

## ***HEDIS<sup>®1</sup> Public Comment Overview***

### **HEDIS Overview**

HEDIS is a set of standardized performance measures designed to help ensure that purchasers and consumers can reliably compare health plan performance. HEDIS is also a model for emerging systems of performance measurement in other areas of health care delivery.

HEDIS is maintained by NCQA, a not-for-profit organization committed to evaluating and publicly reporting on the quality of physicians, health plans, accountable care organizations and other organizations. The HEDIS measurement set contains 87 measures across 6 domains of care.

Items available for public comment are being considered for the HEDIS Measurement Year 2026 publication (released August 2025).

### **Diabetes Recognition Program Overview**

The Diabetes Recognition Program was launched in 1997 to recognize clinicians that provide high-quality ambulatory care to adults with diabetes. Recognition is voluntary and requires applicants to meet criteria for a defined set of clinician-level performance measures. NCQA highlights recognized clinicians on its public Report Card. The Diabetes Recognition Program is maintained by NCQA and currently contains 7 measures. Items available for public comment are being considered for use in the program in 2025.

### **Measure Development Process**

NCQA's consensus development process involves rigorous review of published guidelines and scientific evidence, as well as feedback from multi-stakeholder advisory panels. The NCQA Committee on Performance Measurement, a panel of independent scientists and representatives from health plans, consumers, federal policymakers, purchasers and clinicians, oversees the evolution of each measurement set. Numerous measurement advisory panels provide clinical and technical knowledge required to develop the measures. Additional expert panels and the Technical Measurement Advisory Panel provide invaluable assistance by identifying methodological issues and giving input on new and existing measures.

### **Synopsis**

NCQA seeks public feedback on proposed new measures, changes to existing measures and measure retirements, and NCQA acknowledges that the health care policy environment is rapidly evolving at this time. NCQA will take into account all comments received and the evolving environment as NCQA moves forward to prepare the final versions of these measures.

Reviewers are asked to submit comments to NCQA in writing via the Public Comment website by **5:00 p.m. (ET), Thursday, March 13.**

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

## Submitting Comments

Submit all comments via NCQA’s Public Comment website at <https://my.ncqa.org/>

**Note:** NCQA does not accept comments via mail, email or fax.

### How to Submit a Comment

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1. Go to <https://my.ncqa.org/>.
2. Once logged in, click to select **Public Comments**.
3. Click **Add Comment**.
4. In the **Product** field, click to select **HEDIS Public Comment** from the drop-down menu.
5. Click the **Instructions** link to view public comment materials, including instructions and proposed measure specifications.
6. Click to select the **Topic** and **Element** (measure) on which you want to comment.
7. Click to select your support option (e.g., **Support**, **Do not support**, **Support with modifications**).  
**Note:** If you chose **Do not support**, include the reason in the text box. If you chose **Support with modifications**, enter the suggested modifications in the text box.
8. Enter comments in the **Comments** box.  
**Note:** Comments may not be more than 2,500 characters. We suggest you develop comments in Word to check your character limit, and save a copy for reference. Use the “cut and paste” function to copy your comment into the **Comments** box.
9. Click **Submit** after each comment. After you have submitted all comments, click **Close**. You will be able to view and download all your submitted comments.

**All comments are due Thursday, March 13, by 5:00 p.m. ET.**

## NCQA Review of Public Comments

NCQA appreciates the time and effort required to submit comments, and reviews all feedback submitted within the public comment period. Due to the high volume of comments received, NCQA cannot respond to individual comments, but NCQA advisory panels and the Committee on Performance Measurement will consider comments and advise NCQA staff.

## Items for Public Comment

Refer to the NCQA Public Comment page for detailed documentation (memos, specifications, workups, performance data) on the items listed below.

### Proposed New HEDIS Measures

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- Tobacco Use Screening and Cessation Intervention
- Follow-Up After Acute Care Visits for Asthma
- Disability Description of Membership

### Proposed Changes to Existing HEDIS Measures

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- Social Need Screening and Intervention

- Adult COVID-19 Immunization Status (Indicator)
- Lead Screening in Children
- Follow-Up after High-Intensity Care for Substance Use Disorder
- Statin Therapy for Patients With Cardiovascular Disease
- Statin Therapy for Patients With Diabetes

### **HEDIS Measure Retirement**

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- Asthma Medication Ratio

### **Cross Cutting Item for HEDIS**

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- Alignment with Updated Federal Standards for Race and Ethnicity

### **Proposed New Measures for the Diabetes Recognition Program**

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- Statin Therapy Prescription
- Depression Screening and Follow-Up
- Continuous Glucose Monitoring Utilization

Contact NCQA Customer Support at 888-275-7585, Monday–Friday, 8:30 a.m.–5:00 p.m. (ET).

## ***Proposed New Measure for HEDIS<sup>®1</sup> MY 2026: Tobacco Use Screening and Cessation Intervention (TSC-E)***

NCQA seeks comments on the proposed new HEDIS measure for MY 2026, *Tobacco Use Screening and Cessation Intervention (TSC-E)*. If the proposed new measure is approved, the existing HEDIS measure *Medical Assistance with Smoking and Tobacco Use Cessation (MSC)* would be retired for MY 2026. Public comment on MSC measure retirement took place in 2023.

The United States Preventive Services Task Force recommends that clinicians screen all adults and school-aged children for commercial tobacco use and offer appropriate behavioral counseling and pharmacotherapy for cessation.

The proposed measure reports two rates:

1. The rate of persons 12 years of age and older who are screened for tobacco use.
2. The rate of persons who screen positive for tobacco use who receive tobacco cessation intervention, either through behavioral counseling or dispensed pharmacotherapy for those 18 and older.

After review of performance testing data, our expert panels support the proposed measure as feasible and informative about rates of tobacco use screening and tobacco cessation intervention.

NCQA seeks feedback on the following questions:

1. Do the measure specifications, codes and value sets adequately capture tobacco use screening and cessation intervention?
2. Do you support including age stratification rates for persons 12–17, 18–64 and 65 years of age and older as part of the measure?

Supporting documents include draft measure specifications and the evidence workup.

**NCQA acknowledges the contributions of the Geriatric, Technical and Respiratory Measurement Advisory Panels and the Lung Cancer and Tobacco Use Technical Expert Panel.**

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<b>Measure title</b>	Tobacco Use Screening and Cessation Intervention	<b>Measure ID</b>	TSC-E
<b>Description</b>	<p>The percentage of persons 12 years of age and older who were screened for tobacco use once or more during the measurement period <b>and</b> who received tobacco cessation intervention during the measurement period or the 180 days prior to the measurement period if identified as a tobacco user.</p> <p>Two rates are reported:</p> <ol style="list-style-type: none"> <li>1. <i>Tobacco Use Screening</i>. The percentage of persons 12 years of age and older who were screened for tobacco use once or more during the measurement period.</li> <li>2. <i>Cessation Intervention</i>. The percentage of persons 12 years of age and older who were identified as a tobacco user during the measurement period and who received tobacco cessation intervention during the measurement period or the 180 days prior to the measurement period.</li> </ol>		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a></p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement</b>	<p>The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco (Grade A Recommendation) (U.S. Preventive Services Task Force, 2021).</p> <p>The USPSTF recommends that clinicians ask all pregnant persons about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant persons who use tobacco (Grade A Recommendation) (U.S. Preventive Services Task Force, 2021).</p> <p>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women (Grade I Statement) (U.S. Preventive Services Task Force, 2021).</p> <p>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of electronic cigarettes (e-cigarettes) for tobacco cessation in adults, including pregnant persons. The USPSTF recommends that clinicians direct patients who use tobacco to other tobacco cessation interventions with proven effectiveness and established safety (Grade I Statement) (U.S. Preventive Services Task Force, 2021).</p>		

	<p>The USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents (Grade B Statement) (U.S. Preventive Services Task Force, 2020).</p> <p>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of primary care--feasible interventions for the cessation of tobacco use among school-aged children and adolescents (Grade I Statement) (U.S. Preventive Services Task Force, 2020).</p> <p>All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status or the use of other reminder systems such as chart stickers or computer prompts, significantly increase rates of clinician intervention. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008).</p> <p>All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008).</p> <p>Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008).</p> <p>The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008).</p> <p>For adolescents 11 to 17, the American Academy of Pediatrics recommends the ACT method to assess tobacco product use. Ask: Screen for tobacco use with all youth, during every clinical encounter. Counsel: Advise all youth who use tobacco to quit and have them set a quit date within two weeks. Treat: Link youth to behavioral treatment extenders and prescribe pharmacologic support when indicated. After the visit, follow-up to assess progress and offer support. (American Academy of Pediatrics, 2022).</p>
<p><b>Citations</b></p>	<p>US Preventive Services Task Force. 2021. "Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons." US Preventive Services Task Force Recommendation Statement. <i>JAMA</i> 325(3), 265–279. doi:10.1001/jama.2020.25019</p> <p>US Preventive Services Task Force. 2020. "Primary Care Interventions for Prevention and Cessation of Tobacco Use in Children and Adolescents." US Preventive Services Task Force Recommendation Statement. <i>JAMA</i> 2020;323(16):1590–1598. doi:10.1001/jama.2020.4679</p> <p>Agency for Healthcare Research and Quality. 2008. <i>Treating Tobacco Use and Dependence: 2008 Update</i>. <a href="https://www.ahrq.gov/prevention/guidelines/tobacco/index.html">https://www.ahrq.gov/prevention/guidelines/tobacco/index.html</a></p>

	American Academy of Pediatrics. 2022. "Youth Tobacco Use: Considerations for Clinicians." <i>JAMA</i> <a href="https://downloads.aap.org/AAP/PDF/AAP_Youth_Tobacco_Cessation_Considerations_for_Clinicians.pdf">https://downloads.aap.org/AAP/PDF/AAP_Youth_Tobacco_Cessation_Considerations_for_Clinicians.pdf</a>
<b>Characteristics</b>	
<b>Scoring</b>	Proportion.
<b>Type</b>	Process.
<b>Product lines</b>	<ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• Medicare.</li> </ul>
<b>Stratifications</b>	<ul style="list-style-type: none"> <li>• Age as of the start of the measurement period. <ul style="list-style-type: none"> <li>– 12–17 years (commercial and Medicaid only).</li> <li>– 18–64 years.</li> <li>– 65+ years.</li> </ul> </li> </ul>
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	<p><b>Data collection methodology:</b> ECDS. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine that the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p>
<b>Definitions</b>	
<b>Positive Tobacco User</b>	<p>Persons who were screened for tobacco use and had a documented positive result. Any of the following meet criteria:</p> <ul style="list-style-type: none"> <li>• <u>Tobacco Assessment Value Set</u> <b>with</b> LOINC code LA33-6.</li> <li>• LOINC code 72166-2 <b>with</b> <u>Positive Tobacco Use Status Value Set</u>.</li> <li>• <u>Tobacco Use Screening Value Set</u> <b>with</b> <u>Tobacco User Value Set</u>.</li> </ul>
<b>Negative Tobacco User</b>	<p>Persons who were screened for tobacco use and had a documented negative result. Any of the following meet criteria:</p> <ul style="list-style-type: none"> <li>• <u>Tobacco Assessment Value Set</u> <b>with</b> LOINC code LA32-8.</li> </ul>

	<ul style="list-style-type: none"> <li>• LOINC code 72166-2 <b>with</b> <u>Negative Tobacco Use Status Value Set</u>.</li> <li>• <u>Tobacco Use Screening Value Set</u> <b>with</b> <u>Tobacco Non User Value Set</u>.</li> </ul>
<b>Initial population</b>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefit:</i> Medical.</li> <li>• <i>Continuous enrollment:</i> 180 days prior to the measurement period through December 31 of the measurement period.</li> <li>• <i>Allowable gap:</i> No more than one gap of ≤45 days during the continuous enrollment period. The person must be enrolled on the last day of the measurement period.</li> </ul> <p><i>Ages:</i> 12 years and older at the start of the measurement period.</p> <p><i>Event:</i> None.</p>
<b>Exclusions</b>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> </ul>
<b>Denominator</b>	<p><b>Denominator 1:</b> The initial population minus denominator exclusions.</p> <p><b>Denominator 2:</b> Persons from numerator 1 who were identified as a positive tobacco user between January 1 and December 1 of the measurement period.</p>
<b>Numerator</b>	<p><b>Numerator 1: Tobacco Use Screening</b></p> <p>Persons who were screened for tobacco use and identified as either a positive or negative tobacco user (refer to the Definitions) during the measurement period.</p> <p><b>Numerator 2: Cessation Intervention</b></p> <p>Persons who received tobacco cessation intervention during the measurement period or 180 days prior to the measurement period. The following meet criteria:</p> <ul style="list-style-type: none"> <li>• Persons 12–17 years of age who received tobacco cessation counseling (<u>Tobacco Use Cessation Counseling Value Set</u>) during the measurement period or the 180 days prior to the measurement period.</li> <li>• Persons 18 years of age and older who received tobacco cessation counseling (<u>Tobacco Use Cessation Counseling Value Set</u>) or dispensed pharmacotherapy intervention (<u>Tobacco Use Cessation Pharmacotherapy Medication List</u>) during the measurement period or 180 days prior to the measurement period.</li> </ul>



<b>Summary of changes</b>	<ul style="list-style-type: none"> <li>This is a first-year measure.</li> </ul>																							
<b>Data Elements</b>	<p>Organizations that submit data to NCQA must provide the following data elements in a specified file.</p> <p><b>Table TSC-E-1/2: Data Elements for Tobacco Use Screening and Cessation Intervention</b></p> <table border="1" data-bbox="492 476 1464 772"> <thead> <tr> <th>Metric</th> <th>Age</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>TobaccoUse</td> <td>12-17</td> <td>Benefit</td> <td>Metadata</td> </tr> <tr> <td rowspan="4">Cessation</td> <td>18-64</td> <td>InitialPopulation</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>65+</td> <td>Exclusions</td> <td>For each Metric and Stratification</td> </tr> <tr> <td rowspan="2">Total</td> <td>Denominator</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>Numerator</td> <td>For each Metric and Stratification</td> </tr> <tr> <td></td> <td>Rate</td> <td>(Percent)</td> </tr> </tbody> </table>	Metric	Age	Data Element	Reporting Instructions	TobaccoUse	12-17	Benefit	Metadata	Cessation	18-64	InitialPopulation	For each Metric and Stratification	65+	Exclusions	For each Metric and Stratification	Total	Denominator	For each Metric and Stratification	Numerator	For each Metric and Stratification		Rate	(Percent)
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# ***Tobacco Screening and Follow-Up for Adolescents and Adults (TSC-E)***

## **Measure Workup**

### **Topic Overview**

#### **Importance and Prevalence**

Commercial tobacco use is the leading cause of preventable disease, disability and death in the United States. Smoking causes cancer, heart diseases, stroke, lung disease, type 2 diabetes and other chronic conditions.

In 2020, an estimated 12.5% (30.8 million) of U.S. adults smoked cigarettes (defined as smoking  $\geq 100$  cigarettes during a lifetime and now smoking cigarettes either every day or some days) (CDC 2024). Nearly 70% of adult smokers in the United States said they wanted to quit, according to a 2017 study (Babb 2017). Quitting tobacco products can be exceedingly difficult due to their addictive nature. 55% of adult smokers had made a quit attempt in the past year, but only about 8% were successful in quitting for 6–12 months (Creamer 2019).

Nearly all tobacco use begins during youth and young adulthood, so it is imperative to address children and adolescent initiation of tobacco products (CDC 2012). As of 2022, about 4 of every 100 middle school students (4.5%) and about 1 of every 6 high school students (16.5%) reported current use of tobacco products. Electronic cigarettes (e-cigarettes) are the most used tobacco product among youth, with 14.1% of high school students reporting that they have used an e-cigarette in the past 30 days (Park-Lee 2022). In comparison, only 2% of high school students report using cigarettes (Park-Lee 2022).

Tobacco use harms nearly every organ of the body and can lead to disease and disability (Lushniak 2014). While nicotine itself does not cause cancer, 69 chemicals in tobacco smoke are carcinogenic. Nicotine's addictive nature contributes to people who smoke inhaling those carcinogens.

E-cigarettes also produce a number of dangerous chemicals that are potentially toxic to cells and can cause lung disease, heart disease, COPD, asthma and cancer (Sassano 2018).

More than 16 million Americans live with a smoking-related disease. Cigarette smoking accounts for at least 30% of all cancer deaths, and overall rates of death from cancer are twice as high among smokers as nonsmokers (Islami 2022). Smoking also causes lung disease, such as chronic bronchitis and emphysema, and increases the risk of heart disease.

There have been links between e-cigarette use and hospitalizations due to respiratory issues including shortness of breath, cough and chest pain (Krishnasamy 2020).

Smoking cessation can reduce the risk of negative health effects, regardless of age or how long someone has been smoking (Lushniak 2014). According to a 2020 Surgeon General's report, quitting smoking can add as much as 10 years to life expectancy (General 2020).

#### **Health care disparities**

14.1% of men and 11% of women in the United States are current smokers (Cornelius 2022). Men have higher rates of tobacco use than women. A 2015 survey found that 16.7% percent of men use cigarettes, compared to 13.6% of women (Jamal 2016).

Tobacco use and exposure are also more likely to occur in marginalized groups (Cornelius 2022). Smoking is highest among racial and ethnic minorities. A 2020 survey found that the highest rates of commercial tobacco use occurred in American Indian/Alaska Native adults (27.1%), while rates for

other race groups include non-Hispanic White adults (13.3%), non-Hispanic Black adults (14.4%), Hispanic adults (8%) and non-Hispanic Asian adults (8%) (Cornelius 2022).

This increased likelihood of tobacco use can lead to high rates of tobacco-related health issues in communities. For example, non-Hispanic Black adults are more likely to die from smoking-related diseases, despite starting smoking later in life and smoking fewer cigarettes than non-Hispanic White adults (General 2020).

High-risk groups include incarcerated people, LGBTQ people, people with low socioeconomic status, people with mental illness and people with substance use disorder (Marbin 2021).

**Table 1. Tobacco Related Disparities**

Population	Disparity
Incarcerated people	Smoking prevalence is approximately 4 times higher in criminal justice populations than in the general population.
LGBTQ+ people	20.5% of the LGBTQ population smokes cigarettes, compared to 15.3% of straight adults. 30.7% of transgender people smoke.
People of low socioeconomic status	Adults below the poverty level are approximately twice as likely to use tobacco products than those who are above the poverty level.
People with mental illness and substance use disorders	Approximately 25% of U.S. adults have some form of mental illness or a substance abuse disorder. These adults smoke 40% of all cigarettes smoked by adults.

There are also marked disparities in tobacco product use by race and ethnicity among teens.

Tobacco use was also higher among certain vulnerable populations of students identifying as lesbian, gay or bisexual (16.0%), students identifying as transgender (16.6%) and students reporting severe psychological distress (18.3%) (Park-Lee 2022).

### **Financial importance and cost effectiveness**

Tobacco has an effect on health care costs and lost productivity. A 2022 study found that the cumulative economic loss from cigarette smoking was \$891B in 2020 (Nargis 2022). A 2018 study showed that cigarette smoking costs more than \$240B in health care spending, nearly \$185B in lost productivity from smoking-related illness and health conditions and \$180B in lost productivity from smoking-related deaths (Shrestha 2022).

## Tobacco Screening Guidelines

Numerous studies have demonstrated the effectiveness of screening and treatment for tobacco use. The following section includes information on the evidence for tobacco screening, treatment models, gaps in care and disparities.

### Screening Methods and Supporting Evidence

Tobacco users who can stop smoking lower their risk for heart disease, lung disease and stroke. There is evidence that tobacco screening and brief cessation intervention (including counseling and/or pharmacotherapy) are successful in helping tobacco users quit.

The U.S. Preventive Service Task Force (USPSTF) gave a grade A recommendation for clinicians to ask all adults about tobacco use, advise them to stop using tobacco and provide behavioral interventions; the U.S. Food and Drug Administration (FDA) approved pharmacotherapy for cessation to nonpregnant adults who use tobacco. All patients should be asked about their tobacco use and whether risk factors for use are present and encouraged to stop using tobacco (Krist 2021).

Studies have shown the effectiveness of screening and counseling on increasing smoking cessation. A 2012 *Morbidity and Mortality Weekly Report (MMWR)* article summarized data from the 2005–2008 National Ambulatory Medical Care Survey (NAMCS) and the National Health Interview Survey (NHIS) to determine progress toward Healthy People 2020 objectives calling for increased screening, cessation counseling and cessation success, and reported the following key findings:

1. During the study period, adults 18 years and older made an estimated annual average of approximately 771 million outpatient visits (an estimated total of 3.08 billion visits during 2005–2008 combined) to office-based physicians.
2. Tobacco use screening occurred during the majority of adult visits to outpatient physician offices (62.7%)
3. Of the visits that included tobacco use screening, 17.6% (340 million visits) were made by current tobacco users.
4. Among patients who were identified as current tobacco users, only 20.9% received tobacco cessation counseling and 7.6% received tobacco cessation medication
5. Patients who visited their primary care physician were more likely to receive tobacco screening (66.6% of visits) than patients who visited a physician who was not their primary care physician (61.6% of visits). Screening also varied by physician specialty. Patients visiting general or family practitioners (66.4%) and OB/GYNs (69.6%) were more likely to receive screening than patients who visited physicians in other specialties (58.2%), excluding internal medicine, cardiovascular disease and psychiatry (Jamal 2012).

Given that hospital outpatient visits account for approximately 1 in 10 outpatient visits, Jamal and colleagues sought to assess the rates of tobacco use screening and cessation assistance offered to U.S. adults during hospital outpatient clinic visits, analyzing data from the 2005–2010 NAMCS.

- During the study period, adults 18 or older made, on average, 71.8 million hospital outpatient visits annually to hospital outpatient physicians, or an estimated 431 million visits from 2005–2010 combined.
- On average, 45.2 million (63.0%) hospital outpatient visits included tobacco use screening each year.
- Of the visits that included tobacco use screening, 25.7% (11.6 million annual average visits) were made by current tobacco users.

- Among patients who screened positive for current tobacco use, 24.5% (or an estimated 17.1 million visits) received any cessation assistance, including tobacco counseling, a prescription or order for a cessation medication at the visit, or both.
- Patients who visited general medicine clinics (67.1%) were more likely to receive tobacco use screening than those who visited surgical clinics (55.7%) or clinics with other specialties (45.2%), excluding obstetrics/gynecology (62.8%) and substance abuse clinics (68.3%) (Jamal 2015).

The USPSTF gave a grade I recommendation for school-aged children and adolescents who use tobacco, concluding that the current evidence is insufficient to assess the balance of benefits and harms of primary care—feasible interventions for cessation of tobacco use among school-aged children and adolescents (Krist 2021).

To fill in the gaps from the USPSTF recommendation, other organizations have created resources on how to address youth smoking and cessation. The American Academy of Pediatrics introduced the A.C.T. method for patients over the ages of 11, which has three steps:

1. *Ask*: Screen for tobacco use with all youth during every clinical encounter.
2. *Counsel*: Advise all youth who use tobacco to quit and have them set a quit date within 2 weeks.
3. *Treat*: Link youth to behavioral treatment extenders and prescribe pharmacologic support when indicated. After the visit, follow up to assess progress and offer support (Jensen 2023).

The American Academy of Pediatrics also suggests the use of pharmacological cessation support for people who are severely dependent on nicotine (Jensen 2023). The research is limited on the impact of pharmacotherapy on adolescents with tobacco dependence but given the severe harms of tobacco dependence and the effectiveness of pharmacotherapy in adults, a tobacco-dependent adolescent may be prescribed pharmacotherapy based on the severity of dependence and the readiness to change behavior (Groner 2015).

**Table 2. Tobacco Screening Guidelines**

	Population	Recommendation	Strength of Recommendation
United States Preventive Task Force	Non-pregnant adult	The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco and provide behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco.	A
	School-aged children and adolescents who have not started to use tobacco	The USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents.	B
	School-aged children and adolescents who use tobacco	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of primary care—feasible interventions for the cessation of tobacco use among school-aged children and adolescents.	I

## Data Standards and Use

“Data standards” refers to a common set of agreed-on data elements and definitions that can be implemented in a standardized, structured and interoperable way. Data standards can support quality measurement by providing a common understanding of how data are defined, represented and shared. Measures of tobacco screening and cessation intervention will require standardized data concepts and terms with which to identify people who screen eligible consistently across providers, health systems and plans.

Data standards currently support documentation and exchange of patient smoking status (currently smoke, formerly smoked, never smoked). Standards do not yet support documentation of additional smoking-related data that may be relevant to patient care, such as quit date and pack-years.

**FHIR® U.S. Core IG** FHIR is a data standard maintained by Health Level 7 (HL7®) and comprises a set of data elements that facilitate interoperable exchange of electronic health care data.

The FHIR US Core Implementation Guide includes a Smoking Status Observation Profile.<sup>1</sup> It requires that smoking status be documented using a specific observation code, with a corresponding list of allowed response values. Table 3 lists the required codes for documenting smoking status. Smoking status does not specify tobacco product type—the codes may be used to document non-cigarette (e.g. cigar, pipe) smoking status.

**Table 3: HL7 FHIR Data Standards**

FHIR US Core Profile	Observation Code (LOINC)	Response Values (SNOMED)
Smoking Status Observation	Tobacco smoking status (72166-2)	Never smoked tobacco (266919005) Tobacco smoking consumption unknown (266927001) Occasional tobacco smoker (428041000124106) Light tobacco smoker (428061000124105) Heavy tobacco smoker (428071000124103) Smokes tobacco daily (449868002) Smoker (77176002)

### United States Core Data for Interoperability

The United States Core Data for Interoperability (USCDI) outlines a standardized set of data elements for certified health IT systems to support. As of December 31, 2022, the Cures Act requires that certified health IT systems support USCDI version 1 (ONC 2020). Version 1 includes smoking status as a required data element; certified health IT systems must be capable of documenting and exchanging smoking status using SNOMED terminology.

Smoking Status in USCDI does not specify tobacco product type—it may refer also to non-cigarette (e.g. cigar, pipe) smoking status. Additional versions of the USCDI have been released but are not yet standard for certified health IT systems. Nonetheless, the Smoking Status requirements remain the same in newer versions of the USCDI.

<sup>1</sup> The Observation resource in FHIR includes data elements which are “used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics.”

**Table 4: USCDI Version 1 Standards**

Data Element	Definition	Required Vocabulary
Smoking Status	Representing a patient's smoking behaviors.	SNOMED

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## **Proposed Measure Retirement for HEDIS<sup>®1</sup> MY 2026: Asthma Medication Ratio (AMR)**

## **Proposed New Measure for HEDIS MY 2026: Follow-Up After Acute Care Visits for Asthma (AAF-E)**

NCQA seeks comments on the following for HEDIS Measurement Year (MY) 2026.

**Proposed Retirement: Asthma Medication Ratio (AMR).** Assesses the percentage of Medicaid and commercial members 5–64 years of age who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of  $\geq 0.5$  during the measurement period. The measure is used in several programs, including the CMS Universal Foundation and the Medicaid Adult and Child Core Sets.

*Rationale:* Analyses and discussions with respiratory experts highlight concerns about the measure's reliability and validity. New guidelines recommend the use of a combined inhaler that includes a controller and reliever medications (Maintenance and Reliever Therapy [MART]).<sup>2,3</sup> AMR is calculated by distinguishing between asthma controller and asthma reliever medications and calculating the dispensed units of each. In addition, AMR only includes individuals with persistent asthma, using a proxy definition based on health care utilization and medication dispensing, which restricts the eligible population to those who use health services more frequently. The ratio is calculated using a complex numerator methodology requiring package and unit size, information that is not consistently available for all medications, posing a barrier to health plans accurately calculating performance.

**Proposed New Measure: Follow-Up After Acute Care Visits for Asthma (AAF-E).** Assesses the percentage of acute visits (including urgent care, ED, observation stays and inpatient visits) for Medicaid and commercial members 5–64 years of age with a principal diagnosis of asthma that had a corresponding outpatient follow-up visit within 30 days.

*Rationale:* Studies show that individuals with asthma frequently utilize acute care due to asthma exacerbations, which is an indicator of poorly controlled asthma.<sup>4</sup> Guidelines recommend patients follow up with their primary care doctor after an acute asthma event to assess asthma control and review medication use.<sup>2,3</sup> This measure is intended to incentivize health plans to ensure patients follow up with their doctor after an asthma exacerbation, and to encourage members with asthma to utilize primary care to manage symptoms.

NCQA conducted testing on the commercial population using the OptumLabs<sup>®5</sup> Data Warehouse (OLDW) National View (calendar years 2022 and 2023) to assess the feasibility of the new measure and is performing analogous testing in the Medicaid population early in 2025.

<sup>1</sup> HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup> Global Initiative for Asthma (GINA). 2024. Global Strategy for Asthma Management and Prevention. [https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24\\_05\\_22\\_WMS.pdf](https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf)

<sup>3</sup> National Asthma Education and Prevention Program (NAEPP) Coordinating Committee Expert Working Group. 2020. 2020 Focused Updates to the Asthma Management Guidelines. <https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines>

<sup>4</sup> McIvor A., Kaplan A. 2020. "A Call to Action for Improving Clinical Outcomes in Patients with Asthma." *npj Primary Care Respiratory Medicine* 30(54)

<sup>5</sup> Data for this analysis were obtained from the OptumLabs Data Warehouse, which contains de-identified administrative claims and other data elements and represents a diverse mixture of ages, ethnicities and geographical regions across the United States. The claims data in OLDW includes medical and pharmacy claims, laboratory results and enrollment records for commercial and Medicare Advantage enrollees. Study data were accessed using techniques compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and, because this study involved analysis of pre-existing, de-identified data, it was exempt from Institutional Review Board approval.

The measure denominator is acute visits (urgent care, ED or inpatient visits) with a principal diagnosis of asthma, using the following ICD-10 codes:

J45.20	J45.30	J45.40	J45.50	J45.901	J45.990
J45.21	J45.31	J45.41	J45.51	J45.902	J45.991
J45.22	J45.32	J45.42	J45.52	J45.909	J45.998

The numerator is outpatient follow-up visits. NCQA tested two potential time frames for follow-up: 15 and 30 days.

Testing results highlight marked variation across the commercial population by age and COPD status. The highest rate of denominator events (acute care visits with a principal diagnosis of asthma) was among members 5–11 years of age (59 visits per 1,000 members). NCQA observed a higher rate of denominator events for members with COPD compared to members without COPD (55 visits vs. 31 visits per 1,000 members).

Table 1 presents measure performance (i.e., percentage of acute care visits for asthma that had an outpatient follow-up visit) for each visit type for the 15- and 30-day follow-up time frames. There were 69 total plans in the dataset. The reportable rate (i.e., proportion of plans able to meet the minimum denominator size of 30 acute visits) was lowest for urgent care and inpatient stays; for both follow-up time frames, two commercial plans had a reportable rate for urgent care and 10 plans had a reportable rate for inpatient stays. Reportable rates for any acute care and ED visit type were higher, with 44%–52% of plans able to report a valid rate.

NCQA observed variation in measure performance across commercial plans for each acute care visit type and follow-up time frame, indicating room for improvement. On average, the highest rates of follow-up were seen for inpatient visits for asthma. The lowest rates were seen for urgent care visits.

**Table 1. Measure Performance—Follow-Up After Acute Care Visits for Asthma (15- and 30-day) by Visit Type**

Percentile Distribution (%)											
Time Frame	Visit Type	N of Plans (% of Total)	Avg	Std Dev	Min	10th	25th	50th	75th	90th	Max
15 Days	Any	37 (52.1)	33.9	7.9	16.7	25.0	30.2	34.6	38.0	40.0	56.9
	Urgent Care	2 (2.8)	17.0	1.3	16.1	16.3	16.6	17.0	17.5	17.7	17.9
	ED	35 (49.3)	33.2	6.8	21.1	23.5	30.4	33.9	35.4	37.6	52.3
	Inpatient	10 (14.1)	54.6	6.1	44.4	49.0	50.7	53.9	57.7	63.3	64.2
30 Days	Any	35 (49.3)	46.8	6.8	31.0	37.8	42.8	47.2	50.5	55.2	60.0
	Urgent Care	2 (2.8)	26.6	1.8	25.3	25.6	25.9	26.6	27.2	27.6	27.8
	ED	31 (43.7)	46.8	5.7	31.5	42.0	44.1	46.8	49.5	53.3	59.1
	Inpatient	10 (14.1)	67.0	5.8	57.7	60.9	62.7	66.7	70.4	75.1	75.5

Advisory panels supported adding the new AAF-E measure to HEDIS MY 2026 and suggested either combining all acute care visit types into one category (as opposed to separate rates by visit type) or isolating the measure to ED visits only, since these visits drove the overall performance rate. While the 30-day follow-up time frame aligns with other NCQA follow up measures and enhances feasibility by mitigating potential access and availability issues, experts acknowledged that the 15-day follow-up time frame more closely aligned with clinical guidelines on asthma exacerbation management.

NCQA seeks general feedback on the proposed retirement of AMR and the proposed new AAF-E measure, as well as feedback on the following questions for the AAF-E measure:

1. Should NCQA exclude individuals with a history of acute respiratory failure, emphysema or cystic fibrosis?

2. Should NCQA consider including only ED visits for asthma in this measure?
3. Which time frame (15 days, 30 days) is most appropriate for assessing follow-up after an acute visit for asthma?
4. Should NCQA require follow-up visits to occur in certain settings or with specific provider types?

Supporting documents include the current AMR measure specification and performance data, the proposed new AAF-E measure specification and the evidence workup.

**NCQA acknowledges the contributions of the Respiratory and Technical Measurement Advisory Panels.**

<b>Measure title</b>	Asthma Medication Ratio	<b>Measure ID</b>	AMR
<b>Description</b>	The percentage of persons 5–64 years of age who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement period.		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement/ rationale</b>	The overarching goal of asthma care is to achieve asthma control, enabling a patient to live without functional limitations, impairment in quality of life or risk of adverse events.		
<b>Citations</b>	National Heart, Lung and Blood Institute, National Asthma Education and Prevention Program. 2007. <i>Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma</i> . Full Report.		
<b>Characteristics</b>			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product lines</b>	<ol style="list-style-type: none"> <li>Commercial.</li> <li>Medicaid.</li> </ol>		
<b>Stratifications</b>	<p>Age as of the last day of the measurement period.</p> <ul style="list-style-type: none"> <li>5–11 years.</li> <li>12–18 years.</li> <li>19–50 years.</li> <li>51–64 years.</li> </ul> <p>Race. Refer to <i>General Guideline: Race and Ethnicity Stratification</i>.</p> <ul style="list-style-type: none"> <li>American Indian or Alaska Native.</li> <li>Asian.</li> <li>Black or African American.</li> </ul> <p>Native Hawaiian or Other Pacific Islander.</p> <ul style="list-style-type: none"> <li>White.</li> <li>Some Other Race.</li> <li>Two or More Races.</li> <li>Asked But No Answer.</li> </ul>		

	<ul style="list-style-type: none"> <li>• Unknown.</li> </ul> <p>Ethnicity. Refer to <i>General Guideline: Race and Ethnicity Stratification</i>.</p> <ul style="list-style-type: none"> <li>• Hispanic or Latino.</li> <li>• Not Hispanic or Latino.</li> <li>• Asked But No Answer.</li> <li>• Unknown.</li> </ul>
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	<p><b>Data collection methodology:</b> Administrative. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b></p> <ul style="list-style-type: none"> <li>• Use all paid, suspended, pending and denied claims.</li> <li>• Do not use RxNorm codes when identifying denominator exclusions or assessing the numerator.</li> </ul> <p><b>Medication list:</b> If an organization uses both pharmacy data (NDC codes) and clinical data (RxNorm codes) for reporting, and there are both NDC and RxNorm codes on the same date of service, use only one data source for the date of service. This rule is not included in the measure calculation logic, and must be programmed manually.</p>
<b>Definitions</b>	
<b>Oral medication dispensing event</b>	<p>One prescription of an amount lasting 30 days or less. To calculate dispensing events for prescriptions more than 30 days, divide the days supply by 30 and round down to convert.</p> <p><i>For example:</i> A 100-day prescription is equal to three dispensing events (<math>100/30 = 3.33</math>, round down to 3).</p> <p>Allocate the dispensing events to the appropriate year based on the date when the prescription is dispensed.</p> <p>Multiple prescriptions for different medications dispensed on the same day are counted as separate dispensing events. If multiple prescriptions for the same medication are dispensed on the same day, sum the days supply and divide by 30.</p> <p>Use the medication lists to determine if drugs are the same or different. Drugs in different medication lists are considered different drugs.</p>
<b>Inhaler dispensing event</b>	<p>When identifying the initial population, use the definition below to count inhaler dispensing events.</p> <p>All inhalers (i.e., canisters) of the same medication dispensed on the same day count as one dispensing event. Different inhaler medications dispensed on the same day are counted as different dispensing events.</p>

	<p><i>For example:</i> Three canisters of Medication A and two canisters of Medication B dispensed on the same date counts as two dispensing events.</p> <p>Allocate the dispensing events to the appropriate year based on the date when the prescription was dispensed.</p> <p>Use the medication lists to determine if drugs are the same or different. Drugs in different medication lists are considered different drugs.</p>
<b>Injection dispensing event</b>	<p>Each injection counts as one dispensing event. Multiple dispensed injections of the same or different medications count as separate dispensing events.</p> <p><i>For example:</i> Two injections of Medication A and one injection of Medication B on the same date counts as three dispensing events.</p> <p>Use the medication lists to determine if drugs are the same or different. Drugs in different medication lists are considered different drugs. Allocate the dispensing events to the appropriate year based on the date when the prescription was dispensed.</p>
<b>Units of medication</b>	<p>When identifying medication units for the numerator, count each individual medication, defined as an amount lasting 30 days or less, as one medication unit. One medication unit equals one inhaler canister, one injection, one infusion or an oral medication with a supply of 30 days or less.</p> <p><i>For example:</i> Two inhaler canisters of the same medication dispensed on the same day counts as two medication units and one dispensing event.</p> <p>Use the package size and units columns in the medication lists to determine the number of canisters or injections. Divide the dispensed amount by the package size to determine the number of canisters or injections dispensed.</p> <p><i>For example:</i> If the package size for an inhaled medication is 10 g, and pharmacy data indicate the dispensed amount is 30 g, three inhaler canisters were dispensed.</p>
<b>Initial population</b>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical. Pharmacy during the measurement period.</li> <li>• <i>Continuous enrollment:</i> The measurement period and the year prior to the measurement period.</li> <li>• <i>Allowable gap:</i> No more than one gap of ≤45 days during each year in the continuous enrollment period. The person must be enrolled on the last day of the measurement period.</li> </ul> <p><i>Ages:</i> 5–64 years as of the last day of the measurement period.</p> <p><i>Event:</i></p> <p><b>Step 1.</b> Identify persons as having persistent asthma who met at least one of the following criteria during both the measurement period and the year prior to the measurement period. Criteria need not be the same across both years.</p> <ul style="list-style-type: none"> <li>• At least one ED visit or acute inpatient encounter (<u>ED and Acute Inpatient Value Set</u>), with a principal diagnosis of asthma (<u>Asthma Value Set</u>).</li> </ul>

	<ul style="list-style-type: none"> <li>• At least one acute inpatient discharge with a principal diagnosis of asthma (<u>Asthma Value Set</u>) on the discharge claim. To identify an acute inpatient discharge:             <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>).</li> <li>2. Exclude nonacute inpatient stays (<u>Nonacute Inpatient Stay Value Set</u>).</li> <li>3. Identify the discharge date for the stay.</li> </ol> </li> <li>• At least four outpatient visits, telephone visits or e-visits or virtual check-ins (<u>Outpatient and Telehealth Value Set</u>), on different dates of service, with any diagnosis of asthma (<u>Asthma Value Set</u>) and at least two asthma medication dispensing events for any controller or reliever medication. Visit type need not be the same for the four visits. Use all the medication lists in the tables below to identify asthma controller and reliever medications.</li> <li>• At least four asthma medication dispensing events for any controller or reliever medication. Use all the medication lists in the tables below to identify asthma controller and reliever medications.</li> </ul> <p><b>Step 2.</b> A person identified as having persistent asthma because of at least four asthma medication dispensing events, where leukotriene modifiers or antibody inhibitors were the sole asthma medication dispensed in that year, must also have at least one diagnosis of asthma (<u>Asthma Value Set*</u>) in the same year as the leukotriene modifier or antibody inhibitor (the measurement period or the year prior to the measurement period).</p> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p>
<p><b>Denominator exclusions</b></p>	<p><b>3. Persons with a date of death.</b></p> <p>Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</p> <p><b>4. Persons in hospice or using hospice services.</b></p> <p>Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</p> <p><b>5. Persons with a diagnosis that requires a different treatment approach.</b></p> <p>Persons with a diagnosis that requires a different treatment approach than members with asthma (<u>Respiratory Diseases With Different Treatment Approaches Than Asthma Value Set*</u>) any time during the person’s history through December 31 of the measurement period.</p> <p><b>6. Persons who had <i>no</i> asthma controller or reliever medications dispensed.</b></p> <p>Persons who had no asthma controller or reliever medications (<u>Asthma Controller and Reliever Medications List</u>) dispensed during the measurement period.</p> <p><b>Coding Guidance</b></p>

	*Do not include laboratory claims (claims with POS code 81).																																				
<b>Denominator</b>	The initial population minus denominator exclusions.																																				
<b>Numerator</b>	<p><b>The number of persons who have a medication ratio of <math>\geq 0.50</math> during the measurement period.</b></p> <p>Use all the medication lists in the asthma controller medications and asthma reliever medications to identify asthma controller medications.</p> <p>Drugs in different medication lists are considered different drugs.</p> <p>For each person:</p> <p><b>Step 1.</b> Count the units of asthma controller medications dispensed during the measurement period. Refer to the definition of <i>Units of medication</i>.</p> <p><b>Step 2.</b> Count the units of asthma reliever medications dispensed during the measurement period. Refer to the definition of <i>Units of medication</i>.</p> <p><b>Step 3.</b> Sum the units calculated in step 1 and step 2 to determine units of total asthma medications.</p> <p><b>Step 4.</b> Calculate the ratio of controller medications to total asthma medications using the following formula. Round (using the .5 rule) to the nearest whole number.</p> $\frac{\text{Units of Controller Medications (step 1)}}{\text{Units of Total Asthma Medications (step 3)}}$ <p><b>Step 5.</b> Sum the total number of persons who have a ratio of <math>\geq 0.50</math> in step 4.</p> <p><b>Asthma Controller Medications</b></p> <table border="1"> <thead> <tr> <th>Prescriptions</th> <th>Medication Lists</th> <th>Route</th> </tr> </thead> <tbody> <tr> <td>• Omalizumab</td> <td><a href="#">Omalizumab Medications List</a></td> <td>Injection</td> </tr> <tr> <td>• Dupilumab</td> <td><a href="#">Dupilumab Medications List</a></td> <td>Injection</td> </tr> <tr> <td>• Benralizumab</td> <td><a href="#">Benralizumab Medications List</a></td> <td>Injection</td> </tr> <tr> <td>• Mepolizumab</td> <td><a href="#">Mepolizumab Medications List</a></td> <td>Injection</td> </tr> <tr> <td>• Reslizumab</td> <td><a href="#">Reslizumab Medications List</a></td> <td>Injection</td> </tr> <tr> <td>• Budesonide-formoterol</td> <td><a href="#">Budesonide Formoterol Medications List</a></td> <td>Inhalation</td> </tr> <tr> <td>• Fluticasone-salmeterol</td> <td><a href="#">Fluticasone Salmeterol Medications List</a></td> <td>Inhalation</td> </tr> <tr> <td>• Fluticasone-vilanterol</td> <td><a href="#">Fluticasone Vilanterol Medications List</a></td> <td>Inhalation</td> </tr> <tr> <td>• Formoterol-mometasone</td> <td><a href="#">Formoterol Mometasone Medications List</a></td> <td>Inhalation</td> </tr> <tr> <td>• Beclomethasone</td> <td><a href="#">Beclomethasone Medications List</a></td> <td>Inhalation</td> </tr> <tr> <td>• Budesonide</td> <td><a href="#">Budesonide Medications List</a></td> <td>Inhalation</td> </tr> </tbody> </table>	Prescriptions	Medication Lists	Route	• Omalizumab	<a href="#">Omalizumab Medications List</a>	Injection	• Dupilumab	<a href="#">Dupilumab Medications List</a>	Injection	• Benralizumab	<a href="#">Benralizumab Medications List</a>	Injection	• Mepolizumab	<a href="#">Mepolizumab Medications List</a>	Injection	• Reslizumab	<a href="#">Reslizumab Medications List</a>	Injection	• Budesonide-formoterol	<a href="#">Budesonide Formoterol Medications List</a>	Inhalation	• Fluticasone-salmeterol	<a href="#">Fluticasone Salmeterol Medications List</a>	Inhalation	• Fluticasone-vilanterol	<a href="#">Fluticasone Vilanterol Medications List</a>	Inhalation	• Formoterol-mometasone	<a href="#">Formoterol Mometasone Medications List</a>	Inhalation	• Beclomethasone	<a href="#">Beclomethasone Medications List</a>	Inhalation	• Budesonide	<a href="#">Budesonide Medications List</a>	Inhalation
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	Prescriptions	Medication Lists	Route
	• Ciclesonide	<a href="#">Ciclesonide Medications List</a>	Inhalation
	• Flunisolide	<a href="#">Flunisolide Medications List</a>	Inhalation
	• Fluticasone	<a href="#">Fluticasone Medications List</a>	Inhalation
	• Mometasone	<a href="#">Mometasone Medications List</a>	Inhalation
	• Montelukast	<a href="#">Montelukast Medications List</a>	Oral
	• Zafirlukast	<a href="#">Zafirlukast Medications List</a>	Oral
	• Zileuton	<a href="#">Zileuton Medications List</a>	Oral
	• Fluticasone furoate-umeclidinium-vilanterol	<a href="#">Fluticasone Furoate Umeclidinium Vilanterol Medications List</a>	Inhalation
	• Salmeterol	<a href="#">Salmeterol Medications List</a>	Inhalation
	• Tiotropium	<a href="#">Tiotropium Medications List</a>	Inhalation
	• Theophylline	<a href="#">Theophylline Medications List</a>	Oral
	<b>Asthma Reliever Medications</b>		
	<b>Prescriptions</b>	<b>Medication Lists</b>	<b>Route</b>
	Albuterol-budesonide	<a href="#">Albuterol Budesonide Medications List</a>	Inhalation
	Albuterol	<a href="#">Albuterol Medications List</a>	Inhalation
	Levalbuterol	<a href="#">Levalbuterol Medications List</a>	Inhalation
	<b>Notes:</b>		
	7. For medications described as “injection,” “prefilled syringe,” “subcutaneous,” “intramuscular” or “auto-injector,” map NDCs as “injections” (route).		
	8. For medications described as “metered dose inhaler,” “dry powder inhaler” or “inhalation powder,” map NDCs as “inhalation” (route) medications.		
	9. Do not map medications described as “nasal spray” to “inhalation” medications.		
<b>Summary of changes</b>	Added instructions on allowable adjustments to the race and ethnicity stratifications.		

**Data Element Tables**

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

**Table AMR-A-1/2: Data Elements for Asthma Medication Ratio**

Metric	Age	Data Element	Reporting Instructions
AsthmaMedicationRatio	5-11	Benefit	Metadata
	12-18	InitialPopulation	For each Stratification
	19-50	Exclusions	For each Stratification
	51-64	NumeratorByAdmin	For each Stratification
	Total	NumeratorBySupplemental	For each Stratification
		Rate	(Percent)

**Table AMR-B-1/2: Data Elements for Asthma Medication Ratio: Stratifications by Race**

Metric	Race	Data Element	Reporting Instructions
AsthmaMedicationRatio	AmericanIndianOrAlaskaNative	InitialPopulation	For each Stratification
	Asian	Numerator	For each Stratification
	BlackOrAfricanAmerican	Rate	(Percent)
	NativeHawaiianOrOtherPacificIslander		
	White		
	SomeOtherRace		
	TwoOrMoreRaces		
	AskedButNoAnswer		
	Unknown		

**Table AMR-C-1/2: Data Elements for Asthma Medication Ratio: Stratifications by Ethnicity**

Metric	Ethnicity	Data Element	Reporting Instructions
AsthmaMedicationRatio	HispanicOrLatino	InitialPopulation	For each Stratification
	NotHispanicOrLatino	Numerator	For each Stratification
	AskedButNoAnswer	Rate	(Percent)
	Unknown		

<b>Measure title</b>	Follow-Up After Acute Care Visits for Asthma	<b>Measure ID</b>	AAF-E
<b>Description</b>	The percentage of acute urgent care, emergency department (ED) or hospitalizations (inpatient and observation stays) for persons 5-64 years of age with a principal diagnosis of asthma that had a corresponding outpatient follow-up visit within 30 days.		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement/ rationale</b>	Non-clinical factors (e.g., socioeconomic status, environmental exposures, access to care) can limit individual efficacy in managing chronic conditions such as asthma, leading to an overreliance on acute care instead of preventive care. An accountability mechanism that drives individuals towards non-acute care may help to improve poor and disparate asthma outcomes.		
<b>Citations</b>	<p>Mclvor A., Kaplan A. 2020. “A Call to Action for Improving Clinical Outcomes in Patients with Asthma.” npj Primary Care Respiratory Medicine 30(54).</p> <p>National Asthma Education and Prevention Program (NAEPP) Coordinating Committee Expert Working Group. 2020. 2020 Focused Updates to the Asthma Management Guidelines. <a href="https://www.nhlbi.nih.gov/resources/2020-focused-updatesasthma-management-guidelines">https://www.nhlbi.nih.gov/resources/2020-focused-updatesasthma-management-guidelines</a></p> <p>Global Initiative for Asthma (GINA). 2024. Global Strategy for Asthma Management and Prevention. <a href="https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf">https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf</a></p>		
<b>Characteristics</b>			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product lines</b>	<ol style="list-style-type: none"> <li>Commercial.</li> <li>Medicaid.</li> </ol>		
<b>Stratifications</b>	<ol style="list-style-type: none"> <li>COPD Diagnosis: <ul style="list-style-type: none"> <li>Diagnosed with COPD (COPD Value Set)* any time during the person’s history through the end of the measurement period.</li> <li>Not diagnosed with COPD (COPD Value Set)* any time during the person’s history through the end of the measurement period.</li> </ul> </li> </ol>		
	4. Age as of the episode date.		

