prescription for clomiphene (Clomiphene Medications List) during the measurement period or the year prior to the measurement period. • Patients with evidence of end-stage renal disease (ESRD) (ESRD Diagnosis Value Set) or dialysis (Dialysis Services Value Set) during the measurement period or the year prior to the measurement period. • Patients with cirrhosis (Cirrhosis Value Set) during the measurement period or the year prior to the measurement period. • Patients with a diagnosis of myalgia, myositis, myopathy, or rhabdomyolysis (Muscular Pain and Disease Value Set) during the measurement period.

	• Patients with muscular reactions (Muscular Reactions to Statins Value Set) to statins at any point in their history on or prior to December 31 of the measurement period.
Denominator	The initial population minus denominator exclusions.
Numerator	Patients who were prescribed or were on statin therapy of any intensity (High, Moderate and Low Intensity Statin Medications List) during the measurement period.
Summary of changes	This is a new measure.
Data element tables	NA.

Measure title	Depression Screening and Follow-Up	Measure ID	DRP_DSD
Description	The percentage of patients 18–75 years of age with diabetes who received appropriate screening and follow-up for clinical depression during the measurement period.		
Measurement period	January 1–December 31.		
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	Device Code Mapping Table are copyright © 1995–2025 Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC)		

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Clinical recommendation statement	American Diabetes Association (2024) • Conduct at least annual screening of depressive symptoms in all people with diabetes and more frequently among those with a self-reported history of depression. Use age-appropriate, validated depression screening measures, recognizing that further evaluation will be necessary for individuals who have a positive screen. Level of evidence: A • Beginning at diagnosis of complications or when there are significant changes in medical status, consider assessment for depression. Level of evidence: B • Refer to qualified behavioral health professionals or other trained health care professionals with experience using evidence-based treatment approaches for depression in conjunction with collaborative care with the diabetes treatment team. Level of evidence: A
Citations	American Diabetes Association Professional Practice Committee. 2023. "5. Facilitating Positive Health Behaviors and Well-Being to Improve Health Outcomes: Standards of Care in Diabetes—2024." *Diabetes Care* 47(Supplement_1), S77–S110. https://doi.org/10.2337/dc24-S005
Characteristics	
Scoring	Proportion.
Type	Process.
Product line	NA.
Stratification	None.
Risk adjustment	None.
Improvement notation	Increased score indicates improvement.
Guidance	This measure requires the use of an age-appropriate screening instrument. The member's age is used to select the appropriate instrument. Depression screening captured in health risk assessments, or other types of health assessments, is allowed if the questions align with a specific instrument that is validated for depression screening. *Example:* A health risk assessment that includes questions from the PHQ-2 counts as screening if the patient answered the questions and a total score is calculated.
Definitions	
Depression Screening Instrument	A standard screening instrument that has been normalized and validated for the appropriate patient population. Eligible screening instruments with thresholds for positive findings include:

<table>
<tr><td></td><td>
<table>
<tr><th>Instruments for Adults (18+ years)</th><th>Total Score LOINC Codes</th><th>Positive Finding</th></tr>
<tr><td>Patient Health Questionnaire (PHQ-9)®</td><td>44261-6</td><td>Total score ≥10</td></tr>
<tr><td>Patient Health Questionnaire-2 (PHQ-2)®[1]</td><td>55758-7</td><td>Total score ≥3</td></tr>
<tr><td>Beck Depression Inventory-Fast Screen (BDI-FS)®[1,2]</td><td>89208-3</td><td>Total score ≥8</td></tr>
<tr><td>Beck Depression Inventory (BDI-II)</td><td>89209-1</td><td>Total score ≥20</td></tr>
<tr><td>Center for Epidemiologic Studies Depression Scale—Revised (CESD-R)</td><td>89205-9</td><td>Total score ≥17</td></tr>
<tr><td>Duke Anxiety—Depression Scale (DUKE-AD)®[2]</td><td>90853-3</td><td>Total score ≥30</td></tr>
<tr><td>Geriatric Depression Scale Short Form (GDS)[1]</td><td>48545-8</td><td>Total score ≥5</td></tr>
<tr><td>Geriatric Depression Scale Long Form (GDS)</td><td>48544-1</td><td>Total score ≥10</td></tr>
<tr><td>Edinburgh Postnatal Depression Scale (EPDS)</td><td>99046-5</td><td>Total score ≥10</td></tr>
<tr><td>My Mood Monitor (M-3)®</td><td>71777-7</td><td>Total score ≥5</td></tr>
<tr><td>PROMIS Depression</td><td>71965-8</td><td>Total score (T Score) ≥60</td></tr>
<tr><td>Clinically Useful Depression Outcome Scale (CUDOS)</td><td>90221-3</td><td>Total score ≥31</td></tr>
</table>
[1]Brief screening instrument. All other instruments are full-length.
[2]Proprietary; may include cost or licensing requirements.
</td></tr>
<tr><td>Initial population</td><td>Patients 18–75 years of age by the end of the measurement period who had a qualifying visit (Qualifying Visit Value Set) during the measurement period, and an ongoing or a new diagnosis of diabetes (Diabetes Value Set) during the first 6 months of the measurement period.</td></tr>
<tr><td>Exclusions</td><td>Exclude patients who meet any of the following criteria:
Patients who die any time during the measurement period.
Patients in hospice or using hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) any time during the measurement period. This can include:
Patients discharged from hospital (Acute Inpatient Value Set) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107).
Patients with a completed hospice care Minimum Data Set (LOINC code 45755-6; SNOMEDCT code 373066001).</td></tr>
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	• Patients 66 and older by the end of the measurement period whose housing status (LOINC code 71802-3) indicates they are living in a nursing home (SNOMEDCT code 373066001) any time on or before the end of the measurement period. • Patients 66 and older by the end of the measurement period, with an indication of frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set; LOINC code 98181-1) for any part of the measurement period, who also meet any of the following advanced illness criteria: – Advanced illness (Advanced Illness Value Set) during a qualifying encounter (Outpatient Value Set; Emergency Department Visit Value Set; Acute Inpatient Value Set; Nonacute Inpatient Value Set) during the measurement period or the year prior to the measurement period, ***or*** – Prescribed dementia medications (Dementia Medications List) during the measurement period or the year prior to the measurement period. • Patients receiving palliative care (Palliative Care Encounter Value Set; Palliative Care Intervention Value Set; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period. • Patients with a history of bipolar disorder (Bipolar Disorder Value Set; Other Bipolar Disorder Value Set) any time during their history through the end of the year prior to the measurement period. • Patients with depression (Depression Value Set) that starts during the year prior to the measurement period.
Denominator	Equals initial population.
Numerator	Patients who received appropriate clinical depression screening and follow-up care on or up to 30 days after the date of the first positive screen, as defined by the following: • Patients who were screened (refer to Depression Screening Instrument definition) and had a negative result and no positive results for clinical depression during the measurement period, or • Patients who were screened (refer to Depression Screening Instrument definition), had a positive result for clinical depression during the measurement period and received follow-up as defined below. *Follow-up:* One instance of follow-up on or up to 30 days after the date of the first positive screen that meets any of the following criteria: – An outpatient, telephone, e-visit or virtual check-in follow up visit (Follow Up Visit Value Set) with a diagnosis of depression or other behavioral health condition (Depression or Other Behavioral Health Condition Value Set), ***or*** – A depression case management encounter (Depression Case Management Encounter Value Set) that documents assessment for symptoms of depression (Symptoms of Depression Value Set) or a diagnosis of depression or other behavioral health condition (Depression or Other Behavioral Health Condition Value Set), ***or*** – A behavioral health encounter including assessment, therapy, collaborative care or medication management (Behavioral Health Encounter Value Set), ***or*** – An antidepressant prescription (Antidepressant Medications List).