<p><b>Risk adjustment</b></p> <p><b>Improvement notation</b></p> <p><b>Guidance</b></p>	<ul style="list-style-type: none"> <li>– 5–11 years.</li> <li>– 12–17 years.</li> <li>– 18–50 years.</li> <li>– 51–64 years.</li> </ul> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p> <p>None.</p> <p>Increased score indicates improvement.</p> <p><b>Data collection methodology:</b> ECDS. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the episode occurred in the period being measured.</p> <p><b>Observation Stays.</b> For observation stays (<u>Observation Stay Value Set</u>) that do not have a recorded admission or discharge date, set the admission date to the earliest date of service on the claim and set the discharge date to the last date of service on the claim.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p>
<p><b>Definitions</b></p>	
<p><b>Episode date</b></p>	<p>The date of service for any acute inpatient discharge, observation stay, ED visit or urgent care visit with a principal diagnosis of asthma.</p> <p>For an acute inpatient discharge or observation stay, the episode date is the date of discharge.</p> <p>For direct transfers, the episode date is the discharge date from the last transfer admission.</p>
<p><b>Direct transfer</b></p>	<p>A direct transfer is when the discharge date from the first inpatient setting precedes the admission date to a second inpatient setting by one calendar day or less. For example:</p> <ul style="list-style-type: none"> <li>• An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 1, is a direct transfer.</li> <li>• An inpatient discharge on June 1, followed by an admission to an inpatient setting on June 2, is a direct transfer.</li> <li>• An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 3, is not a direct transfer; these are two distinct inpatient stays.</li> </ul> <p>Direct transfers may occur from and between different facilities and between acute inpatient and observation or between observation and acute inpatient.</p>

	<p>Use the following method to identify admissions to and discharges from inpatient settings.</p> <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>) and observation stays (<u>Observation Stay Value Set</u>).</li> <li>2. Exclude nonacute inpatient stays (<u>Nonacute Inpatient Stay Value Set</u>).</li> <li>3. Identify the admission and discharge date for the stay.</li> </ol>
<b>Initial population</b>	<p><i>Measure item count:</i> Episode.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical.</li> <li>• <i>Continuous enrollment:</i> Episode date through 30 days after episode date (31 total days).</li> <li>• <i>Allowable gap:</i> None.</li> </ul> <p><i>Ages:</i> 5–64 years as of the episode date.</p> <p><i>Event:</i></p> <p><b>Acute visits for asthma from January 1–December 1 of the measurement period.</b></p> <p>Include the following:</p> <p><b>Step 1.</b> Identify all persons with any of the following between January 1 and December 1 of the measurement period:</p> <ul style="list-style-type: none"> <li>• ED visits (<u>ED Value Set</u>) with a principal diagnosis of asthma (<u>Asthma Updated Value Set</u>).</li> <li>• Urgent care visits (<u>Outpatient Value Set</u> <i>with</i> POS code 20) with a principal diagnosis of asthma (<u>Asthma Updated Value Set</u>).</li> <li>• Acute inpatient or observation discharges with a principal diagnosis of asthma (<u>Asthma Updated Value Set</u>) on the discharge claim. To identify an acute inpatient or observation discharge: <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>) and observation stays (<u>Observation Stay Value Set</u>).</li> <li>2. Exclude nonacute inpatient stays (<u>Nonacute Inpatient Stay Value Set</u>).</li> <li>3. Identify the discharge date for the stay.</li> </ol> </li> </ul> <p><b>Step 2.</b> Exclude ED and urgent care visits that result in an inpatient or observation stay.</p> <p>Exclude ED or urgent care visits followed by admission to an acute inpatient care setting on the date of the ED or urgent care visit or within the 30 days after the ED or urgent care visit (31 total days), providing that the inpatient or observation stay discharge has a principal diagnosis of asthma. Only the inpatient or observation stay visit should be counted. Use the discharge date of the inpatient or observation stay to determine follow-up.</p>

	<p><b>Step 3. Test for direct transfers.</b></p> <p>For discharges with one or more direct transfers, use the last discharge. Using the discharges identified in step 1, identify direct transfers using the Direct Transfers definition above. Exclude the episode if the direct transfer’s discharge date occurs after December 1 of the measurement period.</p> <p><i>Note: For acute inpatient or observation stays where there was a direct transfer, use the original stay and any direct transfer stays to identify eligible episode dates in this step.</i></p> <p><b>Step 4. Multiple episodes within a 30-day period.</b></p> <p>If a person has more than one acute visit between January 1 and December 1 of the measurement period, identify all eligible acute, ED or urgent care visits between January 1 and December 1 of the measurement period and only include the first visit in each 30-day period.</p> <p><i>For example, if a person has an eligible acute visit on January 1, include the January 1 visit and do not include eligible acute visits that occur on or between January 2 and January 31; then, if applicable, include the next eligible acute visit that occurs on or after February 1. Identify visits chronologically, including only the first visit in each 30-day period.</i></p> <p><i>Note: Removal of multiple episodes in a 30-day period is based on eligible episode dates. Assess each episode for eligibility before removing multiple episodes in a 30-day period.</i></p>
<p><b>Denominator exclusions</b></p>	<p><b>5. Persons with a date of death.</b></p> <p>Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</p> <p><b>6. Persons in hospice or using hospice services.</b></p> <p>Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</p> <p><b>7. Persons with a diagnosis that requires a different treatment approach.</b></p> <p>Persons with a diagnosis that requires a different treatment approach than members with asthma (<u>Acute Respiratory Failure Value Set</u>; <u>Emphysema Value Set</u>; <u>Cystic Fibrosis Value Set</u>)* at any time in the person’s history through the last day of the measurement period.</p> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p>
<p><b>Denominator</b></p>	<p>The initial population minus denominator exclusions.</p>
<p><b>Numerator</b></p>	<p><b>A follow-up visit within 30 days after the episode. Do not include follow-up visits that occur on the same day as the episode.</b></p> <p>An outpatient visit, telephone visit, e-visits and virtual check-ins (<u>Outpatient and Telehealth Value Set</u>) without POS code 20 within <b>30</b> days.</p>

<p><b>Summary of changes</b></p>	<p>8. This is a first-year measure.</p>																														
<p><b>Data Element Tables</b></p>	<p>Organizations that submit HEDIS data to NCQA must provide the following data elements.</p> <p><i>Table AAF-E-1/2: Data Elements for Follow-Up After Acute Care Visits for Asthma</i></p> <table border="1"> <thead> <tr> <th data-bbox="488 417 662 491">Metric</th> <th data-bbox="662 417 792 491">Age</th> <th data-bbox="792 417 1036 491">Diagnosis</th> <th data-bbox="1036 417 1240 491">Data Element</th> <th data-bbox="1240 417 1468 491">Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td data-bbox="488 491 662 543">FollowUpVisit</td> <td data-bbox="662 491 792 543">5-11</td> <td data-bbox="792 491 1036 543">COPDDiagnosed</td> <td data-bbox="1036 491 1240 543">InitialPopulation</td> <td data-bbox="1240 491 1468 543">Metadata</td> </tr> <tr> <td></td> <td data-bbox="662 543 792 623">12-17</td> <td data-bbox="792 543 1036 623">COPDNotDiagnosed</td> <td data-bbox="1036 543 1240 623">Exclusions</td> <td data-bbox="1240 543 1468 623">For each Stratification</td> </tr> <tr> <td></td> <td data-bbox="662 623 792 703">18-50</td> <td></td> <td data-bbox="1036 623 1240 703">Denominator</td> <td data-bbox="1240 623 1468 703">For each Stratification</td> </tr> <tr> <td></td> <td data-bbox="662 703 792 783">51-64</td> <td></td> <td data-bbox="1036 703 1240 783">Numerator</td> <td data-bbox="1240 703 1468 783">For each Stratification</td> </tr> <tr> <td></td> <td data-bbox="662 783 792 835">Total</td> <td></td> <td data-bbox="1036 783 1240 835">Rate</td> <td data-bbox="1240 783 1468 835">(Percent)</td> </tr> </tbody> </table>	Metric	Age	Diagnosis	Data Element	Reporting Instructions	FollowUpVisit	5-11	COPDDiagnosed	InitialPopulation	Metadata		12-17	COPDNotDiagnosed	Exclusions	For each Stratification		18-50		Denominator	For each Stratification		51-64		Numerator	For each Stratification		Total		Rate	(Percent)
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DRAFT

# **Asthma Health Care Measurement**

## **Measure Workup**

### **Topic Overview**

Asthma is a complex, chronic disease occurring in all ages, with episodic exacerbations. Improperly managed, it is associated with high costs and poor quality of life. In 2021, 6.5% of children and 8% of adults in the United States had asthma; the disease was responsible for 3,517 deaths (Centers for Disease Control and Prevention 2023). The health consequences of uncontrolled asthma were expected to amount to 15.46 million quality adjusted life-years lost and \$300.6B in direct costs between 2019 and 2038, with per capita costs ranging from \$2,209 to \$6,132 (Yaghoubi et al. 2019). These figures have a disparate impact across racial groups, socioeconomic status and area of residence in terms of disease burden, rates of exacerbation and access to adequate treatment.

Successful asthma management is typically associated with a preventive model of care (Wu, Brigham, and McCormack 2019). For optimal asthma management and control, experts emphasize the importance of minimizing symptom burden and risk of exacerbations using anti-inflammatory agents and bronchodilation drug therapy. Key elements for optimizing care and improving outcomes for severe asthma include pharmacological interventions, identifying and referring patients with suspected severe asthma, personalized assessment and management of asthma symptoms, and shared decision making between clinicians and patients (Haughney et al. 2020).

### **Current Approaches to Asthma Diagnosis and Classification**

The most recent clinical guideline for asthma diagnosis and classification relevant to NCQA measure development efforts are the 2024 Global Initiative on Asthma (GINA) guidelines, whose definition of asthma reflects an approach to diagnosis that combines a history of typical variable respiratory symptoms with confirmation via variable expiratory airflow limitation. The *2020 Focused Updates to the Asthma Management Guidelines*, produced by the National Asthma Education and Prevention Program (NAEPP), echo this approach (National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020).

After an asthma diagnosis is made, tailored asthma treatment regimens necessitate identifying precise asthma classifications (or “phenotypes”). 2024 GINA and 2020 NAEPP guidelines identify two main components of asthma classifications: “asthma control” and “asthma severity”(Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020). Although both sets of guidelines align in terms of asthma control, the 2024 GINA guidelines provide a more standardized framework for identifying asthma severity: Asthma severity reflects the intensity of treatment required to control symptoms and exacerbation after 2–3 months. Per both guidelines, asthma control reflects the extent to which the features of asthma can be observed in the patient, or have been reduced or removed by treatment, and is characterized by symptom control and risk of adverse outcomes.

#### **Diagnosis**

According to 2024 GINA and 2020 NAEPP guidelines, the first step of accurate asthma diagnosis in adults, adolescents and children 6–11 years presenting in clinical practice is to collect information on a patient’s current/historic presentation of chronic or recurrent respiratory symptoms (wheeze, shortness of breath, chest tightness, cough). Symptoms that occur variably over time, vary in intensity, are worse at night/on waking, triggered by exercise, laughter, allergens, cold air or that appear/worsen with viral infections support an asthma diagnosis (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020).

If a history/examination supports an asthma diagnosis, the next step is lung function testing to assess variable expiratory airflow limitation before and after a



bronchodilator is administered (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020).<sup>\*</sup> Although current clinical guidelines and recent literature consistently support spirometry as a preferred diagnostic tool for this component of care, NAEPP guidelines note that fractional exhaled nitric oxide (FeNO) testing may be a useful alternative when spirometry is unavailable (National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020). Although GINA guidelines acknowledge the data supporting this recommendation, they cite concerns about testing specificity (Global Initiative for Asthma 2024). 2024 GINA guidelines deviate from recent NAEPP guidelines to endorse peak expiratory flow (PEF) as a less reliable, but suitable, alternative to spirometry testing when the latter is unavailable.

Per both guidelines, significant/frequent variations between baseline lung function test results and post-bronchodilation lung function test results indicate more confident asthma diagnoses. If results are initially negative, GINA recommends repeating the tests while symptoms are present and/or in the early morning (Global Initiative for Asthma 2024). To increase confidence of a diagnosis, both recent guidelines recommend repeating symptom assessment and lung function testing periodically, and more frequently in pediatric populations (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020). In the event of complex asthma presentations, 2024 GINA guidelines recommend using additional, more specialized diagnostic evaluations.

**Classification:  
Control**

2024 GINA guidelines recommend classifying asthma as well-controlled, partly controlled or uncontrolled. Per both GINA and NAEPP, these classifications are informed by 1.) recent asthma symptoms (over the past 4 weeks); and 2.) risk factors for poor asthma outcomes, asthma exacerbations, persistent airflow limitation and medication side-effects (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020). Both guidelines recommend assessing asthma control frequently (during all visits, routine prescribing encounters and dispensing encounters).

Assessing recent asthma symptoms can be completed using questionnaires, tools and clinical interviews. In pediatric populations, these should be completed jointly with pediatric patients and their parents/caregivers. Although asthma symptoms are a strong predictor of future exacerbation risk, subjective and confounding patient self-reporting necessitates more objective approaches to identify risk factors. An example of this approach can be found in Part B of the *GINA Assessment of Asthma Control* (Global Initiative for Asthma 2024). In addition to routinely assessing functional expiratory volume (FEV<sub>1</sub>) and uncontrolled asthma symptoms/exacerbations, providers managing asthma should monitor medication use, comorbidities/medical history, psychosocial stressors, toxin exposures and type 2 inflammatory markers to build a comprehensive assessment of a patient's risk.

**Classification:  
Severity**

The 2020 NAEPP guidelines stratify asthma severity as either intermittent or persistent (National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020). The 2024 GINA guidelines state that this distinction is largely arbitrary, with problematic implications for asthma treatment approaches (Global Initiative for Asthma 2024). GINA uses an

<sup>\*</sup>If the patient is experiencing severely uncontrolled symptoms/signs, this is likely indicative of an asthma exacerbation. 2024 GINA guidelines recommend treating asthma exacerbations as soon as clinically feasible (i.e., before lung function testing occurs).

updated concept of asthma severity that relies on a retrospective assessment of how difficult an individual's asthma is to treat, while acknowledging that additional work is necessary to develop a more precise framework.

Based on the most recent clinical guidelines available (GINA 2024), severe asthma is asthma that remains uncontrolled despite optimized treatment (Global Initiative for Asthma 2024), in contrast to asthma that is uncontrolled because of inadequate treatment (e.g., improper inhaler technique, poor adherence, environmental exposures). The first step of assessing asthma severity is to distinguish asthma symptoms resulting from inadequate/inappropriate treatments, adherence or relevant comorbidities, and then stratifying severity as follows:

*Severe asthma:* Remains uncontrolled despite optimized treatment with high-dose ICS-LABA, or that requires high-dose ICS-LABA to prevent it from becoming uncontrolled.

*Moderate asthma:* Well-controlled with low- or medium-dose ICS LABA.

*Mild asthma:* Well-controlled with low-intensity treatment (low-dose as-needed ICS-formoterol, or low-dose ICS plus as-needed SABA).

Per both GINA and NAEPP guidelines, asthma severity should be reassessed after 2–3 months of treatment and periodically thereafter (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020).

## Current Approaches to Asthma Management

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Most asthma can be adequately diagnosed and managed in primary care settings, where providers can develop asthma care plans, assign treatments and consistently monitor symptoms (Wu, Brigham, and McCormack 2019). Although non-emergent outpatient settings are better suited for the longitudinal approach to asthma care, recent research underscores that provider shortages and health access disparities can pose barriers to accessing these settings. Asthma is shown to be managed less effectively in alternative settings such as ED, urgent care and acute care, where a longitudinal, preventive approach to care is less common. In any setting, personalized interventions and shared decision-making practices are shown to be effective in reducing exacerbations and improving outcomes (Haughney et al. 2020).

The following factors are also critical to developing a complete understanding of asthma management:

1. Use of a stepped treatment framework.
2. Maintenance and Reliever Therapy (MART).
3. Emerging pharmacological treatments.
4. Avoidance of exposures and associations that make patient's asthma more difficult to manage/treat.
5. Quality improvement initiatives that support best practices.
6. Proper adherence to treatment plans.

**Stepped treatment** A “stepped treatment” framework allows clinicians to tailor asthma management strategies to an individual's level of asthma control and severity. GINA 2024 guidelines reflect the most up-to-date edition of this framework (Global Initiative for Asthma 2024). Although the framework in the NAEPP 2020 guidelines largely align with the GINA 2024 version, the latter reflects recent research and thought leadership on asthma control and severity and emerging asthma treatment strategies (Global Initiative for Asthma 2024; National Asthma Education and

Prevention Program Coordinating Committee Expert Panel Working Group 2020).

Per either major guideline, stepped treatment can provide tailored care various points in care. It requires close monitoring of symptoms and modifications to treatment regimens, stepping up if a higher degree of care is required and stepping down if asthma is stable and well managed, until the appropriate medication and dosage are achieved (Global Initiative for Asthma 2024). GINA guidelines detail the steps and appropriate medication regimen for individuals 0–5 years of age, 6–11 years of age and 12+ years of age.

Inhaled corticosteroids (ICS) are a recommended treatment across steps and age groups; controller medications are recommended for steps 3–5. Other controller medications recommended for the highest steps include long-acting antimuscarinic antagonist tiotropium (steps 4–5, patients  $\geq 12$  years of age), anti-immunoglobulin E (step 5, patients  $\geq 6$  years of age), interleukin-5 antibodies (step 5,  $\geq 12$  years of age) and, in some cases, tiotropium. In severe cases, oral corticosteroids may be provided for symptom relief, although both guidelines recommend limiting oral steroid exposure, given the long-term health consequences associated with overuse (Global Initiative for Asthma 2024; National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group 2020).

Stepping down (to a more preventive, less reactive approach) is not frequently implemented, despite evidence of potential effective symptom management and cost reduction (Bernstein and Mansfield 2019; Dilokthornsakul, Thompson, and Campbell 2019). This approach may benefit from increased adoption and refinement, especially in conjunction with patient education and asthma action plans.

## **MART**

The updated 2020 NAEPP and 2024 GINA guidelines include MART as a treatment option for individuals with moderate to severe persistent asthma. MART is a combination medication that includes a controller (ICS) and a reliever (LABA) dispensed in the same inhaler (Global Initiative for Asthma 2024). Patients use the inhaler daily for maintenance and as needed to relieve asthma symptoms. This therapy simplifies asthma management and is available to children (Allergy & Asthma Network, n.d.). MART also aligns with medications recommended for steps 3 and 4 of the GINA guidelines for children 6–11 years of age (Global Initiative for Asthma 2024). Barriers to MART therapy include the need for prior authorization, quantity limits, age limits, step therapy and cost sharing. As of April 2023, the American Lung Association noted that 45 states covered both MART medications in all Medicaid plans, but financial barriers continued to prevent widespread uptake of MART (American Lung Association, n.d.).

## **Emerging pharmacological treatments**

Although intermittent/as needed use of inhaled corticosteroids, with oral corticosteroids only used for severe exacerbations, is the recommended treatment course for less severe forms of asthma, expert consensus cautions the use of oral corticosteroids, given strong associations with the onset of adverse outcomes. A 2021 study published in JAMA found that oral corticosteroid bursts were associated with increased risk of GI bleeding, sepsis and pneumonia in children within the first month of initiating corticosteroid therapy (Yao et al. 2021). Similar results were found in a study population of pregnant women (Tsai et al. 2023).

The safety of short acting beta agonists is controversial. Many studies find that ICS-based treatment with use of short acting beta antagonists (SABA) is a safe and effective course of treatment, and escalating ICS dosage or adding LABAs

results in better symptom control and fewer exacerbations (Al-Turki et al. 2020; Amirav et al. 2023). Recent research also indicates an association between increased use of SABA and deterioration of asthma control and potential increases in exacerbation risk (Lugogo et al. 2021).

Research supports new approaches to phenotyping asthma and targeting the disease with cost-effective biologic treatments for eosinophilic asthma. Summaries of new asthma pharmaceutical treatments concluded: 1.) Dupilumab is associated with decreased exacerbations and improved quality of life; 2.) Benralizumab significantly reduces exacerbations and improves lung function; 3.) Reslizumab, though not cost-effective, and inconvenient due to intravenous delivery, decreases asthma exacerbations, with an advantage in obese patients; 4.) Mepolizumab reduces systemic steroid doses and results in significantly fewer asthma exacerbations; 5.) Omalizumab substantially reduces exacerbations and ICS dosage needed for symptom control (Chupp, Kaur, and Mainardi 2020).

## **Exposures and associations**

Social/physical comorbidities and environmental exposures can exacerbate asthma and make the condition more difficult to manage. Research consistently links exposure to local air pollution and social stressors with more severe asthma outcomes. Obesity, acute rhinosinusitis exacerbations and non-exclusive breastfeeding in newborns are less frequently cited as drivers of severe asthma but seem to have an impact as well.

High particulate matter (PM) concentrations near an individual's residence are significantly associated with asthma episodes and ER visits (Altman et al. 2023; Connor and Zablotsky 2022; Cook 2020). Tobacco smoke exposure is a notable driver of asthma exacerbations as well. Asthma attacks are significantly more common among males with environmental tobacco smoke exposure and among current smokers, and secondhand smoke is associated with both higher odds of asthma exacerbation and higher odds of asthma development in children (Becerra, Arias, and Becerra 2022; Johansson et al. 2021; Neophytou et al. 2018). The small observed variation in these findings can be explained by the modifying effect that lifestyle, genetic differences and area of residence have on the association between air pollutants and asthma severity (Lovinsky-Desir et al. 2019; Zhu et al. 2023).

Social stressors are another significant associate of asthma severity. Multiple variations of chronic psychosocial stress (e.g., adverse childhood experiences, racism, poverty, peer pressure) are associated with adverse asthma outcomes (Barnthouse and Jones 2019; Miadich et al. 2020).

## **Quality improvement initiatives**

Research regarding quality improvement (QI) efforts provides evidence for implementing diagnostic or treatment decision support tools, promoting better adherence to guidelines and capturing care quality through measures.

A study examining the effects of the Enhancing Care for Patients with Asthma (ECPA) collaborative QI program (implemented in 65 community health centers serving asthma patients) found favorable effects on asthma severity, asthma control tests, pulmonary function tests, asthma action plans and controller medications (Rojanasarot et al. 2019). The program implemented efficient workflows, clinical care decision support within EHRs, tools for patient self-management and resources for community members.

Electronic asthma decision support tools incorporating National Heart, Lung and Blood Institute (NHLBI) guidelines for identifying asthma severity can improve the precision of asthma classification and guideline adherence (Shukla et al.

2022).

Other examples included a QI intervention effective at reducing hospitalizations and urgent care visits for children with persistent asthma. Interventions include identifying patients with persistent asthma, contacting patients who were overdue for care and referring to specialist care (Lou et al. 2021). QI programs are important for uptake and continued implementation of care aligned with guidelines; research demonstrates that the end of a pediatric QI initiative can be associated with declines in guideline adherence (Schechter et al. 2021).

Quality measures are crucial tools for QI programs, but a systematic review identifying existing self-reported asthma measures for adolescents concluded that current measures for assessing self-management are limited, and there is a need to develop valid and reliable measures that would identify essential components for asthma management (Isik et al. 2023). Appendix A lists existing asthma care measures as of March 2024.

### **Adherence to treatment plans**

Recent research underscores that non-adherence to asthma controller medication regimens drives poor clinical and economic outcomes for patients living with asthma. Although factors such as ethnicity and food security are associated with treatment adherence, consistent communication and planning between patients, caregivers and physicians is a much stronger driver of adherence.

When used consistently, ICS is an effective asthma treatment option. Patients with asthma can reduce their use of reliever medications, asthma-related ED visits and asthma-related hospitalizations (Averell et al. 2022; Dima et al. 2019). In contrast, structural barriers that prevent patient education on medication use, misinterpreted treatment plans or medication misuse can inhibit ICS treatment adherence, causing patients to experience a greater disease burden and more severe asthma exacerbations (Averell et al. 2021; Kocks et al. 2018; Roche et al. 2022).

Patient-centered approaches that engage individuals with treatment regimens are effective at reducing non-adherence. Inhaler error, a common form of asthma medication misuse, can be mitigated by feedback from health professionals on inhaler technique (Sulaiman et al. 2018). Personalized interventions such as asthma action plans are similarly impactful. In a 2021 study, Makhinova et al. found that 76.6% of patients with poor asthma medication adherence did not have an asthma action plan (AAP), while 81.5% of patients with good adherence did have an AAP (Makhinova et al. 2021).

Both inhaler techniques and AAPs can be developed through good communication and shared decision-making practices between physicians, patients and caregivers. Communication improves patient/caregiver knowledge bases and confidence in medication use, and sets expectations for treatment regimens (Amin et al. 2020; Kan et al. 2021; Sleath et al. 2019). Shared decision-making practices and managed care models can also be effective, ensuring that medication courses and AAPs account for patient beliefs and preferences, and are informed by the psychosocial dynamics inherent to a patient's life (Booster, Oland, and Bender 2019; Gelzer et al. 2019; George and Bender 2019).

## **Health Disparities in Asthma Severity and Prevalence**

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Current evidence suggests that certain racial groups—particularly Black individuals—experience worse disease burdens than others. This finding aligns with other socioeconomic disparities tied to asthma control, most notably including areas of residence, socioeconomic status and access to care. Although

asthma disparities also exist between disabled and non-disabled individuals (in terms of severity), and between LGBTQIA+ individuals and cisgender/heterosexual individuals (in terms of prevalence), most research focused on the association between racial/structural disparities and disparate asthma outcomes in the U.S.

### **Racial disparities**

In studies where presence of asthma symptoms/diagnoses were stratified by race, Black individuals were consistently more likely to experience disease burden than White individuals (Forno, Ortega, and Celedón 2023; Pate et al. 2023; Siegel et al. 2023). Latinx individuals seem to bear a portion of the prevalence burden as well, although to a lesser degree than Black individuals (Perez and Coutinho 2021; Siañez et al. 2019). There are also racial/ethnic disparities in terms of asthma severity and control. Non-Hispanic Black and Hispanic individuals represent the majority of patients experiencing asthma exacerbations in almost all cohort/population-based studies reviewed, and demonstrate that Black individuals bear a greater burden of asthma severity than their Hispanic peers (Lee et al. 2020; Puvvula et al. 2023; Trent et al. 2018; Urquhart and Clarke 2020; Washington et al. 2018).

### **Institutional underpinnings**

Discussions of these disparities often draw ties to institutional factors. Multiple studies indicated that higher levels of structural racism are significantly associated with greater racial disparities in asthma mortality (Adejare et al. 2022; Espaillat, Hernandez, and Burbank 2023; Martinez and Thakur 2023; Siegel and Wiklund 2023). Research on disparities in asthma outcomes focuses on:

- Area of residence/housing and asthma prevalence/severity.
- Insurance status/access to care and asthma severity.
- Income and asthma prevalence/severity.
- Other social risk factors and asthma prevalence.

The links between insurance status, income and other social risk factors with asthma outcomes is also associated with race (Abbott et al. 2023; Buelo et al. 2018; Bukstein et al. 2022; Pate et al. 2020). This aligns with multiple sources that cite the tendency for decreased access to care, economic disenfranchisement and a higher volume of social risk factors to act as barriers to better health.

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**Appendix A: Existing Measures Assessing Asthma Outcomes & Management**

Steward	Measure Name	Measure Description	Level of Accountability	Use in Programs
AHRQ	PDI #14—Asthma Inpatient Admission Rate	Admissions with a principal diagnosis of asthma per 100,000 population 2-17 years of age	Population	n/a
AHRQ	PQI #15—Asthma in Younger Adults Admission Rate	Admissions with a principal diagnosis of asthma per 100,000 population 18-39 years of age	Population	n/a
Health Management Information System (HMIS)	#3890—Optimal Asthma Control	Composite outcome measure evaluating if patients report good asthma control on a validated test based on the age of the patient and if patients report fewer than two ED visits or one hospitalization in the measurement period	Provider	MIPS
IMPAQ International	Timely Follow-Up After Acute Exacerbations of Chronic Conditions (NQF 3455)	The percentage of emergency department visits, observation stays and inpatient admissions for exacerbations of 6 chronic conditions where a patient received follow-up within time frames recommended by clinical practices. The asthma indicator assesses follow-up within 14 days.	Health Plan	n/a
NCQA	Asthma Medication Ratio (AMR)	The percentage of members 5-64 years of age who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications (controllers plus relievers) $\geq 0.5$ during the measurement year (higher is better).	Health Plan	Medicaid Core Set

## HEDIS Health Plan Performance Rates: Asthma Medication Ratio

Table 1. HEDIS AMR Measure Performance—Medicaid Plans

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Age	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
<b>2023*</b>	278	221 (79.5)	5-11	72.8	11.3	59.1	66.2	74.1	80.6	85.7
	278	220 (79.1)	12-18	68.0	9.9	54.8	61.4	68.4	74.6	79.4
	278	235 (84.5)	19-50	62.1	9.5	49.7	55.5	62.4	68.5	72.7
	278	215 (77.3)	51-64	64.1	10.6	51.0	57.1	62.7	71.1	76.7
	<b>278</b>	<b>253 (91.0)</b>	<b>Total</b>	<b>66.0</b>	<b>9.3</b>	<b>54.6</b>	<b>59.5</b>	<b>66.2</b>	<b>72.2</b>	<b>76.7</b>
<b>2022</b>	272	214 (78.7)	5-11	75.2	9.0	63.9	69.3	75.7	81.3	85.3
	272	216 (79.4)	12-18	69.1	9.3	58.1	63.5	69.3	73.8	80.6
	272	232 (85.3)	19-50	60.4	8.7	50.4	54.4	59.7	66.0	70.6
	272	210 (77.2)	51-64	62.4	8.9	51.6	56.3	62.3	68.3	73.9
	<b>272</b>	<b>243 (89.3)</b>	<b>Total</b>	<b>65.5</b>	<b>8.7</b>	<b>55.1</b>	<b>58.9</b>	<b>65.6</b>	<b>70.8</b>	<b>75.9</b>
<b>2021</b>	270	214 (79.3)	5-11	76.7	7.2	67.9	71.9	77.5	81.3	84.5
	270	217 (80.4)	12-18	69.2	8.1	59.5	64.9	69.3	73.5	77.8
	270	235 (87.0)	19-50	58.3	8.0	48.8	53.5	58.3	62.5	66.8
	270	205 (75.9)	51-64	59.6	8.7	48.6	53.9	58.8	64.3	70.3
	<b>270</b>	<b>247 (91.5)</b>	<b>Total</b>	<b>65.0</b>	<b>8.2</b>	<b>54.6</b>	<b>59.9</b>	<b>64.3</b>	<b>69.7</b>	<b>74.3</b>

\*For 2023 the average denominator across plans for the Total rate was 2,630 individuals, with a standard deviation of 3,250.

**Table 2. HEDIS AMR Measure Performance—Commercial Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Age	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
<b>2023*</b>	420	210 (50.0)	5-11	88.0	6.7	79.5	84.7	88.8	92.9	95.1
	420	210 (50.0)	12-18	83.5	6.8	74.9	79.6	84.1	88.4	91.3
	420	363 (86.4)	19-50	81.6	7.4	71.8	76.9	82.7	86.2	90.1
	420	349 (83.1)	51-64	85.6	5.9	77.5	82.2	86.3	89.8	92.4
	<b>420</b>	<b>388 (92.4)</b>	<b>Total</b>	<b>83.6</b>	<b>6.5</b>	<b>75.1</b>	<b>79.8</b>	<b>84.3</b>	<b>87.9</b>	<b>91.0</b>
<b>2022</b>	417	207 (49.6)	5-11	90.1	5.9	84.0	87.2	90.6	94.1	96.4
	417	213 (51.1)	12-18	84.5	6.2	76.2	80.4	85.3	88.3	91.8
	417	363 (87.1)	19-50	81.9	6.5	73.3	78.2	82.1	86.2	89.6
	417	354 (84.9)	51-64	86.1	5.2	79.6	83.0	86.2	89.9	92.4
	<b>417</b>	<b>390 (93.5)</b>	<b>Total</b>	<b>84.2</b>	<b>5.8</b>	<b>77.5</b>	<b>81.1</b>	<b>84.3</b>	<b>87.8</b>	<b>90.6</b>
<b>2021</b>	419	217 (51.8)	5-11	90.2	6.1	83.3	87.8	91.4	94.5	96.1
	419	231 (55.1)	12-18	83.3	5.7	75.7	80.0	83.7	87.2	90.1
	419	378 (90.2)	19-50	79.3	6.2	72.0	76.1	80.1	83.3	87.0
	419	368 (87.8)	51-64	84.4	5.5	77.5	81.2	85.1	88.3	90.5
	<b>419</b>	<b>398 (95.0)</b>	<b>Total</b>	<b>81.9</b>	<b>5.8</b>	<b>75.1</b>	<b>79.3</b>	<b>82.7</b>	<b>85.3</b>	<b>88.3</b>

\*For 2023, the average denominator across plans for the Total rate was 1,322 individuals, with a standard deviation of 2,705.

## Proposed New Measure for HEDIS<sup>®1</sup> MY 2026: *Disability Description of Membership (DDM)*

NCQA seeks comments on a proposed new measure for inclusion in HEDIS Measurement Year 2026.

*Disability Description of Membership*: Describes the disability status of members 15 years of age and older enrolled any time during the measurement year, including information by data source and disability type.

The measure includes two tables for reporting:

- *Table 1* Disability Status by Data Source: Yes Disability, No Disability, Missing
- *Table 1* Data Source: Self-Reported Questionnaire, Self-Reported Accommodations, Enrollment Status, Unknown, No Data.
- *Table 2* Disability Type: Hearing, Seeing, Concentrating, Walking, Dressing or Bathing, Completing Errands, Communicating, Other Disability Type, Asked but No Answer, Not Disabled, and Disabled, No Disability Type Data.

Members may be included in multiple Disability Type categories.

It is estimated that one in four adults in the United States lives with a disability.<sup>2</sup> Persons with disabilities are more likely to report poorer overall health and have less access to adequate health care.<sup>3</sup> In recognition of the need to advance equitable care and outcomes for persons with disabilities, NCQA conducted an environmental scan and developed the proposed *Disability Description of Membership (DDM)* measure as a potentially valuable tool to improve care for this population.

Throughout 2024, NCQA executed a comprehensive literature review of 1,400 articles, conducted 23 stakeholder interviews (with advocates, policymakers, payers, long-term services and supports providers, state agencies, disability community members), and convened a focus group of experts that provided feedback on the proposed concept over the course of three sessions between April and December 2024.

The DDM measure intends to promote collection and documentation of disability data that will be used for quality improvement efforts. Better disability data will allow identification of care disparities through stratification of quality measures; improved risk adjustment for strengthening the accuracy of quality measures and addressing problematic incentive structures; and development of targeted quality measures that address care gaps experienced by persons with disabilities.

The proposed measure would be in line with existing NCQA measures and programs regarding health plan demographic data. Since 2013, NCQA has developed and implemented measures that require health plans to report the completeness of race/ethnicity and preferred language data for their member populations. The *Language Diversity of Membership (LDM)* and *Race/Ethnicity Diversity of Membership (RDM)* measures provide valuable insight into the completeness of these data across product lines. Data from the RDM measure has been instrumental in implementing the race and ethnicity stratification in HEDIS.

Table 1 of the measure will include three data sources to identify populations with disability:

- *Questionnaire*. The best practice for collecting disability status data from members is administration of a self-reported questionnaire. Questionnaires may include, but are not limited to, the American

<sup>1</sup> HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup> Centers for Disease Control and Prevention. 2021. *Prevalence of Disability and Disability Types*.  
<https://www.cdc.gov/ncbddd/disabilityandhealth/features/disability-prevalence-rural-urban.html>

<sup>3</sup> Centers for Disease Control and Prevention. 2020. *Disability and Health Information for Healthcare Providers*.  
<https://www.cdc.gov/ncbddd/disabilityandhealth/hcp.html>

Community Survey Six-item (ACS-6) Disability Questions and the Washington Group Short Set (WG-SS) on Disability, which align with the current federal standard for disability data.

- *Accommodations*: Documentation of self-reported accommodation requests provides another pathway for identifying disability status. NCQA welcomes feedback on the list of accommodations in the measure specifications.
- *Enrollment Status*: Enrollment in health coverage programs based on eligibility due to disability is the least preferable method for collecting disability status, but is more valuable than not identifying any populations with disabilities. Disability status via enrollment may be furnished by state Medicaid agencies or patient enrollment information in claims.

Table 2 of the measure includes different types of functional disabilities, informed by two common standardized tools: the ACS-6 and WG-SS questionnaires. These include difficulty in performing the following functions: hearing, seeing, concentrating, walking, dressing/bathing, completing errands and communicating. NCQA acknowledges the limitations of identifying individuals with disabilities with these survey tools, and is prepared to update the measure upon release of more comprehensive tools in federal standards and definitions.

The measure includes a proposed restriction of age 15 and older. This is because age restrictions are included in the ACS-6 questionnaire for certain functional activities (e.g., difficulty in completing errands). Thus, an age limitation of members 15 years and older is included in the measure to standardize reporting across all disability types. Future efforts from NCQA will aim to include children and adolescents in the collection of disability data.

In fall 2024, NCQA surveyed organizations to gather preliminary information about disability data collection practices; 21 organizations responded. Results indicate that around half of respondents have ongoing efforts to collect data on disability directly from members, and around one third collect information on disability-related accommodations. The most commonly collected functional areas are vision difficulty and speech-related disability, followed by hearing difficulty, cognitive difficulty and physical disability. About half of organizations cited uncertainty on best practices and internal organization priorities as barriers to collecting the data. These findings suggest that a disability data collection measure could be feasible to implement, and useful for improving completeness of disability data across the health care system.

NCQA seeks general feedback on the measure, and specific feedback on the following:

1. Appropriateness of data sources in the measure.
2. Accommodations to include in measure specification.
3. Inclusion of disability type reporting in the measure.
4. Age restrictions in the eligible population.

NCQA expert panel members support the proposed measure, and believe it is an important step forward toward better disability data in health care.

Supporting documents include the draft measure specifications and measure workup.

**NCQA acknowledges the contributions of the Health Equity Expert Work Group, the Technical Measurement Advisory Panel and the Disability Equity Focus Group.**

## ***Disability Description of Membership (DDM)***

### **Description**

Describes the disability status of members 15 years of age and older enrolled any time during the measurement year, including information by data source and disability type.

### **Calculations**

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

**Age** 15 years and older as of January 1 of the measurement year.

**Table instructions** **Table DDM-A-1/2/3**

Enter the number of members by disability status and by data source, including reporting disability status information sourced from:

- Self-reported questionnaires.
- Self-reported accommodations.
- Obtained enrollment status/eligibility criteria.

For members whose disability status is not collected or not documented, include in “Missing” under *Disability Status* and “No Data” under *Source*.

For members whose disability status is known, but the source is not traceable, include under the appropriate *Disability Status* and “Unknown” under *Source*.

**Table DDM-B-1/2/3**

Enter the number of members in each disability status category. Include members in “Other Disability Type” under *Disability Type* if their disability is not related to hearing, seeing, concentrating, walking, dressing/bathing, completing errands or communicating.

Report members as “Disabled, No Disability Type Data” under *Disability Type* if their disability status is “Disabled” in Table DDM-A-1/2/3, but there is no documented disability type.

Report members as “Not Disabled” under *Disability Type* if their disability status is “Not Disabled” in Table DDM-A-1/2/3.

**Data source**

Report the number of members for whom data has been collected from each data source for disability status. Data sources must fall into one of the following types: self-reported questionnaire, self-reported accommodations, enrollment status, unknown, no data.

- *Self-Reported Questionnaire*. Includes data the organization has collected directly from members; for example, through surveys, health risk assessments or case management systems. Questionnaires may include, but are not limited to, the American Community Survey Six-item (ACS-6) Disability Questions and the Washington Group Short Set (WG-SS) on Disability. LOINC codes may be used to report this source category and disability type.



- **Self-Reported Accommodations.** Organizations may collect information on accommodations requested by members. These may include, but are not limited to: wheelchair access, braille materials, text magnifiers, materials in large print, audio recordings of materials, sign language interpreters, audio described content, communication cards/boards, alternative communication devices, text-to-speech or speech-to-text applications, voice amplifiers, Communication Access Real Time Translation (CART), low stimulation environments, sensory fidgets, appointment time accommodations.
- **Enrollment Status:** Enrollment information furnished by state Medicaid agencies, patient enrollment information in claims.
- **Unknown:** When the reported disability status value is known, but the source is unknown (i.e., there is a disability status value on file from a legacy system, but the organization does not know the source).

## Disability Type Definitions

<b>Hearing</b>	Member is deaf or has serious difficulty hearing.
<b>Seeing</b>	Member is blind or has serious difficulty seeing, even when wearing glasses.
<b>Concentrating</b>	Because of a physical, mental or emotional condition, member has serious difficulty concentrating, remembering or making decisions.
<b>Walking</b>	Member has serious difficulty walking or climbing stairs.
<b>Dressing/Bathing</b>	Member has difficulty dressing or bathing.
<b>Completing Errands</b>	Because of a physical, mental or emotional condition, member has difficulty doing errands alone such as visiting a doctor's office or shopping.
<b>Communicating</b>	Using their usual language, the member has difficulty communicating; for example, understanding or being understood.
<b>Other Disability</b>	Member has another type of disability not captured above.
<b>Asked But No Answer</b>	Information was sought but not found (i.e., member was asked but didn't know).

## Notes

- *It is considered "best practice" to collect data directly from members, because this method reflects members' self-identification. If self-reported data from a questionnaire is not available, disability status may be identified by the proxy of accommodation requests. If self-reported accommodations are not available, third-party data collected directly by another entity, such as the state or CMS, are desired. If multiple disability statuses are identified for a single member, report data source according to the following hierarchy: self-reported questionnaire, self-reported accommodations, enrollment status.*
- *When multiple sources of data are used, there may be disagreements in the data collected. To resolve a disagreement, the organization should use a logical process that considers the relative accuracy of each data source. One way to use a stepwise logic for a data disagreement is:*
  - *Select self-reported categories (questionnaire, accommodations) over indirectly measured categories (disability based on enrollment status).*

– If there is documentation that a member has a disability, include it in Table DDM-B-1/2/3.  
The plan might also prioritize data sources based on analysis of the reliability of data sources.

**Table DDM-A-1/2/3: Percentage of Members for Whom the Organization Has Disability Status Information by Data Source**

Metric	DisabilityStatus	Source	Data Element	Reporting Instructions
DisabilityAndSource	Disabled	SelfReportedQuestionnaire	MemberCount***	For each Stratification
	NotDisabled	SelfReportedAccommodations	Rate	(Percent)
	Missing	EnrollmentStatus		
	Total	Unknown*		
		NoData**		
		Total		

\* Source = "Unknown" is only reported for members who have DisabilityStatus = "Disabled" or DisabilityStatus = "NotDisabled," but the data source is unknown.

\*\* DisabilityStatus = "Missing" is only reported for members with Source = "NoData" and Source = "NoData" is only reported for DisabilityStatus = "Missing"

\*\*\* MemberCount numbers in Table DDM-A-1/2/3 are mutually exclusive and will add up to 100% of the health plan population.

**Table DDM-B-1/2/3: Disability Types Reported**

Metric	Disability Type	Data Element	Reporting Instructions
DisabilityType	Hearing	MemberCount*	For each Type
	Seeing	Rate	(Percent)
	Concentrating		
	Walking		
	DressingBathing		
	CompletingErrands		
	Communicating		
	OtherDisabilityType		
	AskedButNoAnswer		
	NotDisabled		
	Disabled,NoDisabilityTypeData		
	Total		

\*MemberCount numbers in Table DDM-B-1/2/3 are not mutually exclusive. Members can be included in multiple Disability Type categories.

## ***Disability Description of Membership (DDM)***

### **Measure Workup**

#### **Executive Summary**

This workup focuses on identifying barriers and current quality measures in health care for persons with disabilities. Research questions regarding barriers, intersectionality considerations, policy implications and existing frameworks for quality measurement are assessed across three key populations in disability, aligned with the Biopsychosocial Model:

1. Individuals with visual, hearing or ambulatory disabilities as captured by the American Community Survey (ACS) questions.
2. Individuals with intellectual or developmental disabilities.
3. Individuals with chronic conditions that result in a disabling or potentially disabling condition.

Barriers range from systemic or population level (e.g., structural ableism, along with other intersecting identities and experiences of discrimination) to interpersonal (e.g., provider stigma, communication challenges) and individual levels (e.g., internalized stigma, fear of disclosure to providers, limited structural access). Gaps in maternal and reproductive health, care coordination and provider education can also perpetuate worse clinical and social outcomes in this population.

Organizations have made efforts to capture disability information through data collection and measurement, but existing quality measures for disability and care needs are limited due to their reliance on patient-reported indicators, underutilized measurement tools and restricted data collection and reporting on disability.

Based on the findings gathered through the environmental scan, the National Committee for Quality Assurance (NCQA) is considering these gaps, and recommendations for improvement, as we identify opportunities to leverage HEDIS<sup>®1</sup> measures and standards to address disability equity.

#### **Environmental Scan Methods**

##### **Literature Review**

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NCQA conducted a literature review from February–July 2024 to gain an understanding of health care quality for individuals with disabilities. Key areas of interest were identified based on the following research questions, grounded in the Biopsychosocial Model:<sup>2</sup>

1. What systemic barriers have been identified for people with disabilities? What unique challenges are experienced by persons with disabilities through an intersectional lens?
2. Have best practices or interventions been identified for supporting inclusion and improving health outcomes for persons with disabilities?
3. Are there frameworks or indicators for monitoring the progress of disability initiatives over time (nationally, state level or within organizations)?

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup>Wade, D.T., & P.W. Halligan. 2017. "The Biopsychosocial Model of Illness: A Model Whose Time Has Come." *Clinical Rehabilitation* 31(8), 995–1004. <https://doi.org/10.1177/0269215517709890>

4. What measures exist for assessing the quality of care for populations with disabilities? What gaps exist? Could these measures create unintentional consequences that might harm persons with disabilities?

The review evaluated literature published in the US between January 1, 2018, and February 1, 2024. The literature search was conducted through PubMed. Over 10,000 articles were screened, resulting in 1,400 articles undergoing final review. The team subsequently conducted an abstract extraction to compile major resulting themes, findings and populations of study.

## Stakeholder Interviews

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NCQA conducted 23 semi-structured interviews with stakeholders across perspective groups, including advocates, policymakers, payers, long-term services and supports providers, state agencies and disability community members. Contacts were identified through existing organizational relationships, web search and stakeholder recommendations. Outreach was conducted through email, and 1-hour interviews were held with each individual/organization between April and July 2024.

NCQA created an interview guide for consistency that included discussion questions about the representative and/or their organization; motivations for engaging in the disability space; organizational use of data (as relevant); goals for the disability community; potential challenges/barriers to these goals; and NCQA's opportunities for involvement.

## Findings

Environmental scan results are summarized in several themes, listed below. While priorities, experiences, concerns, challenges and successes shared during the interviews were consistent with the literature review, they also contributed valuable insights about the opportunities for measures and standards concepts.

***Ableism and Stigma, Bias and Discrimination Toward People With Disabilities.*** The literature review identified that stigma, bias and discrimination experienced by this population in medical and societal settings lead to depressive symptoms and stress, heightened effect of negative environmental factors and decreased social function. Explicit/implicit provider bias against treating persons with disabilities negatively impacts patient-provider relationships, reduces patient engagement in clinical care and potentially induces fear. Stigma and bias rooted in ableism prevent this population from receiving comprehensive care from providers, who may feel inexperienced in caring for persons with disabilities. Providers may also take an “over-medicalized” approach to treatment, highlighted as a concern in interviews. Ableism reduces the number of clinicians with disabilities in the field due to prominent cultural and structural barriers to attending medical school. The intersection of marginalized identities and disability can result in disproportionately worse health and social outcomes for persons with disabilities.

***Accessibility of Care.*** Environmental scan findings emphasized that the lack of accessibility, especially for medical diagnostic equipment (e.g., patient exam tables, scales), and accommodations for people with intellectual and developmental disabilities (e.g., autism) can result in delayed or foregone care, and reduce patient engagement. Outside medical settings, many persons with disabilities rely on public and other transportation to travel to appointments. Difficulties or delays with transportation, particularly for those who need assistance with mobility, can result in missed or rescheduled appointments. Minimal compliance with the Americans with Disabilities Act (ADA) and the potential high financial cost of implementing accessible medical equipment impede access to health settings and worsen health for this population.

**Communication Challenges:** Challenges in communication can affect the patient-provider relationship and result in decreased patient understanding, lower rates of appropriate response to patient accommodation requests, growing patient frustration and potential mistrust of providers. These can reduce coordination and quality of patient-centered care and deviate from expected compliance with ADA accommodations.

**Maternal and Reproductive Health.** Environmental scan findings stated that barriers faced by persons with disabilities range from discussing contraceptive care with clinicians to receiving adequate and comprehensive care during pregnancy. Some persistent challenges include limited adoption by providers of communication modification requests, lack of provider awareness or accommodations during pregnancy, lack of access to reproductive health and contraception education, stigma and ableism resulting in persons with disabilities not being offered reproductive care and reduced screening rates for breast and cervical cancer. The end result can be significantly worse clinical outcomes, including higher likelihood of ED visits during pregnancy or postpartum hospitalization, and increased concerns about judgment, discrimination and intrusive provider surveillance.

**Disability Data Collection and Measurement.** Stakeholder interviews highlighted the limited standardization in data collection and use, although there has been movement toward inclusiveness and urgency in data collection. The ACS-6 and Washington Group Short Set on Functioning (WG-SS) are the most widely used methods to measure disability, despite severely undercounting populations and failing to capture the type and extent of disability among persons with disabilities. The ACA mandates collection of data on disabilities, and the HHS employs the ACS-6 questions in data standards.<sup>3</sup> More recently, the NIH designation of persons with disabilities as a population that experiences disparities, re-evaluation of disability data collection methods by the Census Bureau and development of a roadmap outlining immediate, mid- and long-term goals for disability status data collection bring needed attention to measurement and equity for this population.<sup>4</sup>

Although the landscape for disability quality measurement lacks systemic accountability, some measurement programs—the National Core Indicators for Intellectual and Developmental Disabilities Surveys, the National Core Indicators for Aging and Disabilities, The Consumer Assessment of Healthcare Providers and Systems (CAHPS), Personal Outcome Measures by the Council on Quality and Leadership, and others—act as frameworks or tools for assessing the quality of care for persons with disabilities. These programs rely on patient reporting and voluntary reporting, which highlights the need for disability measurement in accountability programs. Further use for disability data in quality measurement includes stratification and risk adjustment—two approaches that would illuminate disparities and equip health systems with tools to address them.

## Opportunities for Measurement

There are several potential routes for utilizing plan-level quality measurement to equip health systems with tools for quality improvement and disability equity:

**Disability Data Collection.** Methods for collecting and documenting disability status data are not standardized, and the ACS-6 and WG-SS do not comprehensively capture data from this population. Survey tools with self-reported disability, and efforts to incorporate disability status collection in health systems, aim to address gaps in availability of disability data. NCQA has the opportunity to elevate a standard for inclusive and equitable collection of disability status and promote collection and documentation activities across health plans.

<sup>3</sup> U.S. Department of Health & Human Services, Office of Minority Health. (n.d.). Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status.” <https://minorityhealth.hhs.gov/data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>

<sup>4</sup> Landes, S.D., B.K. Swenor, M.A. Clark, K.S. Goddard, J.P. Hall, A. Hermans, C. Ipsen, M. Karpman, N.K. Kurth, A. Myers, S.J. Popkin, M.R. Salinger, & Vaitsiakhovich, N. (n.d.). *A Research Roadmap Toward Improved Measures Of Disability*. Retrieved July 17, 2024, from <https://www.healthaffairs.org/doi/10.1377/forefront.20240708.306851/full/>

*Measure Stratification.* Stratification of performance measures increases understanding of the extent of disparities. Stratification has been implemented in key demographic populations, and provides tools for quality improvement programming. Insights from stratification by disability using dual eligibility status show that disparities exist.<sup>5</sup> Given the limited portion of the disability population captured through this approach, it might not accurately describe the extent of disparities experienced by persons with disabilities. Efforts to stratify performance with complete disability status information, and by disability type, will produce better opportunities for addressing disparities—these would require complete, comprehensive data on disability status.

*Risk Adjustment.* Risk adjustment models in quality measurement are a tool for accounting for factors which may play into measure scores, and allow for the development of measures that more accurately capture quality and improve fairness in comparing performance. Disability is included as a minimum set of variables for risk adjustment, according to a technical guidance report by the National Quality Forum (NQF) that outlines data availability and development considerations regarding disability as a social risk factor, and a functional status factor in risk adjustment models.<sup>6</sup> Work to risk-adjust for disability status has been potentially effective for improving accuracy of quality measures and alleviating incentives for providers to avoid caring for more challenging patient populations.<sup>7</sup> Risk adjustment has potential for addressing problematic incentives in reimbursement structures; ameliorating disability status data collection and documentation would allow for improvements to risk-adjustment models.

*Targeted Measures.* Several aspects of quality in care for disability subpopulations are particularly lacking. To address these, NCQA could develop targeted measures focused on maternal and reproductive health access for persons with disabilities or care for persons with intellectual disabilities, given the gap in data and literature regarding care and outcome disparities for this population. There are opportunities to collaborate with initiatives across NCQA that focus on equity measurement for birth equity and behavioral health.

<sup>5</sup> Center for Medicare & Medicaid Services. (2023, May). *Disparities in Health Care in Medicare Advantage Associated with Dual Eligibility or Eligibility for Low-Income Subsidy and Disability*. CMS.Gov.

<https://www.cms.gov/files/document/2023-disparities-health-care-medicare-advantage-associated-dual-eligibility-or-eligibility-low.pdf>

<sup>6</sup> National Quality Forum. (2022, December 21). *NQF: Risk Adjustment Technical Guidance Final Report—Phase 2*.

[https://www.qualityforum.org/Publications/2022/12/Risk\\_Adjustment\\_Technical\\_Guidance\\_Final\\_Report\\_-\\_Phase\\_2.aspx](https://www.qualityforum.org/Publications/2022/12/Risk_Adjustment_Technical_Guidance_Final_Report_-_Phase_2.aspx)

<sup>7</sup> Sorbero, M., Susan M. Paddock, P., Damberg, C., Ann Haas, M. S., Mallika Kommareddi, M. P. H., Tolpadi, A., Megan Mathews, M. A., & Elliott, M. (2018). *Adjusting Medicare Advantage Star Ratings for Socioeconomic Status and Disability*. 24. <https://www.ajmc.com/view/adjusting-medicare-advantage-star-ratings-for-socioeconomic-status-and-disability>

## **Proposed Changes to Existing Measure for HEDIS<sup>®1</sup> MY 2026: Social Need Screening and Intervention (SNS-E)**

NCQA seeks comments on a proposed measure update for inclusion in HEDIS Measurement Year (MY) 2026.

*Social Need Screening and Intervention (SNS-E)*: The percentage of members who, during the measurement period, were screened at least once for unmet food, housing and transportation needs using prespecified instruments and, if screened positive, received a corresponding intervention. Six rates are reported:

- *Food screening*: The percentage of members who had a screening for unmet food needs.
- *Food intervention*: The percentage of members receiving a corresponding intervention within 1 month of screening positive for unmet food needs.
- *Housing screening*: The percentage of members who had a screening for unmet housing needs.
- *Housing intervention*: The percentage of members receiving a corresponding intervention within 1 month of screening positive for unmet housing needs.
- *Transportation screening*: The percentage of members who had a screening for unmet transportation needs.
- *Transportation intervention*: The percentage of members receiving a corresponding intervention within 1 month of screening positive for unmet transportation needs.

The measure excludes individuals in hospice, enrolled in Institutional Special Needs Plans (I-SNP) or residing in long-term care institutions. The measure is stratified by age ( $\leq 17$ , 18–64, 65+). Screening instruments and intervention codes in the measure align with the Gravity Project, a multi-stakeholder, public collective initiative aimed at developing standardized terminology for documentation and exchange of social determinants of health (SDOH) data.

SNS-E was published in HEDIS for MY 2023 as a first-year measure. To satisfy the screening requirement, submission of a Logical Observation Identifiers Names and Codes (LOINC) code from an approved, evidence-based tool aligned with the Gravity Project is required for the screening numerator. To meet the denominator of the intervention indicator, a positive screen associated with a LOINC code is necessary. For the numerator of the intervention indicator, applicable Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT) and Current Procedural Terminology (CPT) codes are required. The first-year analysis (summer 2024) revealed that submitting administrative codes was easier than relying solely on EHR data. Health plans face challenges in extracting LOINC codes from EHRs, as they can more readily access administrative or case management data. NCQA saw this as an opportunity to explore whether adding new Healthcare Common Procedure Coding System (HCPCS) G and International Classification of Diseases, Tenth Revision (ICD-10) Z codes could improve plans' ability to report performance data.

The implementation of Z codes and G codes marks a significant advancement in capturing SDOH that affect patient care and outcomes. Despite their introduction in 2015 and subsequent expansions in 2021 and 2023, the documentation and utilization of these codes remain low. Ongoing efforts by CMS to enhance SDOH data collection—through mandating social need screenings in various programs and introducing reimbursement policy for standardized assessments—are crucial for advancing health equity and improving overall health care quality.<sup>2</sup> NCQA strives to align with ongoing efforts in the field of SDOH collection and documentation, and therefore is evaluating the addition of relevant administrative codes (G and Z) into the SNS-E measure.

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup> Centers for Medicare & Medicaid Services. *CMS Framework for Health Equity 2022–2032*. <https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework>



**Add G0136 Assessment Code to the Screening Numerator.** NCQA proposes adding G0136 (“Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months”) to food, housing and transportation screening indicators.<sup>3</sup> Thus, the description of screening indicators would be modified to be “the percentage of members who had a screening or were assessed by a provider for unmet needs.” Preliminary results from January–June 2024 data from Optum Labs Data Warehouse demonstrate that the G code is used in Medicare and commercial product lines, and utilization will likely increase.

NCQA acknowledges the potential physician burden associated with adding provider assessments such as G0136. However, assessments align with work already being done, in practice, and could help reduce duplication of services by streamlining inclusion of SDOH data, ultimately minimizing redundant efforts. Additionally, including the G code does not replace the option for health plans to submit LOINC codes to meet the screening numerator. Because this is a population-level measure, it is anticipated that most initial screenings will continue to be conducted by ancillary staff or through technological methods designed to capture screenings effectively.

A Z code is not being considered for the screening numerator, as the intent of this indicator is to capture that a screening or assessment was performed, not the screening result. A member with a documented Z code must have undergone a screening and/or clinical assessment to receive the Z code and will already be captured in the numerator of this screening indicator.

**Add Z Codes to Intervention Denominator.** NCQA proposes adding relevant Z codes (for example, Z59.41 Food Insecurity, Z59.1 Inadequate Housing, Z59.82 Transportation Insecurity) to the appropriate intervention indicator denominators. The intervention denominator captures that a social need was identified. Thus, a description of intervention indicators would be modified to be “the percentage of members receiving a corresponding intervention within 1 month of an identified need.” Individuals with identified needs would be captured through a positive result on a standardized screening *or* with a documented Z code.

Preliminary results from January–June 2024 data from initial testing in Medicare and Commercial data demonstrate that Z code utilization is low. The most documented Z code for commercial plans was Z59.41 (food insecurity), and for Medicare plans was Z59.82 (transportation insecurity). These findings differ from previous utilization studies on Z codes demonstrating that housing-related needs were the most documented. This suggests that utilization of Z codes is increasing, along with recent policy efforts in the 2024 Physician Fee Schedule encouraging documentation of both G and Z codes. Relevant ICD-10 Z codes could be useful for identifying individuals with social needs for SNS-E intervention indicators.

**Add G codes (G0019, G0023, G0140) to the Intervention Numerator.** NCQA proposes adding G0019 (“Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s)”) to the numerator of the food screening, housing screening and transportation intervention indicators. NCQA also proposes adding G0023 and G0140 (“Principal illness navigation services”) to the intervention indicator numerators. These codes were introduced in the 2024 Physician Fee Schedule, and capture services provided by ancillary personnel in addressing social needs. They recognize and formalize the critical role non-clinical staff, such as community health workers and care coordinators, play in identifying and addressing SDOH, and capture a more holistic view of services provided.

**Remove “Assessments” from the Intervention Numerator.** NCQA proposes removing assessments from the list of allowable interventions and related value sets. The intervention indicator currently captures eight broad categories of intervention types, including assessment. To better align with the

<sup>3</sup> Federal Register. (2024). *Medicare and Medicaid programs; CY 2025 payment policies under the physician fee schedule and other revisions to part B (CMS-XXXX-P)*. Federal Register, 89(236). <https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicare-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other>



[Gravity Project and HL7 International Conceptual Framework](#) for SDOH Clinical Care, the assessment category will be removed as an allowable intervention. As a result, CPT codes 96161, 96160 and 96156 will be removed from the value sets for food, housing and transportation interventions. Intervention categories will now be consolidated into seven broad categories: assistance, counseling, coordination, education, evaluation of eligibility, provision, referral.

The assessment activity will instead align with screening efforts and be added to the screening numerator, referencing the G0136 code. The CPT codes 96161, 96160 and 96156 will not be added to the screening numerator, because they are not unique to addressing social needs. These updates aim to improve the clarity and alignment of the measure with established SDOH frameworks, ensuring more accurate tracking of interventions.

NCQA seeks specific feedback on the following:

1. Adding G0136 to count towards screening indicators.
2. Adding Z codes to identify individuals with social needs for intervention indicators.
3. Adding G codes (G0019, G0023, G0140) to the intervention numerator.
4. Removing “assessments” from the intervention numerator.
5. Ensuring that updates deliver meaningful benefits and improved support for patients.

NCQA expert panel members support the proposed measure updates and believe it is an important step toward improving data collection and reporting of SDOH data and addressing the social needs of members.

Supporting documents include the updated measure specifications and the literature review on G and Z codes.

**NCQA acknowledges the contributions of the Health Equity Expert Work Group and the Geriatric and Technical Measurement Advisory Panels.**

Measure title	Social Need Screening and Intervention	Measure ID	SNS-E
Description	<ul style="list-style-type: none"> <li>• The percentage of persons who were screened, using prespecified instruments, <u>or assessed by a provider</u>, for unmet food, housing, and transportation needs at least once during the measurement period. The percentage of persons, <u>with an identified need or positive screen</u>, who received a corresponding intervention. <ul style="list-style-type: none"> <li>– <i>Food Screening</i>. The percentage of persons who were screened, <u>or assessed by a provider</u>, for food insecurity.</li> <li>– <i>Food Intervention</i>. The percentage of persons who received a corresponding intervention within 30 days (1 month) of <u>an identified food need or positive screen</u> for food insecurity.</li> <li>– <i>Housing Screening</i>. The percentage of persons who were screened, <u>or assessed by a provider</u>, for housing instability, homelessness or housing inadequacy.</li> <li>– <i>Housing Intervention</i>. The percentage of persons who received a corresponding intervention within 30 days (1 month) of <u>an identified housing need or positive</u> housing screen.</li> <li>– <i>Transportation Screening</i>. The percentage of persons who were screened, <u>or assessed by a provider</u>, for transportation insecurity.</li> <li>– <i>Transportation Intervention</i>. The percentage of persons who received a corresponding intervention within 30 days (1 month) of <u>an identified transportation need or positive screen for</u> transportation insecurity.</li> </ul> </li> </ul>		
Measurement period	January 1–December 31.		
Copyright and disclaimer notice	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
Clinical recommendation statement and rationale	<p>The American Academy of Family Physicians urges health insurers and payers to provide appropriate payment to support health care practices to identify, monitor, assess and address SDOH.</p> <p>The American Academy of Pediatrics recommends surveillance for risk factors related to social determinants of health during all patient encounters.</p> <p>The American Diabetes Association recommends assessing food insecurity, housing insecurity/homelessness, financial barriers and social capital/social community support to inform treatment decisions, with referral to appropriate local community resources.</p>		
Citations	American Academy of Family Physicians. 2019. “Advancing Health Equity by Addressing the Social Determinants of Health in Family Medicine (Position		

	<p>Paper).” <a href="https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html">https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html</a></p> <p>American Academy of Pediatrics. 2016. “Poverty and Child Health in the United States.” <a href="https://pediatrics.aappublications.org/content/137/4/e20160339#sec-12">https://pediatrics.aappublications.org/content/137/4/e20160339#sec-12</a></p> <p>American Diabetes Association. 2022. “Standards of Medical Care in Diabetes-2022.” <i>Diabetes Care</i> 45(Suppl 1) S4–7. DOI:10.2337/dc22-Srev</p> <p>The Gravity Project. “Terminology Workstream Dashboard.” The Gravity Project Confluence, n.d. <a href="https://confluence.hl7.org/display/GRAV/Terminology+Workstream+Dashboard">https://confluence.hl7.org/display/GRAV/Terminology+Workstream+Dashboard</a></p>
<b>Characteristics</b>	
<b>Scoring</b>	Proportion.
<b>Type</b>	Process.
<b>Product lines</b>	<ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• Medicare.</li> </ul>
<b>Stratifications</b>	<p>Age as of the start of the measurement period.</p> <ul style="list-style-type: none"> <li>• ≤17 years.</li> <li>• 18–64 years.</li> <li>• 65 years and older.</li> </ul>
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	<p><b>Data collection methodology:</b> ECDS. Refer to the General Guideline: Data Collection Methods for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>What services count?</b> When using claims, include all paid, suspended, pending and denied claims. When using SNOMED-CT codes to identify history of a procedure, the date of the procedure must be available.</p>
<b>Definitions</b>	
<b>Food insecurity</b>	Uncertain, limited or unstable access to food that is adequate in quantity and in nutritional quality, culturally acceptable, safe and acquired in socially acceptable ways.

<b>Housing instability</b>	Currently consistently housed, however may have experienced any of the following circumstances in the past 365 days: being behind on rent or mortgage, multiple moves, cost burden or risk of eviction.		
<b>Homelessness</b>	Currently living in an environment that is not meant for permanent human habitation (e.g., car, park, sidewalk, abandoned building, on the street), not having a consistent place to sleep at night, or because of economic difficulties, currently living in a shelter, motel, temporary or transitional living situation.		
<b>Housing inadequacy</b>	Housing does not meet habitability standards.		
<b>Transportation insecurity</b>	Uncertain, limited or no access to safe, reliable, accessible, affordable and socially acceptable transportation infrastructure and modalities necessary for maintaining one's health, well-being or livelihood.		
<b>Food Insecurity Screening Instruments</b>	Eligible screening instruments with thresholds for positive findings include:		
	<b>Food Insecurity Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>
	Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool	88122-7	LA28397-0 LA6729-3
		88123-5	LA28397-0 LA6729-3
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool	88122-7	LA28397-0 LA6729-3
		88123-5	LA28397-0 LA6729-3
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool—short form	88122-7	LA28397-0 LA6729-3
		88123-5	LA28397-0 LA6729-3
	Health Leads Screening Panel <sup>®1</sup>	95251-5	LA33-6
	Hunger Vital Sign <sup>™1</sup> (HVS)	88124-3	LA19952-3
	Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences [PRAPARE] <sup>®1</sup>	93031-3	LA30125-1
	Safe Environment for Every Kid (SEEK) <sup>®1</sup>	95400-8	LA33-6
		95399-2	LA33-6
	U.S. Household Food Security Survey [U.S. FSS]	95264-8	LA30985-8 LA30986-6
	U.S. Adult Food Security Survey [U.S. FSS]	95264-8	LA30985-8 LA30986-6

	<b>Food Insecurity Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>
	U.S. Child Food Security Survey [U.S. FSS]	95264-8	LA30985-8 LA30986-6
	U.S. Household Food Security Survey—Six-Item Short Form [U.S. FSS]	95264-8	LA30985-8 LA30986-6
	We Care Survey	96434-6	LA32-8
	WellRx Questionnaire	93668-2	LA33-6
	<sup>1</sup> Proprietary; may be cost or licensing requirement associated with use.		
<b>Housing Instability, Homelessness and Housing Inadequacy Screening Instruments</b>	Eligible screening instruments with thresholds for positive findings include:		
	<b>Housing Instability and Homelessness Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>
	Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool	71802-3	LA31994-9 LA31995-6
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool	99550-6	LA33-6
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool—short form	71802-3	LA31994-9 LA31995-6
	Children’s Health Watch Housing Stability Vital Signs™ <sup>1</sup>	98976-4	LA33-6
		98977-2	≥3
		98978-0	LA33-6
	Health Leads Screening Panel® <sup>1</sup>	99550-6	LA33-6
	Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences [PRAPARE]® <sup>1</sup>	93033-9	LA33-6
		71802-3	LA30190-5
	We Care Survey	96441-1	LA33-6
	WellRx Questionnaire	93669-0	LA33-6
	<sup>1</sup> Proprietary; may be cost or licensing requirement associated with use.		
<b>Housing Inadequacy Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>	
Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool	96778-6	LA31996-4 LA28580-1 LA31997-2 LA31998-0 LA31999-8 LA32000-4 LA32001-2	

	<b>Housing Inadequacy Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool	96778-6	LA32691-0 LA28580-1 LA32693-6 LA32694-4 LA32695-1 LA32696-9 LA32001-2
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool—short form	96778-6	LA31996-4 LA28580-1 LA31997-2 LA31998-0 LA31999-8 LA32000-4 LA32001-2
	Norwalk Community Health Center Screening Tool [NCHC]	99134-9	LA33-6
		99135-6	LA31996-4 LA28580-1 LA31997-2 LA31998-0 LA31999-8 LA32000-4 LA32001-2
<p><sup>1</sup>Proprietary; may be cost or licensing requirement associated with use.</p>			
<p><b>Transportation Insecurity Screening Instruments</b></p>	Eligible screening instruments with thresholds for positive findings include:		
	<b>Transportation Insecurity Instruments</b>	<b>Screening Item LOINC Codes</b>	<b>Positive Finding LOINC Codes</b>
	Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool	93030-5	LA33-6
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool	99594-4	LA33-6
	American Academy of Family Physicians (AAFP) Social Needs Screening Tool—short form	99594-4	LA33093-8 LA30134-3
	Comprehensive Universal Behavior Screen (CUBS)	89569-8	LA29232-8 LA29233-6 LA29234-4
	Health Leads Screening Panel <sup>®1</sup>	99553-0	LA33-6
	Inpatient Rehabilitation Facility - Patient Assessment Instrument (IRF-PAI)—version 4.0 [CMS Assessment]	101351-5	LA30133-5 LA30134-3
	Outcome and assessment information set (OASIS) form—version E—Discharge from Agency [CMS Assessment]	101351-5	LA30133-5 LA30134-3

	Transportation Insecurity Instruments	Screening Item LOINC Codes	Positive Finding LOINC Codes
	Outcome and assessment information set (OASIS) form—version E—Resumption of Care [CMS Assessment]	101351-5	LA30133-5 LA30134-3
	Outcome and assessment information set (OASIS) form—version E—Start of Care [CMS Assessment]	101351-5	LA30133-5 LA30134-3
	Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences [PRAPARE] <sup>1</sup>	93030-5	LA30133-5 LA30134-3
	PROMIS <sup>1</sup>	92358-1	LA30024-6 LA30026-1 LA30027-9
	WellRx Questionnaire	93671-6	LA33-6
	<p><sup>1</sup>Proprietary; may be cost or licensing requirement associated with use.</p> <p><b>Note:</b> <i>The SNS-E screening numerator counts only screenings that use instruments in the measure specification, as identified by the associated LOINC code(s). Allowed screening instruments and LOINC codes for each social need domain are listed above.</i></p> <p>NCQA recognizes that organizations might need to adapt or modify instruments to meet the needs of their membership. To clarify:</p> <ul style="list-style-type: none"> <li>The SNS-E measure specification does not prohibit cultural adaptations or linguistic translations from being counted toward the measure's screening numerators.</li> </ul> <p><del>Only screenings documented using the LOINC codes specified in the SNS-E measure count toward the measure's screening numerators.</del></p> <ul style="list-style-type: none"> <li>The Regenstrief Institute, which maintains the LOINC database, has indicated that LOINC codes are not developed at the level of granularity that distinguishes between original and adapted or translated instruments.</li> <li>Tool developers have varying policies with regard to cultural adaptation and translations; some state that users may adapt screening instruments, others state that organizations must obtain permission first. NCQA urges organizations to refer to the tool developer for information about adaptations or translations that are available or allowed.</li> </ul>		
<p><b>Interventions</b></p>	<p>An intervention corresponding to the type of need identified on or up to 30 days after the date of the first positive screening during the measurement period.</p> <ul style="list-style-type: none"> <li>An <u>identified positive food insecurity need, or</u> positive <u>food insecurity</u> screen finding, must be met by a food insecurity intervention.</li> <li>An <u>identified housing instability or homelessness need, or</u> positive <u>housing instability or homelessness</u> screen finding, must be met by a housing instability or <u>homelessness</u> intervention.</li> <li>An <u>identified housing inadequacy need, or</u> positive <u>housing inadequacy</u> screen finding, must be met by a housing inadequacy intervention.</li> </ul>		

	<ul style="list-style-type: none"> <li>• An <u>identified positive-transportation need, or</u> positive <u>transportation insecurity</u> screen finding, must be met by a transportation insecurity intervention.</li> </ul> <p>Interventions may include assistance, <u>assessment</u>, counseling, coordination, education, evaluation of eligibility, provision or referral.</p>
<p><b>Initial population</b></p>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefit:</i> Medical.</li> <li>• <i>Continuous enrollment:</i> The measurement period.</li> <li>• <i>Allowable gap:</i> No more than one gap of ≤45 days during the measurement period. -No gaps on the last day of the measurement period.</li> </ul> <p><i>Ages:</i> 0+ as of the start of the measurement period.</p> <p><i>Event:</i> None.</p>
<p><b>Denominator exclusions</b></p>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> <li>• <b>Persons who are 66 years of age and older by the last day of the measurement period, with Medicare benefits, enrolled in an institutional SNP (I-SNP) or living long-term in an institution (LTI).</b> Persons enrolled in an Institutional SNP (I-SNP) any time during the measurement period.  Living long-term in an institution any time during the measurement period 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 period.</li> </ul>
<p><b>Denominator</b></p>	<p><b>Denominators 1, 3, 5:</b> The initial population minus denominator exclusions.</p> <p><b>Denominator 2:</b> All persons in numerator 1 with an <u>identified food need (Food Insecurity Value Set)</u>, <u>or a</u> positive food insecurity screen finding, between January 1 and December 1 of the measurement period.</p> <p><b>Denominator 4:</b> All persons in numerator 3 with an <u>identified -housing need (Housing Instability Value Set; Homelessness Value Set; Housing Inadequacy Value Set)</u> or a housing instability, homelessness or housing inadequacy screen finding, between January 1 and December 1 of the measurement period.</p>



	<p><b>Denominator 6:</b> All persons in numerator 5 with an <a href="#">identified transportation need (ICD10CM code Z59.82)</a>, or a positive transportation insecurity screen finding, between January 1 and December 1 of the measurement period.</p>
<p><b>Numerator</b></p>	<p><b>Numerator 1—Food Screening</b> Persons in denominator 1 with a documented result for food insecurity screening, <a href="#">or assessment by a provider (HCPCS code G0136)</a>, performed between January 1 and December 1 of the measurement period.</p> <p><b>Numerator 2—Food Intervention</b> Persons in denominator 2 who received a food insecurity intervention (<a href="#">Food Insecurity Procedures Value Set</a>) on or up to 30 days after the date of the first <a href="#">food need identified or</a> positive food insecurity screen (31 days total).</p> <p><b>Numerator 3—Housing Screening</b> Persons in denominator 3 with a documented result for housing instability, homelessness or housing inadequacy screening, <a href="#">or assessment by a provider (HCPCS code G0136)</a>, performed between January 1 and December 1 of the measurement period.</p> <p><b>Numerator 4—Housing Intervention</b> Persons in denominator 4 who received an intervention corresponding to the type of housing need identified on or up to 30 days after the date of the first <a href="#">housing need identified or</a> positive housing screen (31 days total).</p> <ul style="list-style-type: none"> <li>• <a href="#">Housing Instability Intervention (Housing Instability Procedures Value Set)</a>.</li> <li>• <a href="#">Homelessness Intervention (Homelessness Procedures Value Set)</a>.</li> <li>• <a href="#">Housing Inadequacy Intervention (Inadequate Housing Procedures Value Set)</a>.</li> </ul> <p><b>Numerator 5—Transportation Screening</b> Persons in denominator 5 with a documented result for transportation insecurity screening, <a href="#">or assessment by a provider (HCPCS code G0136)</a>, performed between January 1 and December 1 of the measurement period.</p> <p><b>Numerator 6—Transportation Intervention</b> Persons in denominator 6 who received a transportation insecurity intervention (<a href="#">Transportation Insecurity Procedures Value Set</a>) on or up to 30 days after the date of the first <a href="#">transportation need identified or</a> positive transportation screen (31 days total).</p>
<p><b>Summary of changes</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Removed the definitions of participation and participation period. These definitions have been integrated into the measure where applicable.</a></li> <li>• <a href="#">Added HCPCS code G0136 to screening numerator for identifying provider assessments.</a></li> <li>• <a href="#">Added diagnostic codes to intervention denominators for identifying individuals with positive social needs.</a></li> <li>• <a href="#">Removed assessments from allowable interventions.</a></li> <li>• <a href="#">Added principal navigator service codes to allowable interventions.</a></li> </ul>

	<ul style="list-style-type: none"> <li>Removed the source system of record (SSoR) exclusions data elements from the data elements tables.</li> </ul>
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<b>Data element tables</b>	<p><b>Source System of Record</b></p> <p>Numerator data are submitted by each SSoR accessed to produce the measure result. The SSoR is the authoritative dataset; it contains the standardized elements required for organizations to generate and report digital quality measure results.</p> <p>A hierarchy is applied if quality data elements that support the numerator are identified in multiple data sources. Each SSoR used for HEDIS ECDS reporting is categorized using the following priority:</p> <ol style="list-style-type: none"> <li>1. Electronic health record (EHR)/personal health record (PHR) (the system of data origin, such as laboratory, pharmacy, pathology, radiology).</li> <li>2. Health information exchange (HIE)/clinical registry.</li> <li>3. Case management system.</li> <li>4. Administrative data.</li> </ol> <p>Organizations compare the list of all unique systems containing relevant member data, and assign members based on the highest-ranked data category in the hierarchy. The applied hierarchy does not imply relevance or validity of a data source; rather, it is applied in cases where a member’s data are in multiple locations.</p> <p>Members are assigned to only one SSoR category for the numerator.</p> <p>Organizations must complete data collection for SSoRs by the supplemental data collection deadline. Refer to <i>General Guideline: Audit Preparation</i> for information about the timeline.</p> <p>When appropriate, an SSoR can be refreshed according to the organization’s schedule and counted appropriately for the measure. Refer to <i>General Guideline: Obtaining Information for the Systematic Sample</i>.</p> <p>Organizations that submit data to NCQA must provide the following data elements in a specified file.</p> <p><b>Table SNS-E-: Metadata Elements for Social Need Screening and Intervention</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #333333; color: white;">Metric</th> <th style="background-color: #333333; color: white;">Age</th> <th style="background-color: #333333; color: white;">Data Element</th> <th style="background-color: #333333; color: white;">Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>FoodScreening*</td> <td>0-17</td> <td>InitialPopulation</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>FoodIntervention</td> <td>18-64</td> <td>Exclusions</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>HousingScreening*</td> <td>65+</td> <td>Denominator</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>HousingIntervention</td> <td>Total</td> <td>NumeratorByEHR</td> <td>For each Metric and Stratification</td> </tr> </tbody> </table>	Metric	Age	Data Element	Reporting Instructions	FoodScreening*	0-17	InitialPopulation	For each Metric and Stratification	FoodIntervention	18-64	Exclusions	For each Metric and Stratification	HousingScreening*	65+	Denominator	For each Metric and Stratification	HousingIntervention	Total	NumeratorByEHR	For each Metric and Stratification
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	TransportationScreening*	NumeratorByCaseManagement	For each Metric and Stratification
	ERegistry		
<p><b>Rules for Allowable Adjustments</b></p>	<p><b>Copyright and use:</b> The “Rules for Allowable Adjustments of HEDIS” (the “Rules”) describe how NCQA’s HEDIS measure specifications can be adjusted for other populations, if applicable. The Rules, reviewed and approved by NCQA measure experts, provide for expanded use of HEDIS measures without changing their clinical intent.</p> <p><b>Adjusted HEDIS measures may not be used for HEDIS health plan reporting.</b></p> <p><b>ADJUSTMENTS ALLOWED</b></p> <ul style="list-style-type: none"> <li>• <i>Product lines.</i> Organizations are not required to use product line criteria; product lines may be combined and all (or no) product line criteria may be used.</li> <li>• <i>Ages.</i> The age determination dates may be changed (e.g., select, “age 60 as of June 30 of the measurement period”).</li> <li>• <i>Attribution.</i> Organizations are not required to use enrollment criteria.</li> <li>• <i>Benefits.</i> Organizations are not required to use a benefit.</li> <li>• <i>Other.</i> Organizations may use additional initial population criteria to focus on an area of interest defined by gender, race, ethnicity, socioeconomic or sociodemographic characteristics, geographic region or another characteristic.</li> <li>• <i>Exclusion.</i> Hospice, deceased persons, I-SNP and LTI exclusions are not required.</li> <li>• <i>Measurement period adjustments.</i> Organizations may adjust the measurement period.</li> <li>• <i>Telehealth.</i> Services/events that allow the use of synchronous telehealth visits, telephone visits and asynchronous telehealth (e-visits, virtual check-ins) may be stratified to identify services performed via telehealth. This adjustment is not allowed for events, numerators and exclusions that do not allow the use of telehealth.</li> </ul> <p><b>ADJUSTMENTS NOT ALLOWED</b></p> <ul style="list-style-type: none"> <li>• <i>Initial Population: Event.</i> Value sets, direct reference codes and logic may not be changed.</li> </ul>		

## **Social Needs Screening: Literature Review on G and Z Codes**

### **Background**

Since their introduction in 2015, Z codes have become essential for capturing social determinants of health (SDOH), supporting a growing focus on health equity and reducing health care disparities.<sup>1</sup> To better document factors such as housing, food and transportation challenges, additional Z codes were introduced in 2021 and 2023, including Z59.02 (unsheltered homelessness), Z59.41 (food insecurity) and Z59.82 (transportation insecurity). These codes help health care providers track critical social factors affecting patient outcomes.<sup>2</sup>

To further support SDOH data collection, the Centers for Medicare & Medicaid Services (CMS) began requiring hospitals to screen inpatients for five key SDOH areas—food insecurity, housing insecurity, interpersonal safety, transportation insecurity, utilities—starting January 1, 2024. Along with this requirement, CMS introduced two SDOH-related quality measures and a new billing code, HCPCS G0136, which enables providers to bill for standardized SDOH risk assessment administration. These assessments, focused on social risk factors such as economic stability and the built environment, are critical for supporting accurate documentation and advancing health equity. Although Z codes are not yet fully integrated into risk-based payment models, they are used by CMS for health equity scoring—underscoring their growing importance. In consideration of the increased focus on Z codes and G codes for SDOH documentation in the industry, NCQA investigated literature related to these codes to inform their potential addition to accepted data elements for the *Social Need Screening and Intervention (SNS-E)* measure.

NCQA conducted a search of PubMed and EBSCO data bases. Search terms used included “Z codes,” “G codes,” “SDOH documentation,” “social determinants of health,” “medical coding for SDOH,” “health equity documentation” and “ICD-10 and social needs.” The search yielded 16 articles; 9 were determined relevant and are included in this literature review report. All the literature was published between 2017 and 2024. NCQA will continue to evaluate literature related to Z and G codes as the field evolves and the evidence-base grows.

### **Documentation and Utilization Patterns of Z and G Codes**

Z codes have become essential for documenting SDOH in clinical settings, but utilization remains low. In Texas, documentation of SDOH Z-codes increased from 1% in 2016 to 1.3% in 2019 among Medicaid beneficiaries. Common categories include upbringing problems (37.8%), support group issues (23.4%) and education-related problems (15.9%).<sup>3</sup> In 2017, only 0.96% of Medicare fee-for-service (FFS) beneficiaries had documented Z-codes: predominantly younger, male, Black individuals living in low-income areas with higher medical complexity.<sup>4</sup> During ED visits from 2015–2019, Z-codes were recorded at a rate of 0.84%, with higher utilization in Maryland than in Florida, particularly among uninsured and Medicaid patients.<sup>5</sup> A study analyzing 2015–2018 EHR data from the OneFlorida Clinical Research Consortium found low use of ICD-10-CM Z codes for documenting SDOH.

At the encounter level, Z codes were recorded at a rate of 270.61 per 100,000 encounters, while at the patient level, only 2.03% of records included a documented Z code. Despite a slight increase following the 2018 guideline change allowing all clinicians to document Z codes, findings suggest the need for clearer guidelines, incentives and EHR improvements to enhance SDOH documentation.<sup>6</sup>

In a study of a Health Care for the Homeless Program from 2016–2022, only 28% of patients experiencing housing instability had a Z59 code, underscoring the limited use of these codes for capturing housing-related challenges.<sup>7</sup> A systematic review published in 2024 found that in mental health settings, Z-code documentation rates remained low, ranging from 0.5%–2.4% among publicly insured patients under 64 years of age with comorbidities, demonstrating variation based on demographics and hospital types.<sup>8</sup>

## Most Frequently Used Z Codes

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In 2021, CMS reported that Z-codes were largely underreported in Medicare FFS claims. By 2019, only 0.11% of claims for Parts A and B included Z codes, representing 1.59% of continuously enrolled beneficiaries.<sup>9</sup>

The most frequently reported Z codes in the Medicare population in 2019 were:

1. **Z59.0:** Homelessness.
2. **Z63.4:** Disappearance and death of a family member.
3. **Z60.2:** Problems related to living alone.
4. **Z59.3:** Problems related to living in a residential institution.
5. **Z63.0:** Problems in relationships with a spouse or partner.

Refer to the appendix for a full list of Z codes related to unmet food, housing and transportation.

## Demographic Characteristics of Beneficiaries with Z Codes

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**Dually Eligible Beneficiaries:** Those eligible for both Medicare and full-benefit Medicaid are overrepresented among Z code claims, indicating a higher likelihood of experiencing social and economic challenges.<sup>9</sup>

**Rural Beneficiaries:** Individuals residing in rural areas accounted for 39.7% of claims related to problems with living in a residential institution (Z59.3).<sup>9</sup>

**Gender Distribution:** Males represented 67.1% of claims for homelessness (Z59.0), despite making up only 45.4% of the overall FFS population.<sup>9</sup>

**Racial Disparities:** Black beneficiaries accounted for 24.8% of Z59.0 claims, while Hispanic beneficiaries comprised 9.2%, even though they constitute 8.8% and 5.9% of the total FFS population, respectively.<sup>9</sup>

## Billing Patterns and Provider Types

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**Billing Patterns:** Nearly half (49.6%) of Z codes were billed under Medicare Part B noninstitutional claims.<sup>9</sup>

**Provider Types:** The top providers billing Z codes in 2019 were:

1. Family practice physicians (15%).
2. Internal medicine physicians (14%).
3. Nurse practitioners (14%).
4. Psychiatry physicians (13%).
5. Licensed clinical social workers (12%).

## SDOH-Related G Codes

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Because G0136 is a new code (2024), research has not been done to understand its prevalence or utilization in documenting social needs. However, the appendix lists G codes that may be considered for use in capturing social needs data but requiring further testing.

## Conclusion

The implementation of Z and G codes marks a significant advancement in capturing the SDOH that affect patient care and outcomes, but documentation and utilization remain low. Ongoing efforts by CMS to enhance SDOH data collection—through mandated screenings and standardized risk assessments—are crucial for advancing health equity and improving health care quality.

CMS requirements enhancing SDOH data collection through screening and assessment, integration of G codes into reimbursement policies and provider-level implementation efforts to facilitate further uptake of Z codes will all contribute to increased use. Increased use of Z codes will also improve data availability for reporting an updated version of the NCQA SNS-E measure.

## Appendix A

### Relevant Z and G Codes for the *Social Need Screening and Intervention (SNS-E) Measure*

#### ICD-10-CM Z Codes

- Z59.00—Homelessness unspecified
- Z59.01—Sheltered homelessness
- Z59.02—Unsheltered homelessness
- Z59.10—Inadequate housing, unspecified
- Z59.11—Inadequate housing environmental temperature
- Z59.12—Inadequate housing utilities
- Z59.19—Other inadequate housing
- Z59.41—Food insecurity
- Z59.48—Other specified lack of adequate food
- Z59.81—Housing instability, housed
- Z59.811—Housing instability, housed, with risk of homelessness
- Z59.812—Housing instability, housed, homelessness in past 12 months
- Z59.819—Housing instability, housed unspecified
- Z59.82—Transportation insecurity
- Z59.89—Other problems related to housing and economic circumstances

#### G Codes

- G0136—Administration of a standardized, evidence-based SDOH assessment, 5–15 minutes, not more often than every 6 months
- G0019—Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s)
- G0023—Principal illness navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator; 60 minutes per calendar month, in the following activities
- G0140—Principal illness navigation: Peer support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities
- G9919—Screening performed and positive and provision of recommendations
- G9920—Screening performed and negative
- G9921—No screening performed, partial screening performed or positive screen without recommendations and reason is not given or otherwise specified

## References

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2. IMPROVING THE COLLECTION OF Social Determinants of Health (SDOH) Data with ICD-10-CM Z Codes. Published online 2023. <https://www.cms.gov/files/document/cms-2023-omh-z-code-resource.pdf>
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## **Proposed Changes to Existing Measure for HEDIS<sup>®1</sup> MY 2026: Adult Immunization Status (AIS-E)**

NCQA seeks comments on proposed modifications to the HEDIS *Adult Immunization Status (AIS-E)* measure. AIS-E assesses the percentage of adults who are up to date on routine vaccinations recommended for adults by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). The measure includes separate indicators for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; pneumococcal; and hepatitis B immunization.

AIS-E is specified for the commercial, Medicaid and Medicare product lines and uses the HEDIS Electronic Clinical Data Systems (ECDS) reporting standard to capture receipt of vaccinations using data from electronic sources including administrative claims, immunization registries and EHRs. The measure is stratified by age, race and ethnicity for each product line. Proposed measure updates are described below.

### **New COVID-19 Indicator**

COVID-19 vaccination helps prevent infection and severe symptoms of infection. Since 2020, ACIP has recommended COVID-19 vaccines and vaccination schedules to protect against severe outcomes. In June 2024, ACIP recommended that people 6 months and older receive an updated 2024–2025 vaccine, regardless of a history of COVID-19 vaccination.<sup>2</sup> But despite the importance and proven effectiveness of vaccination, particularly for adults, uptake of COVID-19 vaccines is low. The CDC estimates that around 21.8% of adults 18 and older received the 2023–2024 COVID-19 vaccine, and an estimated 40% of adults 65 and older received at least one dose of the 2023–2024 updated vaccine.<sup>3</sup> The CDC also estimates adults 65 and older account for more than 70% of COVID-19-associated hospitalizations.<sup>4</sup> In October 2024, ACIP recommended a second dose of 2024–2025 vaccine for people 65 and older and for people who are moderately or severely immunocompromised.<sup>5</sup> Refer to the *Adult Immunization Status Workup* for details on the evidence and guidelines.

Given the move toward annual COVID-19 vaccination, NCQA proposes a new indicator that assesses COVID-19 vaccination for adults 19 years of age and older who received their annual COVID-19 vaccine. Refer to the *Adult Immunization Status Specifications* and Table 1 below for more details on the proposed numerator and denominator.

**Table 1. Proposed COVID-19 Immunization Indicator**

<b>Numerator</b>	Any of the following: <ul style="list-style-type: none"> <li>• Received at least one dose of an updated COVID-19 vaccine (<u><a href="#">Adult COVID19 Immunization Value Set</a></u>; <u><a href="#">Adult COVID19 Vaccine Procedure Value Set</a></u>) on or between July 1 of the year prior to the measurement period through June 30 of the measurement period.</li> <li>• Members with anaphylaxis due to the COVID-19 vaccine (SNOMED CT code 914587451000119107) any time before or during the measurement period.</li> </ul>
<b>Denominator</b>	The initial population minus denominator exclusions.
<b>Exclusions</b>	Hospice or death during the measurement period.

<sup>1</sup> HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup> [https://www.cdc.gov/mmwr/volumes/73/wr/mm7316a4.htm?s\\_cid=mm7316a4\\_w](https://www.cdc.gov/mmwr/volumes/73/wr/mm7316a4.htm?s_cid=mm7316a4_w)

<sup>3</sup> <https://www.cdc.gov/covidvaxview/weekly-dashboard/adult-vaccination-coverage.html>

<sup>4</sup> <https://www.cdc.gov/mmwr/volumes/73/wr/mm7339a2.htm>

<sup>5</sup> <https://www.cdc.gov/media/releases/2024/s1023-covid-19-vaccine.html>

NCQA field-tested the proposed indicator with four health plans of varying sizes and geographic locations, to evaluate its feasibility and performance and gather information to inform implementation at the health plan level. The plans provided de-identified patient-level electronic data to NCQA using data from January 1, 2023–April 30, 2024. After ACIP recommendations were released in 2023, NCQA altered the testing specification slightly: Rather than the July 1–June 30 time frame referenced in Table 1, the numerator was members who received a dose of any recommended 2023–2024 COVID-19 vaccine any time between September 1, 2023, and April 30, 2024.

Performance rates for all four health plans ranged from around 2% to 41% across product lines. When compared to national CDC estimates, only one plan performed close to those estimates. The lower performance scores for the other plans could suggest that the plans might not be receiving all available data for the indicator. NCQA asked plans if they thought the scores were an accurate reflection of their performance, or if they reflected data accessibility issues. Two plans stated that results were an accurate reflection of performance; two plans stated that results were likely affected by complications with access to state immunization registries, given regulations on data access and use.

**Note:** *COVID-19 vaccines are no longer free through the federal government. Gaps in immunization registry data should be able to be supplemented through data sources such as claims, though this will not cover every scenario in which someone may receive a vaccine.*

Although panels have concerns about data accessibility regarding immunization registries, they support moving the indicator forward to public comment.

NCQA seeks general feedback on the proposed new indicator.

Supporting documents include the current measure specification, evidence workup and performance data.

**NCQA acknowledges the contributions of the Immunization, Geriatric and Technical Measurement Advisory Panels.**

Measure title	Adult Immunization Status*	Measure ID	AIS-E
<b>Description</b>	The percentage of persons 19 years of age and older who are up to date on recommended routine vaccines for influenza, tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap), zoster, pneumococcal, <del>and</del> hepatitis B <del>and coronavirus disease 2019 (COVID-19)</del> .		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>*Developed with support from the Department of Health and Human Services (DHHS), Office of the Assistant Secretary for Health (OASH), National Vaccine Program Office (NVPO) and The Hepatitis Education Project.</p> <p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement/ rationale</b>	The Advisory Committee on Immunization Practices recommends annual influenza vaccination; and tetanus, diphtheria and acellular pertussis (Tdap) and/or tetanus and diphtheria (Td) vaccine; herpes zoster, pneumococcal, <del>and</del> hepatitis B <del>and COVID-19</del> -vaccination for adults at various ages.		
<b>Citations</b>	Murthy, N. A.P. Wodi, A.P., V.V. McNally, M.F. Daley, S. Cineas. 2024. "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older—United States, 2024." MMWR Morb Mortal Wkly Rep 73:11–15. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm7301a3">http://dx.doi.org/10.15585/mmwr.mm7301a3</a>		
Characteristics			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product lines</b>	<ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• Medicare.</li> </ul>		
<b>Stratifications</b>	<ul style="list-style-type: none"> <li>• <i>Influenza, <del>and</del> Td/Tdap and COVID-19</i>: Age as of the start of the measurement period. <ul style="list-style-type: none"> <li>– 19–64 years.</li> <li>– 65 years and older.</li> </ul> </li> <li>• <i>Zoster</i>: Age as of the start of the measurement period. <ul style="list-style-type: none"> <li>– 50–64 years.</li> <li>– 65 years and older.</li> </ul> </li> </ul>		

<p><b>Risk adjustment</b></p> <p><b>Improvement notation</b></p> <p><b>Guidance</b></p>	<ul style="list-style-type: none"> <li>• <i>Pneumococcal</i>: Age as of the start of the measurement period.             <ul style="list-style-type: none"> <li>– 65 years and older.</li> </ul> </li> <li>• <i>Hepatitis B</i>: Age as of the start of the measurement period.             <ul style="list-style-type: none"> <li>– 19–30 years.</li> <li>– 31–59 years.</li> </ul> </li> <li>• Race for each numerator. (Refer to <del>the</del> <i>General Guideline: Race and Ethnicity Stratification</i>).             <ul style="list-style-type: none"> <li>– American Indian or Alaska Native.</li> <li>– Asian.</li> <li>– Black or African American.</li> <li>– Native Hawaiian or Other Pacific Islander.</li> <li>– White.</li> <li>– Some Other Race.</li> <li>– Two or More Races.</li> <li>– Asked But No Answer.</li> <li>– Unknown.</li> </ul> </li> <li>• Ethnicity for each numerator. (Refer to <del>the</del> <i>General Guideline: Race and Ethnicity Stratification</i>).             <ul style="list-style-type: none"> <li>– Hispanic or Latino.</li> <li>– Not Hispanic or Latino.</li> <li>– Asked But No Answer.</li> <li>– Unknown.</li> </ul> </li> </ul> <p>None.</p> <p>Increased score indicates improvement.</p> <p><b>Data collection methodology:</b> ECDS. Refer to the General Guideline: Data Collection Methods for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p> <p><del><b>SNOMED-CT codes:</b> When using SNOMED-CT codes to identify a history of a procedure, the date of the procedure must be available.</del></p> <p><b>Other guidance:</b> Measure rates are specific to clinical guideline recommendations for the age group included in the rates.</p>
<p><b>Initial population</b></p>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefit:</i> Medical.</li> <li>• <i>Continuous enrollment:</i> The measurement period.</li> </ul>

	<ul style="list-style-type: none"> <li>• <i>Allowable gap</i>: No more than one gap of ≤45 days during the measurement period. The person must be enrolled on the last day of the measurement period.</li> </ul> <p><i>Ages</i>:</p> <ul style="list-style-type: none"> <li>• <i>Initial populations 1, <del>and 2</del> and 6</i>: 19 years and older at the start of the measurement period.</li> <li>• <i>Initial population 3</i>: 50 years and older at the start of the measurement period.</li> <li>• <i>Initial population 4</i>: 65 years and older at the start of the measurement period.</li> <li>• <i>Initial population 5</i>: 19–59 years at the start of the measurement period.</li> </ul> <p><i>Event</i>: None.</p>
<p><b>Denominator exclusions</b></p>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> </ul>
<p><b>Denominator</b></p>	<p><b>Denominator <del>1</del>, <del>and Denominator 2</del>, <del>and Denominator 6</del>: Immunization Status: Influenza, <del>and Td/Tdap</del> <del>and COVID-19</del></b>: The initial population <del>1, <del>and 2</del> and 6</del> minus denominator exclusions.</p> <p><b>Denominator 3: Immunization Status: Zoster</b>: The initial population 3 minus denominator exclusions.</p> <p><b>Denominator 4: Immunization Status: Pneumococcal</b>: The initial population 4 minus denominator exclusions.</p> <p><b>Denominator 5: Immunization Status: Hepatitis B</b>:- The initial population 5 minus denominator exclusions.</p>
<p><b>Numerator</b></p>	<p><b>Numerator 1: Immunization Status: Influenza</b>:-</p> <p>Persons who meet either of the following criteria:</p> <ul style="list-style-type: none"> <li>• Received the influenza vaccine (<u>Adult Influenza Immunization Value Set</u>; <u>Adult Influenza Vaccine Procedure Value Set</u>; <u>Influenza Virus LAIV Immunization Value Set</u>; <u>Influenza Virus LAIV Vaccine Procedure Value Set</u>) on or between July 1 of the year prior to the measurement period and June 30 of the measurement period.</li> <li>• Had anaphylaxis due to the influenza vaccine (SNOMEDCT code 471361000124100) any time before or during the measurement period.</li> </ul> <p><b>Numerator 2: Immunization Status: Td/Tdap</b>:-</p> <p>Persons who meet any of the following criteria:</p>

- Received at least one Td or Tdap vaccine (Td Immunization Value Set; Td Vaccine Procedure Value Set, CVX code 115; Tdap Vaccine Procedure Value Set) between 9 years prior to the start of the measurement period and the end of the measurement period.
- Had anaphylaxis due to the diphtheria, tetanus or pertussis vaccine (Anaphylaxis Due to Diphtheria, Tetanus or Pertussis Vaccine Value Set).
- Had encephalitis due to the diphtheria, tetanus or pertussis vaccine (Encephalitis Due to Diphtheria, Tetanus or Pertussis Vaccine Value Set).