	OR Documentation of additional depression screening (refer to Depression Screening Instrument definition) on a full-length instrument indicating either no depression or no symptoms that require follow-up (i.e., a negative screen) on the same day as a positive screen on a brief screening instrument (refer to Depression Screening Instrument definition). *Example:* A positive screen resulting from a PHQ-2 score and documentation of a negative finding from a PHQ-9 performed on the same day qualifies as evidence of follow-up. Screening must occur by December 1 of the measurement period.
Summary of changes	1. This is a new measure.
Data elements table	NA.

Measure title	Continuous Glucose Monitoring Utilization	Measure ID	DRP_CGD
Description	The percentage of patients 18–75 years of age with diabetes with evidence of continuous glucose monitoring (CGM) utilization during the measurement period. Two rates are reported: 1. Individuals with type 1 diabetes with evidence of CGM use during the measurement period. 2. Individuals in the initial population *minus* denominator 1 with use of basal insulin, multiple daily injections, or continuous insulin infusion and with evidence of CGM use during the measurement period.		
Measurement period	January 1–December 31.		
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Clinical recommendation statement	American Diabetes Association (2024) • Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. Level of evidence: A • Real-time CGM (Level of evidence: A) or intermittently scanned CGM (Level of evidence: B) should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. • Real-time CGM (Level of evidence: A) or intermittently scanned continuous glucose monitoring (Level of evidence: C) should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. • In people with diabetes on multiple daily injections or continuous subcutaneous insulin infusion, real-time continuous glucose monitoring devices should be used as close to daily as possible for maximal benefit (Level of evidence: A). Intermittently scanned continuous glucose monitoring devices should be scanned frequently, at a minimum once every 8 hours to avoid gaps in data (Level of evidence: A). People with diabetes should have uninterrupted access to their supplies to minimize gaps in continuous glucose monitoring. Level of evidence: A • Use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia. Level of evidence: A
Citations	American Diabetes Association Professional Practice Committee. 2023a. "7. Diabetes Technology: Standards of Care in Diabetes—2024." *Diabetes Care* 47(Supplement_ 1), S126–S144. https://doi.org/10.2337/dc24-S007 American Diabetes Association Professional Practice Committee. 2023b. "6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2024. *Diabetes Care* 47(Supplment_1), S111–S125. https://doi.org/10.2337/dc24-S006
Characteristics	
Scoring	NA.
Type	Utilization.
Product line	NA.