### **Numerator 3: Immunization Status: Zoster**

Persons who meet either of the following criteria:

- Received two doses of the herpes zoster recombinant vaccine (CVX code 187; Herpes Zoster Recombinant Vaccine Procedure Value Set) at least 28 days apart, on October 4<sup>20</sup>, 2017, through the end of the measurement period.
- Had anaphylaxis due to the herpes zoster vaccine (Anaphylaxis Due to Herpes Zoster Vaccine Value Set) any time before or during the measurement period.

### **Numerator 4: Immunization Status: Pneumococcal**

Persons who meet either of the following criteria:

- Received at least one dose of adult pneumococcal vaccine (Adult Pneumococcal Immunization Value Set; Adult Pneumococcal Vaccine Procedure Value Set) on or after their 19th birthday, any time before or during the measurement period.
- Had anaphylaxis due to the pneumococcal vaccine (SNOMEDCT code 471141000124102) any time before or during the measurement period.

### **Numerator 5: Immunization Status: Hepatitis B**

Persons who meet any of the following criteria:

- Received at least three doses of the childhood Hepatitis B vaccine (Hepatitis B Immunization Value Set; Hepatitis B Vaccine Procedure Value Set) with different dates of service on or before their 19th birthday.
  - One of the three vaccinations can be a newborn hepatitis B vaccination (ICD-10-PCS code 3E0234Z) during the 8-day period that begins on the date of birth and ends 7 days after the date of birth.
- Received Hepatitis B vaccine series on or after their 19th birthday, before or during the measurement period, including either of the following:
  - At least two doses of the recommended two-dose adult Hepatitis B vaccine (CVX code 189; Adult Hepatitis B Vaccine Procedure (2 dose) Value Set) administered at least 28 days apart; **or**
  - At least three doses of any other recommended adult Hepatitis B vaccine (Adult Hepatitis B Immunization (3 dose) Value Set; Adult Hepatitis B Vaccine Procedure (3 dose) Value Set) administered on different days of service.
- Had a hepatitis B surface antigen, hepatitis B surface antibody or total antibody to hepatitis B core antigen test with a finding of immunity any

	<p>time before or during the measurement period, including either of the following:</p> <ul style="list-style-type: none"> <li>– A test (<u>Hepatitis B Tests With Threshold of 10 Value Set</u>) with a result greater than 10 mIU/mL.</li> <li>– A test (<u>Hepatitis B Prevacination Tests Value Set</u>) with a finding of immunity (<u>Hepatitis B Immunity Finding Value Set</u>).</li> <li>• History of hepatitis B illness (<u>Hepatitis B Value Set*</u>) any time before or during the measurement period.</li> <li>• Had anaphylaxis due to the hepatitis B vaccine (SNOMED CT code 428321000124101) any time before or during the measurement period.</li> </ul> <p><b><u>Numerator 6: Immunization Status: COVID-19</u></b></p> <p><u>Persons who meet either of the following criteria:</u></p> <ul style="list-style-type: none"> <li>• <u>Received at least one dose of a COVID-19 vaccine (Adult COVID19 Immunization Value Set; Adult COVID19 Procedure Value Set) on or between July 1 of the year prior to the measurement period through June 30 of the measurement period.</u></li> <li>• <u>Had anaphylaxis due to the COVID-19 vaccine (SNOMED CT code 914587451000119107) any time before or during the measurement period.</u></li> </ul> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p>																									
<p><b>Summary of changes</b></p>	<p><del>—Removed the definitions of participation and participation period. These definitions have been integrated into the measure where applicable.</del></p> <ul style="list-style-type: none"> <li>• <u>Added the COVID-19 indicator. This indicator is in first year status for measurement year 2026.</u></li> <li>• <u>Removed the SSoR data elements from the data elements tables.</u></li> <li>• <u>Added instructions on allowable adjustments to the race and ethnicity stratifications.</u></li> </ul>																									
<p><b>Data element tables</b></p>	<p>Organizations that submit data to NCQA must provide the following data elements in a specified file.</p> <p><b><i>Table AIS-E-A: 1/2/3 Data Elements for Adult Immunization Status</i></b></p> <table border="1" data-bbox="488 1434 1479 1875"> <thead> <tr> <th>Metric</th> <th>Age</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>Influenza</td> <td>19-64</td> <td>InitialPopulation</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>TdTap</td> <td>65+</td> <td>ExclusionsByEHR</td> <td>For each Metric and Stratification</td> </tr> <tr> <td rowspan="2"><u>COVID-19</u></td> <td rowspan="2">Total</td> <td>ExclusionsByCaseManagement</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>ExclusionsByHIERegistry</td> <td>For each Metric and Stratification</td> </tr> <tr> <td rowspan="2">Zoster</td> <td>50-64</td> <td>ExclusionsByAdmin</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>65+</td> <td>Exclusions</td> <td>(Sum-over-SSoRs)</td> </tr> </tbody> </table>	Metric	Age	Data Element	Reporting Instructions	Influenza	19-64	InitialPopulation	For each Metric and Stratification	TdTap	65+	ExclusionsByEHR	For each Metric and Stratification	<u>COVID-19</u>	Total	ExclusionsByCaseManagement	For each Metric and Stratification	ExclusionsByHIERegistry	For each Metric and Stratification	Zoster	50-64	ExclusionsByAdmin	For each Metric and Stratification	65+	Exclusions	(Sum-over-SSoRs)
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	Total	Denominator	For each Metric and Stratification
		NumeratorByEHR	For each Metric and Stratification
Pneumococcal	65+	NumeratorByCaseManagement	For each Metric and Stratification
		NumeratorByHIERegistry	For each Metric and Stratification
HepatitisB	19-30	NumeratorByAdmin	For each Metric and Stratification
	31-59	Numerator	(Sum over SSoRs)
	Total	Rate	(Percent)

**Table AIS-E-A:-1/2/3 Data Elements for Adult Immunization Status**

Metric	Age	Data Element	Reporting Instructions
Influenza	19-64	InitialPopulation	For each Metric and Stratification
TdTdap	65+	Exclusions	For each Metric and Stratification
COVID-19	Total	Denominator	For each Metric and Stratification
		Numerator	For each Metric and Stratification
Zoster	50-64	RateNumerator	(Percent)For each Metric and Stratification
	65+	Rate	(Percent)
	Total		
Pneumococcal	65+		
HepatitisB	19-30		

Metric	Age	Data Element	Reporting Instructions
	31-59		
	Total		

**Table AIS-E-B-1/2/3: Data Elements for Adult Immunization Status: Stratifications by Race**

Metric	Race	Data Element	Reporting Instructions
Influenza	AmericanIndianOrAlaskaNative	InitialPopulation	For each Metric and Stratification
TdTdap	Asian	Exclusions	For each Metric and Stratification
Zoster	BlackOrAfricanAmerican	Denominator	For each Metric and Stratification
Pneumococcal	NativeHawaiianOrOtherPacificIslander	Numerator	For each Metric and Stratification
HepatitisB	White	Rate	(Percent)
COVID-19	SomeOtherRace		



		TwoOrMoreRaces																												
		AskedButNoAnswer																												
		Unknown																												
	<p><b>Table AIS-E-C-1/2/3: Data Elements for Adult Immunization Status: Stratifications by Ethnicity</b></p> <table border="1"> <thead> <tr> <th>Metric</th> <th>Ethnicity</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>Influenza</td> <td>HispanicOrLatino</td> <td>InitialPopulation</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>TdTdap</td> <td>NotHispanicOrLatino</td> <td>Exclusions</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>Zoster</td> <td>AskedButNoAnswer*</td> <td>Denominator</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>Pneumococcal</td> <td>Unknown</td> <td>Numerator</td> <td>For each Metric and Stratification</td> </tr> <tr> <td>HepatitisB</td> <td></td> <td>Rate</td> <td>(Percent)</td> </tr> <tr> <td></td> <td><u>COVID-19</u></td> <td></td> <td></td> </tr> </tbody> </table>			Metric	Ethnicity	Data Element	Reporting Instructions	Influenza	HispanicOrLatino	InitialPopulation	For each Metric and Stratification	TdTdap	NotHispanicOrLatino	Exclusions	For each Metric and Stratification	Zoster	AskedButNoAnswer*	Denominator	For each Metric and Stratification	Pneumococcal	Unknown	Numerator	For each Metric and Stratification	HepatitisB		Rate	(Percent)		<u>COVID-19</u>	
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	<u>COVID-19</u>																													

DRAFT

## **Adult Immunization Status**

### **Measure Workup**

#### **Topic Overview**

#### **Importance**

Routine vaccination against influenza, tetanus, diphtheria and pertussis, hepatitis B, herpes zoster, pneumococcal and COVID-19 disease are recommended for adults to prevent serious disease. The Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) publishes vaccination recommendations for adults, including ages for receiving vaccines, number of doses, timing between doses and contraindications.

#### **Health Importance and Prevalence**

##### **Influenza vaccine**

The influenza vaccine protects against influenza, a serious disease that can lead to hospitalization and death (CDC, 2024a). Although anyone can get the flu, people 65 and older, pregnant people, young children and those with chronic conditions are at higher risk of developing serious complications (CDC, 2024a).

The impact of influenza is variable because influenza seasons can vary in severity. The CDC estimates that since 2010, yearly influenza cases have ranged from 9.3–41 million; influenza-related hospitalizations, from 100,000–710,000; and influenza-related deaths, from 4,900–51,000 (CDC, 2024b). Estimates from October 2022–April 2023 ranged from 26–50 million influenza cases, 290,000–670,000 influenza-related hospitalizations; and 17,000–98,000 influenza-related deaths (CDC, 2023c).

Deaths associated with influenza are typically higher in older adults. In an analysis based on the 2022–2023 flu seasons, 72% of deaths from influenza were among adults 65 and older (CDC, 2023a).

##### **Td/Tdap vaccine**

Twelve combination vaccines licensed in the U.S. protect against tetanus and diphtheria; 9 also protect against pertussis (CDC, 2024c). Tetanus results in painful muscle spasms that can cause fractures, difficulty breathing, arrhythmia and death (CDC, 2024d).

Diphtheria can present as a respiratory or cutaneous disease (CDC, 2024e). Complications include myocarditis, which can lead to heart failure, and neuritis, which may temporarily paralyze motor nerves. Death occurs in 5%–10% of cases (CDC, 2024e).

Pertussis, also known as whooping cough, is a respiratory infection characterized by a prolonged cough; it is highly communicable, transmitted via respiratory droplets from coughing or sneezing (CDC, 2024f).

There were 264 tetanus cases and 19 deaths reported from 2009–2017; only 18 of cases were among adults who had been fully vaccinated (CDC, 2024g). Adults 20 or older make up 87% of reported cases (CDC, 2024g).

Disease is more prevalent in other countries: From 2019–2020, over 33,123 cases of diphtheria were reported to the World Health Organization. In 2022,

5,856 cases were reported. Though the number of cases has decreased, there are likely many more unreported cases (WHO, n.d.).

Pertussis is much more prevalent today than tetanus and diphtheria, even though vaccines offer protection against the disease. Before the vaccine was introduced in the 1940s, there were about 200,000 cases of pertussis annually (CDC, 2024h). Since widespread use of the vaccine, pertussis cases decreased by 75% (CDC, 2024h), but have been increasing since the 1980s, with 307 deaths between 2000 and 2017 (CDC, 2024h). Pertussis is usually milder in children, adolescents and adults than in infants and young children who may not be fully immunized. Older adults are often the source of infection for infants and children (CDC, 2024h).

### **Herpes zoster vaccine**

The herpes zoster vaccine protects against herpes zoster, commonly known as shingles, a painful skin rash caused by reactivation of the varicella zoster virus (CDC, 2024i). After a person recovers from primary infection of varicella (chickenpox), the virus stays inactive in the body and can reactivate years later. Most people typically only have one episode of herpes zoster, but second or third episodes are possible. People with compromised immune systems are at higher risk of developing herpes zoster (CDC, 2024i).

The most common complication of herpes zoster is post-herpetic neuralgia (PHN) (CDC, 2023d), severe, debilitating pain at the site of the rash that has no treatment or cure. Herpes zoster can also lead to serious complications of the eye, pneumonia, hearing problems, encephalitis or death (CDC, 2024j). In the U.S., there are 1 million new cases of herpes zoster each year; 1 of every 3 people will be diagnosed with herpes zoster in their lifetime (CDC, 2024i).

A person's risk for developing herpes zoster increases sharply after age 50 (CDC, 2024i). As people age, they are more likely to develop PHN; it rarely occurs in people under 40. (CDC, 2024i).

Between 1% and 4% of adults with herpes zoster are hospitalized for complications, and an estimated 96 deaths each year are directly caused by the virus (CDC, 2024i). The vaccine can reduce the risk of developing herpes zoster and PHN.

### **Pneumococcal vaccine**

Vaccines protect against pneumococcal disease, which is a common cause of illness and death in older adults and in persons with certain underlying conditions. The major clinical syndromes of pneumococcal disease include pneumonia, bacteremia and meningitis, with pneumonia being the most common (CDC, 2024k). Pneumonia symptoms generally include fever, chills, pleuritic chest pain, cough with sputum, dyspnea, tachypnea, hypoxia tachycardia, malaise and weakness (CDC, 2024k).

There are an estimated 150,000 pneumonia-related hospitalizations in the U.S. each year, and a 5%–7% mortality rate, although it may be higher among older adults (CDC, 2024k). Bacteremia, a blood infection, is another complication of pneumococcal disease (CDC, 2024k). Bacteremia has a 20% mortality rate among all adults, and up to a 60% mortality rate among older adults (CDC, 2024k).

Pneumococcal disease causes about 2,000 cases of meningitis each year (CDC, 2024l). Meningitis symptoms may include headache, lethargy, vomiting, irritability, fever, nuchal rigidity, cranial nerve signs, seizures and coma. Meningitis has a 22% mortality rate among adults (CDC, 2024k).

**Hepatitis B vaccine**

The hepatitis B vaccine protects against hepatitis B, a liver disease that causes illness in varying degrees of severity (CDC, 2023b). Acute hepatitis B is characterized by fever, fatigue, loss of appetite, jaundice and diffuse body pains (CDC, 2023b). Those with chronic hepatitis B are often asymptomatic, with threats of cirrhosis, liver cancer and death (CDC, 2023b).

In 2020, there were 2,157 reported cases of acute hepatitis B, but since many people may be asymptomatic, this number was estimated to be about 20,000 acute cases and 880,000 chronic cases (CDC, 2023c). Also in 2020, 1,753 hepatitis-B related deaths were reported, but this number is believed to be underestimated due to underreporting (CDC, 2023c). There were about 13,300 acute cases in 2021. There has been a decrease in reported cases, which is thought to be due to the decrease in patients seeking health care post-COVID-19 pandemic (CDC, 2023d). Adults 30–59 years made up 73% of acute cases, and adults 30 and older made up 89% of chronic cases in 2021 (CDC, 2023d).

**COVID-19**

COVID-19 infection left untreated can lead to severe illness and death (CDC, 2024m). Infection with the disease is characterized by symptoms related to the nose, throat, lungs, and muscles (CDC, 2024n). COVID-19 is spread person-to-person by droplets made when those infected with COVID-19 come into close contact with others (CDC, 2024o). Adults over age 65 and people with underlying medical conditions or comorbidities are at highest risk (CDC, 2024p). For the 2024-2025 COVID-19 season thus far (October-December), people 65 years of age and older had a cumulative hospitalization rate of 93.7 per 100,000 people while those 50-64 years of age had a cumulative hospitalization rate of 17.7 per 100,000 people and those 18-49 had a cumulative rate of 5.6 per 100,000 people (CDC, 2024q). Further, trends show people 75 years and older have higher rates of death compared to those younger than 75 years of age (CDC, 2024q).

The CDC estimates there have been about 6.7 million COVID-19-related hospitalizations and 1.1 million COVID-19-related deaths since the onset of the pandemic (Panagiotakopoulos et al., 2024). At the end of 2022, it was estimated that COVID-19 vaccines prevented 18.5 million hospitalizations and 3.2 million deaths in the United States (Regan et al., 2023).

## **Financial Importance and Cost-Effectiveness**

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Administration of the influenza, Tdap/Td, herpes zoster, pneumococcal and hepatitis B vaccines can decrease overall health care costs by preventing severe disease and hospitalization.

**Influenza vaccine**

Influenza is an important cause of outpatient medical visits and worker absenteeism among adults. The average annual burden of seasonal influenza is estimated to include approximately 9.4–41 million illnesses, 100,000–710,000 hospitalizations and 4,900–51,000 deaths (CDC, 2024b). A 2023 study estimated that the incremental cost-effectiveness ratio of the influenza vaccine was less than \$95,000 per quality-adjusted life year (QALY) for all age and risk groups except for non-high-risk adults 18–49 (Kim DeLuca, 2023).

**Tdap/Td vaccine**

Administering the Tdap vaccine to adults helps prevent the spread of pertussis to infants and hospitalizations. Because of a rise in pertussis over decades in the U.S., studies have evaluated the cost-effectiveness of providing Tdap immunizations to adults.

One study found that that incremental cost-effectiveness ratio of vaccinating adults 19–85 with one Tdap dose ranged from \$248,000–\$900,000 per QALY (Cho et al., 2020). A systematic review found that of 11 studies evaluating cost-effectiveness of adult Tdap vaccination programs across several countries, 6 were considered cost-effective and 2 were considered cost-saving (Fernandes et al., 2019).

**Herpes zoster vaccine**

In 2015, a systematic literature review estimated that total medical costs in the U.S. from zoster were \$2.4B (Harvey et al., 2020). A CDC study estimated that vaccination with the recombinant zoster vaccine, compared with no vaccination, cost \$31,000 per QALY, on average, for immunocompetent adults 50 and older. The number of people who need to be vaccinated with the recombinant zoster vaccine to prevent one case of zoster ranged from 11–17, and to prevent one case of PHN, ranged from 70–187 (Dooling et al., 2018). A study of the cost-effectiveness of the live herpes zoster vaccine among people 50 and older found that vaccination at age 60 would prevent the most cases (103,603 cases per 1 million people) (Curran et al., 2018).

**Pneumococcal vaccine**

Pneumococcal infections result in significant health care costs each year. Adult patients with pneumonia require hospitalization in nearly 10% of cases. (Isturiz et al., 2021). The annual aggregate burden for the fee-for-service Medicare population is approximately \$13B (Brown et al., 2018).

Pneumococcal vaccines have been shown to be highly effective in preventing invasive pneumococcal disease. When comparing costs, outcomes and QALY, immunization with recommended pneumococcal vaccines was found to be economically efficient. In one study comparing all adults 65 and older, cost-effectiveness estimates ranged from \$209,000–\$544,000 per QALY gained for use of PCV20 alone, and from \$531,000–\$676,000 per QALY gained for use of PCV15 in series with PPSV23 (Smith et al., 2021).

**Hepatitis B vaccine**

With over 800,000 cases of chronic hepatitis B, vaccination against this disease will reduce burden and preserve medical resources. A National Center for HIV, Hepatitis, STD and TB Prevention Epidemiologic and Economic Modeling Agreements study showed that universal vaccination against hepatitis B with the 3-dose series in adults reduces acute cases by about 25% and about 23% of hepatitis-B related deaths. This is approximately \$152,722 per QALY gained (CDC, 2024r). Results were similar with the 2-dose strategy. The study also showed cost-effectiveness of \$262,857 and 135 QALYs per 100,000 adults screened with a 1-dose strategy (CDC, 2024r).

**COVID-19**

Administration of the COVID-19 vaccine can decrease overall health care costs by preventing severe disease and hospitalization. For the 2023–2024 formulation of the updated COVID-19 vaccine, vaccination was shown to be cost-effective. For adults 18–49 years of age, the incremental cost-effectiveness ratio for the updated COVID-19 vaccine was estimated to be \$115,599 per QALY. For adults 50–64 years of age, the incremental cost-effectiveness ratio of the updated vaccine was estimated to be \$25,787 per QALY. For adults 65 years and older, a dose of the vaccine was found to be cost saving (Regan et al., 2023). For the 2024–2025 formulation, preliminary estimated of incremental cost-effectiveness ratios provide a societal perspective of \$212,225 per QALY for 18–49 years of age, \$113,248 per QALY for 50–64 years of age and \$23,308 per QALY for people 65 and older (University of Michigan, 2024).

## Supporting Evidence

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<b>Influenza vaccine</b>	<p>ACIP recommends routine annual influenza vaccination for all people 6 months of age and older (Grohskopf et al., 2023). For people 19 years and older, any age-appropriate inactivated influenza vaccine (IIV) formulation or recombinant influenza vaccine (RIV) formulation are acceptable options. Vaccination should occur before the onset of influenza activity in the community, ideally by the end of October, although vaccination efforts should continue throughout flu season, into February and March (Grohskopf et al., 2023). People who have a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine should not receive the influenza vaccine (CDC, 2024a).</p>
<b>Tdap/Td vaccine</b>	<p>ACIP recommends that, regardless of the interval since the last tetanus or diphtheria toxoid-containing vaccine, adults 19 and older who have never received a dose of Tdap should receive one dose. To ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life (Havers et al., 2020).</p> <p>Pregnant women should receive a dose of Tdap during each pregnancy, irrespective of a history of receiving Tdap. Tdap should be administered at 27–36 weeks gestation, preferably during the earlier part of this period, although it may be administered at any time during pregnancy.</p> <p>For women not previously vaccinated with Tdap, if not administered during pregnancy, it should be administered immediately postpartum (Havers et al., 2020). People who have a history of severe allergic reaction (e.g., anaphylaxis) to any component of the Tdap or Td vaccine should not receive it. Tdap is contraindicated for adults with a history of encephalopathy (e.g., coma or prolonged seizures) not attributable to an identifiable cause within 7 days of administration of a vaccine with pertussis components (CDC, 2024s).</p>
<b>Herpes zoster vaccine</b>	<p>One type of zoster vaccine is currently recommended for older adults: the recombinant zoster vaccine (RZV). In October 2017, the FDA approved the RZV for adults 50 and older. In January 2018, ACIP published a guideline recommending RZV for immunocompetent adults 50 and older, irrespective of prior receipt of varicella vaccine or ZVL (Dooling et al., 2018). In July 2021, the FDA expanded the indication to include immunodeficient or immunosuppressed adults. In October 2021, ACIP published a guideline recommending two RZV doses for prevention of herpes zoster and related complications in immunodeficient or immunosuppressed adults ≥19 years (Anderson et al., 2022).</p>
<b>Pneumococcal vaccine</b>	<p>In 2021, two new pneumococcal vaccines were licensed for use in the U.S.: the 15-valent pneumococcal conjugate vaccine (PCV15) and the 20-valent pneumococcal conjugate vaccine (PCV20). Both include additional serotypes and therefore provide better coverage against pneumococcal disease than the 13-valent pneumococcal conjugate vaccine (PCV13) or 23-valent pneumococcal polysaccharide vaccine (PPSV23). In October 2021, ACIP approved new recommendations for pneumococcal disease, stating that a dose of the newer pneumococcal conjugate vaccine (either PCV20 or PCV15) is beneficial for immunocompetent adults 65 and older, and for adults 19–64 with certain underlying medical conditions or risk factors, given that both populations account for over 90% of invasive pneumococcal disease cases in</p>

the U.S.<sup>1</sup> (Kobayashi et al., 2022).<sup>2</sup> The rationale for this change is the increasing burden of pneumococcal disease in U.S. adults.

## Hepatitis B vaccine

ACIP recommends universal HepB vaccination for adults 19–59 years and adults 60 years and older with risk factors for HepB. Adults 60 years and older without known risk factors for HepB may also receive HepB vaccines (Weng et al. 2022). ACIP also states that persons who have completed a HepB vaccination series at any point, or who have a history of HBV infection, should not receive additional HepB vaccination, although there is no evidence that receiving additional vaccine doses is harmful (Weng et al., 2022).

In settings where the patient population has a high rate of previous HBV infection, prevaccination testing, which may be performed concomitantly with administration of the first dose of vaccine, might reduce costs by avoiding complete vaccination of persons who are already immune.

There are five approved HepB vaccines for adults 19–59; the recommended dosage and schedule varies (Murthy et al., 2024):

- Two-dose series applies when 2 doses of Heplisav-B are used at least 4 weeks apart.
- Three-dose series of Engerix-B, PreHevbrio or RecombivaxHB at 0, 1 and 6 months (minimum intervals: dose 1 to dose 2, 4 weeks; dose 2 to dose 3, 8 weeks; dose 1 to dose 3, 16 weeks).
- Three-dose series of HepA–HepB (Twinrix) standard schedule at 0, 1 and 6 months (minimum intervals: dose 1 to dose 2, 4 weeks; dose 2 to dose 3, 5 months).
- Four-dose series HepA–HepB (Twinrix) accelerated schedule of 3 doses at 0, 7 and 21–30 days, followed by a booster dose at 12 months.

Special situations: Patients on dialysis should complete a 3- or 4-dose series:

- Three-dose series of RecombivaxHB at 0, 1 and 6 months.
- Four-dose series of Engerix-B at 0, 1, 2 and 6 months.

## COVID-19

In 2023, ACIP began recommending annual COVID-19 vaccination for all people 6 months of age and older. In October 2023, ACIP recommended vaccination with the updated 2023–2024 formulation of the COVID-19 vaccine for all persons 6 months and older (Regan et al., 2023). In April 2024, ACIP recommended that all people 65 years and older receive additional dose of the updated 2023–2024 COVID-19 vaccine (Panagiotakopoulos et al., 2024a). In June 2024, ACIP recommended the updated 2024–2025 COVID-19 vaccine for all people 6 months of age or older, whether or not they had previously been vaccinated with a COVID-19 vaccine (Panagiotakopoulos et al., 2024b). In October 2024, ACIP recommended that all persons 65 and older, and immunocompromised persons 6 months–64 years receive a second dose of the COVID-19 vaccine (Roper et al., 2024).

<sup>1</sup> Includes alcoholism, chronic heart/liver/lung disease, cigarette smoking, diabetes mellitus, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, CSF leak or cochlear implant.

<sup>2</sup> ACIP includes additional guidance on dosing and timing based on receipt of previous vaccinations at: <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-pneumo>

## Gaps in Care

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Healthy People 2030, which provides science-based, 10-year national objectives for improving the health of all Americans, has established goals for routinely recommended adult vaccinations (U.S. Department of Health and Human Services 2022):

- Reduce the rate of deaths with hepatitis B as a cause.
- Reduce the rate of acute hepatitis B.
- Reduce the rate of hepatitis A.
- Increase the proportion of adults aged 19 years or older who get recommended vaccines.
- Increase the proportion of people who get the flu vaccine every year.

Estimates of national vaccination coverage are available through the National Health Interview Survey (NHIS), in which a sample of adults self-report receipt of vaccines. Data from 2021 indicate that:

- 50.3% of adults 19 and older reported receiving the influenza vaccine during the 2020–2021 flu season.
- 34% of adults 19 and older reported receiving the hepatitis B vaccination (Hung et al., 2023).
- 41.1% of adults 60 and older and 32.6% of adults 50 and older reported receiving the herpes zoster vaccine.
- 65.8% of adults 65 and older reported receiving one or more doses of any type of pneumococcal vaccine (Hung et al., 2023).

NHIS data from 2019 found that 62.9% of adults reported receiving any tetanus toxoid-containing vaccination during the past 10 years, and 30.1% reported receiving the Tdap vaccine in the past 10 years (Jatlaoui et al., 2022).

As of May 2023, 81% of the U.S. population received at least one dose of any COVID-19 vaccine (USA Facts, 2023). More recent estimates of national vaccination coverage, available through the National Center for Immunization and Respiratory Diseases, show that as of December 14, 2024, 20.9% of adults had received an updated 2024–2025 COVID-19 vaccine (CDC, 2024u).

Barriers to adult vaccination in general include provider and patient lack of knowledge and awareness of the importance of vaccines, missed opportunities for vaccination and operational and systemic barriers (e.g., cost, lack of access to immunization records) (Chadi et al., 2023; Eiden et al., 2022; Kilich et al., 2020; Kolobova et al., 2022; Wang et al., 2023). Having health insurance coverage is also associated with higher vaccination coverage (Chadi et al., 2023; Kolobova et al., 2022). There are some unique barriers to COVID-19 vaccination. For example, one study found that one of the most quoted reasons for hesitancy toward COVID-19 vaccination is due to how fast the vaccines were developed and subsequently brought to market (Nawas et al., 2023). The same article also found that hesitancy is also related to a lack of understanding regarding the ingredients of the COVID-19 vaccines and how the vaccine works (Nawas et al., 2023). Some articles cited politically motivated skepticism toward the COVID-19 vaccine as a barrier to vaccine uptake (Kuehn et al., 2022; Nawas et al., 2023).

There are evidence-based practices for improving adult vaccination coverage. Health care providers should routinely assess patients' vaccination history, offer needed vaccines to adults or refer patients to a provider who can administer the vaccine and document vaccinations received by their patients in an immunization information system (Lu et al., 2021). In addition, providing easy access and convenience for adult vaccination in and outside the health care setting is important for increasing equitable adult vaccine uptake (Kaiser Family Foundation 2020). Influenza vaccines are commonly offered at retail pharmacies; offering other types of adult vaccines at retail pharmacies could potentially increase uptake (Murray et al., 2021).



For COVID-19 vaccination specifically, a major strategy was educating patients on vaccine safety and efficacy (Nawas et al., 2023). Sharing immunization information between providers, health systems, public health agencies and patients is required to increase vaccination coverage and ensure high-quality data to inform clinical and public health interventions (Scharf et al., 2021). Leveraging health information technology, such as immunization information systems, is important for targeting and monitoring immunization program activities and providing clinical decision support at the point of care (Scharf et al., 2021).

## Health Care Disparities

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There are racial and ethnic disparities in adult vaccination coverage. The 2021 NHIS survey found that White adults 65 and older had higher pneumococcal vaccination coverage rates (70.1%) than Black (54.8%), Hispanic (46.2%) and Asian (55.8%) adults 65 and older (Hung et al., 2023). Further, White adults 50 and older reported higher herpes zoster vaccination coverage rates (36.6%) than Black (18.9%), Hispanic (20.7%) and Asian (33%) adults 50 and over. Similar trends were seen for adults 60 and older who reported receiving a herpes zoster vaccine (Hung et al., 2023). The 2021 NHIS survey also found that White 19–49-year-olds were more likely to have received the HepB vaccine (48%) than Black (34%) and Hispanic (38%) adults, but less likely than Asian adults (54%) (Hung et al., 2023). White 30–59-year-olds were more likely to have received the HepB vaccine (38%) than Black (31%) and Hispanic (32%) adults, but less likely than Asian adults (47%) (Hung et al., 2023). The 2018 NHIS survey found that White adults for both any tetanus vaccination and Tdap-specific vaccination reported higher rates of coverage (67.3% and 33.5%, respectively) compared to Black (51.2% and 21.3%), Hispanic (55.9% and 23.1%) and Asian (55.5% and 29.1%) adults (Jatlaoui et al., 2022).

Vaccination coverage also varies by age for influenza. In the 2023–2024 influenza season the overall vaccination rate among adults was 45%; 33% of adults 18–49 reported receiving the flu vaccine, compared with 46% of adults 50–64 and 70% of adults 65 and older (CDC, 2024t); however, compared to the 2021–2022 influenza season, adult influenza vaccination coverage was lower for adults 65 and older than for adults 19–64 in the 2022–2023 season (CDC, 2024t).

There are also geographical and racial-ethnic disparities in adult HepB infection rates. In 2021, states in the Appalachian region had higher rates of acute hepatitis B than the nationwide average (CDC, 2023d). Non-Hispanic Black adults had the highest rates of acute hepatitis B in 2021. The rate of newly reported chronic hepatitis B cases was 14 times higher among non-Hispanic Asian/Pacific Islanders in 2021 (CDC, 2023d).

CDC's National Immunization Survey found that White adults had higher vaccination coverage (25.6%) than all other race and ethnicity groups for the updated 2023–2024 COVID-19 vaccine, with the lowest coverage being among American Indian/Alaska Native (15.6%) and Hispanic (16.2%) adults (CDC, 2024u). The National Immunization Survey also found disparities in receipt of the 2023–2024 COVID-19 vaccination by geography and insurance coverage. Adult vaccination coverage was lower in rural areas, at 17.9%, and highest in urban areas, at 24.0% (CDC, 2024u). Other studies support this; one states that living in a rural area is associated with higher COVID-19 incidence and mortality because rural residents tend to be 65 and older, uninsured, have underlying conditions and live further from health care facilities (Ullrich & Mueller, 2023).

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## Guidelines and Recommendations

**Table 1: Routine Adult Immunizations: Recommendations from the CDC ACIP\***

Vaccine Recommendation Date & Title	ACIP Recommendation	Contraindications (CDC 2024)
Influenza (Grohskopf et al. 2023)	ACIP recommends routine annual influenza vaccination for all people 6 months and older.  Vaccination should occur before the onset of influenza activity in the community, ideally by the end of October; however, vaccination efforts should continue throughout flu season into February and March.	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
Td/Tdap (Havers et al. 2020)	ACIP recommends that regardless of the interval since the last tetanus or diphtheria toxoid-containing vaccine, persons 19 and older who have never received a dose of Tdap should receive one dose. To ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life.  Pregnant women should receive a dose of Tdap during each pregnancy, irrespective of a history of receiving Tdap. Tdap should be administered at 27–36 weeks gestation, preferably during the earlier part of this period, although it may be administered any time during pregnancy.	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component  Tdap: Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause within seven days of administration of a previous dose of a vaccine with pertussis components
Zoster (Dooling et al., 2018; Anderson et al. 2022)	ACIP recommends the two-dose recombinant zoster vaccine (RZV) for use in immunocompetent adults 50 and older, irrespective of prior receipt of varicella vaccine or zoster vaccine live (ZVL).  This recommendation was expanded in 2022 to include adults 19 and older who are, or will be, immunodeficient or immunosuppressed for prevention of herpes zoster.	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
Pneumococcal (Kobayashi et al. 2023)	ACIP recommends that adults 19-64 with certain chronic or immunocompromising conditions, <sup>2</sup> and adults 65 and older who have not previously received a pneumococcal conjugate vaccine, or whose previous vaccination history is unknown, receive a pneumococcal conjugate vaccine (either PCV20 or PCV15).  If PCV15 is used, this should be followed by a dose of pneumococcal polysaccharide vaccine (PPSV23) at least 1 year later. A minimum interval of 8 weeks can be considered for adults with underlying conditions. ACIP includes additional guidance on dosing and timing based on receipt of previous vaccinations at: <a href="https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-pneumo">https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-pneumo</a>	PCV13, PCV15, PCV20: Severe allergic reaction (e.g., anaphylaxis) after a previous dose to any vaccine containing diphtheria toxoid or to any component of these vaccines.  PPSV23: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
Hepatitis B (Weng et al. 2022)	ACIP recommends that adults 19-59 and 60 years and older with risk factors for hepatitis B should receive HepB vaccines, and that adults 60 years and older without known risk factors for hepatitis B may receive HepB vaccines.	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.  Hypersensitivity to yeast

Vaccine Recommendation Date & Title	ACIP Recommendation	Contraindications (CDC 2024)
COVID-19 (Panagiotakopoulos, et al. 2024)	ACIP recommends that all persons 6 months of age and older receive the 2024-2025 COVID-19 vaccine.	Severe allergic reaction (e.g., anaphylaxis) after a previous dose to a component of an mRNA COVID-19 vaccine.

\*ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the director of CDC on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized, to the greatest extent possible, with recommendations made by the American Academy of Pediatrics, the American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists. Recommendations for routine use of vaccines in adults are reviewed and approved by the American College of Physicians, AAFP, the American College of Obstetricians and Gynecologists and the American College of Nurse-Midwives. ACIP recommendations adopted by the CDC director become agency guidelines on the date published in the *Morbidity and Mortality Weekly Report (MMWR)*.

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## HEDIS Health Plan Performance Rates: Adult Immunization Status (AIS-E)

The data included below for MY 2021–2022 are based on rates reported by the following product lines and age ranges.

Indicator	Commercial, Medicaid	Medicare
Influenza	19-65	66 and older
Td/Tdap	19-65	66 and older
Zoster	50-64	66 and older
Pneumonia	NA	66 and older

For MY 2023 in the data below, all product lines reported each indicator and stratified by age.

Indicator	Commercial, Medicaid, Medicare		
Influenza	19-65	66 and older	Total
Td/Tdap	19-65	66 and older	Total
Zoster	50-64	66 and older	Total
Pneumonia	66 and older		

### Influenza Immunization Indicator

**Table 1. HEDIS AIS-E Influenza Indicator Performance—Commercial Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	23.5	9.8	10.9	16.4	22.5	30.1	35.8
2022	417	388 (93.1)	22.7	9.3	11.5	15.8	21.6	28.9	34.6
2021	419	312 (74.5)	23.1	9.6	12.4	15.8	21.5	28.9	36.4

\*For 2023 the average denominator across plans was 166,232 individuals, with a standard deviation of 295,594.



**Table 2. HEDIS AIS-E Influenza Indicator Performance—Commercial Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	401 (95.5)	41.6	14.7	21.5	31.5	41.9	52.9	60.3

\*For 2023 the average denominator across plans was 6,146 individuals, with a standard deviation of 10,548.

**Table 3. HEDIS AIS-E Influenza Indicator Performance—Commercial Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	24.2	9.9	11.6	17.4	23.3	31.0	37.2

\*For 2023 the average denominator across plans was 172,185 individuals, with a standard deviation of 304,742.

**Table 4. HEDIS AIS-E Influenza Indicator Performance—Medicaid Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	238 (85.6)	15.4	7.1	7.4	10.8	14.8	18.3	24.6
2022	272	162 (59.6)	14.2	6.5	6.5	9.5	13.6	17.8	21.1
2021	270	122 (45.2)	16.4	7.1	8.0	11.5	15.8	21.2	24.4

\*For 2023 the average denominator across plans was 97,632 individuals, with a standard deviation of 137,791.

**Table 5. HEDIS AIS-E Influenza Indicator Performance—Medicaid Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	182 (65.5)	33.9	12.7	16.7	25.5	35.2	43.2	50.1

\*For 2023 the average denominator across plans was 5,515 individuals, with a standard deviation of 8,987.

**Table 6. HEDIS AIS-E Influenza Indicator Performance—Medicaid Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	239 (86.0)	16.2	7.9	7.4	11.0	15.5	19.8	26.4

\*For 2023 the average denominator across plans was 101,424 individuals, with a standard deviation of 143,210.

**Table 7. HEDIS AIS-E Influenza Indicator Performance—Medicare Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	691 (90.9)	30.6	16.4	10.7	18.8	28.8	41.4	52.6

\*For 2023 the average denominator across plans was 7,499 individuals, with a standard deviation of 22,019.

**Table 8. HEDIS AIS-E Influenza Indicator Performance—Medicare Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	713 (93.8)	37.0	20.4	10.4	22.5	35.3	53.1	65.6
2022	750	477 (63.6)	34.4	19.7	8.7	19.7	31.0	51.0	62.1
2021	714	317 (44.4)	33.0	20.1	6.1	19.7	30.4	43.7	64.7

\*For 2023 the average denominator across plans was 32,977 individuals, with a standard deviation of 127,969.

**Table 9. HEDIS AIS-E Influenza Indicator Performance—Medicare Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	723 (95.1)	35.4	19.8	9.4	21.5	33.1	49.7	63.7

\*For 2023 the average denominator across plans was 39,689 individuals, with a standard deviation of 145,356.

## Td/Tdap Immunization Indicator

**Table 10. HEDIS AIS-E Td/Tdap Indicator Performance—Commercial Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	39.9	14.1	23.1	29.5	38.4	50.1	58.2
2022	417	388 (93.1)	36.3	13.8	19.9	26.4	34.2	45.9	54.7
2021	419	312 (74.5)	32.5	13.7	18.0	23.2	29.2	39.3	52.9

\*For 2023 the average denominator across plans was 166,232 individuals, with a standard deviation of 295,594.

**Table 11. HEDIS AIS-E Td/Tdap Indicator Performance—Commercial Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	401 (95.5)	41.3	14.2	24.0	31.9	39.8	50.3	60.0

\*For 2023 the average denominator across plans was 6,146 individuals, with a standard deviation of 10,548.

**Table 12. HEDIS AIS-E Td/Tdap Indicator Performance—Commercial Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	40.0	14.1	23.4	29.8	38.3	50.2	58.3

\*For 2023 the average denominator across plans was 172,185 individuals, with a standard deviation of 304,742.

**Table 13. HEDIS AIS-E Td/Tdap Indicator Performance—Medicaid Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	238 (85.6)	40.4	14.5	22.1	30.6	38.4	50.7	60.0
2022	272	162 (59.6)	36.7	14.3	18.7	27.6	34.4	47.1	56.5
2021	270	122 (45.2)	34.6	15.0	17.8	22.4	32.4	41.7	54.8

\*For 2023 the average denominator across plans was 97,632 individuals, with a standard deviation of 136,791.

**Table 14. HEDIS AIS-E Td/Tdap Indicator Performance—Medicaid Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	182 (65.5)	30.2	13.6	14.7	20.3	27.9	39.5	49.8

\*For 2023 the average denominator across plans was 5,515 individuals, with a standard deviation of 8,987.

**Table 15. HEDIS AIS-E Td/Tdap Indicator Performance—Medicaid Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	239 (86.0)	40.0	14.5	21.3	30.4	38.1	50.3	57.7

\*For 2023 the average denominator across plans was 101,424 individuals, with a standard deviation of 143,210.

**Table 16. HEDIS AIS-E Td/Tdap Indicator Performance—Medicare Plans, Ages 19–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	691 (90.9)	28.5	19.2	5.1	13.2	25.9	40.1	55.3

\*For 2023 the average denominator across plans was 7,499 individuals, with a standard deviation of 22,019.

**Table 17. HEDIS AIS-E Td/Tdap Indicator Performance—Medicare Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	713 (93.8)	25.5	17.5	4.4	12.1	23.0	35.4	50.6
2022	750	477 (63.6)	23.2	17.1	4.3	9.8	19.8	32.4	48.9
2021	714	317 (44.4)	21.4	17.5	3.3	8.3	16.6	28.4	46.8

\*For 2023 the average denominator across plans was 32,977 individuals, with a standard deviation of 127,969.

**Table 18. HEDIS AIS-E Td/Tdap Indicator Performance—Medicare Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	723 (95.1)	26.3	18.0	4.4	12.0	23.7	37.0	51.5

\*For 2023 the average denominator across plans was 39,689 individuals, with a standard deviation of 145,356.

## Herpes Zoster Immunization Indicator

**Table 19. HEDIS AIS-E Zoster Indicator Performance—Commercial Plans, Ages 50–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	19.5	9.5	8.1	12.5	18.5	25.9	32.4
2022	417	388 (93.1)	16.0	8.2	6.3	10.1	14.7	21.1	26.9
2021	419	312 (74.5)	11.3	6.9	4.0	6.5	9.7	14.5	21.1

\*For 2023 the average denominator across plans was 56,031 individuals, with a standard deviation of 98,799.

**Table 20. HEDIS AIS-E Zoster Indicator Performance—Commercial Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	401 (95.5)	29.4	16.1	10.5	16.2	28.0	41.6	52.2

\*For 2023 the average denominator across plans was 6,146 individuals, with a standard deviation of 10,548.

**Table 21. HEDIS AIS-E Zoster Indicator Performance—Commercial Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	414 (98.6)	20.6	10.1	8.4	13.1	19.3	27.2	34.8

\*For 2023 the average denominator across plans was 61,984 individuals, with a standard deviation of 108,039.

**Table 22. HEDIS AIS-E Zoster Indicator Performance—Medicaid Plans, Ages 50–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	234 (84.2)	10.5	7.0	2.2	4.7	9.8	14.2	19.4
2022	272	159 (58.5)	7.8	5.1	1.7	3.4	7.1	11.2	14.5
2021	270	121 (44.8)	6.0	4.4	1.0	2.3	5.7	8.9	11.4

\*For 2023 the average denominator across plans was 23,606 individuals, with a standard deviation of 36,732.

**Table 23. HEDIS AIS-E Zoster Indicator Performance—Medicaid Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	182 (65.5)	16.2	10.6	3.9	8.5	14.7	21.7	31.3

\*For 2023 the average denominator across plans was 5,515 individuals, with a standard deviation of 8,987.

**Table 24. HEDIS AIS-E Zoster Indicator Performance—Medicaid Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	235 (84.5)	11.3	7.6	2.2	5.3	10.7	15.8	20.6

\*For 2023 the average denominator across plans was 27,777 individuals, with a standard deviation of 43,727.

**Table 25. HEDIS AIS-E Zoster Indicator Performance—Medicare Plans, Ages 50–65**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	687 (90.4)	12.9	13.9	0.1	1.4	7.6	20.9	33.5

\*For 2023 the average denominator across plans was 6,261 individuals, with a standard deviation of 18,916.

**Table 26. HEDIS AIS-E Zoster Indicator Performance—Medicare Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	713 (93.8)	16.9	18.3	0.2	1.7	9.8	27.1	44.2
2022	750	477 (63.6)	14.6	17.9	0.1	0.9	5.6	24.7	42.6
2021	714	317 (44.4)	12.9	16.2	0.0	0.9	4.1	19.9	37.9

\*For 2023 the average denominator across plans was 32,977 individuals, with a standard deviation of 127,969.

**Table 27. HEDIS AIS-E Zoster Indicator Performance—Medicare Plans, Total**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	723 (95.1)	16.1	17.6	0.2	1.6	9.7	25.5	42.3

\*For 2023 the average denominator across plans was 38,471 individuals, with a standard deviation of 143,071.

## Pneumococcal Immunization Indicator

**Table 28. HEDIS AIS-E Pneumococcal Indicator Performance—Commercial Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	401 (95.5)	50.8	16.2	28.9	37.6	51.8	64.1	71.4

\*For 2023 the average denominator across plans was 5,957 individuals, with a standard deviation of 10,310.

**Table 29. HEDIS AIS-E Pneumococcal Indicator Performance—Medicaid Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	182 (65.5)	45.7	17.1	21.0	35.1	44.4	58.2	68.1

\*For 2023 the average denominator across plans was 5,515 individuals, with a standard deviation of 8,987.