Stratification	None.
Risk adjustment	None.
Improvement notation	NA.
Guidance	The American Diabetes Association recommends that a CGM device be worn for at least 14 days. Professional or personal CGM devices may be used to capture utilization.
Definitions	
CGM utilization	CGM utilization is defined by the 2024 American Diabetes Association—Standards of Care in Diabetes clinical practice guidelines, which recommend offering CGM to a subset of individuals with diabetes. Refer to the Clinical recommendation statement.
Initial population	Patients 18–75 years of age by the end of the measurement period who had a qualifying visit (Qualifying Visit Value Set) during the measurement period, and had an ongoing or a new diagnosis of diabetes (Diabetes Value Set) during the first 6 months of the measurement period.
Exclusions	Exclude patients who meet any of the following criteria: • Patients who die any time during the measurement period. • Patients in hospice or using hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) any time during the measurement period. This can include: – Patients discharged from hospital (Acute Inpatient Value Set) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107). – Patients with a completed hospice care Minimum Data Set (LOINC code 45755-6; SNOMEDCT code 373066001). • Patients 66 and older by the end of the measurement period whose housing status (LOINC code 71802-3) indicates they are living in a nursing home (SNOMEDCT code 373066001) any time on or before the end of the measurement period. • Patients 66 and older by the end of the measurement period, with an indication of frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set; LOINC code 98181-1) for any part of the measurement period, who also meet any of the following advanced illness criteria: – Advanced illness (Advanced Illness Value Set) during a qualifying encounter (Outpatient Value Set; Emergency Department Visit Value Set; Acute Inpatient Value Set; Nonacute Inpatient Value Set) during the measurement period or the year prior to the measurement period, ***or*** – Prescribed dementia medications (Dementia Medications List) during the measurement period or the year prior to the measurement period. • Patients receiving palliative care (Palliative Care Encounter Value Set; Palliative Care Intervention Value Set; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period.

Denominator	**Denominator 1: Utilization of CGM Group 1** All patients from the initial population ***with*** a diagnosis of type 1 diabetes (Type 1 Diabetes Value Set). **Denominator 2: Utilization of CGM Group 2** All patients from the initial population ***with*** a diagnosis of diabetes (Diabetes Value Set) *minus* denominator 1, ***with*** at least one instance of use of basal insulin (Basal Insulin Medications List), multiple daily injections (Basal Insulin Medications List) or continuous insulin infusion (Insulin Infusion Value Set; Presence of Insulin Pump Value Set) during the first 6 months of the measurement period.
Numerator	**Numerator 1: Utilization of CGM Group 1** Patients with evidence of CGM utilization during the measurement period. **Numerator 2: Utilization of CGM Group 2** Patients with evidence of CGM utilization during the measurement period. *Utilization:* One instance of CGM use within the measurement period that meets any of the following criteria: • CGM prescription, ***or*** • Documentation of a CGM device (Continuous Glucose Monitoring Device Value Set), metric (Continuous Glucose Management Value Set) or Ambulatory Glucose Profile report (Ambulatory Continuous Glucose Monitoring Value Set).
Summary of changes	1. This is a new measure.
Data element tables	NA.

Statin Therapy Prescription (STP)
Diabetes Recognition Program
Measure Workup

Topic Overview

Measure Description

The percentage of patients 40–75 years of age with diabetes and evidence of statin therapy during the measurement period.

Importance and Prevalence

Diabetes increases the risk of developing cardiovascular disease (CVD) by 2–4 times compared to people without diabetes (Johns Hopkins Medicine, 2019). CVD is the current leading cause of death among those with diabetes, accounting for two-thirds of deaths among people with type 2 diabetes (T2D) (ADA, n.d.). Diabetes often increases the risk of other factors that lead to an increased risk of heart disease, including high blood pressure, high triglycerides and too much low-density lipoprotein cholesterol (LDL-C) (CDC, 2022). High LDL-C in the body leads to a buildup of plaque in the walls of blood vessels. Plaque buildup creates an increased risk for cardiovascular events. Individuals with diabetes who are 40 and older are at even higher risk of CVD.

Statins are a group of medications that lower LDL-C by blocking an enzyme in the liver that is needed to make cholesterol. The liver is then able to remove cholesterol from the blood, lowering the risk of atherosclerotic cardiovascular disease (ASCVD) (Mayo Clinic, 2023; Abukhalil et al., 2022). Management of cholesterol levels has a direct effect on overall health and on CVD risk. Guidelines recommend that patients older than 40, with diabetes, adhere to statin therapy (Abukhalil et al., 2022). Appendix 1 details guidelines for the use of statin therapy.

Addressing Controversies

NCQA is reevaluating the Healthcare Effectiveness Data and Information Set (HEDIS®[1]) health-plan level measures, *Statin Therapy for Patients With Cardiovascular Disease* and *Statin Therapy for Patients With Diabetes*. These measures, which rely on health plan data, assess both receipt of statin therapy and statin adherence. In contrast, the provider-level *Statin Therapy Prescription* measure in the Diabetes Recognition Program focuses on prescription. However, several topics in the reevaluation are also pertinent to the provider-level measure. As a result, relevant measure changes identified during this reevaluation will be considered for the provider-level measure. Topics under review in this reevaluation include the following.

Age

The American Diabetes Association (ADA) recommends that moderate-intensity statin therapy be initiated as primary prevention for people with diabetes who are 40 or older (ADA, 2024). Evidence on using statins as primary prevention finds a 20%–30% reduction of relative risk of major vascular events in people 75 and younger (Saeed & Mehta, 2020). Individuals without ASCVD who are under the age of 40 have a lower risk of cardiovascular event (ADA, 2024), but all adults with diabetes and established ASCVD are recommended to initiate high-intensity statin therapy as secondary prevention (ADA, 2024).

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

The current measure focuses on people with diabetes, regardless of ASCVD status, and aligns with guideline recommendations for statin treatment as primary prevention. The measure allows any intensity statin to accommodate individuals who may not tolerate moderate- or high-intensity statin.