**Table 30. HEDIS AIS-E Pneumococcal Indicator Performance—Medicare Plans, Ages 66+**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	713 (93.8)	44.0	23.2	11.8	26.4	43.9	62.2	75.5
2022	750	477 (63.6)	30.2	20.7	5.4	13.1	26.4	43.9	60.7
2021	714	317 (44.4)	29.7	20.2	5.8	13.0	26.5	42.1	58.3

\*For 2023 the average denominator across plans was 32,771 individuals, with a standard deviation of 126,266.



## ***Proposed Changes to Existing Measure for HEDIS<sup>®1</sup> MY 2026: Lead Screening in Children (LSC)***

NCQA seeks comments on proposed updates to the *Lead Screening in Children (LSC)* measure, which assesses the percentage of persons 2 years of age who had one or more capillary or venous lead blood test for lead poisoning by their second birthday. The measure is specified for the Medicaid product line and uses the Administrative and Hybrid reporting methods.

NCQA proposes to remove the Administrative and Hybrid methods and transition to the Electronic Clinical Data Systems (ECDS) reporting method in measurement year (MY) 2026.

### **Background**

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The digital transformation of health care, supported by emerging data standards, enables enhanced use of electronic clinical data to create more detailed quality assessments, address clinical outcomes and support care improvement. NCQA aims to transition HEDIS to a fully digital system based on standards-based, interoperable electronic data and digital quality measures by 2030. Several ongoing NCQA efforts support the digital transition of HEDIS. The ECDS reporting method<sup>2</sup> facilitates the use of electronic clinical data from diverse data sources, including administrative claims, EHRs, registries and care management systems. As the quality of clinical data improves and becomes more accessible for quality measurement and care improvement, NCQA is expanding the ECDS reporting standard across HEDIS, phasing out the Hybrid reporting method to reduce the burden of medical record review and facilitate the transition to a fully digital quality measurement system.

NCQA established a multi-year [timeline](#) for the phase-out by MY 2029, beginning with the transition of LSC for MY 2026. This plan is informed by stakeholder feedback, feasibility considerations and measure-specific reporting insights.

### **HEDIS Reporting Analysis**

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Currently, plans can report LSC using either administrative data or administrative data supplemented with medical record review for a sample of members.

Since 2020, administrative data has accounted for a large percentage of numerator submissions (88.6%–91.2%) among plans using the Hybrid Method. The percentage point difference in average performance rates, with and without inclusion of manual medical record review, has been small (2.48%–3.55%). This suggests there will be minimal impact on performance with removal of the Hybrid method. Transitioning to ECDS reporting will encourage efficient use and exchange of electronic clinical data sources and will better enable the transition to digital quality measures.

Stakeholders support the transition, indicating that lead screening information is highly structured and often identified using administrative data.

NCQA seeks general comments on the proposal to remove the Administrative and Hybrid reporting methods from LSC and transition to ECDS-only reporting.

Supporting documents include the measure specifications, evidence workup and performance data.

***NCQA acknowledges the contributions of external stakeholders.***

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup><https://www.ncqa.org/hedis/the-future-of-hedis/hedis-electronic-clinical-data-system-ecds-reporting/>

<b>Measure title</b>	Lead Screening in Children	<b>Measure ID</b>	LSC-E
<b>Description</b>	The percentage of persons 2 years of age who had one or more capillary or venous lead blood test for lead poisoning by their second birthday.		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement and rationale</b>	The Centers for Disease Control and Prevention recommends testing blood for lead exposure. Health care providers may use a capillary or venous sample for initial blood lead level screening.		
<b>Citations</b>	<p>Centers for Medicare &amp; Medicaid Services (CMS). (n/d) “Lead Screening.” <a href="https://www.medicare.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html">https://www.medicare.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html</a></p> <p>Centers for Disease Control and Prevention (CDC). (n/d) “Recommended Actions Based on Blood Lead Level.” <a href="https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm">https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm</a></p>		
<b>Characteristics</b>			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product line</b>	Medicaid.		
<b>Stratification</b>	None.		
<b>Risk adjustment</b>	None.		
<b>Improvement notation</b>	Increased score indicates improvement.		
<b>Guidance</b>	<p><b>Data collection methodology:</b> ECDS. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p>		
<b>Initial population</b>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical.</li> </ul>		

	<ul style="list-style-type: none"> <li>• <i>Continuous enrollment</i>: 365 days prior to the second birthday and the second birthday.</li> <li>• <i>Allowable gaps</i>: No more than one gap of ≤45 days during the continuous period. No gaps on the second birthday.</li> </ul> <p><i>Ages</i>: 2 years old during the measurement period.</p> <p><i>Event</i>: None.</p>														
<p><b>Denominator exclusions</b></p>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> </ul>														
<p><b>Denominator</b></p>	<p>The initial population minus denominator exclusions.</p>														
<p><b>Numerator</b></p>	<p><b>Persons with at least one lead capillary or venous blood test.</b> Lead capillary blood test (<u>Lead Tests Value Set</u>) on or before the person’s second birthday.</p>														
<p><b>Summary of changes</b></p>	<p>This is the first year the measure is reported using ECDS.</p>														
<p><b>Data element tables</b></p>	<p>Organizations that submit HEDIS data to NCQA must provide the following data elements.</p> <p><b>Table LSC-E-1: Data Elements for Lead Screening in Children</b></p> <table border="1" data-bbox="483 1360 1513 1665"> <thead> <tr> <th>Metric</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td rowspan="5">LeadScreeningChildren</td> <td>InitialPopulation</td> <td>Report once</td> </tr> <tr> <td>Exclusions</td> <td>Report once</td> </tr> <tr> <td>Denominator</td> <td>Report once</td> </tr> <tr> <td>Numerator</td> <td>Report once</td> </tr> <tr> <td>Rate</td> <td>(Percent)</td> </tr> </tbody> </table>	Metric	Data Element	Reporting Instructions	LeadScreeningChildren	InitialPopulation	Report once	Exclusions	Report once	Denominator	Report once	Numerator	Report once	Rate	(Percent)
Metric	Data Element	Reporting Instructions													
LeadScreeningChildren	InitialPopulation	Report once													
	Exclusions	Report once													
	Denominator	Report once													
	Numerator	Report once													
	Rate	(Percent)													

## **Lead Screening in Children (LSC-E)**

### **Measure Workup**

#### **Topic Overview**

#### **Importance and Prevalence**

In 2020, an estimated 590,000 American children 1–5 years of age had elevated blood lead levels (Jacobs & Brown, 2023). Lead exposure has detrimental health effects on almost all of the body's systems (CDC, 2012; Wani et al., 2015). For developing children, elevated blood lead levels can cause irreversible damage, especially to the nervous system (CDC, 2012). Even low levels of lead exposure can lead to cognitive and behavioral impairment, including poor executive functioning and attention-related behavioral challenges, often contributing to lower academic attainment (Wani et al., 2015).

Young children are particularly vulnerable due to increased lead absorption and the potential for chronic exposure during critical windows of development (CDC, 2012). Severe lead exposure can result in acute neurological symptoms, including seizures and death (WHO, 2024). For children exposed to lead, blood lead level screening enables intervention to prevent long-lasting neurocognitive damage.

#### **Financial importance and cost-effectiveness**

Lead screening is a first step in alleviating economic burden by enabling identification of children who are exposed to lead and interventions to protect their health and functioning. Inadequate screening and follow-up has a significant economic impact. One study estimates \$192B–\$270B in costs from lead exposure per birth cohort (The Pew Center on the States, 2010), likely related to health care, decreased cognitive function, increased special education needs, lower lifetime economic productivity, behavioral challenges and crime (The Pew Center on the States, 2010).

#### **Evidence Supporting Lead Screening in Children Before 24 Months of Age**

National guidelines recommend screening children who live in environments that confer a higher risk of lead exposure for blood lead levels before 24 months of age. Guidelines vary slightly in recommended timing and frequency of screening. Table 1 lists current clinical guidelines for lead screening in children.

**Screening age** Children 12–24 months.

**Screening frequency** The American Academy of Pediatrics (AAP) and the Centers for Disease Control and Prevention (CDC) recommend universal blood lead level testing for children who are enrolled in Medicaid or who live in neighborhoods with higher risk for lead exposure. The CDC recommends testing at 12 months and 24 months of age. The AAP recommends targeted testing between 12 and 24 months of age.

**Screening methods** A capillary test (finger prick or heel prick) can determine if a child has lead in their blood. If the results are above 3.5 µg/dL, the CDC recommends following up with a venous blood draw to confirm. If a venous sample was taken during the first screening test, no second confirmation test is needed.

#### **Digital Concept Feasibility**

NCQA intends to transition to a fully digital quality measurement portfolio. In preparation, we conducted a digital concept feasibility assessment that is an initial assessment of the measure's intent and clinical

concepts as a digital measure construct. The primary objectives are to determine if the clinical concepts can be defined using a standardized data model and nationally recognized terminologies, and to assess plans' ability to capture and extract the clinical data in a discrete and structured format to meet the measure's intent.

LSC-E has been specified for the ECDS reporting method, and will replace the current LSC measure, which is specified for the Administrative and Hybrid reporting methods. LSC-E aligns with the current measure and includes all the same data elements.

## Data and Terminology Standards

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NCQA uses the Fast Healthcare Interoperability Resources (FHIR®) as the basis of our digital quality measures. FHIR comprises a set of data elements that facilitate interoperable exchange of electronic health care data. The US Core FHIR Profiles are requirements for implementing FHIR in the United States.

Separately, the Office of the National Coordinator for Health Information Technology (ONC)<sup>1</sup> adopted the United States Core Data for Interoperability (USCDI) as part of the Cures Act Final Rule, which requires certified health IT systems to support USCDI for interoperable health information exchange. ONC's USCDI and FHIR US Core are complementary initiatives, with USCDI defining high-level data requirements and FHIR US Core providing detailed FHIR-based profiles for meeting those requirements. Mapping between them is necessary for achieving interoperability and consistency in health care data exchange in the United States. When creating value sets for each clinical concept, NCQA uses nationally recognized terminologies (e.g., International Classification of Diseases [ICD]-10, Current Procedural Terminology [CPT]) to ensure clinical data are interpreted and represented in the measures in a standardized way.

## Digital Concept Feasibility Assessment

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The digital feasibility scorecard in Figure A is an assessment for each concept across three primary domains, scored high to low.

- High = Feasible with no concerns.
- Medium = Feasible with some concerns.
- Low = Low feasibility with concerns.

Figure A assesses the digital feasibility of all the clinical concepts used in the measure. As shown, all clinical concepts in the measure, including those used in the hybrid specification, can be modeled in the FHIR data standard.

**Figure A. Digital Feasibility Scorecard**

Clinical Concept	Data Standards	Data Structured & Available	Terminology Standards
Encounter: Hospice	High	High	High
Intervention: Hospice	High	High	High
Observation: Hospice flag	High	High	High
Disposition: Death	High	High	High
Observation: Lead Test	High	High	High

<sup>1</sup>ONC has been renamed to Office of the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC).

## **Data Sources**

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Data used for digital measures may come directly from clinical systems, such as EHRs, or from billing and claims data, and are discrete and structured. However, we expect most plans will continue to use administrative claims data to meet LSC-E measure criteria.

**Table 1: Guidelines for Lead Screening Using Capillary or Venous Blood Test in Children Before 24 Months of Age**

Year	Population	Recommendation	Testing Procedure and Thresholds
<b>US Preventive Services Task Force (USPSTF): Elevated Blood Lead Levels in Children and Pregnant Women: Screening</b>			
2024	NA	USPSTF recognizes the importance of screening and testing for blood lead levels in children and pregnant persons (USPSTF, 2024). However, the USPSTF does not wish to duplicate the investment of resources made by others to review the evidence on this topic and make recommendations. The USPSTF therefore will not update its 2019 recommendation.	USPSTF refers to CDC Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) guidelines (below)
2019 (currently inactive)	Screening not recommended for at any age or risk level (if asymptomatic)	USPSTF concluded that evidence is insufficient to recommend for or against routine screening for elevated blood lead levels in asymptomatic children aged 1 to 5 who are at increased risk (Cantor et al., 2019). (I recommendation). USPSTF recommends against routine screening for elevated blood lead levels in asymptomatic children aged 1 to 5 years who are at average risk (Cantor et al., 2019). (D Recommendation).	NA
<b>Centers For Disease Control and Prevention (CDC) Advisory Committee on Childhood Lead Poisoning Prevention</b>			
2024	Children enrolled in Medicaid at ages 12 and 24 months.(CDC, 2024a)	CDC recommends testing blood for lead exposure (CDC, 2024b). All children enrolled in Medicaid should be screened with a blood lead test twice before age 2—at ages 12 and 24 months, or at ages 36–72 months if they have not previously been screened.	A capillary test can determine a child's blood lead level. If the results are above 3.5 µg/dL, CDC recommends following up with a venous blood draw to confirm. Follow-up actions and care should be provided for children whose results show any quantifiable amount of lead.
<b>American Academy of Pediatrics (AAP)</b>			
2025	<ul style="list-style-type: none"> <li>Asymptomatic children: Screening according to federal, local, and state requirements.</li> <li>Children at high risk of lead poisoning: Targeted screening.</li> </ul>	<p>Pediatricians and other primary care providers should test asymptomatic children for elevated blood lead concentrations according to federal, local, and state requirements (AAP, 2025). The following groups should receive targeted testing:</p> <ul style="list-style-type: none"> <li>Immigrant, refugee, and internationally adopted children also should be tested for blood lead concentrations when they arrive in the United States</li> <li>Children 12 to 24 months of age and live in communities or census block groups with ≥25% of housing built before 1960 or a prevalence of children's blood lead concentrations ≥5 µg/dL (≥50 ppb) of ≥5%</li> <li>Children who live in or visit a home or child care facility with an identified lead hazard or a home built before 1960 that is in poor repair or was renovated in the past 6 months</li> </ul>	Testing procedures align with above CDC recommendations. A comprehensive environmental inspection is conducted in the housing units of children who have blood lead concentrations ≥5 µg/dL (≥50 ppb) and that they receive appropriate case management (AAP, 2025).

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## Lead Screening in Children (LSC) Reporting and Performance Results Report February 2025

### Background

NCQA is seeking public comment on the recommendation to remove the hybrid and administrative reporting methods of the *Lead Screening in Children (LSC)* measure and transition to reporting via the ECDS reporting method (LSC-E) in measurement year (MY) 2026. To understand the potential impact on reporting, data source use, and performance, NCQA evaluated LSC HEDIS reporting results.

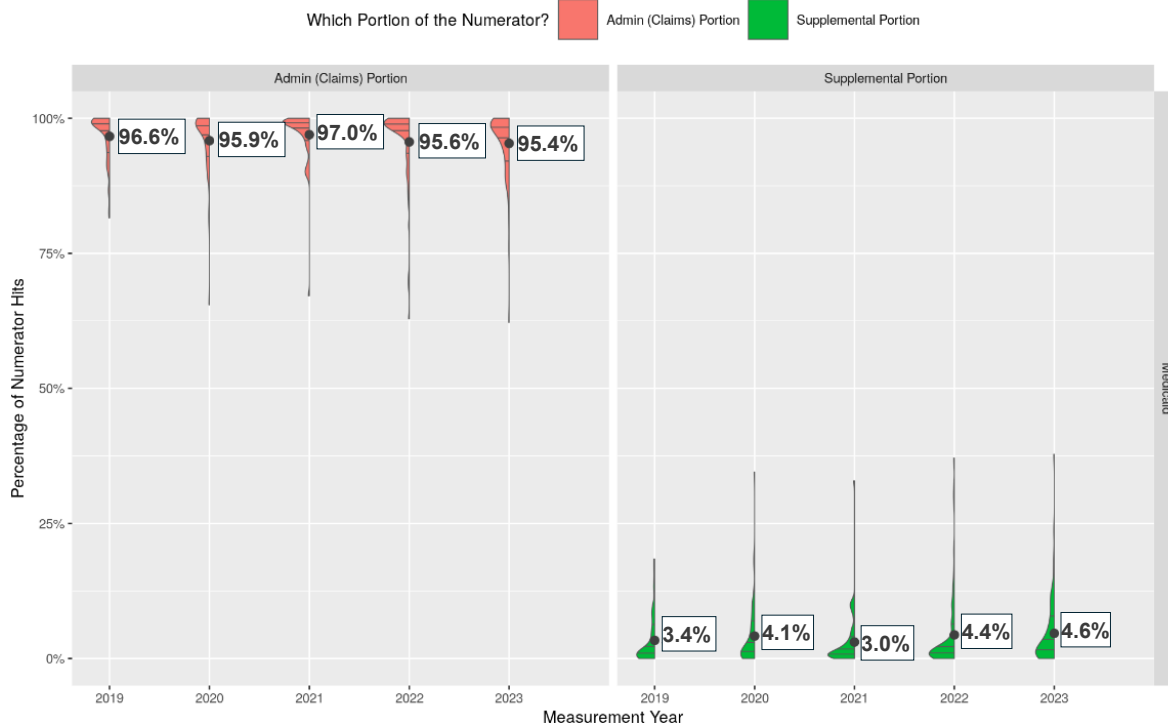
### Results

The table and figures below represent reporting and performance results for the LSC measure from MY 2019–MY 2023. Currently, most health plans submit the hybrid version of the measure (Table 1), but among both administrative (Figure 1) and hybrid (Figure 2) submissions, the majority of contributions to the numerator are attributed to administrative data. Additionally, the hybrid lift for the LSC measure has been stable and consistently low for 5 years (Figure 3). The quantitative results below, in combination with the qualitative analysis of the measure, suggest there will be minimal impact on performance with the transition to ECDS reporting.

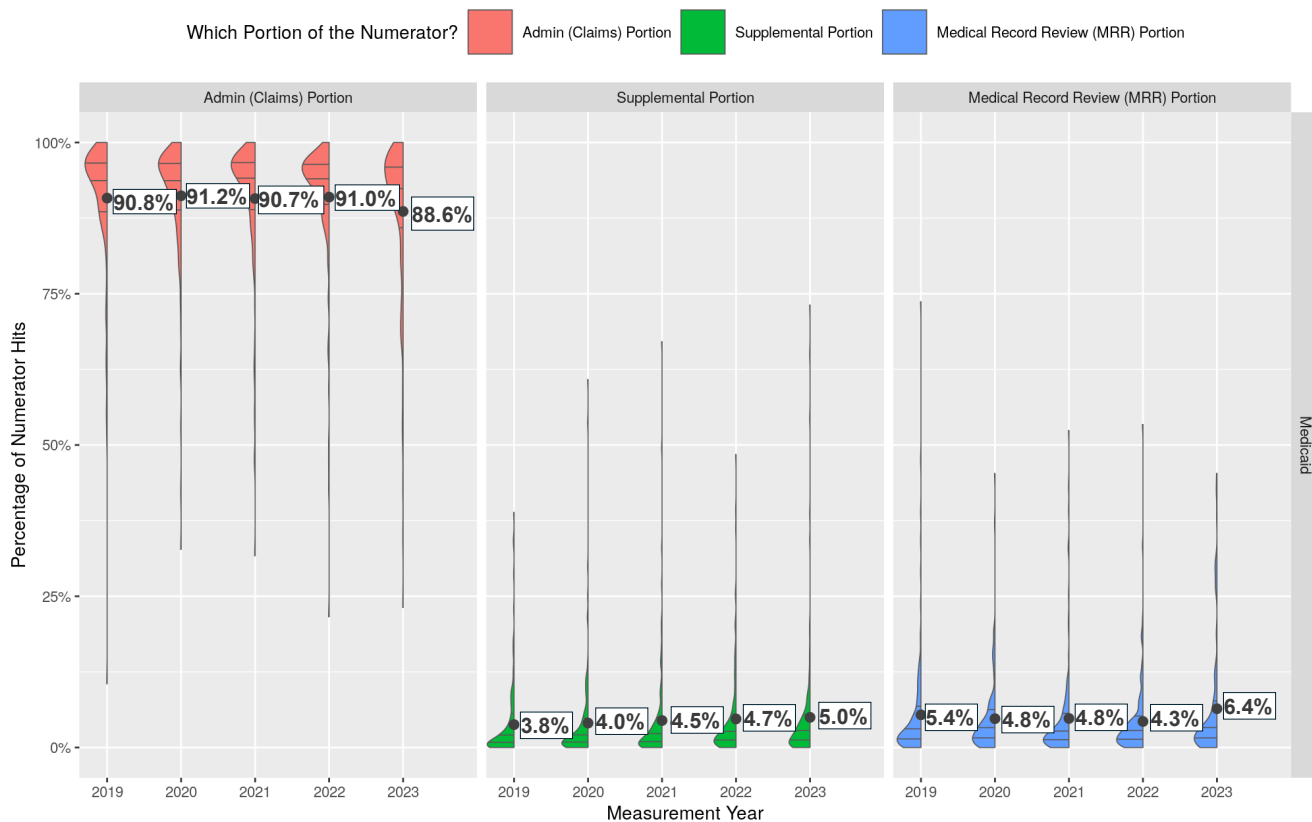
**Table 1. Number of LSC Submissions Using Administrative vs. Hybrid Reporting Method, MY 2021–MY 2023**

MY 2021		MY 2022		MY 2023	
Hybrid	Admin	Hybrid	Admin	Hybrid	Admin
132 (70.2)	56 (29.8)	139 (66.5)	70 (33.5)	143 (64.4)	79 (35.6)

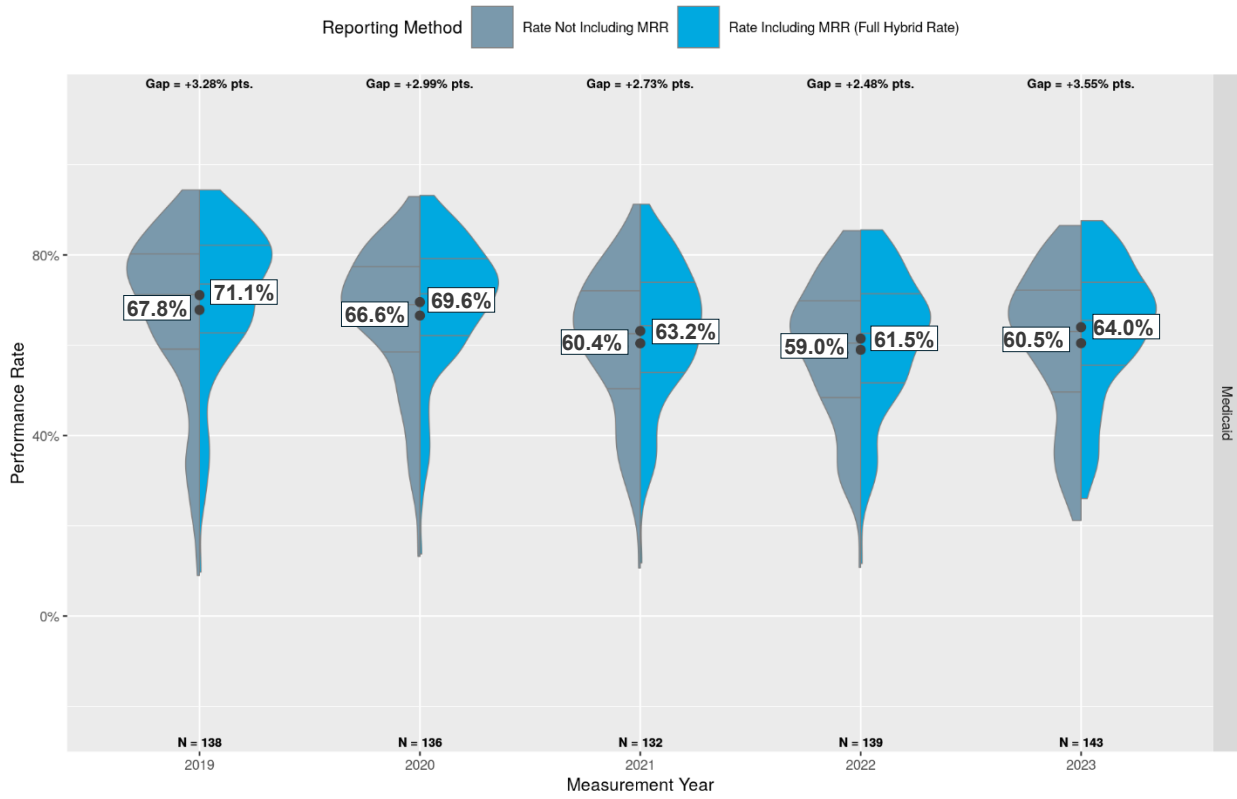
**Figure 1. Proportion of LSC Numerator From Each Data Source Among Administrative Reporters, MY 2019–MY 2023**



**Figure 2. Proportion of LSC Numerator From Each Data Source Among Hybrid Reporters, MY 2019–MY 2023**



**Figure 3. Comparing Performance Rates When Including vs. Excluding Manual Medical Record Review, LSC, MY 2019–MY 2023**



## **Proposed Changes to Existing Measure for HEDIS<sup>®1</sup> MY 2026: Follow-Up After High-Intensity Care for Substance Use Disorder (FUI)**

NCQA seeks comments on proposed modifications to the HEDIS *Follow-Up After High-Intensity Care for Substance Use Disorder (FUI)* measure.

FUI assesses the percentage of acute inpatient hospitalizations, residential treatment or withdrawal management visits for a diagnosis of substance use disorder (SUD) among members 13 years of age or older that result in a follow-up visit or service for SUD. Two rates are reported:

- **Rate 1:** The percentage of discharges for which the member received follow-up for SUD within 30 days after the visit or discharge.
- **Rate 2:** The percentage of discharges for which the member received follow-up for SUD within 7 days after the visit or discharge.

The intent of this measure is to help ensure coordinated care for members with a SUD who are discharged from a high-intensity setting (e.g., residential treatment, inpatient hospitalization). To align with the intent and with NCQA's Continuity of Care measures, NCQA proposes the following revisions:

- **Allow an SUD diagnosis in any diagnosis position for all numerator events.** Stakeholders recommend allowing any diagnosis position on numerator claims to ensure that all substance use-related follow-up is captured in measure numerators. This change will also keep FUI in alignment with *Follow-Up After Emergency Department Visit for Substance Use (FUA)* and the recently re-evaluated *Follow-Up After Hospitalization for Mental Illness (FUH)* and *Follow-Up after Emergency Department Visit for Mental Illness (FUM)*, which currently allow a diagnosis in any position for the numerator event. This change will align all Continuity of Care measures.
- **Add peer support services as a follow-up option.** Stakeholders identified that peer support services, when incorporated into a care team, improve outcomes, especially in substance use populations. This change is also being explored to align FUI with FUA, FUM and FUH, and to expand the eligible workforce to be able to provide follow-up (given the shortage of behavioral health providers).
- **Remove pharmacotherapy dispensing events as follow-up.** Stakeholders identified that a pharmacy dispensing event of a medication for SUD does not indicate compliance with treatment or facilitate interaction with providers or ongoing treatment; thus, these numerator events may not align with the intent of follow-up or match the severity of the situation.

**Note:** *Methadone is not in the pharmacotherapy dispensing value sets (Alcohol Use Disorder Treatment Medication List and Opioid Use Disorder Treatment Medication List). Methadone treatment will be counted in the numerator of the measure through the medication treatment event value sets (AOD Medication Treatment Value Set and OUD Weekly Drug Treatment Service Value Set).*

Our expert panels support the proposed changes. NCQA seeks feedback on the following questions:

1. Do you agree with allowing an SUD diagnosis in any diagnosis position for all numerator events? If not, please describe why.
2. Do you agree with adding peer support services as a follow-up option? If not, please describe why.
3. Do you agree with removing pharmacotherapy dispensing events as follow-up? If not, please describe why.

Supporting documents include the current measure specifications, evidence workup and performance data.

**NCQA acknowledges the contributions of the Behavioral Health, Geriatric and  
Technical Measurement Advisory Panels.**

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

Measure title	Follow-Up After High-Intensity Care for Substance Use Disorder	Measure ID	FUI
<b>Description</b>	<p>The percentage of acute inpatient hospitalizations, residential treatment or withdrawal management visits for a diagnosis of substance use disorder among persons 13 years of age and older that result in a follow-up visit or service for substance use disorder. Two rates are reported:</p> <ol style="list-style-type: none"> <li>1. The percentage of visits or discharges for which the person received follow-up for substance use disorder within the 30 days after the visit or discharge.</li> <li>2. The percentage of visits or discharges for which the person received follow-up for substance use disorder within the 7 days after the visit or discharge.</li> </ol>		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement and rationale</b>	<p>Timely follow-up and continuity of care following a high-intensity event for a diagnosis of SUD is critical, as individuals receiving SUD care in these settings are vulnerable to losing contact with the health care system. Lack of timely follow-up can result in negative outcomes, such as continued substance use, relapse, high utilization of intensive care services and mortality. Although clinical practice guidelines and expert consensus do not define the ideal timing for follow-up, guidelines recommend that individuals with SUD receive patient-centered, timely follow-up care in an appropriate care setting, to ensure ongoing treatment and management.</p>		
<b>Citations</b>	<p>National Institute on Drug Abuse (NIDA). 2017. <i>Trends &amp; Statistics</i>. National Institute on Drug Abuse, April 2017. <a href="https://www.drugabuse.gov/related-topics/trends-statistics#supplemental-references-for-economic-costs">https://www.drugabuse.gov/related-topics/trends-statistics#supplemental-references-for-economic-costs</a></p> <p>National Institute on Drug Abuse (NIDA). 2018. <i>Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition)</i>. National Institute on Drug Abuse, 17 Jan. 2018. <a href="https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition">https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition</a></p> <p>Work Group on Substance Use Disorders. 2006. <i>Practice Guideline for the Treatment of Patients With Substance Use Disorders Second Edition</i>. American Psychiatric Association (APA); Aug. 276 pg. [1789 references]. <a href="https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf">https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf</a></p>		

Characteristics	
<b>Scoring</b>	Proportion.
<b>Type</b>	Process.
<b>Product lines</b>	<ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• Medicare.</li> </ul>
<b>Stratifications</b>	<p>Age as of date of the discharge, stay or event.</p> <ul style="list-style-type: none"> <li>• 13–17 years.</li> <li>• 18–64 years.</li> <li>• 65 years and older.</li> </ul>
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	<p><b>Data collection methodology:</b> Administrative. Refer to the General Guideline: Data Collection Methods for additional information.</p> <p><b>Date specificity.</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p> <p><b>Other guidance.</b> Methadone is not included on the medication lists for this measure. Methadone for opioid use disorder is only administered or dispensed by federally certified opioid treatment programs and does not show up in pharmacy claims data. A pharmacy claim for methadone would be more indicative of treatment for pain than for an opioid use disorder and therefore is not included on medication lists. The <a href="#">AOD Medication Treatment Value Set</a> and <a href="#">OUD Weekly Drug Treatment Service Value Set</a> include codes that identify methadone treatment for opioid use disorder because these codes are used on medical claims, not on pharmacy claims.</p>
Definitions	
<b>Episode date</b>	<p>The date of service for any acute inpatient discharge, residential treatment discharge or withdrawal management visit with a principal diagnosis of SUD.</p> <p>For an acute inpatient discharge or residential treatment discharge or for withdrawal management that occurred during an acute inpatient stay or residential treatment stay, the episode date is the date of discharge.</p> <p>For direct transfers, the episode date is the discharge date from the transfer admission.</p> <p>For withdrawal management (other than withdrawal management that occurred during an acute inpatient stay or residential treatment stay), the episode date is the date of service.</p>

<p><b>Direct transfer</b></p>	<p>A direct transfer is when the discharge date from the first acute inpatient or residential care setting precedes the admission date to a second acute inpatient or residential care setting by one calendar day or less. For example:</p> <ul style="list-style-type: none"> <li>• An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 1, is a direct transfer.</li> <li>• An inpatient discharge on June 1, followed by an admission to an inpatient setting on June 2, is a direct transfer.</li> <li>• An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 3, is not a direct transfer; these are two distinct inpatient stays.</li> </ul>
<p><b>Initial population</b></p>	<p><i>Measure item count:</i> Episode.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical, chemical dependency and pharmacy. <b>Note:</b> A withdrawal management/detoxification-only chemical dependency benefit does not meet this criteria.</li> <li>• <i>Continuous enrollment:</i> Episode date through 30 days after the episode date (31 total days).</li> <li>• <i>Allowable gap:</i> None.</li> </ul> <p><i>Ages:</i> 13 years or older as of date of the discharge, stay or event.</p> <p><i>Event:</i></p> <p><b>Acute inpatient discharge, residential treatment or withdrawal management event for a principal diagnosis of substance use disorder from January 1–December 1 of the measurement period. Include all episodes.</b></p> <p>Either of the following meets criteria:</p> <ul style="list-style-type: none"> <li>• An acute inpatient discharge or a residential behavioral health stay with a principal diagnosis of substance use disorder (<u>AOD Abuse and Dependence Value Set</u>) on the discharge claim. To identify acute inpatient discharges: <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>).</li> <li>2. Exclude nonacute inpatient stays other than behavioral health (<u>Nonacute Inpatient Stay Other Than Behavioral Health Accommodations Value Set</u>).</li> <li>3. Identify the discharge date for the stay.</li> </ol> </li> <li>• A withdrawal management visit (<u>Detoxification Value Set</u>) <b>with</b> a principal diagnosis of substance use disorder (<u>AOD Abuse and Dependence Value Set</u>).</li> </ul> <p><b>Direct transfers</b></p> <p>Identify direct transfers to an acute inpatient care or residential setting. If the direct transfer to the acute inpatient or residential care setting was for a principal diagnosis of substance use disorder (<u>AOD Abuse and Dependence Value Set</u>), use the date of last discharge. Refer to the direct transfer definition above for examples.</p>

	<p>Use the following method to identify direct transfers:</p> <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>).</li> <li>2. Exclude nonacute inpatient stays other than behavioral health (<u>Nonacute Inpatient Stay Other Than Behavioral Health Accommodations Value Set</u>).</li> <li>3. Identify the admission date for the stay.</li> </ol> <p>Exclude both the initial discharge and the direct transfer discharge if the last discharge occurs after December 1 of the measurement period.</p> <p>If the direct transfer to the acute inpatient or residential behavioral health care setting was for any other principal diagnosis, exclude both the original and the direct transfer discharge.</p> <p><b>Multiple discharges, visits or events in a 31-day period</b></p> <p>After evaluating for direct transfers, if a person has more than one episode in a 31-day period, include only the first eligible episode. For example, if a person is discharged from a residential treatment stay on January 1, include the January 1 discharge and do not include subsequent episodes that occur on or between January 2 and January 31; then, if applicable, include the next episode that occurs on or after February 1. Identify episodes chronologically, including only the first episode per 31-day period.</p> <p><i><b>Note:</b> Removal of multiple episodes in a 31-day period is based on eligibility. Assess each episode for eligibility before removing multiple episodes in a 31-day period.</i></p>
<p><b>Denominator exclusions</b></p>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> </ul>
<p><b>Denominator</b></p>	<p>The initial population minus denominator exclusions</p>
<p><b>Numerator</b></p>	<p><b>Numerator 1- 30-Day Follow-Up</b></p> <p>A follow-up visit or event with any practitioner for a <del>principal</del> diagnosis of substance use disorder within the 30 days after an episode for substance use disorder.</p> <p><b>Numerator 2- 7-Day Follow-Up</b></p> <p>A follow-up visit or event with any practitioner for a <del>principal</del> diagnosis of substance use disorder within the 7 days after an episode for substance use disorder.</p> <p>For both indicators, any of the following meet criteria for a follow-up visit. Do not include visits that occur on the date of the denominator episode.</p>



- An acute or nonacute inpatient admission or residential behavioral health stay with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set) on the discharge claim. To identify acute and nonacute inpatient admissions:
  1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
  2. Identify the admission date for the stay.
- An outpatient visit (Visit Setting Unspecified Value Set) with (Outpatient POS Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- An outpatient visit (BH Outpatient Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- An intensive outpatient encounter or partial hospitalization (Visit Setting Unspecified Value Set) with POS code 52 with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- An intensive outpatient encounter or partial hospitalization (Partial Hospitalization or Intensive Outpatient Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- A non-residential substance abuse treatment facility visit (Visit Setting Unspecified Value Set) with (Nonresidential Substance Abuse Treatment Facility POS Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- A community mental health center visit (Visit Setting Unspecified Value Set) with POS code 53 with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- A telehealth visit (Visit Setting Unspecified Value Set) with (Telehealth POS Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- A substance use disorder service (Substance Use Disorder Services Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- Substance use disorder counseling and surveillance (Substance Abuse Counseling and Surveillance Value Set)\* with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set)\*.
- An opioid treatment service that bills monthly or weekly (OUD Weekly Non Drug Service Value Set; OUD Monthly Office Based Treatment Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- Residential behavioral health treatment (Residential Behavioral Health Treatment Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- A telephone visit (Telephone Visits Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).
- An e-visit or virtual check-in (Online Assessments Value Set) with a ~~principal~~ diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).

	<ul style="list-style-type: none"> <li>• <a href="#">Peer support services (Peer Support Services Value Set) with a diagnosis of substance use disorder (AOD Abuse and Dependence Value Set).</a></li> <li>• A <a href="#">pharmacotherapy dispensing event (Alcohol Use Disorder Treatment Medications List; Opioid Use Disorder Treatment Medications List)</a> or medication treatment event (AOD Medication Treatment Value Set; OUD Weekly Drug Treatment Service Value Set).</li> </ul> <p><b>Note:</b> Follow-up does not include withdrawal management. Exclude all withdrawal management events (Detoxification Value Set) when identifying follow-up care for numerator compliance. Detoxification does not need to be excluded from pharmacotherapy dispensing events identified using pharmacy claims (<a href="#">Alcohol Use Disorder Treatment Medications List; Opioid Use Disorder Treatment Medications List</a>), because detoxification codes are not used on pharmacy claims.</p> <p><b>Coding Guidance</b> *Do not include laboratory claims (claims with POS code 81).</p>																												
<p><b>Summary of changes</b></p>	<ul style="list-style-type: none"> <li>• Moved the direct transfer definition from the event/diagnosis section to the definitions section.</li> <li>• <a href="#">Removed the Opioid Use and Alcohol Use Disorder Treatment Medication List tables. This information is now found in the MLD.</a></li> <li>• <a href="#">Modified the numerators to allow a substance use disorder diagnosis to take any position on the claim.</a></li> <li>• <a href="#">Added peer support services to the numerators.</a></li> </ul>																												
<p><b>Data element tables</b></p>	<p>Organizations that submit HEDIS data to NCQA must provide the following data elements.</p> <p><b>Table FUI-1/2/3: Data Elements for Follow-Up After High Intensity Care for Substance Use Disorder</b></p> <table border="1" data-bbox="488 1241 1466 1793"> <thead> <tr> <th>Metric</th> <th>Age</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>FollowUp30Day</td> <td>13-17</td> <td>Benefit</td> <td>Metadata</td> </tr> <tr> <td rowspan="2">FollowUp7Day</td> <td>18-64</td> <td>InitialPopulation</td> <td>For each Stratification, repeat per Metric</td> </tr> <tr> <td>65+</td> <td>Exclusions</td> <td>For each Stratification, repeat per Metric</td> </tr> <tr> <td rowspan="4"></td> <td>Total</td> <td>Denominator</td> <td>For each Stratification, repeat per Metric</td> </tr> <tr> <td></td> <td>NumeratorByAdmin</td> <td>For each Metric and Stratification</td> </tr> <tr> <td></td> <td>NumeratorBySupplemental</td> <td>For each Metric and Stratification</td> </tr> <tr> <td></td> <td>Rate</td> <td>(Percent)</td> </tr> </tbody> </table>	Metric	Age	Data Element	Reporting Instructions	FollowUp30Day	13-17	Benefit	Metadata	FollowUp7Day	18-64	InitialPopulation	For each Stratification, repeat per Metric	65+	Exclusions	For each Stratification, repeat per Metric		Total	Denominator	For each Stratification, repeat per Metric		NumeratorByAdmin	For each Metric and Stratification		NumeratorBySupplemental	For each Metric and Stratification		Rate	(Percent)
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		Rate	(Percent)																										

## ***Follow-Up After High Intensity Care for Substance Use Disorder (FUI)*** **Measure Workup**

### **Topic Overview**

In 2022, 48.7 million U.S. residents 12 years of age and older (17.3% of the population) were classified as having a substance use disorder (SUD) within the past year (SAMHSA, 2022). SUDs are a significant contributor to morbidity and mortality in the United States and cost the health care system billions of dollars per year in direct and indirect expenditures. Although evidence supports follow-up care after “high intensity” treatment for a SUD (e.g., inpatient hospitalization, medically managed withdrawal/detoxification, residential treatment visit or stay) to reduce negative health outcomes, few individuals receive appropriate follow-up care (SAMHSA, 2022; Cole et al., 2022; Acevedo et al., 2018; Rubinsky et al., 2018).

### **Prevalence and Importance**

SUD is defined as when recurrent use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability and failure to meet major responsibilities at work, school or home. (SAMHSA, 2023). Commonly abused substances include alcohol and marijuana, cocaine, methamphetamine, nonprescription opioids and stimulants (SAMHSA, 2017). SUDs can be mild, moderate or severe, according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (SAMHSA, 2015).

According to the National Survey on Drug Use and Health (NSDUH), the number of Americans classified with an SUD increased from 2002–2022 (20.6 million–48.7 million) (SAMHSA, 2015; SAMHSA 2022). In 2022, 29.5 million individuals 12 and older reported an alcohol use disorder, and 27.2 million reported an illicit drug use disorder (SAMHSA, 2022). An estimated 8 million individuals with an SUD reported both alcohol use and illicit drug use disorders within the past year (SAMHSA, 2022).

SUD-related mortality and overdose rates have risen significantly in the past decade (Spencer, 2024). The age-adjusted rate of drug overdose deaths increased from 8.2 deaths per 100,000 in 2002, to 32.6 in 2022 (Spencer, 2024). Today in the U.S., drug overdose is the leading cause of injury, and an estimated 10% of deaths among working adults are due to excessive drinking (CDC, 2017; Stahre et al., 2014).

Individuals with SUD have higher utilization of high-intensity care setting treatment, such as inpatient hospitalizations. The National Survey on Drug Use and Health (NSDUH) data from 2009–2013 indicate that people with SUDs have higher rates of all-cause hospitalization than those without SUDs (Gryczynski et al., 2016). In 2019, the number of SUD treatment admissions per 10,000 was 65.9 (Cantor 2022). In 2021, alcohol-related disorders and opioid-related disorders accounted for 22.18% and 11.51% of readmissions within 30 days for any cause in the Medicaid population, respectively (HCUPnet Data Tools).

#### **Health importance**

SUDs pose significant health risks that necessitate a comprehensive understanding and approach to treatment. Individuals with SUD are at increased risk of overdose, injury, soft tissue infections and mortality (Bahorik, A.L, 2017). Consequently, addressing these risks is critical. The primary goals of alcohol and drug abuse or dependence treatment are abstinence, relapse prevention, rehabilitation and recovery (NIDA, 2018a).

Research supports the need for individuals with SUD to not only receive timely follow-up care following treatment in a high-intensity care setting (e.g. hospitalization, medically managed withdrawal/detoxification, residential treatment visit), but also to stabilize or cease using the substance(s) and engage in ongoing treatment to prevent relapse (NIDA, 2018a; Proctor & Herschman, 2014; McKay, 2021). Individuals who receive timely follow-up care

may be more likely to complete treatment or receive more days of treatment than those who do not receive follow-up care (Proctor & Herschman, 2014).

### **Financial importance and cost-effectiveness**

Total overall costs of substance misuse and SUDs in the U.S., including loss of work productivity, direct health care expenditures and crime-related costs, exceed \$700B annually (NIDA, 2020). One study estimated that the hospital costs for treating SUD are \$13.2B annually (Peterson et al., 2021). Another study modeled commercial health insurance costs for SUD and found that the attributable medical expenditure each year was over \$15,000 per enrollee with an SUD diagnosis (Li et al., 2023). Conservative estimates suggest that for every dollar invested in addiction treatment programs, between \$4 and \$7 are directly returned in decreased drug-related crime, criminal justice costs and theft (NIDA, 2018b).

## **Opportunities for Improvement**

### **Potential for Improvement**

Studies have found that timely follow-up after treatment in an intensive care setting for SUD is an effective method for improving patient outcomes, reducing health care utilization and decreasing the overall cost of care for patients with SUD. Patients can receive needed services to help manage their condition and reduce the likelihood of relapse, readmissions and utilization of other intensive services (Lee et al., 2014; VA/DoD, 2015; NIDA, 2018a; Reif, 2017).

#### **Gaps in care**

Despite the high prevalence of SUDs, only a portion of those in need of services receive them. SAMHSA found that only 24% of people classified as needing treatment for substance use (with or without an SUD diagnosis) received treatment (2022), and only 14.9% of those who had been formally diagnosed with an SUD in the past year received treatment. Findings also indicated that people who had a higher acuity SUD were less likely to receive treatment than those with a mild SUD.

A study of Medicaid enrollees with opioid use disorder (OUD) in 10 states found that 62.5% of enrollees did not receive a follow-up visit or medications for opioid use disorder (MOUD) within 7 days of discharge from residential treatment. Additionally, 46.9% did not have a follow-up visit or receive MOUD within 30 days of discharge (Cole et al., 2022). The literature also indicates significant variability in follow-up rates across programs and agencies (Acevedo et al., 2018; Rubinsky et al., 2018).

SAMHSA survey data of individuals 12 years and older indicate common reasons for not receiving treatment for an SUD (2022). 47.9% of respondents thought treatment would cost too much; 41.9% did not have health insurance coverage for treatment. An additional 37.7% reported that insurance would not pay enough of the related costs of treatment. 52.2% did not know where or how to get treatment. 61.3% were not ready to start treatment, and 52.9% were not ready to stop or cut back on using drugs. 24.2% reported that they had problems with activities such as transportation, childcare or getting convenient appointment times.

#### **Health care disparities**

Several patient characteristics are associated with an increased prevalence and risk of SUDs, including age, gender, ethnicity/race and geography. In 2022, SAMHSA reported that 24% of American Indian or Alaska Native individuals were affected by substance abuse or dependence, compared with

9.0% of Asian Americans. Research has shown that American Indians/Alaska Natives are at a higher risk of alcohol and opioid-related deaths and overdoses (Karaye et al., 2023; Oluwoye et al., 2020; White et al., 2020).

Studies suggest that women suffer greater harms than men from alcohol-induced hangovers, liver inflammation, cardiovascular diseases and infant death (CDC ARDI, 2024; White, 2020; van Lawick van Pabst et al., 2019; Vatsalya et al., 2018; Kirpich et al., 2017).

From 1999–2019, drug overdose death rates in the U.S. fluctuated, initially higher in urban areas, then higher in rural areas from 2007–2015 and again higher in urban areas by 2019, with specific drug types showing varied patterns between urban and rural regions (Hedegaard & Spencer, 2021). Unemployment has also been associated with a higher risk and prevalence of SUDs (SAMHSA, 2022).

Reports reveal differences in receiving OUD treatment based on race/ethnicity, age, employment status and geography. A CDC report indicates that higher percentages of non-Hispanic White adults received OUD treatment (60.3%) than non-Hispanic Black or African American (43.8%) and Hispanic or Latino (45.7%) adults. Adults 50 or older, and those who are unemployed, have lower rates of receiving OUD treatment (Dowell et al., 2024).

Studies suggest that individuals in rural areas are less likely to receive treatment for SUDs or alcohol-related concerns than those in urban or suburban areas (Davis & O'Neill, 2022; Ali et al., 2022; Abraham & Yarbrough, 2021; Edmonds et al., 2021). A SAMHSA trends report notes that the admission rate in the South is consistently the lowest, compared to the other three regions in the U.S. (2022).

**Peer support services**

In 2022, the NSDUH reported that 3.4% of individuals received services for substance use, including support groups, peer support specialists or recovery coaches, ER visits and detoxification or withdrawal support. Two million people (0.7%) received assistance from a peer support specialist or recovery coach.

While peers may not be able to provide clinical care, they can provide alternative services such as advocacy and care linkage and can strengthen engagement in care. In a pilot project conducted by SAMHSA, people in crisis who were referred to peers showed a decrease in inpatient days, an increase in outpatient visits, reduced re-admission rate and an overall decrease in total costs related to behavioral health (Hajny et al., 2015). Additional studies found that peer support services in populations with SUD are associated with lower rates of relapse and homelessness, and higher rates of abstinence (Boisvert et al., 2008; Tracy & Wallace, 2016).

**Guideline recommendations**

Key stakeholder groups such as the American Society of Addiction Medicine (ASAM, 2015), the Substance Abuse and Mental Health Services Administration (SAMHSA, 2015), the National Institute on Drug Addiction (NIDA, 2018), the Veteran Affairs/Department of Defense (Management of Substance use Disorders Work Group, 2015) and the American Psychiatric Association (Work Group on Substance Use Disorders, 2006) have all issued guidelines and recommendations on the treatment of SUDs. Existing guidelines for SUD treatment target drug of choice, age range and other

factors such as pregnancy or justice involvement. Overall, guidelines suggest that clinicians should ensure that treatment plans are personalized and frequently reassessed to maintain effectiveness and safety, and to reduce the risk of relapse. The guidelines support services that continue care after discharge from inpatient and other high-intensity settings and ensure timely access to care.

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## HEDIS Health Plan Performance Rates: Follow-Up After High-Intensity Care for Substance Use Disorder (FUI)

### Commercial Results: Tables 1–8

**Table 1. HEDIS FUI Measure Performance—Commercial Plans (30 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	266 (63.3)	62.8	8.7	51.5	57.9	63.0	68.4	73.5
2022	417	277 (66.4)	62.5	8.8	50.8	58.2	62.8	67.7	73.6
2021	419	285 (68.0)	63.7	8.0	53.1	59.0	64.1	68.7	73.5

\*For 2023 the average denominator across plans was 298 individuals, with a standard deviation of 391.