Statin intolerance

Complete or partial statin intolerance can vary from 5%–30% of the population, depending on the population studied (Webb, 2022). Statin intolerance is classified as one or more adverse effects and the complete inability to tolerate any dose of a statin, or partial intolerance to the dose necessary to achieve the patient-specific therapeutic objective (Webb, 2022). Additionally, a minimum of two statins must have been attempted, with at least one at the lowest approved daily dosage.

Adverse effects associated with intolerance include muscle disorders such as myalgia, myopathy, or rhabdomyolysis. However, the definition of statin intolerance is not consistent, and can differ between studies and organizations (ADA, 2024). Diagnosis of statin intolerance is also related to and diagnostically coded for statin associated muscle symptoms (SAMS) (Warden et al., 2023). Currently there are no diagnostic codes specific to statin intolerance not related to muscle symptoms; thus, the measure excludes members with a diagnosed muscle condition during the measurement year as proxy for statin intolerance.

Patients deemed truly intolerant go through an arduous statin rechallenging process, which requires close monitoring and shared decision making with the managing clinician to weigh the risks against the benefits of discontinuing statins. To allow exclusion of patients with a history of statin intolerance, the current measure also excludes muscular reactions any time in the individual's history through the measurement year.

Guidelines currently recommend that all people who have diabetes and are 40–75 initiate statin therapy (ADA, 2024). In the event of statin intolerance, the ADA first recommends switching to a different statin, lowering the dosage or using nondaily dosing of statins (ADA, 2024). Alternative non-statin treatment plans such as PCSK9 inhibition therapy and bempedoic acid are rising treatments for statin intolerance. Exclusion of other cholesterol-lowering agents from the measure aligns with other performance measures in HEDIS, and addresses challenges in diagnosing statin intolerance.

Guidelines also encourage adding these treatments to the maximum tolerated statin dosage to improve adherence and lower LDL-C (ADA, 2024). Ultimately, guidelines recommend statin therapy as primary and secondary prevention, and only when multiple statin therapies and dosages have been attempted, to then initiate other cholesterol lowering agents.

Pregnancy

In July 2021 the US Food and Drug Administration (FDA) requested removal of the "Pregnancy Category X" label for statins (Mauricio and Khera, 2022). However, the FDA stated, "Health care professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy" (Mauricio and Khera, 2022). According to the FDA, removal of the pregnancy label was not to approve statin use in all pregnant patients, but rather was intended for high-risk patients such as those with previous ASCVD events and those with familial

hypercholesterolemia (Mauricia and Khera, 2022). Additional data are needed on the efficacy, risks and benefits of statin therapy during pregnancy.

Childbearing individuals with diabetes are at increased risk for adverse perinatal and neonatal outcomes compared to individuals without diabetes. Individuals with diabetes are also at increased risk for high blood pressure, high triglycerides and high LDL-C (CDC, 2022). In combination, high cholesterol during pregnancy can lead to blocked blood vessels, which puts individuals at risk for high blood pressure, preterm birth, heart attack and stroke (HealthMatch, 2022). However, ADA guidelines state that statin therapy is contraindicated in pregnancy (ADA, 2024). Guidelines also state that potentially harmful medications in pregnancy (statins) should be stopped prior to conception (ADA, 2024). The current measure aligns with this recommendation and excludes pregnant individuals. Many studies call for additional research examining statin use in people with diabetes who are pregnant or planning to become pregnant.

A systematic review and meta-analysis of cohort studies and randomized controlled trials found that exposure to statins during pregnancy was not associated with an overall increased risk of congenital malformations (Hirsch et al., 2022), but cardiac malformations were more prevalent in babies exposed to statins in the first trimester than in babies who were not exposed. A higher rate of spontaneous abortions was also associated with statin users when compared to pregnant individuals who did not use statins (Hirsch et al., 2022). However, the studies did not focus on people with diabetes.

A retrospective cohort study examined perinatal outcomes among individuals who used statins during pregnancy compared to those who did not use statins (Chang et al., 2021). Among those who used statins, 41.8% had a diagnosis of diabetes. The study found a higher prevalence of comorbid conditions in individuals who used statins than in those who did not. Statin exposure during pregnancy was associated with low birth weight, preterm birth and a low 1-minute APGAR score (Chang et al., 2021). Additional evidence is needed to examine the effects of statins during pregnancy. Contraindication of statins in individuals who are pregnant or planning to be pregnant may relate to the differences in utilization of statin therapy by men and women.

The 2013 guidelines on management of blood cholesterol by the American College of Cardiology (ACC) and the American Heart Association (AHA) include supporting text that states statins “should not be used in women of childbearing potential unless these women are using effective contraception and are not nursing.” The 2018 updated guidelines shifted to be more inclusive, and added recommendations that “women of childbearing age who are treated with statin therapy and are sexually active should be counseled to use a reliable form of contraception” and that “women of childbearing age with hypercholesterolemia who plan to become pregnant should stop the statin 1 to 2 months before pregnancy is attempted, or if they become pregnant while on a statin, should have the statin stopped as soon as the pregnancy is discovered.” However, the current measure is not specified by biological sex, because ADA guidelines do not differentiate recommendations based on biological sex; the primary prevention recommendation for adults that have diabetes but do not have ASCVD do not include individuals of childbearing age, and they clearly state that statin therapy is contraindicated in pregnancy.