**Table 2. HEDIS FUI Measure Performance—Commercial Plans (30 Day Rate: 13–17 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	3 (0.7)	65.6	23.6	45.0	45.0	60.4	91.4	91.4
2022	417	5 (1.2)	60.6	13.6	50.0	52.5	55.8	60.6	83.9
2021	419	4 (1.0)	57.0	18.2	38.7	42.9	54.5	71.1	80.3

\*For 2023 the average denominator across plans was 75 individuals, with a standard deviation of 30.

**Table 3. HEDIS FUI Measure Performance—Commercial Plans (30 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	263 (62.6)	63.2	8.5	51.8	58.0	63.3	68.9	73.7
2022	417	274 (65.7)	62.8	8.9	51.1	58.4	63.2	68.3	74.0
2021	419	279 (66.6)	64.3	8.1	53.5	59.6	64.5	69.7	74.2

\*For 2023 the average denominator across plans was 292 individuals, with a standard deviation of 378.

**Table 4. HEDIS FUI Measure Performance—Commercial Plans (30 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	4 (1.0)	51.2	13.2	37.8	42.6	48.8	59.7	69.4
2022	417	6 (1.4)	43.7	21.9	18.2	27.5	39.2	67.3	70.6
2021	419	3 (0.7)	48.2	31.0	26.5	26.5	34.4	83.7	83.7

\*For 2023 the average denominator across plans was 45 individuals, with a standard deviation of 13.

**Table 5. HEDIS FUI Measure Performance—Commercial Plans (7 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	266 (63.3)	44.6	10.5	30.4	38.1	44.5	51.1	57.6
2022	417	277 (66.4)	44.3	10.6	29.9	37.7	44.1	50.2	58.3
2021	419	285 (68.0)	45.0	10.4	32.1	38.2	45.3	51.8	57.5

\*For 2023 the average denominator across plans was 298 individuals, with a standard deviation of 391.

**Table 6. HEDIS FUI Measure Performance—Commercial Plans (7 Day Rate: 13–17 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	3 (0.7)	48.4	21.7	32.5	32.5	39.6	73.1	73.1
2022	417	5 (1.2)	38.1	11.3	26.5	29.5	39.4	40.0	55.2
2021	419	4 (1.0)	43.7	18.7	19.6	29.2	46.7	58.3	61.7

\*For 2023 the average denominator across plans was 75 individuals, with a standard deviation of 30.

**Table 7. HEDIS FUI Measure Performance—Commercial Plans (7 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	263 (62.6)	44.8	10.3	31.3	38.0	44.6	51.5	57.5
2022	417	274 (65.7)	44.8	10.7	30.6	38.2	44.6	50.5	59.4
2021	419	279 (66.6)	45.7	10.6	32.3	38.9	45.6	52.5	59.3

\*For 2023 the average denominator across plans was 292 individuals, with a standard deviation of 378.

**Table 8. HEDIS FUI Measure Performance—Commercial Plans (7 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	4 (1.0)	28.3	15.2	12.5	17.4	26.1	39.2	48.4
2022	417	6 (1.4)	29.8	17.9	12.5	15.2	24.5	49.1	52.9
2021	419	3 (0.7)	26.5	24.8	11.8	11.8	12.5	55.1	55.1

\*For 2023 the average denominator across plans was 45 individuals, with a standard deviation of 13.

## Medicaid Results: Tables 9–16

**Table 9. HEDIS FUI Measure Performance—Medicaid Plans (30 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	187 (67.3)	51.8	14.4	31.7	40.1	53.3	63.7	69.8
2022	272	177 (65.1)	49.8	14.6	30.9	38.3	50.8	61.2	68.7
2021	270	165 (61.1)	49.1	15.1	27.7	37.8	52.5	60.7	69.6

\*For 2023 the average denominator across plans was 1,592 individuals, with a standard deviation of 2,312.

**Table 10. HEDIS FUI Measure Performance—Medicaid Plans (30 Day Rate: 13–17 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	20 (7.2)	37.7	20.2	12.9	22.6	31.5	54.4	66.2
2022	272	15 (5.5)	49.0	21.4	18.8	26.2	56.4	64.3	73.0
2021	270	16 (5.9)	42.1	19.3	20.2	25.4	39.4	56.2	72.5

\*For 2023 the average denominator across plans was 85 individuals, with a standard deviation of 62.

**Table 11. HEDIS FUI Measure Performance—Medicaid Plans (30 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	185 (66.5)	52.3	14.2	33.0	41.1	53.7	63.8	69.9
2022	272	176 (64.7)	50.0	14.6	31.8	38.8	51.1	61.7	68.8
2021	270	164 (60.7)	49.5	14.9	29.0	38.3	52.9	60.9	69.8

\*For 2023 the average denominator across plans was 1,582 individuals, with a standard deviation of 2,303.

**Table 12. HEDIS FUI Measure Performance—Medicaid Plans (30 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	29 (10.4)	45.6	12.2	26.4	37.7	47.4	53.9	60.0
2022	272	20 (7.4)	42.4	13.3	31.2	32.1	42.2	52.1	58.0
2021	270	15 (5.6)	37.9	16.7	10.0	30.0	39.5	52.4	56.4

\*For 2023 the average denominator across plans was 52 individuals, with a standard deviation of 17.

**Table 13. HEDIS FUI Measure Performance—Medicaid Plans (7 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	189 (68.0)	32.8	12.8	15.9	23.1	32.3	41.5	50.8
2022	272	178 (65.4)	31.0	12.8	15.2	20.8	30.0	40.4	49.6
2021	270	168 (62.2)	30.4	13.4	13.3	18.8	28.9	40.2	49.4

\*For 2023 the average denominator across plans was 1,578 individuals, with a standard deviation of 2,304.

**Table 14. HEDIS FUI Measure Performance—Medicaid Plans (7 Day Rate: 13–17 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	20 (7.2)	22.3	15.7	4.7	10.2	15.8	36.4	45.6
2022	272	15 (5.5)	33.1	23.3	4.7	9.5	30.6	39.3	68.2
2021	270	16 (5.9)	25.8	13.4	11.8	14.8	22.8	32.8	46.8

\*For 2023 the average denominator across plans was 85 individuals, with a standard deviation of 62.

**Table 15. HEDIS FUI Measure Performance—Medicaid Plans (7 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	187 (67.3)	33.3	12.8	16.1	24.1	33.0	42.4	50.9
2022	272	177 (65.1)	31.0	12.8	15.4	21.2	30.1	39.8	50.0
2021	270	167 (61.9)	30.6	13.4	12.6	19.4	29.2	40.0	49.5

\*For 2023 the average denominator across plans was 1,568 individuals, with a standard deviation of 2,294.

**Table 16. HEDIS FUI Measure Performance—Medicaid Plans (7 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	29 (10.4)	26.5	8.2	14.5	22.2	27.3	31.6	38.1
2022	272	20 (7.4)	25.1	8.9	15.1	17.1	23.3	33.3	37.2
2021	270	15 (5.6)	25.2	13.1	7.3	13.6	26.0	39.5	42.9

\*For 2023 the average denominator across plans was 52 individuals, with a standard deviation of 17.

**Medicare Results Tables 17–22**

**Table 17. HEDIS FUI Measure Performance—Medicare Plans (30 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	215 (28.3)	39.7	12.2	23.7	32.2	38.8	46.8	55.9
2022	750	214 (28.5)	39.1	11.8	25.0	30.9	37.9	46.2	54.1
2021	714	153 (21.4)	40.4	12.6	25.3	31.6	39.5	47.6	59.5

\*For 2023 the average denominator across plans was 189 individuals, with a standard deviation of 298.

**Table 18. HEDIS FUI Measure Performance—Medicare Plans (30 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	144 (18.9)	43.4	13.1	27.6	34.3	42.9	50.7	60.4
2022	750	144 (19.2)	42.1	13.0	24.2	33.2	42.2	50.7	59.8
2021	714	97 (13.6)	42.3	13.5	24.4	31.6	42.9	50.0	59.3

\*For 2023 the average denominator across plans was 152 individuals, with a standard deviation of 209.

**Table 19. HEDIS FUI Measure Performance—Medicare Plans (30 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	135 (17.8)	34.8	11.9	21.1	26.7	33.3	42.2	50.8
2022	750	129 (17.2)	34.2	11.6	19.5	26.0	33.5	40.5	49.5
2021	714	75 (10.5)	36.0	10.2	24.1	29.4	35.5	41.1	50.0

\*For 2023 the average denominator across plans was 119 individuals, with a standard deviation of 156.

**Table 20. HEDIS FUI Measure Performance—Medicare Plans (7 Day Rate: Total, All Ages)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	215 (28.3)	21.2	10.1	10.3	13.6	19.6	26.6	33.3
2022	750	214 (28.5)	20.9	9.4	10.9	14.5	19.5	25.0	32.3
2021	714	153 (21.4)	21.1	10.0	9.7	14.6	19.5	25.8	34.7

\*For 2023 the average denominator across plans was 189 individuals, with a standard deviation of 298.

**Table 21. HEDIS FUI Measure Performance—Medicare Plans (7 Day Rate: 18–64 Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	144 (18.9)	24.5	10.5	11.6	17.1	23.7	31.2	37.2
2022	750	144 (19.2)	24.1	10.8	10.8	16.7	23.0	29.7	36.7
2021	714	97 (13.6)	23.1	11.2	9.8	15.3	21.3	27.9	40.0

\*For 2023 the average denominator across plans was 152 individuals, with a standard deviation of 209.

**Table 22. HEDIS FUI Measure Performance—Medicare Plans (7 Day Rate: 65+ Years)**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Std Dev	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	135 (17.8)	17.7	9.0	8.5	11.9	15.9	21.7	29.6
2022	750	129 (17.2)	17.3	8.5	8.2	11.9	16.5	21.1	26.7
2021	714	75 (10.5)	17.7	8.2	8.9	12.2	16.7	21.1	29.4

\*For 2023 the average denominator across plans was 119 individuals, with a standard deviation of 156.



## **Proposed Changes to Existing Measures for HEDIS<sup>®1</sup> MY 2026: Statin Therapy for Patients With Cardiovascular Disease (SPC) Statin Therapy for Patients With Diabetes (SPD)**

NCQA seeks comments on proposed modifications to the following two HEDIS measures.

*Statin Therapy for Patients With Cardiovascular Disease (SPC).* The percentage of males 21–75 years of age and females 40–75 years of age during the measurement year who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and met the following criteria. The following rates are reported:

- Received Statin Therapy. Members who were dispensed at least one high-intensity or moderate-intensity statin medication during the measurement year.
- Statin Adherence 80%. Members who remained on a high-intensity or moderate-intensity statin medication for at least 80% of the treatment period.

*Statin Therapy for Patients With Diabetes (SPD).* The percentage of members 40–75 years of age during the measurement year with diabetes, who do not have clinical ASCVD and who met the following criteria. Two rates are reported:

- Received Statin Therapy. Members who were dispensed at least one statin medication of any intensity during the measurement year.
- Statin Adherence 80%. Members who remained on a statin medication of any intensity for at least 80% of the treatment period.

SPC focuses on the use of moderate or high-intensity statin therapy for secondary prevention in people with established cardiovascular disease.

SPD focuses on prevention for people with diabetes who do not have diagnosed cardiovascular disease and recognizes the use of statin therapy at any intensity. Proposed revisions to each measure are described below.

### **Changes Proposed to SPC**

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- **Remove sex-specific age bands.** SPC currently excludes females 21–39 and transgender and nonbinary individuals. Studies show that women are less likely than men to receive statin therapy, despite having diagnosed cardiovascular disease. NCQA proposes removing the sex-specific age bands.
  - **Note:** *Pregnancy, IVF, and Clomiphene remain an exclusion for both measures.*
- **Expand the upper age limit to 85.** Expand the upper age limit to 85, to accommodate clinical guideline recommendations such as from the American College of Cardiology and American Heart Association, which state that for patients older than 75 with clinical ASCVD, it is reasonable to initiate or continue moderate or high-intensity statin therapy. Guidelines also state that in older adults, it may be reasonable to discontinue statin use when functional decline, multimorbidity, frailty or reduced life expectancy limits the potential benefits. SPD age bands which capture members 40-75 align with current clinical guidelines and will not be updated.
  - **Note:** *Older, frailer populations are already excluded from SPC.*

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

## Changes Proposed to SPC and SPD

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- **Approach to ASCVD identification.** Update the definition of “ASCVD” used to identify the eligible population in the SPC measure and as exclusion criteria in the SPD measure. Currently, plans identify people with ASCVD using two methods:
  1. An event, such as a myocardial infarction or coronary artery bypass graft procedure, in the year prior to the measurement year.
  2. One diagnosis consistent with ASCVD (e.g., coronary heart disease, peripheral arterial disease) during the measurement year *and* one diagnosis during the year prior to the measurement year.

In keeping with NCQA’s goal of modernizing and streamlining measures, NCQA proposes broadening the diagnosis method to read, “*two diagnoses any time during the measurement year or the year prior to the measurement year,*” and relaxing the place of service requirements.

This change aligns with updates to other measures that identify chronic conditions (e.g., hypertension, diabetes). NCQA and clinical expert guidance reviewed and updated the ASCVD value set to ensure that the coding used in the measure accurately identifies clinical ASCVD.

- **Include members in I-SNPs or living long-term in an institution.** Based on recommendations from our Geriatric Measurement Advisory Panel, remove the exclusion for individuals enrolled in an institutional SNP or living long-term in an institution during the measurement year. Exclusion from the measure should be determined by clinical criteria similar to that used in the Advanced Illness and Frailty, ESRD and cirrhosis exclusions, not by plan enrollment or place of residence.
- **Transition to ECDS reporting.** Transition SPC and SPD to ECDS reporting in Measurement Year (MY) 2026.

## Testing and Panel Feedback

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Proposed changes to SPC were tested in commercial and Medicare populations. We observed a significant increase in the eligible population, as a result of the changes to age range and to the approach to ASCVD identification. Across both product lines, performance decreased by approximately 6–7% for Rate 1 and by approximately 1% for Rate 2. Measurement advisory panels support all proposed changes.

## Public Comment Request

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NCQA seeks feedback on **the following**:

1. Remove sex-specific age bands to include all members 21–39 years in **SPC**.
2. Expand the upper age limit to include members 76–85 years in **SPC**.
3. Edit the definition of “ASCVD” used in **SPC and SPD**.
4. Include members in I-SNPs or living long-term in an institution in **SPC and SPD**.

Supporting documents include the current measure specifications, evidence workup and performance data.

**NCQA acknowledges the contributions of the Cardiovascular, Geriatric, Diabetes and Technical Measurement Advisory Panels.**

<b>Measure title</b>	Statin Therapy for Patients With Cardiovascular Disease	<b>Measure ID</b>	SPC-E
<b>Description</b>	<p>The percentage of <del>persons 21–85 years of age males 21–75 years of age and females 40–75</del> during the measurement period who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and met the following criteria. The following rates are reported:</p> <ol style="list-style-type: none"> <li>1. <i>Received Statin Therapy</i>. Persons who were dispensed at least one high-intensity or moderate-intensity statin medication during the measurement period.</li> <li>2. <i>Statin Adherence 80%</i>. Persons who remained on a high-intensity or moderate-intensity statin medication for at least 80% of the treatment period.</li> </ol>		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a>.</p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement and rationale</b>	<p>Guidelines from the American Heart Association (AHA) recommend that for men and women 21–75 years of age with a diagnosis of clinical ASCVD, high-intensity statin therapy is recommended. <u>In patients older than 75 years of age the AHA finds it reasonable to initiate or continue moderate or high-intensity statin therapy after evaluation of contraindications.</u></p> <p>If high-intensity therapy is contraindicated, or when adverse effects are present, moderate-intensity statin therapy should be used. Adherence to both medication and lifestyle regimens are required for ASCVD risk reduction.</p>		
<b>Citations</b>	<p><u>Grundy, S.M., N.J. Stone, A.L. Bailey, C. Beam, K.K. Birtcher, R.S. Blumenthal, L.T. Braun, S. de Ferranti, J. Faiella-Tommasino, D.E. Forman, R. Goldberg, P.A. Heidenreich, M.A. Hlatky, D.W. Jones, D.M. Lloyd-Jones, N. Lopez-Pajares, C.E. Ndumele, C.E. Orringer, C.A. Peralta, ... J. Yeboah. 2019. "2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol." <i>Journal of the American College of Cardiology</i> 73(24).</u></p>		
<b>Characteristics</b>			
<b>Scoring Type</b>	Proportion.		
<b>Product lines</b>	<p>Process.</p> <ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• Medicare.</li> </ul>		

<p><b>Stratifications</b></p> <p><b>Risk adjustment</b></p> <p><b>Improvement notation</b></p> <p><b>Guidance</b></p>	<p><u>None.</u></p> <p><del>Age as of the last day of the measurement period and gender.</del></p> <ul style="list-style-type: none"> <li><del>• Males 21–75 years.</del></li> <li>• <del>Females 40–75 years.</del></li> </ul> <p>None.</p> <p>Increased score indicates improvement.</p> <p><b>Data collection methodology:</b> <u>Administrative ECDS</u>. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p> <p><b>Medication lists:</b> If an organization uses both pharmacy data (NDC codes) and clinical data (RxNorm codes) for reporting, and there are both NDC and RxNorm codes on the same date of service, use only one data source for the date of service. This rule is not included in the measure calculation logic, and must be programmed manually.</p> <p><b>Other guidance:</b> All persons who are numerator compliant for Rate 1 must be used as the denominator for Rate 2 (regardless of the data source used to capture the Rate 1 numerator). <del>For example, if supplemental data were used to identify compliance for the Rate 1 numerator, then supplemental data will be included in identifying the Rate 2 denominator.</del></p>
<b>Definitions</b>	
<b>IPSD</b>	Index prescription start date. The earliest prescription dispensing date for any statin medication of at least moderate intensity during the measurement period.
<b>Treatment period</b>	The period of time beginning on the IPSD through the last day of the measurement period.
<b>PDC</b>	Proportion of days covered. The number of days the person is covered by at least one statin medication prescription of appropriate intensity, divided by the number of days in the treatment period.
<b>Calculating number of days covered for multiple prescriptions</b>	<p>If multiple prescriptions for different medications are dispensed on the same day, calculate the number of days covered by a statin medication (for the numerator) using the prescriptions with the longest days supply. For multiple different prescriptions dispensed on different days with overlapping days supply, count each day in the treatment period only once toward the numerator.</p> <p>If multiple prescriptions for the same medication are dispensed on the same day or on different days, sum the days supply and use the total to calculate the number of days covered by a statin medication (for the numerator).</p>

	<p><i>For example</i>, three prescriptions for the same medication are dispensed on the same day, each with a 30-days supply. Sum the days supply, for a total of 90 days covered by a statin. Subtract any days supply that extends beyond December 31 of the measurement period.</p> <p>Use the medication lists to determine if drugs are the same or different. Drugs in different medication lists are considered different drugs.</p>
<p><b>Initial population</b></p>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical. Pharmacy during the measurement period.</li> <li>• <i>Continuous enrollment:</i> The measurement period and the year prior to the measurement period.</li> <li>• <i>Allowable gap:</i> No more than one gap of ≤45 days during each year of continuous enrollment. No gaps on the last day of the measurement period.</li> </ul> <p><i>Ages:</i></p> <ul style="list-style-type: none"> <li>• <u>21–85 years as of the last day of the measurement period.</u></li> <li>• <del>Males 21–75 years as of the last day of the measurement period.</del></li> <li>• <del>Females 40–75 years as of the last day of the measurement period.</del></li> </ul> <p><del><i>Gender/sex criteria:</i></del></p> <p><del><u>Administrative Gender: Female (AdministrativeGender code female).</u></del></p> <p><del><u>Administrative Gender: Male (AdministrativeGender code male).</u></del></p> <p><i>Event:</i></p> <p><b>Persons with clinical atherosclerotic cardiovascular disease.</b></p> <p>There are two methods to identify persons with ASCVD: by event and by diagnosis data. The organization must use both methods to identify the initial population, but a person only needs to be identified by one method to be included in the measure.</p> <p>Any of the following during the year prior to the measurement period meet criteria:</p> <ul style="list-style-type: none"> <li>• Discharged from an inpatient setting with an MI (<u>MI Value Set</u>; <u>Old Myocardial Infarction Value Set</u>) on the discharge claim. To identify discharges:             <ol style="list-style-type: none"> <li>1. Identify all acute and nonacute inpatient stays (<u>Inpatient Stay Value Set</u>).</li> <li>2. Identify the discharge date for the stay.</li> </ol> </li> <li>• CABG (<u>CABG Value Set</u>) in any setting.</li> <li>• PCI (<u>PCI Value Set</u>) in any setting.</li> <li>• Any other revascularization procedures (<u>Other Revascularization Value Set</u>) in any setting.</li> </ul>

	<p><i>Diagnosis.</i> At least <del>two one</del> encounters with a diagnosis of <del>IVD (IVD Value Set ASCVD (ASCVD Value Set))*</del> on different dates of service during the measurement period <del>and/or the year prior to the measurement period.</del> <del>Do not include laboratory claims (claims with POS code 81).</del></p> <p><del>The following encounters meet criteria:-</del></p> <ul style="list-style-type: none"> <li><del>• An outpatient visit, telephone visit, e-visit, virtual check in or acute inpatient encounter (Outpatient, Telehealth and Acute Inpatient Value Set) with an IVD diagnosis (IVD Value Set).</del></li> <li><del>• At least one acute inpatient discharge with an IVD diagnosis (IVD Value Set) on the discharge claim. To identify an acute inpatient discharge:-</del> <ol style="list-style-type: none"> <li><del>1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).</del></li> <li><del>2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).</del></li> <li><del>3. Identify the discharge date for the stay.</del></li> </ol> </li> </ul>
<p><b>Denominator exclusions</b></p>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> <li>• <b>Persons receiving palliative care.</b> Persons receiving palliative care (<u>Palliative Care Assessment Value Set</u>; <u>Palliative Care Encounter Value Set</u>; <u>Palliative Care Intervention Value Set</u>) or who had an encounter for palliative care (ICD-10-CM code Z51.5*) any time during the measurement period.</li> <li><del>• <b>Persons who are 66 years of age and older by the last day of the measurement period, with Medicare benefits, enrolled in an institutional SNP (I-SNP) or living long term in an institution (LTI).</b></del> <del>Persons enrolled in an Institutional SNP (I-SNP) any time during the measurement period.</del> <del>Living long term in an institution any time during the measurement period 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 period.</del></li> <li>• <b>Persons age 66 years or older by the last day of the measurement period, with both frailty and advanced illness.</b> <ol style="list-style-type: none"> <li>1. <i>Frailty.</i> At least two indications of frailty (<u>Frailty Device Value Set</u>; <u>Frailty Diagnosis Value Set</u>; <u>Frailty Encounter Value Set</u>; <u>Frailty Symptom Value Set</u>)* with different dates of service during the measurement period.</li> </ol> </li> </ul>

	<p>2. <i>Advanced Illness</i>. Either of the following during the measurement period or the year prior to the measurement period:</p> <ul style="list-style-type: none"> <li>– Advanced illness (<u>Advanced Illness Value Set</u>)* on at least two different dates of service.</li> <li>– Dispensed dementia medication (<u>Dementia Medications List</u>).</li> </ul> <ul style="list-style-type: none"> <li>• Persons with a diagnosis of pregnancy (<u>Pregnancy Value Set*</u>), in vitro fertilization (<u>IVF Value Set</u>), ESRD (<u>ESRD Diagnosis Value Set*</u>), dialysis (<u>Dialysis Procedure Value Set</u>), cirrhosis (<u>Cirrhosis Value Set*</u>), or dispensed at least one prescription for clomiphene (<u>Estrogen Agonists Medications List</u>) during the measurement period or the year prior to the measurement period.</li> <li>• Myalgia, myositis, myopathy or rhabdomyolysis (<u>Muscular Pain and Disease Value Set*</u>) during the measurement period.</li> <li>• Myalgia or rhabdomyolysis caused by a statin (<u>Muscular Reactions to Statins Value Set</u>) any time during the person's history through the last day of the measurement period.</li> </ul> <p><b>Coding Guidance</b> *Do not include laboratory claims (claims with POS code 81).</p>																								
<p><b>Denominator</b></p>	<p><b>Denominator 1—Received Statin Therapy</b> Initial population minus denominator exclusions.</p> <p><b>Denominator 2—Statin Adherence 80%</b> Persons who meet the numerator criteria for Rate 1.</p>																								
<p><b>Numerator</b></p>	<p><b>Numerator 1—Received Statin Therapy</b> At least one dispensing event for a high-intensity or moderate-intensity statin medication (<u>High and Moderate Intensity Statin Medications List</u>) during the measurement period.</p> <p><b>High- and Moderate-Intensity Statin Medications</b></p> <table border="1" data-bbox="490 1276 1466 1879"> <thead> <tr> <th>Description</th> <th>Prescription</th> <th>Medication Lists</th> </tr> </thead> <tbody> <tr> <td>High-intensity statin therapy</td> <td>• Atorvastatin 40-80 mg</td> <td><u>Atorvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Amlodipine-atorvastatin 40-80 mg</td> <td><u>Amlodipine Atorvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Rosuvastatin 20-40 mg</td> <td><u>Rosuvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Simvastatin 80 mg</td> <td><u>Simvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Ezetimibe-simvastatin 80 mg</td> <td><u>Ezetimibe Simvastatin High Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Atorvastatin 10-20 mg</td> <td><u>Atorvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Amlodipine-atorvastatin 10-20 mg</td> <td><u>Amlodipine Atorvastatin Moderate Intensity Medications List</u></td> </tr> </tbody> </table>	Description	Prescription	Medication Lists	High-intensity statin therapy	• Atorvastatin 40-80 mg	<u>Atorvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Amlodipine-atorvastatin 40-80 mg	<u>Amlodipine Atorvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Rosuvastatin 20-40 mg	<u>Rosuvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Simvastatin 80 mg	<u>Simvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Ezetimibe-simvastatin 80 mg	<u>Ezetimibe Simvastatin High Intensity Medications List</u>	Moderate-intensity statin therapy	• Atorvastatin 10-20 mg	<u>Atorvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Amlodipine-atorvastatin 10-20 mg	<u>Amlodipine Atorvastatin Moderate Intensity Medications List</u>
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	Moderate-intensity statin therapy	• Ezetimibe-simvastatin 20-40 mg	<a href="#">Ezetimibe Simvastatin Moderate Intensity Medications List</a>
	Moderate-intensity statin therapy	• Pravastatin 40-80 mg	<a href="#">Pravastatin Moderate Intensity Medications List</a>
	Moderate-intensity statin therapy	• Lovastatin 40-60 mg	<a href="#">Lovastatin Moderate Intensity Medications List</a>
	Moderate-intensity statin therapy	• Fluvastatin 40-80 mg	<a href="#">Fluvastatin Moderate Intensity Medications List</a>
	Moderate-intensity statin therapy	• Pitavastatin 1-4 mg	<a href="#">Pitavastatin Moderate Intensity Medications List</a>
	<p><b>Numerator 2—Statin Adherence 80%</b></p> <p>PDC of at least 80% during the treatment period.</p> <p>Follow the steps below to identify numerator compliance:</p> <p><b>Step 1.</b> Identify the IPSD. Use the <i>High- and Moderate-Intensity Statin Medications</i> table to identify statin medication dispensing events.</p> <p><b>Step 2.</b> Determine the treatment period. Calculate the number of days beginning on the IPSD through the end of the measurement period.</p> <p><b>Step 3.</b> Count the days covered by at least one prescription for any high-intensity or moderate-intensity statin medication during the treatment period. To ensure that days-supply that extends beyond the measurement period is not counted, subtract any days supply that extends beyond December 31 of the measurement period.</p> <p><b>Step 4.</b> Calculate the person’s PDC using the following equation. Multiply the equation by 100 and round (using the .5 rule) to the nearest whole number.</p> $\frac{\text{Total Days Covered by a Statin Medication in the Treatment Period (step 3)}}{\text{Total Days in Treatment Period (step 2)}}$ <p><i>Example:</i> If a person has 291 total days covered by a medication during a 365-day treatment period, this calculates to 0.7972. Multiply this number by 100, convert it to 79.72% and round it to 80%, the nearest whole number.</p> <p><b>Step 5.</b> Sum the number of persons whose PDC is <math>\geq 80\%</math> for the treatment period.</p>		
Summary of changes	<ul style="list-style-type: none"> <li>• <a href="#">This is the first year the measure is reported using ECDS.</a></li> <li>• <a href="#">Removed sex-specific age bands.</a></li> <li>• <a href="#">Expanded the upper age limit to include members up to 85 years of age.</a></li> <li>• <a href="#">Removed exclusion for members enrolled in an Institutional SNP (I-SNP) or living long-term in an institution (LTI).</a></li> </ul>		



<b>Data element tables</b>	Organizations that submit HEDIS data to NCQA must provide the following data elements.		
	<b>Table SPC-1/2/3: Data Elements for Statin Therapy for Patients With Cardiovascular Disease</b>		
	Metric	Data Element	Reporting Instructions
	ReceivedTherapy	Benefit	Meta data
	Adherence	InitialPopulation	For each Metric
	Total	Exclusions	Only for ReceivedTherapy Metric
		Denominator	For each Metric
		Numerator	For each Metric
	Rate	(Percent)	

DRAFT

<b>Measure title</b>	Statin Therapy for Patients With Diabetes	<b>Measure ID</b>	SPD-E
<b>Description</b>	<p>The percentage of persons 40–75 years of age during the measurement period with diabetes who do not have clinical atherosclerotic cardiovascular disease (ASCVD) and met the following criteria. Two rates are reported:</p> <ol style="list-style-type: none"> <li>1. <i>Received Statin Therapy</i>. Persons who were dispensed at least one statin medication of any intensity during the measurement period.</li> <li>2. <i>Statin Adherence 80%</i>. Persons who remained on a statin medication of any intensity for at least 80% of the treatment period.</li> </ol>		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a></p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement and rationale</b>	<p>The use of statins for primary prevention of cardiovascular disease in patients with diabetes, based on their age and other risk factors, is recommended by guidelines from the American Diabetes Association and the American College of Cardiology/American Heart Association. Cholesterol-lowering medications, such as statins, are among the most commonly prescribed drugs in America. In the United States, 22% of adults 45 and older take statins. Evidence shows statin use decreases cardiovascular mortality in patients with established cardiovascular disease, and decreases total mortality rates overall. Primary and secondary prevention trial data strongly support starting lipid-lowering therapy with a statin in most patients with type 2 diabetes.</p>		
<b>Citations</b>	<p><a href="#">Grundy, S.M., N.J. Stone, A.L. Bailey, C. Beam, K.K. Birtcher, R.S. Blumenthal, L.T. Braun, S. de Ferranti, J. Faiella-Tommasino, D.E. Forman, R. Goldberg, P.A. Heidenreich, M.A. Hlatky, D.W. Jones, D.M. Lloyd-Jones, N. Lopez-Pajares, C.E. Ndumele, C.E. Orringer, C.A. Peralta, ... J. Yeboah. 2019. "2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol." <i>Journal of the American College of Cardiology</i> 73(24):</a></p>		
<b>Characteristics</b>			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product lines</b>	<p>Commercial.</p> <p>Medicaid.</p> <p>Medicare.</p>		
<b>Stratification</b>	None.		
<b>Risk adjustment</b>	None.		

<p><b>Improvement notation</b></p> <p><b>Guidance</b></p>	<p>Increased score indicates improvement in both rates.</p> <p><b>Data collection methodology:</b> <a href="#">Administrative ECDS</a>. Refer to <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine the event occurred in the period being measured.</p> <p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p> <p><b>Medication lists:</b> If an organization uses both pharmacy data (NDC codes) and clinical data (RxNorm codes) for reporting, and there are both NDC and RxNorm codes on the same date of service, use only one data source for the date of service. This rule is not included in the measure calculation logic, and must be programmed manually.</p> <p><b>Other guidance:</b> All persons who are numerator compliant for Rate 1 must be used as the denominator for Rate 2, regardless of the data source used to capture the Rate 1 numerator.</p> <p><i>For example</i>, if supplemental data were used to identify compliance for the Rate 1 numerator, then supplemental data must be included in identifying the Rate 2 denominator.</p>
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<b>IPSD</b>	Index prescription start date. The earliest prescription dispensing date for any statin medication, of any intensity, during the measurement period.
<b>Treatment period</b>	The period beginning on the IPSD through the last day of the measurement period.
<b>PDC</b>	Proportion of days covered. The number of days the person is covered by at least one statin medication prescription of appropriate intensity, divided by the number of days in the treatment period.
<b>Calculating number of days covered for multiple prescriptions</b>	<p>If multiple prescriptions for different medications are dispensed on the same day, calculate number of days covered by a statin medication (for the numerator) using the prescriptions with the longest days supply.</p> <p>For multiple prescriptions for different medications dispensed on different days, with overlapping days supply, count each day within the treatment period only once toward the numerator.</p> <p>If multiple prescriptions for the same medication are dispensed on the same or different days, sum the days supply and use the total to calculate the number of days covered by a statin medication (for the numerator).</p> <p><i>For example</i>, if three prescriptions for the same medication are dispensed on the same day, each with a 30-days supply, sum the days supply, for a total of 90 days covered by a statin. Subtract any days supply that extends beyond December 31 of the measurement period.</p> <p>Use the medication lists to determine if drugs are the same or different. Drugs in different lists are considered different drugs.</p>

	<p><i>For example</i>, a dispensing event from the <u>Amlodipine Atorvastatin High Intensity Medications List</u> and a dispensing event from the <u>Amlodipine Atorvastatin Moderate Intensity Medications List</u> are dispensing events for different medications.</p>
<p><b>Initial population</b></p>	<p><i>Measure item count:</i> Person.</p> <p><i>Attribution basis:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefits:</i> Medical during measurement period and the year prior to the measurement period. Pharmacy during the measurement period.</li> <li>• <i>Continuous enrollment:</i> The measurement period and the year prior to the measurement period.</li> <li>• <i>Allowable gap:</i> No more than one gap of ≤45 days during each year of continuous enrollment. No gaps on the last day of the measurement period.</li> </ul> <p><i>Ages:</i> 40–75 years as of last day of the measurement period.</p> <p><i>Event:</i></p> <p><b>Identify persons with a diagnosis of diabetes.</b></p> <p>There are two methods to identify persons with diabetes: by claim/encounter data and by pharmacy data. The organization must use both methods to identify the initial population, but a person only needs to be identified by one method to be included in the measure.</p> <ul style="list-style-type: none"> <li>• <i>Claim/encounter data method.</i> At least two diagnoses of diabetes (<u>Diabetes Value Set*</u>) on different dates of service during the measurement period or the year prior to the measurement period.</li> <li>• <i>Pharmacy data method.</i> At least one diagnosis of diabetes (<u>Diabetes Value Set*</u>) and at least one diabetes medication dispensing event of insulin or a hypoglycemic/antihyperglycemic medication (<u>Diabetes Medication List</u>) during the measurement period or the year prior to the measurement period.</li> </ul> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p>
<p><b>Denominator exclusions</b></p>	<p><b>Persons with a date of death.</b></p> <p>Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</p> <p><b>Persons in hospice or using hospice services.</b></p> <p>Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</p> <p><b>Persons receiving palliative care.</b></p> <p>Persons receiving palliative care (<u>Palliative Care Assessment Value Set</u>; <u>Palliative Care Encounter Value Set</u>; <u>Palliative Care Intervention Value Set</u>) or who had an encounter for palliative care (ICD-10-CM code Z51.5)* any time during the measurement period.</p>

~~• Persons who are 66 years of age and older by the last day of the measurement period, with Medicare benefits, enrolled in an institutional SNP (I-SNP) or living long-term in an institution (LTI).~~

~~Persons enrolled in an Institutional SNP (I-SNP) any time during the measurement period.~~

~~Living long-term in an institution any time during the measurement period 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 period.~~

**Persons age 66 years or older by the last day of the measurement period, with both frailty and advanced illness.**

1. *Frailty*. At least two indications of frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set)\* with different dates of service during the measurement period.
2. *Advanced Illness*. Either of the following during the measurement period or the year prior to the measurement period:
  - Advanced illness (Advanced Illness Value Set)\* on at least two different dates of service.
  - Dispensed dementia medication (Dementia Medications List).

Persons with a diagnosis of pregnancy (Pregnancy Value Set)\*, in vitro fertilization (IVF Value Set), ESRD (ESRD Diagnosis Value Set)\*, dialysis (Dialysis Procedure Value Set), cirrhosis (Cirrhosis Value Set)\*, dispensed at least one prescription for clomiphene (Estrogen Agonists Medications List) during the measurement period or the year prior to the measurement period.

Myalgia, myositis, myopathy or rhabdomyolysis (Muscular Pain and Disease Value Set)\* during the measurement period.

Myalgia or rhabdomyolysis caused by a statin (Muscular Reactions to Statins Value Set) any time during the person's history through the last day of the measurement period.

Discharged from an inpatient setting with an MI (MI Value Set; Old Myocardial Infarction Value Set) on the discharge claim. To identify discharges:

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

Persons who had CABG (CABG Value Set), PCI (CABG Value Set) or other revascularization procedures (Other Revascularization Value Set) in any setting during the year prior to the measurement period.

~~Persons who had at least two encounters with an ASCVD diagnosis (ASCVD Value Set)\* on different dates of service during the measurement period or the year prior to the measurement period.~~

~~Persons who had an outpatient visit, telephone visit, e-visit, virtual check-in or acute inpatient encounter (Outpatient, Telehealth and Acute Inpatient Value Set) with an IVD diagnosis (IVD Value Set).~~

Persons with at least one acute inpatient discharge with an IVD diagnosis (IVD Value Set) on the discharge claim. To identify an acute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).

	<p>2. Exclude nonacute inpatient stays (<u>Nonacute Inpatient Stay Value Set</u>).</p> <p>3. Identify the discharge date for the stay.</p> <p><b>Coding Guidance</b></p> <p>*Do not include laboratory claims (claims with POS code 81).</p>																																							
<b>Denominator</b>	<p><b>Denominator 1—Received Statin Therapy</b></p> <p>Initial population minus denominator exclusions.</p> <p><b>Denominator 2—Statin Adherence 80%</b></p> <p>Persons who meet the numerator criteria for Rate 1.</p>																																							
<b>Numerator</b>	<p><b>Numerator 1—Received Statin Therapy</b></p> <p>At least one dispensing event for a high-intensity, moderate-intensity or low-intensity statin medication (<u>High, Moderate and Low Intensity Statin Medications List</u>) during the measurement period.</p> <p><b>High, Moderate and Low-Intensity Statin Medications</b></p> <table border="1"> <thead> <tr> <th>Description</th> <th>Prescription</th> <th>Medication Lists</th> </tr> </thead> <tbody> <tr> <td>High-intensity statin therapy</td> <td>• Atorvastatin 40-80 mg</td> <td><u>Atorvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Amlodipine-atorvastatin 40-80 mg</td> <td><u>Amlodipine Atorvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Rosuvastatin 20-40 mg</td> <td><u>Rosuvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Simvastatin 80 mg</td> <td><u>Simvastatin High Intensity Medications List</u></td> </tr> <tr> <td>High-intensity statin therapy</td> <td>• Ezetimibe-simvastatin 80 mg</td> <td><u>Ezetimibe Simvastatin High Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Atorvastatin 10-20 mg</td> <td><u>Atorvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Amlodipine-atorvastatin 10-20 mg</td> <td><u>Amlodipine Atorvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Rosuvastatin 5-10 mg</td> <td><u>Rosuvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Simvastatin 20-40 mg</td> <td><u>Simvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Ezetimibe-simvastatin 20-40 mg</td> <td><u>Ezetimibe Simvastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Pravastatin 40-80 mg</td> <td><u>Pravastatin Moderate Intensity Medications List</u></td> </tr> <tr> <td>Moderate-intensity statin therapy</td> <td>• Lovastatin 40-60 mg</td> <td><u>Lovastatin Moderate Intensity Medications List</u></td> </tr> </tbody> </table>	Description	Prescription	Medication Lists	High-intensity statin therapy	• Atorvastatin 40-80 mg	<u>Atorvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Amlodipine-atorvastatin 40-80 mg	<u>Amlodipine Atorvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Rosuvastatin 20-40 mg	<u>Rosuvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Simvastatin 80 mg	<u>Simvastatin High Intensity Medications List</u>	High-intensity statin therapy	• Ezetimibe-simvastatin 80 mg	<u>Ezetimibe Simvastatin High Intensity Medications List</u>	Moderate-intensity statin therapy	• Atorvastatin 10-20 mg	<u>Atorvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Amlodipine-atorvastatin 10-20 mg	<u>Amlodipine Atorvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Rosuvastatin 5-10 mg	<u>Rosuvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Simvastatin 20-40 mg	<u>Simvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Ezetimibe-simvastatin 20-40 mg	<u>Ezetimibe Simvastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Pravastatin 40-80 mg	<u>Pravastatin Moderate Intensity Medications List</u>	Moderate-intensity statin therapy	• Lovastatin 40-60 mg	<u>Lovastatin Moderate Intensity Medications List</u>
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Low-intensity statin therapy	• Ezetimibe-simvastatin 10 mg	<a href="#">Ezetimibe Simvastatin Low Intensity Medications List</a>
Low-intensity statin therapy	• Fluvastatin 20 mg	<a href="#">Fluvastatin Low Intensity Medications List</a>
Low-intensity statin therapy	• Lovastatin 10-20 mg	<a href="#">Lovastatin Low Intensity Medications List</a>
Low-intensity statin therapy	• Pravastatin 10–20 mg	<a href="#">Pravastatin Low Intensity Medications List</a>
Low-intensity statin therapy	• Simvastatin 5-10 mg	<a href="#">Simvastatin Low Intensity Medications List</a>

### Numerator 2—Statin Adherence 80%

PDC of at least 80% during the treatment period.

Follow the steps below to identify numerator compliance:

**Step 1.** Identify the IPSD. The IPSD is the earliest dispensing event for any high-intensity, moderate-intensity or low-intensity statin medication during the measurement period. Use the medication list table in Rate 1 to identify dispensing events.

**Step 2.** To determine the treatment period, calculate the number of days beginning on the IPSD through the end of the measurement period.

**Step 3.** Count the days covered by at least one prescription for any high-intensity, moderate-intensity or low-intensity statin medication during the treatment period. To ensure the days supply that extends beyond the measurement period is not counted, subtract any days supply that extends beyond December 31 of the measurement period.

**Step 4.** Calculate the PDC using the following equation. Multiply the equation by 100 and round (using the .5 rule) to the nearest whole number.

$$\frac{\text{Total Days Covered by a Statin Medication in the Treatment Period (step 3)}}{\text{Total Days in Treatment Period (step 2)}}$$

Total Days in Treatment Period (step 2)

*For example*, if a person has 291 total days covered by a medication during a 365-day treatment period, this calculates to 0.7972. Multiply this number by 100, convert it to 79.72% and round it to 80%, the nearest whole number.

**Step 5.** Sum the number of persons whose PDC is  $\geq 80\%$  for the treatment period.

<p><b>Summary of changes</b></p>	<p><u>This is the first year the measure is reported using ECDS.</u>  <u>Expanded ASCVD diagnosis criteria to allow diagnosis in the measurement year or the year prior to the measurement year.</u>  <u>Renamed the IVD Value Set to ASCVD Value Set and removed inappropriate codes</u>  <u>Removed denominator exclusion for persons enrolled in an Institutional SNP (I-SNP) or living long-term in an institution (LTI).</u></p>																	
<p><b>Data element tables</b></p>	<p>Organizations that submit HEDIS data to NCQA must provide the following data elements.</p> <p><b>Table SPD-1/2/3: Data Elements for Statin Therapy for Patients With Diabetes</b></p> <table border="1" data-bbox="440 604 1468 961"> <thead> <tr> <th>Metric</th> <th>Data Element</th> <th>Reporting Instructions</th> </tr> </thead> <tbody> <tr> <td>ReceivedTherapy</td> <td>Benefit</td> <td>Metadata</td> </tr> <tr> <td rowspan="5">Adherence</td> <td>InitialPopulation</td> <td>For each Metric</td> </tr> <tr> <td>Exclusions</td> <td>Only for ReceivedTherapy Metric</td> </tr> <tr> <td>Denominator</td> <td>For each Metric</td> </tr> <tr> <td>Numerator</td> <td>For each Metric</td> </tr> <tr> <td>Rate</td> <td>(Percent)</td> </tr> </tbody> </table>	Metric	Data Element	Reporting Instructions	ReceivedTherapy	Benefit	Metadata	Adherence	InitialPopulation	For each Metric	Exclusions	Only for ReceivedTherapy Metric	Denominator	For each Metric	Numerator	For each Metric	Rate	(Percent)
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## ***Statin Therapy for Patients With Cardiovascular Disease (SPC) and Statin Therapy for Patients With Diabetes (SPD)***

### **Measure Workup**

#### **Topic Overview**

Cardiovascular disease (CVD), which includes coronary heart disease, heart failure, stroke and hypertension, is the leading cause of death in the United States. Between 2019 and 2022 the death rate due to CVD increased from 200.8 per 100,000 to 210.9 per 100,000 (CDC, n.d.). Diabetes increases the risk of developing CVD by 2–4 times (Johns Hopkins Medicine, 2019). CVD is the current leading cause of death among people with diabetes, accounting for two-thirds of deaths among those with type 2 diabetes (T2D) (ADA, n.d.).

Diabetes often increases risk of other cofactors that lead to an increased risk of heart disease, including high blood pressure, too much low-density lipoprotein cholesterol (LDL-C) and high triglycerides (CDC, 2022). More than 127.9 million (48.6%) American adults have one or more types of CVD (Martin et al., 2024). National initiatives to improve cardiovascular health include the Million Hearts initiative to prevent 1 million heart attacks and strokes by 2027 (CDC, 2024) and the American Heart Association (AHA) goal to increase healthy life expectancy from 66 years to at least 68 years across the United States by 2030 (Angell et al., 2020).

Atherosclerotic cardiovascular disease (ASCVD) occurs when plaque builds up within artery walls. Cholesterol is a primary causal risk factor for development of atherosclerosis and CVD because it can narrow arteries, which reduces the flow of oxygen to organs and throughout the body, resulting in most cardiovascular events like heart attack and stroke (American Heart Association, 2024). LDL-C is most closely associated with CVD risk and is therefore the target of both lifestyle and pharmacological treatment (Martin et al., 2024).

Coronary heart disease (CHD) occurs when plaque builds up in arteries that supply oxygen to the heart (American Heart Association, 2024). An estimated 20.5 million Americans 20 years of age and older have CHD, and the prevalence is higher for males than females (Martin et al., 2024). Plaque buildup can lead to peripheral arterial disease, which results when plaque builds up in arteries that supply oxygen to the legs, arms and pelvis (NHLBI, 2014). About 6.5 million adults 40 years of age and older have peripheral artery disease. The prevalence is higher in older adults and non-Hispanic Black individuals (Martin et al., 2024).

A myocardial infarction (MI) (heart attack) occurs when oxygen rich blood is suddenly blocked from reaching the heart. Approximately 3.2% of U.S adults 20 and older have had an MI; the rate is more than twice as high in men (4.5%) than in women (2.1%) (Martin et al., 2024). Data show that about 14% of people with MI will die from it (Martin et al., 2024).

#### **Relevance**

##### **Health importance**

Data from the National Health and Nutrition Examination Survey (NHANES) estimate that about 20.5 million American adults 20 and older have CHD. This disease is more prevalent in males than in females (8.7% vs. 5.8 %), and there are slight differences by race/ethnicity. Based on data from the National Health Interview Survey (NHIS), the prevalence of CHD is highest in American Indian/Alaska Native individuals (8.6 %) and lowest in Asian individuals (4.4 %). CHD prevalence among White people is estimated to be around 5.7%, and around 4.3% among Black people (Martin et al., 2024). Data from the Framingham Heart Study estimate that the incidence of CHD occurs, on average, 10 years earlier for men than women (Sanchis-Gomar et

al., 2016). In addition, the incidence of cardiovascular events, such as MI and sudden death, occurs, on average, 20 years earlier for men than women (Sanchis-Gomar et al., 2016). In the US, deaths due to CHD account for about 40.3% of total CVD deaths in 2021 (Martin et al., 2024).

### **Financial importance**

In addition to being the leading cause of death in the US, CVD is also among the costliest health conditions. CVD accounted for around \$320B in direct health care costs in 2016; this total includes direct costs (e.g., physicians and other health professionals, hospital services, prescribed medications, home health care) (Tajeu et al., 2024). Costs of treating ASCVD specifically are expected to increase 2.5 fold, from \$126B in 2015 to \$309B in 2035 (Khera et al., 2020). Additionally, the cost of direct expenditures by patients with ASCVD increased by 30% between 2008 and 2019 (Shah et al., 2024). Assuming trends for the cost of treating ASCVD follows those described above, the burden of cost will not only increase for health plans and systems, but also for patients.

Having a diagnosis of diabetes while seeking cardiovascular care has been associated with higher medical expenditures. The ADA estimates that \$39.3B is associated with cardiovascular-related spending associated with diabetes (ADA, 2023). In a cost-effective analysis of interventions focused on managing diabetes, statin therapy as secondary prevention of CVD was found to be very cost-effective, at \$4,627 per quality-adjusted life year (QALY) (Siegel et al., 2020). This is defined as the incremental cost-effectiveness ratio (ICER) greater than zero but less than or equal to \$25,000 per QALY or life years gained (LYG). Statin treatment for individuals with type 2 diabetes, compared with no lipid-regulating treatment, was also found to be very cost effective (\$3,294/QALY) (Siegel et al., 2020).