Biological sex

Although there is an overall lack of evidence surrounding sex differences and the use of statins, perception and utilization of statins differs between men and women. A retrospective cohort study examining patients across 3 years found women had lower rates of statin acceptance than men (Brown et al., 2023). Women in the study were also more likely to never initiate statins. Nonacceptance of statins is thus associated with a longer time to achieve lower LDL-C levels (Brown et al., 2023). While there is a difference between the sexes regarding who first initiates statins, there also appears to be a difference in who is prescribed statins in the first place.

A cross-sectional analysis of the national Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study was conducted to describe statin use patterns and LDL-C control, an examine if individual-level factors known to influence health care utilization explain race-sex differences in statin use and LDL-C control (Gamboa et al., 2017). The study found that White men are treated with stains more frequently than Black men, White women and Black women. Statin usage is higher for men than women in both racial categories (Gamboa et al., 2017). Although the treatment effect of statins does not differ, further research is needed to examine the differences in statin use between sexes.

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Appendix 1. Specific Guideline Recommendations

Clinical Practice Guidelines: Statin Therapy for Patients With Diabetes

Organization, Year	Target Population	Recommendation	Grade
American Diabetes Association, 2024	Patients with type 1 and type 2 diabetes	For people with diabetes aged 40-75 years without ASCVD, use moderate-intensity statin therapy in addition to lifestyle therapy	A
		For people with diabetes aged 40-75 at higher cardiovascular risk, including those with one or more ASCVD risk factors, it is recommended to use high-intensity statin therapy to reduce LDL cholesterol by > 50% of baseline and to target an LDL cholesterol goal of <70 mg/dL	A
		For people of all ages with diabetes and ASCVD, high-intensity statin therapy should be added to lifestyle therapy	A
		For individuals who do not tolerate the intended intensity, the maximum tolerated statin should be used	E
US Preventive Services Task Force, 2022	Adults 40-75 years who have 1 or more cardiovascular risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year cardiovascular disease (CVD) risk of 10% or greater	Initiate a statin	B
	Adults 40-75 years who have 1 or more cardiovascular risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year cardiovascular disease (CVD) risk of 7.5% to less than 10%	Selectively offer a statin	C
American College of Cardiology, 2018	Patients with diabetes mellitus	In adults 40 to 75 years of age with diabetes mellitus, regardless of estimated 10-year ASCVD risk, moderate-intensity statin therapy is indicated	Class I; LOE—A
		In adults with diabetes mellitus who have multiple ASCVD risk factors, it is reasonable to prescribe high-intensity statin therapy with the aim to reduce LDL-C levels by 50% or more	Class IIa; LOE—B-R

Grading System Key

American Diabetes Association

Evidence-Grading System for Standards of Care in Diabetes

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: • i.e., "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. 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

U.S. Preventive Services Task Force

What the Grade Means and Suggestions for Practice

Grade	Definition	Suggestion for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.

Grade	Definition	Suggestion for Practice
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Levels of Certainty Regarding Net Benefit

Level	Definition
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is insufficient to determine the effects of the preventive services on health outcomes, but confidence in the estimate is constrained by factors such as: (1) the number, size or quality of individual studies, (2) Inconsistency of findings across individual studies, (3) Limited generalizability of findings to routine primary care practice, (4) Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: (1) the limited number of size of studies, (2) important flaws in study design and methods, (3) inconsistency of findings across individual studies, (4) gaps in the chain of evidence, (5) findings not generalizable to routine primary care practice, (6) and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

American College of Cardiology

Class (Strength) of Recommendation

Class	Recommendation
Class I (Strong)	Suggested phrases for writing recommendations: • Is recommended. • Is indicated/useful/effective/beneficial. • Should be performed/administered/other. • Comparative-Effectiveness Phrases: – Treatment/strategy A is recommended/indicated in preference to treatment B. – Treatment A should be chosen over treatment B.
Class IIa (Moderate)	Suggested phrases for writing recommendations: • Is reasonable. • Can be useful/effective/beneficial. • Comparative-Effectiveness Phrases: – Treatment/strategy A is probably recommended/indicated in preference to treatment B. – It is reasonable to choose treatment A over treatment B.
Class IIb (Weak)	Suggested phrases for writing recommendations: • May/might be reasonable. • May/might be considered. • Usefulness/effectiveness is unknown/unclear/uncertain or not well established.

Class	Recommendation
Class III: No Benefit (Weak)	Suggested phrases for writing recommendations: • Is not recommended. • Is not indicated/useful/effective/beneficial. • Should not be performed/administered/other.
Class III: Harm (Strong)	Suggested phrases for writing recommendations: • Potentially harmful. • Causes harm. • Associated with excess morbidity/mortality. • Should not be performed/administered/other.

Level (Quality) of Evidence

Level of Evidence	Recommendation
A	• High-quality evidence from more than 1 randomized control trial (RCT). • Meta-analyses of high-quality RCTs. • One or more RCTs corroborated by high-quality registry studies.
B-R	• Moderate-quality evidence from 1 or more RCTs. • Meta-analysis of moderate-quality RCTs.
B-NR	• Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. • Meta-analysis of such studies.
C-LD	• Randomized or nonrandomized observational or registry studies with limitations of design or execution. • Meta-analysis of such studies. • Physiological or mechanistic studies in human subjects.
C-EO	• Consensus of expert opinions on clinical experience.

Depression Screening and Follow-Up (DSD)
Diabetes Recognition Program
Measure Workup

Topic Overview

Measure Description

The percentage of patients 18–75 years of age with diabetes who received appropriate screening and follow-up for clinical depression during the measurement period.

Importance and Prevalence

Individuals living with diabetes are 2–3 times more likely to experience depression (CDC, 2023). Depressed individuals with type 2 diabetes are twice as likely to suffer from poor control of HbA1c, blood pressure and cholesterol than non-depressed individuals with type 2 diabetes (Owens-Gary et al., 2019). In individuals with both type 1 diabetes and type 2 diabetes, evidence shows that depression is significantly associated with treatment nonadherence and has a large effect on missed medical appointments and composite measures of self-care (Gonzalez et al., 2008).

General population risk factors for depression, including female sex, marital status, childhood circumstances and social deprivation, are also shown to apply to people with diabetes. And people who use insulin are at higher risk for depression than those who use noninsulin medications or lifestyle intervention programs (Li et al., 2008).

Supporting Evidence

Financial importance and cost-effectiveness

The estimated total cost of diagnosed diabetes in 2022 was $412.9B, including $306.6B in direct medical costs and $106.3B in indirect costs (lost productivity at work, unemployment from chronic disability, premature mortality). Medical costs for individuals living with diabetes increased by 35% over the last 10 years. On average, individuals with diabetes have 2.6 times higher medical expenditures than those who do not have it (Parker et al., 2023).

The U.S. government spent approximately $280B on mental health services in 2020 (The White House, 2022). The estimated economic burden of US adults with major depressive disorder has risen from $210.5B in 2010 to $326.2B in 2018, with observable increases in all components of incremental economic burden (direct costs, suicide-related costs, workplace costs) increasing during this period (Greenberg et al., 2021).

Failure to treat depression in individuals with diabetes has been shown to be associated with increased health care costs. A study using data from the 2004–2011 Medical Expenditure Panel Survey (MEPS), a nationally representative estimate of health care expenditures maintained and cosponsored by the Agency of Healthcare Research and Quality, found that the overall mean medical expenditures for patients with diabetes and no depression was $10,016, with undiagnosed depression, $15,155, with asymptomatic depression, $16,134, and with symptomatic depression, $20,105 (Bogner & McClintock, 2016). The authors attributed the increased cost of asymptomatic depression to treatment costs, demonstrating that treating depression in patients with diabetes can ultimately be a cost-saving measure (Bogner & McClintock, 2016).

Screening gaps and disparities

Only 25%–50% of people with diabetes who have depression are diagnosed and treated (CDC, 2023). Undiagnosed depression in people with diabetes has been found to be associated with increased risk of diabetes-related complications (Li et al, 2006). Although evidence-based guidelines recommend screening individuals with type 1 and type 2 diabetes for depression and diabetes regularly, screening rates remain low overall (Owens-Gary et al., 2019).

Some evidence suggests that African Americans with diabetes are significantly less likely than their White counterparts to discuss depression with their primary care physician, be prescribed antidepressant medication or see a psychiatrist (Wagner et al., 2009).

Opportunity to improve care

Patients with diabetes and depression can respond well to traditional methods of treatment (CDC, 2023). Psychosocial interventions, particularly cognitive behavioral therapy, have been shown to be effective in treating depression in people with diabetes (Markowitz et al., 2011). Pharmacotherapy studies show selective serotonin reuptake inhibitors to be successful in both alleviating depression symptoms and improving glycemic control. (Markowitz et al., 2011; Holt, de Groot, & Golden, 2014).

There is also evidence to support that collaborative care models, involving coordination between primary care physicians, nurses and other specialists, can be particularly effective at improving depression outcomes, adherence to antidepressant medication and oral hypoglycemic agents (Huang et al., 2013; Atlantis, Fahey, & Foster, 2014).

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Appendix 1. Specific Guideline Recommendations

Clinical Practice Guidelines: Depression Screening and Follow-up for Patients with Diabetes

Organization, Year	Target Population	Recommendation	Grade
American Diabetes Association, 2024	Adults with T1D and T2D	Psychosocial care should be provided to all people with diabetes, with the goal of optimizing health-related quality of life and health outcomes. Such care should be integrated with routine medical care and delivered by trained health care professionals using a collaborative, person-centered, culturally informed approach.	A
		When indicated, refer to behavioral health professionals or other trained health care professionals, ideally those with experience in diabetes, for further assessment and treatment for symptoms of diabetes distress, depression, suicidality, anxiety, treatment-related fear of hypoglycemia, disordered eating and/or cognitive capacities. Such specialized psychosocial care should use age-appropriate standardized and validated tools and treatment approaches	B
		Diabetes care teams should implement psychosocial screening protocols for general and diabetes-related mood concerns as well as other topics such as stress, quality of life, available resources) financial, social, family, and emotional), and/or psychiatric history, Screening should occur at least annually or when there is a change in disease, treatment, or life circumstances. Level of evidence	C