### **Potential for improvement**

Statin therapy is a first-line treatment for lowering blood cholesterol. In patients with clinical ASCVD, LDL-C lowering therapy should include maximally tolerated statin therapy. In patients with ASCVD who are judged to be very high risk with LDL-C 70 mg/dL or higher ( $\geq 1.8$  mmol/L), the addition of a PCSK9 inhibitor and/or ezetimibe may be appropriate to meet LDL-C goals (Grundy et al., 2018). Similarly, in patients 40–75 years of age with diabetes, LDL-C lowering therapy should be initiated (Grundy et al., 2018).

Guidelines suggest that when initiating or continuing statin therapy, the goal of treatment should be to lower LDL-C by 30%–50% depending on statin tolerance (Grundy et al., 2018).

### **Safety considerations and contraindications**

Statin therapy is a first-line treatment for lowering blood cholesterol. While statins are considered safe for most patients, there are safety concerns to consider before prescribing and throughout treatment. Previously, statins were contraindicated for people who are pregnant or breastfeeding, and in people of childbearing potential unless they are using effective forms of contraception (Stone et al., 2013). However, studies have shown no increased risk of congenital abnormalities among statin-exposed pregnant individuals (Poornima et al., 2023). As a result, the FDA removed the contraindication for statin use during preconception planning and pregnancy. Despite this change, statins are discouraged for use among pregnant people except in cases of familial hypercholesterolemia, other severe LDL-C increases or established (prior) ASCVD when benefits are judged to outweigh risks (Poornima et al., 2023).

End stage renal disease is an independent risk factor for cardiovascular events; however, evidence does not provide strong consensus for the usefulness of statins in these individuals (Abdelnabi et al., 2021). Guidelines suggest people with renal disease can use statins but should start with a low dose statin (Mach et al., 2020; Grundy et al., 2019).

The most common side effect of statin therapy is statin-associated muscle symptoms (SAMS), which can occur in varying forms of severity. However, the mechanisms behind these side effects due to statin therapy is unclear (Ward et al., 2019). Statin therapy should not be used in patients with rhabdomyolysis, the most severe form of muscle symptoms (Selva-O'Callaghan et al., 2018). Clinicians can discontinue or adjust statin therapy in patients that develop mild to moderate muscle symptoms to assess other muscle related conditions and determine a tolerated statin intensity (Selva-O'Callaghan et al., 2018).

Statins are cleared in the liver and can cause elevated liver biochemistries. This presents a concern for patients with existing liver disease. Research suggests that patients with decompensated cirrhosis and acute liver failure should not receive statin therapy due to the risks associated with elevated liver biochemistries (Vargas et al., 2017).

### **Statin adherence**

ACC/AHA guidelines suggest that adherence to both medication and lifestyle regimens support ASCVD risk reduction (Grundy et al., 2019). This measure uses the proportion of days covered (PDC) to assess adherence. According to the Pharmacy Quality Alliance, a PDC threshold of 80% is supported by clinical evidence for most classes of chronic medications (Pharmacy Quality Alliance, 2022).

The impact of adherence on statin efficacy has been shown to reduce risk of CVD mortality to 1 per 10,000 individuals (Hope et al., 2019). However, research shows that adherence to statin medications is poor in the United States. In real-world clinical registries, more than 50% of patients no longer adhere to statin therapy within 1 year of starting treatment (Rodriguez et al., 2019). NCQA seeks to improve statin adherence in patients with CVD and thereby reduce the risk for cardiovascular related mortality.

### **Gaps in care**

A recent multicenter cohort study analyzed data from Cerner Real-World Data. The study identified 322,153 patients with ASCVD who would benefit from statin therapy, according to the ACC/AHA guidelines, and found that more than 23.9% of patients were not receiving statin therapy. The percentage of patients using non-statin LDL-C lowering therapies was low, with only 4.4% of patients using ezetimibe and 0.7% using a PCSK9 inhibitor (Navar et al., 2023). These results highlight gaps in care for patients with ASCVD and the need for improvement. Alignment with blood cholesterol guidelines will improve quality of care for patients with CVD.

### **Health care disparities**

Systemic racism, inequitable access to general care and specialized services and complexity in navigating the health care system may all contribute to widening disparities in healthy outcomes for people with ASCVD. The challenges to accessing quality care for historically marginalized individuals have contributed to lower statin use among these groups, namely Black, Indigenous and people of color who are uninsured or underinsured, those who identify as female and those who are 65 years and older (Schroff et al., 2017).

Similar challenges are observed amongst patients with diabetes (Mester et al., 2021; Gamboa et al., 2017).

These disparities signal gaps in quality that may contribute to higher cardiovascular mortality rates among some historically marginalized populations.

## Scientific Soundness

### Clinical importance and evidence

Statins (HMG CoA reductase inhibitors) are a class of drugs that lower blood cholesterol. Statins work in the liver by reducing the formation of cholesterol, and help the liver remove cholesterol already in the blood (CDC, 2021). Statins are most effective in lowering LDL-C. The amount of cholesterol lowering effect is based on statin intensity, which is classified as either high, moderate or low intensity.

According to the most recent blood cholesterol treatment guidelines from the American College of Cardiology and American Heart Association (ACC/AHA), statins of moderate or high intensity are recommended for adults with established clinical ASCVD. Many studies support the use of statins to reduce ASCVD events in primary and secondary prevention.

One systemic review observed large-scale evidence from randomized trials that showed statin therapy reduces the risk of major cardiovascular events like coronary deaths, MI and stroke (Collins et al., 2016). The benefits of statins are shown to increase during each year therapy continues, so larger benefits would accrue with prolonged therapy and persist long term (Collins et al., 2016).

**Table 1. Statin Therapy Dosage Intensities**

Description	Prescription
High-intensity statin therapy	<ul style="list-style-type: none"> <li>• Atorvastatin 40–80 mg</li> <li>• Amlodipine-atorvastatin 40-80 mg</li> <li>• Ezetimibe-atorvastatin 40-80 mg</li> <li>• Rosuvastatin 20–40 mg</li> <li>• Simvastatin 80 mg</li> <li>• Ezetimibe-simvastatin 80 mg</li> </ul>
Moderate-intensity statin therapy	<ul style="list-style-type: none"> <li>• Atorvastatin 10–20 mg</li> <li>• Amlodipine-atorvastatin 10-20 mg</li> <li>• Ezetimibe-atorvastatin 10-20 mg</li> <li>• Rosuvastatin 5–10 mg</li> <li>• Simvastatin 20–40 mg</li> <li>• Ezetimibe-simvastatin 20-40 mg</li> <li>• Niacin-simvastatin 20-40 mg</li> <li>• Sitagliptin-simvastatin 20-40 mg</li> <li>• Pravastatin 40–80 mg</li> <li>• Aspirin-pravastatin 40-80 mg</li> <li>• Lovastatin 40 mg</li> <li>• Niacin-lovastatin 40 mg</li> <li>• Fluvastatin XL 80 mg</li> <li>• Fluvastatin 40 mg bid</li> <li>• Pitavastatin 2–4 mg</li> </ul>
Low-intensity statin therapy	<ul style="list-style-type: none"> <li>• Simvastatin 10 mg</li> <li>• Ezetimibe-simvastatin 10 mg</li> <li>• Sitagliptin-simvastatin 10 mg</li> <li>• Pravastatin 10–20 mg</li> <li>• Aspirin-pravastatin 20 mg</li> <li>• Lovastatin 20 mg</li> <li>• Niacin-lovastatin 20 mg</li> <li>• Fluvastatin 20–40 mg</li> <li>• Pitavastatin 1 mg</li> </ul>

## Specific Guideline Recommendations

### 2018 Guidelines on Management of Blood Cholesterol (AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA)

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In patients who are 75 years of age or younger with clinical ASCVD, high-intensity statin therapy should be initiated or continued with the aim of achieving 50% or greater reduction in LDL-C levels.

Strength: I; LOE: A

In patients with clinical ASCVD in whom high-intensity statin therapy is contraindicated or who experience statin-associated side effects, moderate-intensity statin therapy should be initiated or continued with the aim of achieving 30% to 49% reduction in LDL-C levels.

Strength: I; LOE: A

In patients with clinical ASCVD who are receiving maximally tolerated statin therapy and whose LDL-C level remains 70 mg/dL or higher ( $\geq 1.8$  mmol/L) it may be reasonable to add ezetimibe.

Strength IIb; LOE: B-R

In patients with clinical ASCVD who are judged to be very high risk and who are on maximally tolerated LDL-C lowering therapy with LDL-C 70 mg/dL or higher ( $\geq 1.8$  mmol/L) or a non-HDL-C level of 100 mg/dL or higher ( $\geq 2.6$  mmol/L) it is reasonable to add a PCSK9 inhibitor following a clinician-patient discussion about the net benefit, safety, and cost.

Strength: IIa LOE: A

In patients with clinical ASCVD who are judged to be very high risk and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe (I B-NR).

Strength: I; LOE: B-NR

In patients older than 75 years of age with clinical ASCVD, it is reasonable to initiate moderate- or high-intensity statin therapy after evaluation of the potential for ASCVD risk reduction, adverse effects, and drug-drug interactions, as well as patient frailty and patient preferences.

Strength: IIa; LOE: B-R

In patients older than 75 years of age who are tolerating high-intensity statin therapy, it is reasonable to continue high-intensity statin therapy after evaluation of the potential for ASCVD risk reduction, adverse effects, and drug-drug interactions, as well as patient frailty and patient preferences.

Strength: IIa; LOE: C-LD

In adults 40 to 75 years of age with diabetes mellitus, regardless of estimates 10-year ASCVD risk, moderate-intensity statin therapy is indicated.

Strength: I; LOE: A

## Grading System Key

### American College of Cardiology/American Heart Association: Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatment, or Diagnostic Testing in Patient Care

#### Class (Strength) of Recommendation:

Class	Suggestion for Practice
I (Strong) Benefit >>> Risk	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Is recommended</li> <li>• Is indicated/useful/effective/beneficial</li> <li>• Should be performance/administered/other</li> <li>• Comparative-Effectiveness Phrases:               <ul style="list-style-type: none"> <li>– Treatment/strategy A is recommended/indicated in preference to treatment B</li> <li>– Treatment A should be chosen over treatment B</li> </ul> </li> </ul>
Class IIa (Moderate) Benefit >> Risk	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Is reasonable</li> <li>• Can be useful/effective/beneficial</li> <li>• Comparative-Effective Phrases:               <ul style="list-style-type: none"> <li>– Treatment/strategy A is probably recommended/indicated in preference to treatment B</li> <li>– It is reasonable to choose treatment A over treatment B</li> </ul> </li> </ul>
Class IIb (weak) Benefit ≥ Risk	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• May/might be reasonable</li> <li>• May/might be considered</li> <li>• Usefulness/effectiveness is unknown/unclear/uncertain or not well established</li> </ul>
Class III: No Benefit (moderate) Benefit = Risk	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Is not recommended</li> <li>• Is not indicated/useful/effective/beneficial</li> <li>• Should not be performed/administered/other</li> </ul>
Class III: Harm (strong) Risk > Benefit	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Potentially harmful</li> <li>• Causes harm</li> <li>• Associated with excess morbidity/mortality</li> <li>• Should not be performed/administered other</li> </ul>

#### Level (Quality) of Evidence

Level	Definition
A	<ul style="list-style-type: none"> <li>• High-quality evidence from more than 1 randomized control trial (RCT)</li> <li>• Meta-analyses of high-quality RCTs</li> <li>• One or more RCTs corroborated by high-quality registry studies</li> </ul>
B-R (randomized)	<ul style="list-style-type: none"> <li>• Moderate-quality evidence from 1 or more RCTs</li> <li>• Meta-analyses of moderate-quality RCTs</li> </ul>
B-NR (nonrandomized)	<ul style="list-style-type: none"> <li>• Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies</li> <li>• Meta-analyses of such studies</li> </ul>

Level	Definition
C-LD (limited data)	<ul style="list-style-type: none"> <li>• Randomized or nonrandomized observational or registry studies with limitations of design or execution</li> <li>• Meta-analyses of such studies</li> <li>• Physiological or mechanistic studies in human subjects</li> </ul>
C-EO (Expert Opinion)	Consensus of expert opinion based on clinical experience

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## Statin Therapy for Patients With Cardiovascular Disease

The percentage of males 21–75 years of age and females 40–75 years of age during the measurement year who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and met the following criteria. The following rates are reported:

- *Received Statin Therapy.* Members who were dispensed at least one high-intensity or moderate-intensity statin medication during the measurement year. (Tables 1–3)
- *Statin Adherence 80%.* Members who remained on a high-intensity or moderate-intensity statin medication for at least 80% of the treatment period. (Tables 4–6)

### HEDIS Health Plan Performance Rates: Statin Therapy for Patients With Cardiovascular Disease (SPC)

**Table 1. HEDIS Received Statin Therapy Indicator Performance—Commercial Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	420	388 (92)	84.0	7.0	78.3	81.7	76.5	80.6	83.7
	F 40-75		335 (80)	75.9	8.0	68.6	72.5	76.5	80.6	83.7
	<b>Total</b>		<b>393 (94)</b>	<b>81.9</b>	7.0	76.6	79.5	82.9	85.6	87.8
2022	M 21-75	417	389 (93)	84.3	6.3	79.1	82.3	85.1	87.8	89.7
	F 40-75		335 (80)	75.9	7.7	68.6	72.8	76.5	80.3	84.0
	<b>Total</b>		<b>396 (95)</b>	<b>81.9</b>	7.6	76.2	80.0	83.1	85.7	87.8
2021	M 21-75	419	396 (94)	84.3	6.4	79.1	82.3	85.2	87.6	90.0
	F 40-75		337 (80)	75.8	8.0	67.7	72.6	76.9	80.7	83.3
	<b>Total</b>		<b>400 (95)</b>	<b>82.3</b>	6.7	76.8	80.3	82.8	85.8	88.5

\*For 2023, the average denominator across plans was 440 for females, with a standard deviation of 656, and 1,039 for males, with a standard deviation of 1,651.

**Table 2. HEDIS Received Statin Therapy Indicator Performance—Medicaid Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	278	207 (74.5)	80.2	8.2	68.8	79.2	82.6	84.8	86.8
	F 40-75		204 (73.9)	77.4	8.3	64.0	75.0	79.5	82.5	84.8
	Total		213 (76.6)	79.3	8.0	66.6	77.9	81.4	83.9	85.9
2022	M 21-75	272	202 (74.3)	79.8	7.9	71.6	78.6	81.5	84.0	86.1
	F 40-75		194 (71.3)	76.7	8.2	67.0	74.6	78.2	81.8	83.5
	Total		205 (75.4)	78.7	7.7	70.0	77.7	80.4	82.6	85.0
2021	M 21-75	270	199 (73.7)	80.2	8.0	68.4	78.6	82.2	84.7	87.3
	F 40-75		190 (70.4)	76.7	9.1	63.8	74.4	79.1	82.1	85.0
	Total		203 (75.2)	78.5	8.7	65.1	77.6	80.8	83.2	85.9

\*For 2023, the average denominator across plans was 641 for females, with a standard deviation of 770, and 873 for males, with a standard deviation of 1,079.

**Table 3. HEDIS Received Statin Therapy Indicator Performance—Medicare Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	760	524 (69.0)	87.3	3.9	82.6	85.5	87.6	89.5	91.5
	F 40-75		478 (62.9)	83.3	4.7	77.3	80.7	83.5	86.1	88.6
	Total		560 (73.7)	85.8	4.2	80.7	84.0	86.0	87.9	90.5
2022	M 21-75	750	513 (68.4)	86.4	4.5	81.5	84.6	86.8	88.9	90.9
	F 40-75		471 (62.8)	82.5	4.7	77.0	79.7	82.8	85.3	88.1
	Total		545 (72.7)	85.1	4.4	80.1	82.9	85.1	87.4	90.0
2021	M 21-75	714	481 (67.4)	85.9	4.6	81.1	83.8	86.0	88.6	91.3
	F 40-75		448 (62.8)	82.0	5.1	75.6	79.2	82.3	85.1	88.0
	Total		509 (71.3)	84.5	4.3	79.7	82.3	84.8	87.0	89.5

\*For 2023, the average denominator across plans was 1,081 for females, with a standard deviation of 2,724, and 1,568 for males, with a standard deviation of 4,244.

**Table 4. HEDIS Statin Adherence 80% Indicator Performance—Commercial Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	420	380 (90)	80.5	6.4	73.1	77.2	80.8	84.2	88.2
	F 40-75		313 (75)	77.6	7.6	67.9	73.5	78.5	82.5	86.2
	Total		388 (92.4)	79.7	6.5	72.2	76.5	80.0	83.9	87.3
2022	M 21-75	417	384 (92)	79.7	6.4	72.0	76.8	80.3	84.0	86.7
	F 40-75		315 (76)	77.5	7.0	68.8	73.8	78.0	82.4	85.4
	Total		391 (94)	79.2	6.4	71.7	76.0	80.0	83.3	86.1
2021	M 21-75	419	389 (93)	80.4	5.9	73.4	77.2	80.9	84.2	86.9
	F 40-75		316 (75)	77.6	7.1	69.0	73.51	77.7	81.9	86.1
	Total		400 (95)	79.6	6.1	72.9	76.6	80.0	83.7	86.4

\*For 2023, the average denominator across plans was 352 for females, with a standard deviation of 487, and 887 for males, with a standard deviation of 1,368.

**Table 5. HEDIS Statin Adherence 80% Indicator Performance—Medicaid Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	278	202 (72.7)	71.0	9.3	60.0	65.4	71.0	76.6	82.4
	F 40-75		198 (71.2)	71.0	9.6	59.0	65.3	72.2	76.8	81.5
	Total		212 (76.3)	70.7	9.2	60.0	65.2	70.5	76.5	81.8
2022	M 21-75	272	196 (72.1)	70.3	9.8	57.1	64.1	70.8	76.6	81.6
	F 40-75		188 (69.1)	70.1	10.2	58.3	65.0	70.7	76.5	81.9
	Total		204 (75.0)	69.9	9.8	56.7	64.6	71.1	76.2	81.0
2021	M 21-75	270	191 (70.8)	70.0	9.0	58.3	64.2	69.8	76.1	81.2
	F 40-75		181 (67.0)	70.7	9.7	59.0	65.5	71.4	77.1	82.8
	Total		199 (73.7)	70.2	9.0	59.2	65.3	70.0	76.2	81.3

\*For 2023, the average denominator across plans was 512 for females, with a standard deviation of 602, and 725 for males, with a standard deviation of 887.

**Table 6. HEDIS Statin Adherence 80% Indicator Performance—Medicare Plans**

Measurement Year	Stratification	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
				Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	M 21-75	760	508 (66.8)	86.9	5.0	81.2	84.1	87.2	89.8	93.2
	F 40-75		467 (61.5)	85.8	5.4	80.0	83.1	85.7	88.8	92.3
	Total		546 (71.8)	86.4	5.1	80.5	83.5	86.5	89.4	92.4
2022	M 21-75	750	498 (66.4)	86.2	5.0	80.1	83.2	86.6	89.5	92.1
	F 40-75		448 (59.7)	84.6	5.6	77.1	81.6	84.9	88.5	91.2
	Total		538 (71.7)	85.3	6.5	79.2	82.2	85.7	88.9	91.5
2021	M 21-75	714	470 (65.8)	85.5	5.1	78.3	82.6	85.8	88.8	91.9
	F 40-75		431 (60.4)	84.1	5.4	77.5	81.2	84.2	87.5	90.6
	Total		503 (70.5)	84.9	5.3	78.2	82.1	85.2	88.4	91.1

\*For 2023, the average denominator across plans was 927 for females, with a standard deviation of 2,279, and 1,420 for males, with a standard deviation of 3,766.

## Statin Therapy for Patients With Diabetes

The percentage of members 40–75 years of age during the measurement year with diabetes who do not have clinical atherosclerotic cardiovascular disease (ASCVD) who met the following criteria. Two rates are reported:

- *Received Statin Therapy.* Members who were dispensed at least one statin medication of any intensity during the measurement year. (Tables 1–3)
- *Statin Adherence 80%.* Members who remained on a statin medication of any intensity for at least 80% of the treatment period. (Tables 4–6)

### HEDIS Health Plan Performance Rates: Statin Therapy for Patients with Diabetes (SPD)

**Table 1. HEDIS Received Statin Therapy Indicator Performance—Commercial Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	401 (95.5)	63.6	6.3	57.4	61.2	64.1	67.1	69.5
2022	417	404 (96.9)	64.5	6.0	58.6	62.5	64.9	67.7	70.2
2021	419	405 (96.7)	65.4	5.7	60.6	62.9	65.9	68.7	71.2

\*For 2023, the average denominator across plans was 6,276 individuals, with a standard deviation of 13,264.

**Table 2. HEDIS Received Statin Therapy Indicator Performance—Medicaid Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	225 (81.0)	63.8	7.4	52.0	60.8	65.3	68.1	71.4
2022	272	214 (78.9)	63.8	7.9	54.2	60.4	65.1	68.4	72.1
2021	270	214 (79.3)	64.7	8.3	53.2	62.0	66.2	69.5	72.9

\*For 2023, the average denominator across plans was 6,324 individuals, with a standard deviation of 9,275.

**Table 3. HEDIS Received Statin Therapy Indicator Performance—Medicare Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	605 (79.6)	78.5	6.2	72.5	76.1	78.8	81.8	84.7
2022	750	589 (78.5)	78.6	5.2	72.9	75.9	78.6	81.7	84.7
2021	714	553 (77.5)	78.3	5.0	72.8	75.5	78.3	81.5	84.1

\*For 2023, the average denominator across plans was 4,335 individuals, with a standard deviation of 11,979.

**Table 4. HEDIS Statin Adherence 80% Indicator Performance—Commercial Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	420	395 (94.1)	74.7	7.4	65.9	70.3	74.7	80.0	83.6
2022	417	397 (95.2)	74.0	7.0	65.7	70.0	74.5	79.0	82.0
2021	419	402 (95.9)	73.9	6.4	65.6	70.3	74.4	78.6	81.3

\*For 2023 the average denominator across plans was 4,094 individuals, with a standard deviation of 8,954.

**Table 5. HEDIS Statin Adherence 80% Indicator Performance—Medicaid Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	278	224 (80.6)	67.4	9.8	53.2	61.4	68.1	73.4	79.7
2022	272	213 (78.3)	66.1	10.0	52.7	60.2	66.3	72.3	78.0
2021	270	213 (78.9)	66.2	9.5	54.6	60.8	66.4	71.9	77.4

\*For 2023, the average denominator across plans was 4,201 individuals, with a standard deviation of 6,267.

**Table 6. HEDIS Statin Adherence 80% Indicator Performance—Medicare Plans**

Measurement Year	Total Number of Plans (N)	Number of Plans Reporting (N (%))	Performance Rates (%)						
			Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2023*	760	594 (78.2)	84.9	5.1	78.7	82.2	85.0	87.9	91.6
2022	750	577 (76.9)	83.9	5.7	77.1	80.4	84.2	87.6	90.3
2021	714	544 (76.2)	83.0	5.7	76.2	79.7	83.3	86.8	89.7

\*For 2023, the average denominator across plans was 3,547.4 individuals, with a standard deviation of 9,697.6.



## ***Proposed Changes to the Race and Ethnicity Stratification for HEDIS<sup>®1</sup> MY 2026:***

### **Alignment with Updated Federal Standards for Race and Ethnicity**

NCQA seeks comments on the proposed alignment of the HEDIS race and ethnicity stratification (RES) with 2024 updates to the Office of Management and Budget (OMB) Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15).<sup>2</sup>

NCQA requires health plans to report race and ethnicity as defined by the OMB; to remain aligned with the federal standards for race and ethnicity data collection and reporting, NCQA proposes to update the HEDIS RES from the previous 1997 OMB standard to the revised March 2024 standard. The planned updates are as follows:

- Add Middle Eastern or North African (MENA) as a minimum reporting category.
- Update terminology in SPD 15.
- Combine race and ethnicity into a single reporting unit that allows multiple responses.

The revisions are tailored to organizations that collect race and ethnicity data and require collection of detailed categories as a default. Due to the nature of HEDIS reporting, NCQA will not change reporting categories to reflect the more granular format required of entities collecting these data. However, we are evaluating opportunities to encourage organizations to transition to detailed race and ethnicity data collection through educational materials, standards and other avenues.

NCQA will postpone updating Table RES-A-D-1/2/3 in *General Guideline: Race and Ethnicity Stratification* pending updates from the Centers for Medicare and Medicaid Services, Health Level 7 International<sup>®</sup> and the Centers for Disease Control and Prevention; our team will revise these tables prior to finalizing specifications as these agencies release plans to update direct reference codes and value sets to align with OMB revisions. Additionally, NCQA intends to include mapping guidance for organizations that have data in the prior OMB format during the transition period. This guidance will be developed in conjunction with the anticipated updates to Table RES-A-D-1/2/3 which will be incorporated after the NCQA public comment period closes.

### **Scope of Changes**

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Planned OMB alignment updates will impact the following areas in HEDIS MY 2026:

- *General Guideline: Race and Ethnicity Stratification.*
- *Race/Ethnicity Diversity of Membership (RDM) measure.*
- The 23 measures stratified by race and ethnicity as of MY 2025.
  - NCQA is not expanding the RES to additional measures in MY 2026 to reduce organizational burden while implementing proposed OMB updates.

### **Proposed Revisions**

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**Add MENA Minimum Reporting Category:** Prior to the 2024 OMB update, MENA was classified under the White category. However, the OMB recognized that this framing does not accurately reflect the lived experiences and perceptions of MENA individuals. Per the OMB update, MENA is now a distinct minimum reporting category, separate from White. As such, NCQA proposes to add MENA as a minimum reporting category for the RES, separate from White.

<sup>1</sup> HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

<sup>2</sup> Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Notice 2024–06469, 84 FR 22182 (2024). <https://www.federalregister.gov/d/2024-06469>

**Update Terminology in SPD 15:** In the 2024 update, OMB made changes to modernize how race and ethnicity are reflected in society and to improve clarity for respondents. NCQA proposes to make the following terminology updates to category definitions and supporting language in HEDIS:

- Remove “majority” and “minority” except when statistically accurate.
- Use the term “race and/or ethnicity” in the question stem.
- Use “Multiracial and/or Multiethnic” in tabulations to include those who identify with multiple options.
- Use at least six example groups when presenting category definitions to illustrate the diversity of categories.
- For American Indian or Alaska Native, remove the phrase “who maintains tribal affiliation or community attachment.”
- For American Indian or Alaska Native, update language from “including Central America” to listing “Central America” equally with North and South America.
- For Asian, remove the term “Far East” and “Indian Subcontinent” and add “Central or East Asia” and “South Asia.”
- For Black or African American, remove the term “Negro.”
- For Hispanic or Latino, the definition will read as follows, “Includes individuals of Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, and other Central or South American or Spanish culture or origin.”
- For Native Hawaiian or Other Pacific Islander, remove “Other” from the title.

**Combine Race and Ethnicity Into a Single Unit That Allows Multiple Responses:** Prior to the 2024 OMB update, SPD 15 used two separate questions for race and ethnicity data collection and reporting. With the update, the OMB combined these categories into a single question, and race and ethnicity are now treated equally, with the expectation that organizations will report them as “race and/or ethnicity” categories. NCQA will update the RES to combine race and ethnicity into a single reporting unit and include a “Multiracial/Multiethnic” reporting category to capture the quality of care provided to multiracial/multiethnic individuals.

NCQA seeks general feedback on the proposed changes and specific feedback on the following questions:

1. Do you support the proposed revisions to the HEDIS RES to align with OMB 2024 standards?
2. The OMB SPD 15 update requires federal agencies to comply with updates no later than March 28, 2029. How is this deadline informing your organization’s strategy? What resources would be beneficial to support the transition to the new standards during the intermediary period (when both standards are in use)?

Supporting documents include example measure specification, updated general guidelines and literature review summaries supporting changes to add the MENA and Multiracial/Multiethnic reporting categories.

**NCQA acknowledges the contributions of the Health Equity Expert Work Group and the Technical Measurement Advisory Panel.**

<b>Measure title</b>	Prenatal Immunization Status*	<b>Measure ID</b>	PRS-E
<b>Description</b>	The percentage of deliveries in the measurement period in which persons received influenza and tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccinations.		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p><i>*Developed with support from the Department of Health and Human Services (DHHS), Office of the Assistant Secretary for Health (OASH), National Vaccine Program Office (NVPO).</i></p> <p>Refer to the complete copyright and disclaimer information at the front of this publication.</p> <p>NCQA website: <a href="http://www.ncqa.org">www.ncqa.org</a></p> <p>Submit policy clarification support questions via My NCQA (<a href="https://my.ncqa.org">https://my.ncqa.org</a>).</p>		
<b>Clinical recommendation statement and rationale</b>	Advisory Committee on Immunization Practices (ACIP) clinical guidelines recommend that all women who are pregnant or who might be pregnant in the upcoming influenza season receive inactivated influenza vaccines. ACIP also recommends that pregnant women receive one dose of Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36, regardless of prior history of receiving Tdap.		
<b>Citations</b>	Murthy, N., A.P. Wodi, V.V. McNally, M.F. Daley, S. Cineas. 2024. “Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older—United States, 2024.” <i>MMWR Morb Mortal Wkly Rep</i> 73:11–15. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm7301a3">http://dx.doi.org/10.15585/mmwr.mm7301a3</a>		
<b>Characteristics</b>			
<b>Scoring</b>	Proportion.		
<b>Type</b>	Process.		
<b>Product lines</b>	<ul style="list-style-type: none"> <li>• Commercial.</li> <li>• Medicaid.</li> <li>• <del>Multiracial and/or Multiethnic.</del></li> <li>• <del>Two or More Races.</del></li> <li>• Asked But No Answer.</li> <li>• Unknown.</li> </ul>		
<b>Risk adjustment</b>	None.		
<b>Improvement notation</b>	Increased score indicates improvement.		
<b>Guidance</b>	<p><b>Data collection methodology:</b> ECDS. Refer to the <i>General Guideline: Data Collection Methods</i> for additional information.</p> <p><b>Date specificity:</b> Dates must be specific enough to determine that the event occurred in the period being measured.</p>		

	<p><b>Which services count?</b> When using claims, include all paid, suspended, pending and denied claims.</p> <p><b>Other Guidance:</b> The denominator for this measure is based on deliveries. When using SNOMED-CT codes to identify a history of a procedure, the date of the procedure must be available.</p>
<b>Definitions</b>	
<b>Pregnancy episode</b>	Calculate pregnancy start date by subtracting the gestational age (in weeks) at the time of delivery from the delivery date. Use the last gestational age assessment or diagnosis within 1 day of the delivery date.
<b>Initial population</b>	<p><i>Measure item count:</i> Episode.</p> <p><i>Attribution:</i> Enrollment.</p> <ul style="list-style-type: none"> <li>• <i>Benefit:</i> Medical.</li> <li>• <i>Continuous enrollment:</i> From 28 days prior to the delivery date through the delivery date.</li> <li>• <i>Allowable gap:</i> None.</li> </ul> <p><i>Ages:</i> None.</p> <p><i>Event:</i></p> <p><b>Deliveries (<u>Deliveries Value Set</u>) during the measurement period that have a gestational age assessment (SNOMED CT code 412726003; value is not null) or gestational age diagnosis within 1 day of the start or end of the delivery.</b> A code from any of the following value sets meets criteria for gestational age diagnosis:</p> <ul style="list-style-type: none"> <li>• <u>Weeks of Gestation Less Than 37 Value Set.</u></li> <li>• <u>37 Weeks Gestation Value Set.</u></li> <li>• <u>38 Weeks Gestation Value Set.</u></li> <li>• <u>39 Weeks Gestation Value Set.</u></li> <li>• <u>40 Weeks Gestation Value Set.</u></li> <li>• <u>41 Weeks Gestation Value Set.</u></li> <li>• <u>42 Weeks Gestation Value Set.</u></li> <li>• 43 weeks gestation (ICD-10-CM code Z3A.49). <ul style="list-style-type: none"> <li>– Include deliveries that occur in any setting.</li> <li>– Determine the delivery date using the date as of the end of the delivery procedure.</li> <li>– If a person has more than one delivery in a 180-day period, include only the first eligible delivery. Then, if applicable include the next delivery that occurs after the 180-day period. Identify deliveries chronologically, including only one per 180-day period.</li> </ul> </li> </ul> <p><b>Note:</b> Removal of multiple deliveries in a 180-day period is based on eligible deliveries. Assess each delivery for exclusions and participation before removing multiple deliveries in a 180-day period.</p>

<b>Denominator exclusions</b>	<ul style="list-style-type: none"> <li>• <b>Persons with a date of death.</b> Death in the measurement period, identified using data sources determined by the organization. Method and data sources are subject to review during the HEDIS audit.</li> <li>• <b>Persons in hospice or using hospice services.</b> Persons who use hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these persons must use only the run date of the file.</li> <li>• <b>Deliveries that occur at less than 37 weeks of gestation.</b> Length of gestation in weeks is identified by one of two methods: <ul style="list-style-type: none"> <li>– Gestational age assessment (SNOMED CT code 412726003; value &lt;37 weeks), <b>or</b></li> <li>– Gestational age diagnosis (<u>Weeks of Gestation Less Than 37 Value Set</u>).</li> </ul> </li> </ul>
<b>Denominator</b>	The initial population minus denominator exclusions.
<b>Numerator</b>	<p><b>Numerator 1—Immunization Status: Influenza</b></p> <ul style="list-style-type: none"> <li>• Deliveries where persons received an adult influenza vaccine (<u>Adult Influenza Immunization Value Set</u>; <u>Adult Influenza Vaccine Procedure Value Set</u>) on or between July 1 of the year prior to the measurement period and the delivery date, or</li> <li>• Deliveries where persons had anaphylaxis due to the influenza vaccine (SNOMED CT code 471361000124100) on or before the delivery date.</li> </ul> <p><b>Numerator 2—Immunization Status: Tdap</b></p> <ul style="list-style-type: none"> <li>• Deliveries where persons received at least one Tdap vaccine (CVX code 115; <u>Tdap Vaccine Procedure Value Set</u>) during the pregnancy (including on the delivery date), <b>or</b></li> <li>• Deliveries where persons had any of the following: <ul style="list-style-type: none"> <li>– Anaphylaxis due to the diphtheria, tetanus or pertussis vaccine (<u>Anaphylaxis Due to Diphtheria, Tetanus or Pertussis Vaccine Value Set</u>) on or before the delivery date.</li> <li>– Encephalitis due to the diphtheria, tetanus or pertussis vaccine (<u>Encephalitis Due to Diphtheria, Tetanus or Pertussis Vaccine Value Set</u>) on or before the delivery date.</li> </ul> </li> </ul> <p><b>Numerator 3—Immunization Status: Combination</b></p> Deliveries that met criteria for numerator 1 and numerator 2.
<b>Summary of changes</b>	<ul style="list-style-type: none"> <li>– Removed the definitions of participation and participation period. These definitions have been integrated into the measure where applicable.</li> <li>– <u>Updated the race and ethnicity stratification to align with OMB SPD 15 2024.</u></li> </ul>
<b>Data element tables</b>	Organizations that submit data to NCQA must provide the following data elements.

**Table PRS-E-A-1/2 Data Elements for Prenatal Immunization Status**

Metric	Data Element	Reporting Instructions
Influenza	InitialPopulationByEHR	Repeat per Metric
Tdap	InitialPopulationByCaseManagement	Repeat per Metric
Combination	InitialPopulationByHIERegistry	Repeat per Metric
	InitialPopulationByAdmin	Repeat per Metric
	InitialPopulation	(Sum over SSoRs)
	ExclusionsByEHR	Repeat per Metric
	ExclusionsByCaseManagement	Repeat per Metric
	ExclusionsByHIERegistry	Repeat per Metric
	ExclusionsByAdmin	Repeat per Metric
	Exclusions	(Sum over SSoRs)
	Denominator	Repeat per Metric
	NumeratorByEHR	For each Metric
	NumeratorByCaseManagement	For each Metric
	NumeratorByHIERegistry	For each Metric
	NumeratorByAdmin	For each Metric
	Numerator	(Sum over SSoRs)
	Rate	(Percent)

**Table PRS-E-B-1/2: Data Elements for Prenatal Immunization Status: Stratifications by Race and Ethnicity**

Metric	Race <u>and/or</u> Ethnicity	Data Element	Reporting Instructions
Influenza	AmericanIndianOrAlaskaNative	InitialPopulation	For each Stratification, repeat per Metric
Tdap	Asian	Exclusions	For each Stratification, repeat per Metric
Combination	BlackOrAfricanAmerican	Denominator	For each Stratification, repeat per Metric
	<u>HispanicOrLatino</u>	<u>Numerator</u>	<u>For each Metric and Stratification</u>
	<u>MiddleEasternOrNorthAfrican</u>	<u>Rate</u>	<u>(Percent)</u>

**Table PRS-E-C-1/2: Data Elements for Prenatal Immunization Status: Stratifications by Ethnicity**

	Metric	Race <u>and/or</u> Ethnicity	Data Element	Reporting Instructions
		NativeHawaiianOrOtherPacificIslander	_Numerator	_For each Metric and Stratification
		White	_Rate	(Percent)
		SomeOtherRace <u>AndOr</u> Ethnicity		
		<u>TwoOrMoreRaces</u> Multiracial <u>AndOr</u> Multiethnic		
		AskedButNoAnswer		
		Unknown		

DRAFT

## General Guideline: Race and Ethnicity Stratification

This guideline provides instructions on how organizations categorize Medicare, Medicaid and commercial members by the race and ethnicity stratification (RES) when it is included in a measure. Refer to *Appendix 7: Logical Measure Groups* for measures that include RES by logical measure group.

### Reporting categories

NCQA requires reporting race and ethnicity as defined by the Office of Management and Budget (OMB) [2024](#) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.<sup>1,2</sup>

Race and ethnicity values must be rolled up into the OMB categories specified in this guideline. [NCQA supports efforts to collect more detailed race and ethnicity data, beyond the minimum OMB reporting categories.](#) If more detailed race ~~and/or~~ ethnicity data are collected, data must be aggregated and reported in the OMB categories provided. For health plans using the CMS classification scheme for race and ethnicity, refer to Table RES-A-1/2/3 for a crosswalk to HEDIS reporting. Report member race and ethnicity ~~together separately.~~ ~~If a combined race/ethnicity category question is used to collect data, data must be disaggregated, and race and ethnicity categories must be reported separately.~~ ~~When using the combined race/ethnicity data format for collection, refer to Table RES B-1/2/3 for a crosswalk of reporting categories.~~

Tables RES-C-1/2/3 and RES-D-1/2/3 crosswalk the HEDIS reporting categories to code values specified by the Race and Ethnicity extensions of the HL7 US Core Implementation Guide. Organizations must use or map to the documented direct reference codes and value sets described here. Code values originate from two code systems:

- “Race & Ethnicity – CDC” (CDCREC) is used to report distinct OMB race and ethnicity categories.
- “Some Other Race,” “Asked But No Answer” and “Unknown” use the HL7 version 3 NullFlavor code system.

### Determining race and ethnicity reporting category

For each product line, report members in only one of the ~~eleven~~ race stratifications listed below and the total.

- *American Indian or Alaska Native*: Identification with any of the original peoples of North, ~~Central~~ and South America ~~(including Central America) and who maintain tribal affiliation or community attachment.~~ [Examples of these groups include, but are not limited to, It includes](#) people who identify as “American Indian” or “Alaska Native” and includes groups such as Navajo Nation, Blackfeet Tribe [of the Blackfeet Indian Reservation of Montana](#), Mayan, Aztec, Native Village of Barrow Inupiat Traditional Government and Nome Eskimo Community.
- *Asian*: Identification with one or more nationalities or ethnic groups originating in [any of the original peoples of Central, East](#) ~~the Far East,~~ Southeast [or South](#) Asia ~~or the Indian subcontinent.~~ Examples of these

<sup>1</sup> Office of Management and Budget Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. <https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf>  
<https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>

<sup>2</sup> Improvements to the 2020 Census Race and Hispanic Origin Question Designs, Data Processing, and Coding Procedures OMB Statistical Policy Directive No. 15 on Race and Ethnicity Data Standards: Categories and Definitions: <https://spd15revision.gov/content/spd15revision/en/2024-spd15/categories-definitions.html>  
<https://www.census.gov/newsroom/blogs/random-samplings/2024/08/improvements-to-2020-census-race-hispanic-origin-question-designs.html>



groups include, but are not limited to, Chinese, Filipino, Asian Indian, Vietnamese, Korean, ~~and Japanese.~~ ~~The category also includes groups such as~~ Pakistani, Cambodian, Hmong, Thai, Bengali or Mien.

- *Black or African American*: Identification with one or more nationalities or ethnic groups originating in any of the Black racial groups of Africa. Examples of these groups include, but are not limited to, African American, Jamaican, Haitian, Nigerian, Ethiopian, ~~and Somali.~~ ~~The category also includes groups such as~~ Ghanaian, South African, Barbadian, Kenyan, Liberian and Bahamian.
- *Hispanic or Latino*: Identification with one or more nationalities or ethnic groups originating in Mexico, Puerto Rico, Cuba, Central and South America and other Spanish cultures. Examples of these groups include, but are not limited to, Mexican or Mexican American, Puerto Rican, Cuban, Salvadoran, Dominican and Colombian.
- *Middle Eastern or North African*: Identification with one or more nationalities or ethnic groups originating in the Middle East or North Africa. Examples of these groups include, but are not limited to, Lebanese, Iranian, Egyptian, Syrian, Iraqi and Israeli.
- *Native Hawaiian or ~~Other~~ Pacific Islander*: Identification with one or more nationalities or ethnic groups originating in Hawaii, Guam, Samoa, or other Pacific Islands. Examples of these groups include, but are not limited to, Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, ~~and Marshallese.~~ ~~The category also includes groups such as~~ Palauan, Tahitian, Chuukese, Pohnpeian, Saipanese ~~and~~ Yapese.
- *White*: Identification with one or more nationalities or ethnic groups originating in Europe, ~~the Middle East or North Africa.~~ Examples of these groups include, but are not limited to, German, Irish, English, Italian, ~~Lebanese, Egyptian,~~ Polish, French, ~~Iranian,~~ Slavic ~~and~~ Cajun ~~and Chaldean.~~
- *Some Other Race ~~and/or~~ Ethnicity*: People whose race information has been collected but does not fit into any of the other ~~seven~~ race categories. ~~This category includes people who may be Mulatto, Creole and Mestizo or another race not specified in the Census “Race” categories.~~
- *Two or More Races ~~Multiracial and/or Multiethnic~~*: People with any combination of races, including “Some Other Race ~~and/or~~ Ethnicity.”
- *Asked But No Answer*: People who the organization asked to identify race/~~ethnicity~~ but who declined to provide a response.
- *Unknown*: People for whom the organization did not obtain race ~~or ethnicity~~ information and for whom the organization did not receive a declined response (i.e., “Asked But No Answer”).
- *Total*: Total of all categories above.

**Determining ethnicity reporting category**

~~For each product line, report members in only one of the four ethnicity stratifications listed below and the total.~~

- ~~*Hispanic or Latino*: Identification with one or more nationalities or ethnic groups originating in Mexico, Puerto Rico, Cuba, Central and South America and other Spanish cultures. Examples of these groups include, but are not limited to, Mexican or Mexican American, Puerto Rican, Cuban, Salvadoran, Dominican and Colombian. “Hispanic, Latino or~~

~~Spanish origin” also includes groups such as Guatemalan, Honduran, Spaniard, Ecuadorian, Peruvian or Venezuelan.~~

- ~~• *Not Hispanic or Latino:* People not of Hispanic, Latino or Spanish culture or origin.~~
- ~~• *Asked But No Answer:* People who the organization asked to identify ethnicity but who declined to provide a response.~~
- ~~• *Unknown:* People for whom the organization did not obtain ethnicity information and for whom the organization did not receive a declined response (i.e., “Asked But No Answer”).~~
- ~~*Total:* Total of all categories above.~~

## Data source

Reporting the data collection source is only required for the Race/Ethnicity Diversity of Membership (RDM) measure.

Approved data sources include data collected directly from members and data obtained through imputation methods. In cases where a plan has a race or ethnicity value but no data source, the plan must report using the “unknown” data source category. In cases where the race or ethnicity value and the source are missing, plans must record this as no data. NCQA strongly encourages plans to report directly collected data when available and emphasizes the importance of improving completeness of directly collected member race and ethnicity data. Additionally, NCQA strongly encourages plans to track the source of their race and ethnicity data in order to facilitate valid disparities assessments.

For the RDM measure, plans will report each race and ethnicity value by data source. Plans will report the number of members in the eligible population from the direct, imputed, unknown and no data source categories, and the number of members in the numerator from the direct, imputed, unknown and no data source categories. IDSS will calculate the total number of members in the eligible population and numerator (combining direct, imputed, unknown and no data sources).

Supplemental data may be used as a data source for the race and ethnicity stratification.

### **Direct data**

Data collected directly from members method reflects members’ self-identification and is the preferred data source.

Directly collected data include any source for which the member self-identified race or ethnicity. This includes member self-reported data collected directly from members under the full control of the health plan (i.e., no data were obtained through an intermediary), as well as third-party data collected directly from a member by another entity (e.g., the state, CMS, Health Information Exchanges [HIE] or clinical feeds). Direct sources may include, but are not limited to:

- Surveys.
- Health risk assessments.
- Disease management registries.
- Case management systems.
- EHRs.
- CMS/state databases.

- Enrollment information furnished by enrolling entities (e.g., state Medicaid agencies, employers).
- CCDs.
- HIEs.

**Note:** The “Asked But No Answer” category is only reported using direct data.

**Imputed data** Plans may choose to report race and ethnicity data supplemented by imputed methods. Imputed assignment of race and ethnicity values include using an alternate data source (e.g., nationally representative data obtained from databases like the American Community Survey) to assign a race or ethnicity value to a member based on their primary location of residence. Some commonly used imputed methods combine geographic data with additional imputation methods such as surname analysis.

NCQA reiterates that directly collected race and ethnicity is considered the gold standard and is highly preferred to imputed race and ethnicity. For plans choosing to use imputed methods to report the HEDIS race and ethnicity stratification, NCQA emphasizes the following:

- When applying imputed methods that involve assignment of race or ethnicity based on geographic data and member’s location of residence, the smallest geographic unit possible is preferred. For example, geographic assignment at the census block level is likely to be more accurate than assignment using census tract or ZIP code-level data.
- Imputed data sources and methods should be evaluated for reliability and validity and selection of a source and method should be prioritized based on demonstrated validity and reliability for the population in which it will be applied (e.g., age group, geography, product line).
- Imputed methods of race and ethnicity assignment are to be used for population-level reporting and analysis but are not appropriate for member-level intervention.

**Unknown data** When the reported value for race or for ethnicity is known, but the source is unknown (i.e., cases where an organization has a race or ethnicity value on file from a legacy system but does not know the source).

**No data** When both the race or ethnicity value and the source are missing.

**Note:** The “unknown” category is only reported using the “no data source” category because unknown values cannot be attributed to a particular data source.

**Sampling** For measures collected using the Hybrid Method with the race and ethnicity stratification, follow the guidelines for sampling outlined in *Guidelines for Calculation* and *Sampling Guidelines for the Hybrid Method*. The race and ethnicity stratifications are applied to the eligible population and denominator after hybrid sampling.

**Reporting** Reporting of the race and ethnicity stratification follows the parameters for denominator size outlined in General Guideline: *Reporting*.

**Table RES-A-1/2/3: CMS Categories Crosswalked to HEDIS/OMB Race and Ethnicity**

CMS Category	HEDIS/OMB Race	HEDIS/OMB Ethnicity
American Indian/Alaska Native	American Indian or Alaska Native	Unknown
Asian/Pacific Islander	Asian	Unknown

CMS Category	HEDIS/OMB Race	HEDIS/OMB Ethnicity
Black	Black	Unknown
White	White	Unknown
Hispanic	Unknown	Hispanic or Latino
Other	Some Other Race	Unknown
Unknown	Unknown	Unknown
(No equivalent category)	Native Hawaiian or Other Pacific Islander	Unknown
(No equivalent category)	Two or more races	Unknown

**Table RES-B-1/2/3: Combined Categories Crosswalked to HEDIS/OMB Race and Ethnicity**

Race/Ethnicity Combined Category	HEDIS/OMB Race	HEDIS/OMB Ethnicity
American Indian/Alaska Native	American Indian or Alaska Native	Not Hispanic or Latino
Asian	Asian	Not Hispanic or Latino
Black	Black	Not Hispanic or Latino
Native Hawaiian and Other Pacific Islander	Native Hawaiian or Other Pacific Islander	Not Hispanic or Latino
White	White	Not Hispanic or Latino
Hispanic/Latino/Black	Black	Hispanic or Latino
Hispanic/Latino/White	White	Hispanic or Latino
Other	Some Other Race	Unknown
Multiple races marked	Two or More Races	Unknown
Unknown	Unknown	Unknown

**Table RES-C-1/2/3: HEDIS/OMB Race Crosswalked for Use With HEDIS Reporting Categories**

HEDIS/OMB Race	CDCREC OMB Category: Direct Reference Code*	CDCREC Detailed Category: Value Set
American Indian or Alaska Native	1002-5	<u>American Indian or Alaska Native Detailed Race Value Set</u>
Asian	2028-9	<u>Asian Detailed Race Value Set</u>
Black	2054-5	<u>Black or African American Detailed Race Value Set</u>
Native Hawaiian or Other Pacific Islander	2076-8	<u>Native Hawaiian or Other Pacific Islander Detailed Race Value Set</u>
White	2106-3	<u>White Detailed Race Value Set</u>
Some Other Race	OTH**	NA
Two or More Races	NA***	NA
Asked But No Answer	ASKU**	NA
Unknown	UNK**	NA

\*Codes to identify race and ethnicity are from the CDC Race and Ethnicity code system developed by the U.S. Centers for Disease Control and Prevention (CDC). They resemble, but are not, LOINC codes.