Organization, Year	Target Population	Recommendation	Grade
Joslin Diabetes Center, 2020	Adults with Diabetes	Newly diagnosed diabetes: Assess the following: • Ability to cope with the diagnosis and follow the new treatment regimen (ex. medication, BGM, CGM, diet changes, exercise) • Potential psychosocial barriers to treatment and self-management (behavioral, developmental, social, economic) • Cultural background and practices (ex. beliefs about medicine, diabetes, dietary practices) • Presence of coping skills for living with the emotional impact of diabetes • Level of family and social support • Non-diabetes related life stressors	1C
	Adults with Diabetes	During times of significant stress or transition (ex. hospitalizations, intensification in treatment regimen, significant life change, problems with self- management, significant deterioration in glycemic control, newly diagnosed complications, onset of mental health/ behavioral health condition). Assess the following: • Ability to follow the treatment regimen • Psychosocial barriers to treatment and self-management • Coping skills for living with the emotional impact of living with diabetes. (ex. diabetes burnout and distress: consider using PAID as a screening tool) • Level of family and social support (ex. assess for family conflict, diabetes police, positive and negative supports) • Fear of hypoglycemia: consider referral for blood glucose awareness training • Non-diabetes life stressors • Depression: consider using PHQ-9 or PHQ-2 as a screening tool • Anxiety • Disordered eating/eating disorder: consider inquiry about insulin omission or bingeing if A1c>9% or recurrent DKA • Substance abuse: consider use of CAGE (alcohol screening tool) Consider making a referral to a behavioral and mental health counselor familiar with the challenges of living with diabetes if patients are struggling with a new diagnosis or during follow-up care.	1C

Grading System Key

American Diabetes Association

ADA evidence-grading system for "Standard of Care in Diabetes"

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
	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, including: • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies
	Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies, including: • 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

Joslin Diabetes Center

Grading System

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
1A Strong recommendation High quality of evidence	Benefits clearly outweigh risk, and vice versa.	Consistent evidence from well-performed, randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B Strong recommendation Moderate quality of evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results; methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.
1C Strong recommendation Low quality of evidence	Benefits outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
2A Weak recommendation High quality of evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed, randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B Weak recommendation Moderate quality of evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results; methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
2C Weak recommendation Low quality of evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.

Continuous Glucose Monitoring Utilization (CGD)
Diabetes Recognition Program
Measure Workup

Topic Overview

Measure Description

The percentage of patients 18–75 years of age with diabetes who had evidence of continuous glucose monitoring (CGM) utilization during the measurement period. Two rates are reported:

- Individuals with type 1 diabetes with evidence of CGM use during the measurement period.
- Individuals in the initial population *minus* denominator 1 with use of basal insulin, multiple daily injections or continuous insulin infusion. and with evidence of CGM use during the measurement period.

Overview

In the last 20 years, the number of adults with diabetes has more than doubled. In 2021, diabetes was the eighth leading cause of death in the United States (CDC, 2023a). Despite high rates, 8.5 million adults with lab test results indicating diabetes were unaware of their diagnosis (CDC, 2022a).

Diabetes is a chronic condition that affects insulin production in the body, disturbing the regulation of blood sugar. Type 1 diabetes prevents the body from producing insulin naturally and commonly occurs in children, teens and young adults. Type 2 diabetes inhibits the body's ability to regulate blood sugar at a normal level. The majority of individuals with diabetes have type 2 (90%–95%) and are typically diagnosed during adulthood (CDC, 2023b). Diabetes incidence increases with age, with the highest rates in adults 45–64 years (10.1 per 1,000 adults), while prevalence of diabetes is highest in individuals 65 and older (29.2% of the US population) (CDC, 2022b).

Diabetes risk factors for type 1 include family history and age. Risk factors for type 2 may include weight, physical activity level, smoking and high blood pressure. Race and ethnicity also play a role in diabetes: Some minorities are more likely to have diagnosed diabetes than non-Hispanic White individuals. Among all U.S. racial and ethnic groups, American Indians or Alaska Natives had the highest rates of diagnosed diabetes (13.6%), followed by non-Hispanic Black individuals (12.1%). Diagnosed diabetes in non-Hispanic White individuals was lowest (6.9%) (ADA, 2023a). When not managed, both types of diabetes can lead to more severe health conditions like heart disease, vision loss, nerve and foot damage and kidney disease (CDC, 2023b). In the US, diabetes is the number one cause of kidney failure, lower-limb amputations and adult-blindness (CDC, 2022a). Diabetes is also associated with increased risk of psychosocial conditions such as anxiety, depression and diabetes distress, which can undermine patients' self-management efforts (CDC, 2023c). It is imperative that individuals effectively manage their diabetes to prevent more serious chronic conditions and achieve better health outcomes.

Importance and Prevalence

Management of blood sugar levels in people with diabetes is vital to prevent heart disease, vision loss and kidney disease (CDC, 2021). Individuals with diabetes use blood glucose meters (glucometers) and continuous glucose monitors (CGMs) to measure blood sugar. Glucometers measure the amount of sugar in a sample of blood, typically from the individual's fingertip. The sample of blood is then placed on a test strip and read by the glucometer. Glucometers can only measure blood sugar levels at a single moment in time (CDC, 2021). However, CGM devices have a sensor placed under the skin to report interstitial glucose levels in real time (Farnsworth, 2022).

There are two categories of CGM devices, personal and professional devices. Professional CGM devices are owned and applied by a health care provider and provide data for a discrete period, typically 7–14 days. Personal devices are owned by the user and are intended for frequent or continuous use. Devices measure glucose levels continuously but can either present real-time data or are intermittently scanned (ADA, 2023b).

Reporting real time glucose levels allows users to monitor glucose levels 24/7 and react immediately, if needed. (Fierce Biotech & Medpace, 2022). CGMs often report levels with up and down arrows, or "trend arrows" to indicate if levels are trending upward or downward (blood glucose is rising or falling), and help the user anticipate changes in glucose levels (Ziegler et al., 2019) and take corrective action or continue monitoring the trends. CGM devices also store historical data to be used for retrospective analysis to identify patterns. Identification of patterns allow individuals with diabetes to build management plans and adjust lifestyle behaviors with their provider to prevent glycemic events and better manage their diabetes.

CGM devices produce an Ambulatory Glucose Profile (AGP), a single-page report with standardized statistical and graphic information that presents time in glycemic ranges, glucose variability and glycemic exposure over a defined period of time (Johnson et al., 2019). Metrics outlined in the AGP, such as glucose management indicator (GMI), glycemic variability, time in range (TIR) and time below range (TBR), provide patients and providers real-time, retrospective data to help better manage patients' diabetes care. TIR reports the time an individual spends within the target blood glucose range, typically 70–180 mg/dL. The AGP also reports the amount of time an individual's blood glucose is below the target range (TBR) (ADA, n.d.a) While A1C provides an average blood glucose for the previous 3 months, it does not report additional data metrics like the AGP report does.

While there is evidence that CGM can improve glycemic outcomes for both types of diabetes, there is more research surrounding the use of CGMs and type 1 diabetes. Few studies have focused on the impacts of CGM and type 2 diabetes, but the evidence base is growing. Currently, American Diabetes Association (ADA) guidelines do not specify either type but recommend that CGM devices be offered for individuals on multiple daily injections or continuous subcutaneous insulin infusions and for individuals using basal, short- or rapid-acting insulin types (ADA, 2023c). ADA guidelines also recommend CGM use for individuals at high risk for hypoglycemia (ADA, 2023b). Appendix 1 details the relevant guidelines for CGMs. Assessing the number of patients who utilized a CGM device will provide additional insight into populations that use CGMs and how frequently providers offer them to patients.

Supporting Evidence

Financial importance and cost-effectiveness	The estimated total cost of diagnosed diabetes in 2022 was $412.9B, including $306.6B in direct medical costs and $106.3B in indirect costs (lost productivity at work, unemployment from chronic disability, premature mortality). Medical costs for individuals living with diabetes increased by 35% over the last 10 years. On average, individuals with diabetes have 2.6 times higher medical expenditures than those without (Parker et al., 2023). The use of CGMs leads to reduction of the number of non-severe hypoglycemic events and can thus lead to cost saving. CGM devices have been shown to be cost-effective ($100,000 per quality-adjusted life years) due to a decrease in experiencing diabetes distress and decreased fear of hypoglycemia, reduction of finger stick tests and improved changes in A1c (Howe and Chavis, 2022). CGM devices also help reduce the cost associated with short- and long-term complications such as hospitalizations, ED visits and procedures for individuals with type 1 diabetes (Howe and Chavis, 2022).
Opportunity to improve care	Analysis of the data reported from CGMs helps guide therapeutic decision making and enhance patient understanding in order to adjust behaviors and

lifestyles. This leads to an increase in discussions between patients and providers on how to effectively manage diabetes (Johnson et al., 2019). CGMs can benefit older individuals by allowing them to continuously share glucose readings with family members or care givers and increase awareness of hypoglycemia in those with reduced or impaired awareness (Huang et al., 2023). CGMs also help relieve the burden of multiple finger sticks by continuously measuring blood glucose levels (Kravarusic and Aleppo, 2020).

Health care disparities

An ADA study on barriers to accessing CGMs found that Medicaid beneficiaries who take insulin are 2–5 times less likely to use CGMs than individuals with commercial health insurance (ADA, 2021). When accounting for race, states with higher rates of White Medicaid beneficiaries had a higher use of CGMs than states with higher rates of Black Medicaid beneficiaries. Hispanic beneficiaries were also less likely to have CGMs when covered by Medicaid than commercial health insurance (ADA, 2021).

The study also found that insulin-dependent children younger than 18 are more likely to get CGM devices than individuals between 45 and 64. Individuals 18 or younger with commercial health insurance were significantly more likely to get a CGM device compared to all age groups, regardless of commercial or Medicaid benefits.

Relationship to outcomes

Real time data reported from CGMs help treat and prevent serious, short- and long-term diabetes complications, adjust lifestyle changes to address glycemic patterns and provide more data to a care team to adjust treatment plans more precisely (ADA, n.d.b). Research also shows a number of positive glycemic outcomes in both Type 1 and Type 2 diabetes, including increased time in target range, reduced time spent in hypoglycemia, prevention of severe hypoglycemic events and reduced mean HbA1c. Increased patient satisfaction, reduction of diabetes-related distress and improvement in quality of life have also been reported.

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Appendix 1. Specific Guideline Recommendations

Clinical Practice Guidelines: Continuous Glucose Monitoring for Patients with Diabetes

Organization, Year	Target Population	Recommendation	Grade
American Diabetes Association, 2024	Patients with Type 1 and Type 2 Diabetes	Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.	A—real-time B—intermittently
		Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.	A—real-time B—intermittently
		Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs	A—real-time E—intermittently
		Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.	E
		Use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia	A
American Association of Clinical Endocrinology Clinical Practice Guideline, 2021	Persons with diabetes mellitus	CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump.	A

Organization, Year	Target Population	Recommendation	Grade
		CGM is recommended for all individuals with problematic hypoglycemia (frequent/sever hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness).	A

Grading System Key

American Diabetes Association

Evidence-Grading System for Standards of Care in Diabetes

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 • i.e., "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 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

American Association of Clinical Endocrinology

Evidence Grade

Grade	Definition
A	Very Strong
B	Strong
C	Not Strong
D	Primarily based on expert opinion