\*\*HL7 v3 Code System NullFlavor.

\*\*\*This value is defined by the measure calculation logic as the presence of two or more distinct CDCREC category codes and does not map to a specific direct reference code or value set.

**Table RES-D-1/2/3: HEDIS/OMB Ethnicity Crosswalked for Use With HEDIS Reporting Categories**

HEDIS/OMB Race	CDCREC OMB Category: Direct Reference Code*	CDCREC Detailed Category: Value Set
Hispanic or Latino	2135-2	Hispanic or Latino Detailed Ethnicity
Not Hispanic or Latino	2186-5	NA
Asked But No Answer	ASKU**	NA
Unknown	UNK**	NA

\*Codes to identify race and ethnicity are from the CDC Race and Ethnicity code system developed by the U.S. Centers for Disease Control and Prevention (CDC). They resemble, but are not, LOINC codes.

\*\*The NullFlavor concepts “Asked But No Answer” and “Unknown” are not included in the terminology binding for the US Core Ethnicity FHIR extension on which this digital logic is structured. NCQA allows these concepts to express ethnicity data to align with bound values for the US Core Race extension.

### Note

- *Race and ethnicity are social constructs, not biological; stratifying HEDIS measures by race and ethnicity is intended to be used to further understanding of racial and ethnic disparities in care and to hold health plans accountable to address such disparities, with the goal of achieving equitable health care and outcomes. Data are not to be used to further bias in health care or suggest that race and ethnicity are biological determinants of health.*
- *When multiple sources of data are used for race and ethnicity, there may be disagreements in the data collected. When this happens, data sources should be prioritized based on evaluation of anticipated accuracy. This includes use of specific categories over nonspecific categories, most frequent or consistently reported category and selection of data with clear provenance (source, method of collection) over data without clear provenance. Known data sources should be prioritized over unknown data sources, and data collected directly by the organization should be prioritized over all other data sources.*
- *Race and ethnicity data may come from different categories of data source (direct, imputed, unknown, no data). In such cases, use the data source that applies to the data element (race, ethnicity). If the same data element is received from two different data sources, prioritize data sources based on the second bullet above.*

## ***Race and Ethnicity Stratification:***

### **Workup on the Addition of Middle Eastern or North African Category**

#### **Background**

Historically, Middle Eastern or North African (MENA) individuals were classified as “White” under federal race and ethnicity data collection, reporting and maintenance standards. However, MENA individuals often do not perceive themselves to be White, nor do their shared experiences and societal perceptions identify them as White (Maghbouleh et al., 2022). Due to a lack of federal reporting standards, there is variability in how MENA individuals are defined in administrative datasets, self-reported datasets and surveys. Only two publicly available, nationally representative data sets allow separation of MENA individuals from other non-Hispanic White individuals: the National Health Interview Survey (NHIS) and American Community Survey (ACS). Both surveys have indirect methodologies for identifying MENA individuals, the NHIS through a “place of birth” question and the ACS through “place of birth” and “ancestry” questions, which can underrepresent the number of MENA identifying individuals (Kindratt et al., 2022).

The Office of Management and Budget (OMB) 2024 changes now allow standardized, direct identification of MENA individuals in official record keeping, such as the Census, ACS and NHIS. Standardized definitions and direct reporting will allow health care quality improvement and research to empirically identify health disparities, provide culturally and linguistically appropriate care and address other areas of need locally and nationally.

To continue promoting health equity within HEDIS<sup>®</sup>, NCQA will continue stratification of HEDIS measures by race and ethnicity according to updated OMB guidelines. NCQA conducted a literature review to summarize recent knowledge on the current state of health outcomes, behaviors, disparities and social determinants of health (SDOH) experienced by MENA individuals and communities to highlight areas where stratification can be most impactful. Refer to Table 1 in the appendix.

#### **Findings**

##### **Limited Areas of Research**

The studies in this review identified key areas of health disparities experienced by MENA individuals and advocated for disaggregation from White in federal race and ethnicity data reporting guidelines. Studies focused on disparities in morbidity, maternal and infant health, mental and cognitive health and health behaviors. A 2024 scoping review of Arab and MENA health disparities research by Fleischer and Sadek noted, “Arab/MENA health disparity research remains at the detection phase” (Fleischer & Sadek, 2024). Relative to other racial and ethnic minority groups in the United States, there is a lack of widely available research investigating health disparities experienced by MENA individuals. An older literature review from Abuelezam et al. in 2018 discussed that the majority of research samples come from convenience sampling within distinct ethnic enclaves, particularly in Dearborn, Michigan, and in Minnesota, which limits the ability of researchers to generalize findings (Abuelezam et al., 2018).

##### **Limitations in Nationally Representative Datasets**

The data sources used by studies in this review confirm that few studies could capture nationally representative samples of MENA-identifying individuals. Six studies utilized the NHIS to compare health outcomes for samples of foreign-born MENA immigrants in the United States to foreign-born White immigrants and US-born White individuals (Kindratt et al., 2022; Dallo et al., 2024; Kindratt et al., 2023; Kindratt, Dallo, et al., 2024; Kindratt, Zahodne, et al., 2024; Samari et al., 2020). Researchers identified

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

MENA individuals through the NHIS question asking for place of birth, limiting its capacity to identify non-MENA-country born individuals who identify racially and ethnically as being from the region. These studies also noted that their US-born White samples include MENA-identifying individuals, due to the NHIS use of the 1997 OMB race and ethnicity data standards.

One study investigated differences in health insurance coverage among children using both the NHIS and ACS, with the ACS having some capacity to identify US-born MENA individuals through a combination of place of birth and ancestry questions (Dallo et al., 2024). Refer to Healthcare Utilization Disparities. Another study used the ACS in conjunction with state disease surveillance databases to identify the burden of COVID-19 among MENA individuals (Dallo et al., 2023). Studies leveraging the Centers for Disease Control and Prevention (CDC) Restricted-Use Detail Natality Data and unedited ACS race responses characterize national estimates for birth outcome disparities and demographic factors associated with MENA racial self-identification respectively (Moustafa et al., 2024; Ennis et al., 2024).

A Canadian study highlighted the need for detailed race and ethnicity reporting for MENA individuals (Sharif et al., 2023). COVID-19 infection rates were compared across sociodemographic groups in Toronto, noting that MENA individuals were overrepresented in the proportion of confirmed cases to the city's population share. This finding provided support for targeted government COVID responses among communities at higher risk for COVID-19 infection. Similar targeted interventions are not currently possible across the US due to the previous lack of federally recognized MENA racial identification in data collection and reporting. The aggregation of MENA within the broader White race category obscures racial disparities in health outcomes and access.

Despite the limited number of nationally representative datasets that include MENA identifiers and reliance on oversampling within ethnic enclaves, studies have found health-related disparities experienced by MENA individuals compared to White individuals and other race groups within the US.

## Healthcare Utilization Disparities

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Studies in the review evaluated insurance status, health care utilization and health outcomes, with a focus on maternal and infant health and cognitive health. Four studies focused on health care utilization; the first found that MENA adults had higher prevalence of being uninsured in the past year in a California sample, compared to non-Hispanic White adults (23.8% vs. 11.9%) (Abuelezam et al., 2019). The second used an NHIS sample and found that foreign-born MENA children had 1.50 times higher odds (OR, 1.50; 95% CI, 1.10–2.05) of being uninsured than US-born, non-Hispanic White children. The same study conducted analyses in an ACS sample and found foreign-born MENA children had 2.11 times higher odds (OR, 2.11; 95% CI, 1.88–2.37) of being uninsured than US-born, non-Hispanic White children. US-born MENA children had no statistically significant difference in odds of being uninsured compared to US-born, non-Hispanic White children.

The study also examined the proportion of children with commercial private insurance, or any public insurance, including Medicaid, Children's Health Insurance Coverage (CHIP) or any other government program. US-born MENA children had 1.32 times higher odds (OR, 1.32; 95% CI, 1.27–1.36) and foreign-born MENA children had 1.63 times higher odds (OR, 1.63; 95% CI, 1.51–1.77) of having any public insurance, compared to US-born, non-Hispanic White children. US-born MENA children had 1.43 times lower odds (OR, 0.70; 95% CI, 0.67–0.72) and foreign-born MENA children had 2.38 times lower odds (OR, 0.42; 95% CI, 0.38–0.45) of having private commercial insurance than US-born, non-Hispanic White children (Dallo et al., 2024).

The third study found, in an NHIS sample of MENA immigrant adults, that White-identifying MENA immigrant adults had 2.94 times lower odds (OR, 0.34; 95% CI, 0.14–0.81) of delaying care in the past 12 months, compared to non-White MENA immigrants (Samari et al., 2020).



The final study, focused on utilization, found that MENA men between the ages of 18–34 had lower HPV vaccine initiation rates compared to White and Black men (23.2% vs 44.5% and 46.2% respectively) (Harper, Rego, et al., 2022).

### **Maternal and Infant Health Disparities**

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Beyond overall health care utilization, a major area of outcomes-based health disparities research for MENA individuals is in the field of maternal and infant health. This search yielded six studies focused in this area. All studies identified health disparities experienced by MENA women and infants, with MENA women having 3.03 times lower odds (OR, 0.33; 95% CI, 0.15–0.70) of completing both cervical and colorectal cancer screenings, 2.55 times higher odds (OR, 2.55; 95% CI, 1.04–6.27) of miscarriage during IVF treatment and 1.16 times higher odds (OR, 1.16; 95% CI, 1.05–1.27) of giving birth to a low-birthweight infant, and 1.37 times lower odds (OR, 0.73; 95% CI, 0.60–0.89) of completing a well-woman visit, compared to White women (Kindratt, Dallo, et al., 2024; Moustafa et al., 2024; Salem et al., 2017; Harper et al., 2021; Abuelezam et al., 2020).

A 2022 study investigated previously held beliefs that religious, cultural or same-sex concordance between MENA women and physicians improved completion and uptake of routine health exams. The researchers found that patient and physician gender and religious concordance—previously identified facilitators of exam uptake—may be significantly associated with avoidance of routine physical exams and increased feelings of discomfort undergoing health exams (Harper, Sen, et al., 2022). This study, using a small cross-sectional convenience sample in Michigan, identifies that not all MENA individuals are homogenous in their beliefs, health outcomes and health care utilization, reinforcing the need for detailed reporting criteria on MENA individuals nationally and locally to best identify and address disparities in health care access and outcomes.

### **COVID-19 Disparities**

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Two studies investigated disparities in COVID-19 burden among MENA individuals compared to non-Hispanic White individuals. The first found that MENA individuals had nearly twice the proportion of confirmed COVID-19 cases than non-Hispanic White individuals (16.78% vs. 7.50%) and that MENA individuals, after adjusting for age and sex, had 2.48 times higher odds (OR, 2.48; 95% CI, 2.45–2.51) to test positive for Covid-19 than non-Hispanic White individuals. This study extrapolated Covid-19 rates from Michigan, indicating possible overestimation due to the large proportion of MENA individuals in the state (Dallo et al., 2023). The second study was conducted in Toronto, where MENA is recognized as a minimum racial reporting category. Researchers found that MENA individuals had a 3.51 infection rate ratio of reported COVID-19 cases, relative to White individuals (Sharif et al., 2023).

### **Cognitive Health Disparities**

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The last area of concentrated research in MENA health outcomes found from this search is in the field of cognitive and psychological health. Three studies were identified that focused on this topic, with MENA immigrants at increased odds of reporting a cognitive limitation, having undiagnosed Alzheimer’s disease and related dementias and psychological health concerns, compared to US-born, non-Hispanic White adults (Kindratt et al., 2022, 2023; Kindratt, Zahodne, et al., 2024).

### **Commonalities in Research**

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Despite the limited number of studies in relatively few research topic areas examining health outcomes and disparities experienced by MENA populations, nearly all researchers captured in this review note similar needs for the future of health equity work for MENA communities. Researchers commonly cite the need for disaggregation of MENA from White in race and ethnicity reporting to properly identify health disparities, allow larger sample analysis through standardized self-reported race identification and properly target future interventions at communities with the greatest need.



Aggregation of those two racial groups conflicts with socially and self-perceived categorizations of “Whiteness” and biases population health outcomes toward null values when performing between group comparisons (Awad et al., 2022). For example, a 2019 study found that, when disaggregating MENA from White in a California sample, MENA individuals had 2.03 times higher odds (OR, 2.03; 95% CI, 1.23–3.34) of self-reported diabetes and 1.56 times lower odds (OR, 0.64; 95% CI, 0.50–0.83) of hypertension than White individuals (Abuelezam et al., 2019). Keeping these distinct racial groups aggregated in population health research artificially alters disparities that are not identified due to lack of measurement. Researchers additionally state that the ability to systematically identify MENA individuals allows more stratified and detailed analyses of outcomes research by examining the intersectional nature of race, socioeconomic status, educational attainment and other SDOH (Maghbouleh et al., 2022; Awad et al., 2022).

## Conclusions

This targeted literature review yielded relatively few articles (n = 21) investigating health outcomes, behaviors and disparities experienced by MENA individuals and communities in the United States. Several articles found were published by the same research teams, leading to a focus on outcomes related to cognitive, maternal and infant health. Studies were unable to have standardized, direct identification methodologies for gathering samples. In some large, nationally representative, public health surveys, place of birth or ancestry questions have been used as a proxy for MENA race identification. Studies conducted based on smaller, convenience samples allowed more flexibility for racial self-identification questionnaires to gather a sample of interest; however, this limited their ability to make claims outside the overrepresented ethnic enclaves where these studies typically occurred.

The OMB’s March 2024 updates to Statistical Policy Directive 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) (Revisions to OMB’s Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 2024), which add MENA as a required minimum reporting category, alleviates many methodological concerns experienced by researchers in identifying MENA populations, and expands the ability of other researchers to identify health disparities experienced by these populations. Including a new required minimum reporting category will allow researchers to identify MENA health disparities and outcome performance without having to use specialized methodologies to identify the population, expanding the breadth of understanding of MENA health experiences in the United States. This much needed step, previously referred to as the “detection phase” of health disparities, builds the foundational understanding of how MENA individuals are impacted by the health system, and where future intervention and equity efforts can have the most targeted impact in reducing gaps in care (Fleischer & Sadek, 2024).

This review confirmed that the lack of a distinct MENA reporting category obfuscates the true experiences and outcomes of MENA individuals as distinct from White individuals. When researchers are able to directly compare behaviors and outcomes of MENA individuals to non-MENA White individuals, they find worse outcomes related to maternal, infant and cognitive health, lower vaccination and preventive screening rates and increased odds of being uninsured. By updating HEDIS stratifications, health plans and researchers will have the ability to identify disparities in care and outcomes experienced by MENA populations, compare their performance to national performance metrics and target areas for focused quality improvement.

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## Appendix

**Table 1: Detailed List of Studies Included in Review**

Study	Sample Size (n)	Sampling Method	Geography	Design	Area of Interest
Abuelezam et al. (2018)	247 articles for review	Varied by study	Varied, but all within the United States	Comprehensive Literature Review	Health related outcomes including tobacco use, cardiovascular disease, stroke, cancer, diabetes, maternal and child health, depression, mental health, trauma, substance abuse and general mental and physical health
Abuelezam et al. (2019)	1,359 Arab Americans and 192,868 non-Hispanic White Americans	California Health Interview Survey (CHIS) respondents	Single State: California	Retrospective cross-sectional study	<ul style="list-style-type: none"> <li>• Health Behaviors: Flu vaccination, soda consumption, smoking, alcohol intake and binge drinking, sexual partners, ER visits, contemplating suicide</li> <li>• Health Outcomes: Self-rated health, diabetes, hypertension, heart disease, obesity</li> </ul>
Abuelezam et al. (2020)	8,901 Arab American mothers and 343,566 non-Arab American mothers	Massachusetts Standard Certificate Live Birth record review from 2012-2016	Single State: Massachusetts	Retrospective cross-sectional study	<ul style="list-style-type: none"> <li>• Maternal Health Behaviors: Initiation of prenatal care, breastfeeding initiation, alcohol consumption, smoking</li> <li>• Maternal Health Outcomes: Gestational diabetes</li> <li>• Infant Health Outcomes: Pre-term birth, birth weight, low birth weight and size for gestational age</li> </ul>
Awad et al. (2022)	NA	NA	NA	Editorial	Identifying areas of need for MENA health research
Dallo et al. (2023)	7,617,576 COVID-19 cases, age 18 and older	Michigan Department of Health and Human Services Disease Surveillance System (MDHHS MDSS) and American Community Survey Public Use	Single State: Michigan	Retrospective cross-sectional study	COVID-19 burden among Arab Americans

Study	Sample Size (n)	Sampling Method	Geography	Design	Area of Interest
		Microdata Samples (ACS PUMS)			
Dallo et al. (2024)	311,961 children from the NHIS and 1,892,255 children from the ACS	National Health Interview Survey (NHIS) and ACS	National	Retrospective cross-sectional study	Health insurance coverage among foreign-born MENA children, US-born White children, US-born MENA children
Ennis et al. (2024)	604,500 respondents	ACS	National	Retrospective cross-sectional study	Investigate how people of MENA ancestry report their race in unedited ACS race responses
Fleischer and Sadek (2024)	43 articles for review	Varied by study	Varied, but all within the United States.	Scoping review	Physical and mental health disparities
Harper et al. (2021);	394 women aged 50–65 years old	Survey implemented via convenience sampling and online recruiting within the local community	Within a single state: Southeast Michigan	Cross-sectional study	Cervical and colorectal cancer screening and cancer risk perception and communication behavior
Harper, Sen, et al. (2022)	97 MENA women aged 30–65 years old	Community survey conducted at sites within the Arab American community	Within a single state: Southeast Michigan	Cross-sectional study	Avoidance of routine physical or women's health exam due to religious/cultural issues
Harper, Rego, et al. (2022)	507 men aged 18–34 years old	Community survey administered via random phone dial, online, or in targeted MENA communities	Within a single state: Southeast Michigan	Cross-sectional study	HPV vaccination initiation prevalence in southeast Michigan among adult males
Kindratt et al. (2022)	24,827 adults aged 65 years and older	NHIS and Medical Expenditure Panel Survey (MEPS)	National	Cross-sectional retrospective study	Prevalence of cognitive limitations among MENA immigrants compared to US-born and foreign-born non-Hispanic White individuals
Kindratt et al. (2023)	23,981 adults aged 65 years and older	NHIS and MEPS	National	Cross-sectional retrospective study	Estimating undiagnosed Alzheimer's disease and related dementias among MENA adults compared to non-Hispanic White adults
Kindratt, Zahodne, et al. (2024)	108,695 adults aged 18 years and older	NHIS and MEPS	National	Cross-sectional retrospective study	Estimate the prevalence of modifiable risk factors for ADRD among MENA

Study	Sample Size (n)	Sampling Method	Geography	Design	Area of Interest
					immigrants compared to US and foreign-born White adults
Kindratt, Dallo, et al. (2024)	411,709 adult women aged 18 years and older and 311,961 children	NHIS	National	Cross-sectional retrospective study	<ul style="list-style-type: none"> <li>• Maternal Health Behaviors: Well-visits, dentist visits, smoking</li> <li>• Infant Health Outcomes: Birth weight</li> </ul>
Maghbouleh et al. (2022)	417 non-Hispanic White adults and 171 MENA adults	Convenience sampling with two online survey experiments	Non-representative national sample	Cross-sectional experimental study	Perception of racial identification among non-MENA White and MENA adults
Moustafa et al. (2024)	575,509 adult mothers aged 18–44 years old	Restricted-Use Detail Natality Data accessed through the National Center for Health Statistics (NCHS)	National	Cross-sectional retrospective study	Risk of giving birth to a low-birth-weight infant among foreign-born non-Hispanic White mothers by MENA/non-MENA status
Neumayer et al. (2017)	588 Arab adults aged 18 years and older (Arab BRFS) and 7,709,196 adults aged 18 years and older (MiBRFS)	Michigan Behavioral Risk Factor Survey (MiBRFS) and Arab Behavioral Risk Factor Survey (Arab BRFS)	Single State: Michigan	Cross-sectional study	Statewide estimates in demographics, risk behaviors, clinical preventative practices, chronic conditions, adverse childhood experiences of Arab adults compared to non-Arab adults in Michigan
Salem et al. (2017)	190 MENA and 200 non-Hispanic White adult women undergoing their first IVF cycle	Cohort sampling with 1:1 matching on race	Single academically affiliated private fertility clinic in Michigan	Retrospective cohort study	Investigate IVF outcome disparities among MENA and non-Hispanic White women
Samari et al. (2020)	1,013 Americans born in the Middle East	NHIS	National	Cross-sectional retrospective study	Health care utilization outcomes: currently insured, lacking usual source of care, ED visit, doctor visit, delaying healthcare, forgoing care due to costs, being rejected as a new patient
Sharif et al. (2023)	119,018 confirmed COVID-19 cases	Infection registry data from Ontario Ministry of Public Health Case and Contact Management Solution and Integrated Public Health System	Single city: Toronto	Cross-sectional retrospective study	COVID-19 burden and infection rate among MENA populations compared to non-MENA populations

## ***Race and Ethnicity Stratification:*** **Workup on the Multiracial/Multiethnic Reporting Category**

### **Background**

The multiracial population has experienced a 276% increase since 2010, growing from 9 million people to 33.8 million. This dramatic increase is likely attributed to a combination of demographic changes and to the introduction of census questionnaires that allow people to accurately reflect their identity (Jones et al., 2021). Despite the growth of this population, limited health research exists detailing outcomes and disparities experienced by multiracial individuals. Challenges in studying this population may be due to researchers' lack of a systematic identification method for multiracial individuals. For example, limitations in health databases require individuals to only select a single race option, creating misalignment between how individuals may perceive themselves and how they may be characterized in public databases. This limitation also highlights the question of whether self-identity should be considered separately or in conjunction with parental heritage (Charmaraman et al., 2014).

Office of Management and Budget (OMB) 2024 changes support collecting race and ethnicity data utilizing a single question, as well as allowing multiple responses and requiring collection of data beyond the minimum reporting categories (Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 2024). Requirements to collect more granular data, and prompt individuals to select all racial and ethnic identities they identify with, will allow health researchers and health care organizations to improve health care quality for multiracial/multiethnic populations—referred to as “multiracial,” going forward—by accurately identifying health disparities in outcomes, utilization and access, and targeting interventions to address these needs.

To continue promoting health equity within HEDIS<sup>®</sup>,<sup>1</sup> NCQA intends to continue stratification of HEDIS measures by race and ethnicity according to updated OMB standards. NCQA conducted a literature review to summarize recent knowledge on the current state of health outcomes, behaviors, disparities and social determinants of health (SDOH) experienced by multiracial individuals and communities to highlight particular areas where stratification can be most impactful. Refer to Table 1 in the appendix for a complete list of included studies.

### **Findings**

#### **Limited Areas of Research**

The studies in this review highlight the limited areas of existing health research that focus on multiracial individuals. In particular, studies of multiracial individuals in nationally representative datasets is lacking due to aforementioned limiting data collection requirements. A 2019 study by Veenstra et al., investigating disparities between Black, White and mixed race Black-White individuals, noted that while literature on the Black and White health disparities is growing, the health-related experiences of multiracial people is neglected by the research community, despite an increasing number of multiracial individuals (Veenstra, 2019).

The majority of identified research focuses on the mental and behavioral health of multiracial individuals, particularly for adolescent and pediatric multiracial individuals. Studies on other health outcomes primarily focused on the American Indian and Alaska Native population, a group that is disproportionately burdened by poor health outcomes and contributes to one of the largest multiracial groups in the US (American Indian and White) (Running Bear et al., 2020).

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

## Commonalities in Research

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Studies analyzed for this review had several common refrains when discussing and attempting to analyze outcomes for multiracial individuals. The first was that in studies not specifically recruiting multiracial individuals, or not explicitly supporting collection of multiple race identities, sample sizes of multiracial individuals are frequently too low for meaningful analysis. Some studies combine the multiracial and “Other” race reporting groups to meet minimum sample thresholds, or if still too small relative to other groups, this catch-all category is excluded from analysis. When multiracial and “Other” race groups are combined during data analysis, this further limits the capacity of researchers to make meaningful interpretations that adequately explain the impact of inequities in care or outcomes experienced by multiracial individuals (Choi & Reichman, 2019; Gutman et al., 2023; Shaff et al., 2024; Weller et al., 2022).

A study by Choi and Reichman, investigating the health of biracial children in the US, found no significant difference between the rates of poor overall health for children with Black mothers and White fathers, children with same-race White parents or children with White mothers and Black fathers. The authors noted this lack of significant difference was likely attributable to the relatively small sample size—202 children with Black mothers and White fathers, compared to 752 children with White mothers and Black fathers and 42,858 children with same-race White parents (Choi & Reichman, 2019).

Studies also highlight the heterogeneity of the multiracial population and the differences experienced by individuals within this large group. Health outcomes and daily experiences of multiracial individuals vary by their own unique self-identity, which makes researching broad generalizations for this group difficult and often not actionable when attempting to develop interventions and programs aimed at reducing identified disparities. Studies found that subgroups within the multiracial group can experience differing levels of disparities, or even improved outcomes, relative to other multiracial subgroups or monoracial control groups.

In a study investigating self-rated health among young adults 24–34 years, when aggregating all multiracial adults, there was no significant difference in reporting fair/poor self-rated health status compared to monoracial White adults (OR: 0.84; 95% CI, 0.52–1.36); however, when analyzing specific multiracial subgroups, health ratings varied greatly. When investigating specific subgroups, Asian-White adults had 12.5 times lower odds (OR: 0.08; 95% CI, 0.014–0.51) of reporting fair/poor self-rated health compared to monoracial White adults, while the other multiracial subgroups had no significantly different odds of reporting fair/poor self-rated health compared to monoracial White adults. Further analysis in this study compared multiracial subgroups with each monoracial group that comprise the multiracial subgroups and found differing directionality of outcomes by subgroup. For example, the Native American-White subgroup had 6.25 times lower odds (OR: 0.16; 95% CI, 0.05–0.51) of reporting fair/ poor self-rated health compared to monoracial Native American adults; however, the same subgroup had no statistically significant difference in odds of reporting fair/poor self-rated health compared to monoracial White adults (OR: 0.68; 95% CI, 0.34–1.37). Additionally, the Asian-White subgroup had 25 times lower odds (OR: 0.04; 95% CI, 0.004–0.038) of reporting fair/poor self-rated health compared to monoracial Asian adults; and the previously mentioned 12.5 times lower odds of reporting fair/poor self-rated health compared to monoracial White adults. This study highlights the complexities of reporting and collating all multiracial individuals into a single category, which often needs minimum analytic sample size requirements; however, this aggregation can mask within-group differences, such as some multiracial groups experiencing improved outcomes relative to their monoracial counterparts (i.e., Asian-White adults compared to monoracial Asian or White adults), while some groups experience outcomes similar to one of their monoracial counterparts (i.e., Native American-White adults having no difference from monoracial White adults, but significantly improved outcomes compared to Native American monoracial adults) (Tabb et al., 2019).



## Overall Health Outcomes and Chronic Conditions

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While studies focusing on other non-White racial groups, such as Black and Asian, have found disparities and outcomes and chronic disease prevalence, few studies focus explicitly on inequities in multiracial groups, indicating the need for foundational research among these groups. One of the first studies to document these outcome disparities is from 2017, where researchers identified that multiracial adults had 1.22 times higher odds (OR: 1.22; 95% CI, 1.07–1.39) of obesity; 1.57 times higher odds (OR: 1.57; 95% CI, 1.21–2.04) of diabetes; 1.44 times higher odds (OR: 1.44; 95% CI, 1.25–1.66) of reporting poor/fair health; and 1.54 times higher odds (OR: 1.54; 95% CI, 1.35–1.75) of physical disability compared to non-Hispanic White adults. These increased odds, relative to White adults, mirror disparities reported by other racial groups, such as Black adults, with 1.31 times higher odds (OR: 1.31; 95% CI, 1.18–1.45) of reporting poor/fair health than White adults (Subica et al., 2017).

As mentioned above, certain subgroups of multiracial individuals can experience differential health outcomes and conditions, and grouping all multiracial individuals into a single category can obfuscate meaningful differences within the population. A study investigating access, chronic diseases and general health in a sample comprising single-race American Indian/Alaska Native (SR AIAN), single-race White and multiracial American Indian/Alaska Native (MR AIAN) individuals found significant differences between the SR AIAN and MR AIAN groups and between these two groups and the single-race White group. Of note, one was that the SR AIAN group had 1.61 times lower odds (OR: 0.62) of reporting they couldn't see a doctor in the past year due to cost, compared to the MR AIAN group, and MR AIAN individuals had 1.61 times higher odds (OR: 1.61) of reporting they couldn't see a doctor in the past year due to cost than the single-race White group, with no significant difference between SR AIAN and single-race White groups (Running Bear et al., 2020).

Another study, emphasizing the importance of disaggregating multiracial subgroups, examined obesity among a sample of multiracial Asian and Pacific Islander individuals compared to non-Hispanic White individuals. The study found that when comparing Asian and Pacific Islander, Asian and White, and Pacific Islander and White groups individually to the non-Hispanic White group, there was no statistically significant difference in odds of obesity; however, the multiracial Asian, Pacific Islander and White group had 1.80 times higher odds (OR: 1.80; 95% CI, 1.37–2.38) of obesity than the White group (Bacong et al., 2024).

## Adolescent Research

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A population of interest for researchers is multiracial youth, as these individuals may not follow the patterns of monoracial youth due to their distinct experiences and self-identities associated with the multiracial experience (Goodhines et al., 2020). Studies on multiracial adolescents focus primarily on behavioral health, mental health and comparative outcomes relative to monoracial adolescents. A previously mentioned study investigated the overall health of children born to same race parents compared to different race parents. Researchers found children with Black parents had 2.08 times higher odds (OR: 2.08;  $\beta$ /se = 14.84) of having poor overall health than children with White parents. The researchers additionally found that children with a White mother and Black father had 1.48 times higher odds (OR: 1.48;  $\beta$ /se = 3.07) of having poor overall health compared to children with White parents, but did not find a statistically significant difference in the odds between children with a Black mother and White father and children with White parents, although, as noted, this may be due to low sample size (Choi & Reichman, 2019).

A study from 2012 may have been the first study to investigate multiracial adolescent health care disparities in a national sample. In a broad secondary analysis of the 2003 National Survey of Children's Health researchers identified disparities for multiracial adolescents, including, but not limited to, the highest proportion of respiratory allergies (22.7% compared to 18.8% for White children) and 1.57 times higher odds (OR: 1.57; 95% CI, 1.07–2.30) of not receiving preventive dental care compared to White children (Lau et al., 2012).

In a study on a sample of multiracial adolescents, researchers developed a statistical model to investigate the relationship between adverse childhood experiences, particularly household dysfunction, and mental

health conditions. This model had a good fit (RMSEA 0.000; 90% CI, 0.000–0.053; CFI = 1.000), and household dysfunction was significantly, positively associated with depression ( $\beta = 0.504$ ; 95% CI, 0.355–0.653), anxiety ( $\beta = 0.606$ ; 95% CI, 0.479–0.733), behavioral problems ( $\beta = 0.578$ ; 95% CI, 0.441–0.715) and ADHD ( $\beta = 0.536$ ; 95% CI, 0.382–0.691) (Weller et al., 2022).

Two studies investigated alcohol use among multiracial adolescents, with previous studies hypothesizing that these youth may be at higher risk for alcohol use compared to monoracial individuals. One study, which performed a systematic review of literature, found that multiracial youth had 1.98 times higher odds (number of studies (k) = 4; OR: 1.98; 95% CI, 1.62–2.44) of participating in binge drinking compared to Black youth, and 2.82 times higher odds (k = 4; OR: 2.82; 95% CI, 2.28–3.48) than Asian youth; however, multiracial youth had 1.33 times lower odds (k = 5; OR: 0.75; 95% CI, 0.70–0.81) of participating in binge drinking than White youth and 1.28 times lower odds (k = 3; OR: 0.78; 95% CI, 0.71–0.85) than American Indian/Alaska Native youth (Dobani et al., 2024). These findings conflict with an older study indicating that associations between discrimination experiences and subsequent negative emotional affects in monoracial youth compared to multiracial youth are not significantly associated with drinking frequency in the past year, but are associated with insomnia severity in the past year for multiracial individuals (Goodhines et al., 2020).

## Mental and Behavioral Health Outcomes

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The largest areas of existing research for multiracial individuals are in the domains of mental and behavioral health. Results from the 2022 National Survey on Drug Use and Health found that multiracial people 12 and older had a higher percentage of use of tobacco products in the past month (32.4%) than White (24.7%), Black (23.6%), Hispanic (17.7%) and Asian (10.0%) people. Additionally, among adults 18 or older, Multiracial adults (35.2%) were more likely to have had any mental illness (AMI) in the past year, compared with White (24.6%), Hispanic (21.4%), Black (19.7%), American Indian or Alaska Native (19.6%) or Asian adults (16.8%), but the percentage of adults 18 or older with AMI in the past year who received mental health treatment in the past year was lower among Asian (36.1%), Black (37.9%) or Hispanic adults (39.6%) than among Multiracial (56.0%) or White adults (56.1%) (Substance Abuse and Mental Health Services Administration, 2023).

Other studies found that, relative to multiracial adults, Black adults with adverse childhood experiences had 1.08 times lower odds (OR: 0.93; 95% CI, 0.86–0.99) of anxiety, Asian adults had 1.15 times lower odds (OR: 0.87; 95% CI, 0.82–0.94) of anxiety and American Indian/Alaska Native adults had 1.12 times lower odds (OR: 0.89; 95% CI, 0.81–0.97) of anxiety; when comparing an aggregate multiracial group to an aggregate group of monoracial individuals, regardless of race, monoracial individuals have 1.70 times lower odds ( $\beta = -0.53$ ; se = -0.26) of depression than multiracial individuals; and the prevalence of life dissatisfaction was 24% higher for multiracial adults compared to White adults (Lam-Hine et al., 2023; Miller et al., 2019; Town et al., 2024).

## Conclusions

This literature review identified two major themes to keep in mind when considering the multiracial population. The first focused on the need for researchers to recognize that while it is a rapidly growing demographic group in the United States, the experiences, challenges and outcomes of any individual subgroup should not be considered the de facto standard for which all multiracial individuals should be held, nor should aggregated results for multiracial individuals, without consideration of their unique racial combinations be applied homogeneously to all multiracial individuals.

Studies additionally noted challenges in achieving adequate sample sizes for any aggregate group of multiracial individuals. While this challenge may be due to previous data reporting and collection practices, it is still an important consideration when performing health care quality research; where possible, multiracial groups should not be overly reduced into groups too small for statistically-sound analysis, depending on the sample used in the study.

The second major theme that emerged from this review is the infancy of understanding the health outcomes and utilization of any multiracial population in the literature. The majority of studies focused on mental and behavioral health for adolescent populations. While these areas are important for understanding the experiences of multiracial individuals, greater knowledge in chronic disease prevalence, health care access and utilization and outcomes research is expected to be furthered with the change to federal standards, allowing individuals to select multiple race categories.

At NCQA, the HEDIS race and ethnicity stratification supports equity efforts in health care quality measurement. In order to adequately stratify HEDIS measures while maintaining meaningful interpretability, NCQA requires health plans to report a minimum denominator of 30 members for a stratification rate to be considered reportable. As NCQA begins to implement combined race and ethnicity reporting, in alignment with recent revisions to OMB standards, reporting quality measure rates for all potential multiracial combinations of the OMB minimum reporting categories would likely be infeasible for health plans, and would potentially reduce the usability of HEDIS data to inform meaningful targeted interventions at the health plan level.

NCQA acknowledges that research supports disaggregation of multiracial individuals into specific subgroups (e.g., Asian/White, Black/White) for more meaningful analysis of the quality of care these populations receive; however, input from our expert advisory panels and internal data analysis, audit and measure certification teams support using a general multiracial/multiethnic reporting category for measure reporting at this time, while health plans transition to the 2024 OMB standards. This review identified key areas of health disparities for multiracial individuals and supports the need to transition to a data environment where more granular race/ethnicity reporting can be performed at scale, to allow detailed analysis and targeted interventions to advance health equity for multiracial individuals.

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## Appendix

**Table 1: Detailed List of Studies Included in Review**

Study	Sample Size (n)	Population	Multiracial Definition	Comparator Groups	Area of Focus
Bacong et al (2024)	5,229 adults (1,471 multiracial adults)	Adults 18 years or older from two large health care systems in California and Hawai'i with at least 1 visit for a primary care provider	Self-identified race and ethnicity from electronic health records (Asian/Pacific Islander; Asian/Pacific Islander/White; Asian/White; Pacific Islander/White)	Monoracial White	Obesity
Choi & Reichman (2019)	49,267 children	Non-Hispanic White and non-Hispanic Black children 2–14 years living in two biological/adoptive parent families	Dependent on the race of mother and father	Monoracial White for odds modeling; rate differences measured between all four groups	Overall health status and developmental disability
Dobani et al (2024)	1,555,635 youths	Individuals 10-24 years collected through meta-analyses of literature	Varied by study aggregated, but had to be a distinct reporting group from other racial categories; often self-reported race identification	Monoracial (White/ American Indian or Alaska Native/ Hispanic or Latinx/ Black/ Asian) compared to multiracial	Youth alcohol use
Goodhines et al (2020)	414 adolescents (70 multiracial)	Students at an urban public high school in the northeastern US enrolled in 9, 10 or 11 grades	<ul style="list-style-type: none"> <li>Self-identified, single item questionnaire response</li> <li>Two race categories or three plus race categories</li> </ul>	Combined monoracial groups compared to combined multiracial status	Sleep disorders, youth alcohol use, discrimination
Gutman et al (2023)	206 children (17 multiracial)	Convenience sample of parents at a pediatric emergency department	Electronic health record values; parent reported race and ethnicity	Multiracial compared to all monoracial groups	Race and ethnicity data quality reported in electronic health records compared to self-identified race and ethnicity
Lam-Hine et al (2023)	12,372 adults (834 multiracial)	Adults 18–34 years enrolled in the National Longitudinal Study of Adolescent to Adult Health	Self-identified responses	Multiracial as reference group compared to all monoracial groups	Childhood adverse experiences, mental health, behavioral health, asthma, hypertension
Lau et al (2012)	48,742 children (1,609 multiracial)	Children 10-17 years in the 2003 National Survey of Children's Health	Identified by parental response	Monoracial White	Overall physical health, oral health, access to health care, health care utilization

Study	Sample Size (n)	Population	Multiracial Definition	Comparator Groups	Area of Focus
Miller et al (2019)	10,535 adults (437 multiracial)	Adults 18–25 years in the National Longitudinal Study of Adolescent to Adult Health	Self-reported Categorized as either Nonwhite-Nonwhite or White-Nonwhite	Compared aggregated multiracial to aggregated monoracial; compared each multiracial group to aggregated monoracial group	Mental and self-rated health
Running Bear et al (2020)	393,681 adults (5,512 multiracial)	Adults 18 years or older from the 2012 Behavioral Risk Factor Surveillance System	Self-reported, combination of American Indian or Alaska Native and any other race	Compared multiracial to single-race American Indian or Alaska Native and multiracial to single-race White	General health outcomes, access to health care, diagnosed chronic conditions, risk behaviors
Shaff et al (2024)	1,359 multiracial adults	Adults 18 years or older who responded to an online survey who identified as multiracial or multiethnic	Self-reported from 8 available race and ethnicity response options	Compared White/Non-White multiracial group to Non-White multiracial group	Mental health outcomes, associated risk factors
Subica et al (2017)	184,617 adults (4,383 multiracial)	Adults 18 years or older who responded to the California Health Interview Survey	Self-reported from OMB race and ethnicity classifications	Monoracial White	Diabetes, obesity, overall health, physical disability
Tabb et al (2019)	7,880 adults (575 multiracial)	Adults 24–34 years in the National Longitudinal Study of Adolescent to Adult Health	Self-reported race with option to select multiple race categories	<ul style="list-style-type: none"> <li>• Monoracial White compared to other monoracial groups and specific multiracial subgroups</li> <li>• Compared specific multiracial subgroups to both monoracial counterparts</li> </ul>	Health behaviors, chronic health conditions, overall self-rated health
Town et al (2024)	323,877 adults (6,001 multiracial)	Adults 18 years or older from the 2022 Behavioral Risk Factor Surveillance Survey	Self-reported with separate race and ethnicity questions	Monoracial White	SDOH, health-related social needs

Study	Sample Size (n)	Population	Multiracial Definition	Comparator Groups	Area of Focus
Veenstra (2019)	672,148 adults (675 multiracial)	Adults ages 18 years or older who responded to the Canadian Community Health Survey Limited analytic sample to those who identified as Black, White or only Black & White	Self-reported with option to select multiple race categories	Monoracial White	Hypertension, self-rated physical health, mental health
Weller et al (2022)	1,231 multiracial children	Children 12–17 years whose caregivers completed the 2016 National Survey of Children's Health Limited analytic sample to multiracial children	Reported by caregivers	No direct comparison within group, identified correlations with household dysfunction and several mental health conditions	Adverse childhood experiences, mental health



## ***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**

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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**

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

<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> Undiagnosed depression has been linked to an increased risk of diabetes-related complications.<sup>3</sup> 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<sup>®4</sup> *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.<sup>5</sup> 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.**

<sup>2</sup> 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>

<sup>3</sup> 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>

<sup>4</sup> HEDIS is a registered trademark of the National Committee for Quality Assurance.

<sup>5</sup> 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>

<b>Measure title</b>	Statin Therapy Prescription	<b>Measure ID</b>	DRP_STP
<b>Description</b>	The percentage of patients 40–75 years of age with diabetes with evidence of statin therapy during the measurement period.		
<b>Measurement period</b>	January 1–December 31.		
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<b>Clinical recommendation statement</b>	<p>American Diabetes Association (2024)</p> <ul style="list-style-type: none"> <li>• For people with diabetes aged 40–75 years without ASCVD, use moderate-intensity statin therapy in addition to lifestyle therapy. Level of evidence: A</li> <li>• 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 <math>\geq 50\%</math> of baseline and to target an LDL cholesterol goal of <math>&lt; 70\text{mg/dL}</math>. Level of evidence: A</li> <li>• For people of all ages with diabetes and ASCVD, high-intensity statin therapy should be added to lifestyle therapy. Level of evidence: A</li> </ul> <p>US Preventive Services Task Force (2022)</p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p>American College of Cardiology (2018)</p> <ul style="list-style-type: none"> <li>• 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</li> </ul>
<b>Citations</b>	<p>American Diabetes Association Professional Practice Committee. 2023. “10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes—2024.” <i>Diabetes Care</i> 47(Supplement_1), S179–S218. <a href="https://doi.org/10.2337/dc24-S010">https://doi.org/10.2337/dc24-S010</a></p> <p>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.” <i>Journal of the American College of Cardiology</i> 73 (24): e285–350. <a href="https://doi.org/10.1016/j.jacc.2018.11.003">https://doi.org/10.1016/j.jacc.2018.11.003</a></p> <p>US Preventive Services Task Force. 2022. “Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement.” <i>JAMA</i> 328(8), 746–53. <a href="https://doi.org/10.1001/jama.2022.13044">https://doi.org/10.1001/jama.2022.13044</a></p>
<b>Characteristics</b>	
<b>Scoring</b>	Proportion.
<b>Type</b>	Process.
<b>Product line</b>	NA.
<b>Stratification</b>	None.
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	None.

<b>Definitions</b>	
<b>Initial population</b>	Patients 40–75 years of age by the end of the measurement period who had a qualifying visit ( <u>Qualifying Visit Value Set</u> ) during the measurement period and had an ongoing or a new diagnosis of diabetes ( <u>Diabetes Value Set</u> ) during the first 6 months of the measurement period.
<b>Exclusions</b>	<p>Exclude patients who meet any of the following criteria:</p> <ul style="list-style-type: none"> <li>• Patients who die any time during the measurement period.</li> <li>• Patients in hospice or using hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) any time during the measurement period. This can include: <ul style="list-style-type: none"> <li>– Patients discharged from hospital (<u>Acute Inpatient Value Set</u>) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107).</li> <li>– Patients with a completed hospice care Minimum Data Set (<u>LOINC code 45755-6</u>; <u>SNOMEDCT code 373066001</u>).</li> </ul> </li> <li>• Patients 66 and older by the end of the measurement period whose housing status (<u>LOINC code 71802-3</u>) indicates they are living in a nursing home (<u>SNOMEDCT code 373066001</u>) any time on or before the end of the measurement period.</li> <li>• Patients 66 and older by the end of the measurement period, with an indication of frailty (<u>Frailty Device Value Set</u>; <u>Frailty Diagnosis Value Set</u>; <u>Frailty Encounter Value Set</u>; <u>Frailty Symptom Value Set</u>; <u>LOINC code 98181-1</u>) for any part of the measurement period, who also meet any of the following advanced illness criteria: <ul style="list-style-type: none"> <li>– Advanced illness (<u>Advanced Illness Value Set</u>) during a qualifying encounter (<u>Outpatient Value Set</u>; <u>Emergency Department Visit Value Set</u>; <u>Acute Inpatient Value Set</u>; <u>Nonacute Inpatient Value Set</u>) during the measurement period or the year prior to the measurement period, <b>or</b></li> <li>– Prescribed dementia medications (<u>Dementia Medications List</u>) during the measurement period or the year prior to the measurement period.</li> </ul> </li> <li>• Patients receiving palliative care (<u>Palliative Care Encounter Value Set</u>; <u>Palliative Care Intervention Value Set</u>; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period.</li> <li>• Patients with a diagnosis of pregnancy (<u>Pregnancy Value Set</u>) during the measurement period or the year prior to the measurement period.</li> <li>• Patients undergoing in vitro fertilization (<u>IVF Value Set</u>) in the measurement period or the year prior to the measurement period.</li> <li>• At least one prescription for clomiphene (<u>Clomiphene Medications List</u>) during the measurement period or the year prior to the measurement period.</li> <li>• Patients with evidence of end-stage renal disease (ESRD) (<u>ESRD Diagnosis Value Set</u>) or dialysis (<u>Dialysis Services Value Set</u>) during the measurement period or the year prior to the measurement period.</li> <li>• Patients with cirrhosis (<u>Cirrhosis Value Set</u>) during the measurement period or the year prior to the measurement period.</li> <li>• Patients with a diagnosis of myalgia, myositis, myopathy, or rhabdomyolysis (<u>Muscular Pain and Disease Value Set</u>) during the measurement period.</li> </ul>

	<ul style="list-style-type: none"> <li>Patients with muscular reactions (<u>Muscular Reactions to Statins Value Set</u>) to statins at any point in their history on or prior to December 31 of the measurement period.</li> </ul>
<b>Denominator</b>	The initial population minus denominator exclusions.
<b>Numerator</b>	Patients who were prescribed or were on statin therapy of any intensity ( <u>High, Moderate and Low Intensity Statin Medications List</u> ) during the measurement period.
<b>Summary of changes</b>	This is a new measure.
<b>Data element tables</b>	NA.

DRAFT

<b>Measure title</b>	Depression Screening and Follow-Up	<b>Measure ID</b>	DRP_DSD
<b>Description</b>	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.		
<b>Measurement period</b>	January 1–December 31.		
<b>Copyright and disclaimer notice</b>	<p>This measure and specification were developed by and are owned by the National Committee for Quality Assurance (“NCQA”). Financial support was provided via a grant from the Leona M. and Harry B. Helmsley Charitable Trust. NCQA holds a copyright to these materials and may rescind or alter these materials at any time. Users of the measure and specification shall not have the right to alter, enhance or otherwise modify the measure and specification, and shall not disassemble, recompile or reverse engineer the measure and specification. Anyone desiring to use or reproduce the materials, without modification, for an internal, noncommercial purpose, may do so without obtaining approval from NCQA. All other uses, including a commercial use (including, but not limited to, vendors using the measure and specification with a product or service to calculate measure results), or any external reproduction, distribution or publication of the measure or results (“rates”) therefrom must be approved by NCQA, and is subject to a license at the discretion of NCQA. Any use of the materials to identify records or calculate measure results, for example, requires a custom license and may necessitate certification pursuant to NCQA’s Measure Certification Program.</p> <p>The measure and specification are not clinical guidelines, do not establish a standard of medical care and have not been tested for all potential applications. The measure and specification are provided “as is” without warranty of any kind. NCQA makes no representations, warranties or endorsements about the quality of any product, test or protocol identified as numerator compliant or otherwise identified as meeting the requirements of the measure or specification. NCQA also makes no representations, warranties or endorsements about the quality of any organization or clinician who uses or reports performance measures. NCQA has no liability to anyone who relies on the measure and specification or data reflective of performance under such measures and specifications.</p> <p>Limited proprietary coding is contained in the measure specification for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. NCQA disclaims all liability for use or accuracy of any coding contained in the specification.</p> <p>CPT® codes, descriptions and other data are copyright © 2025 American Medical Association. All rights reserved. CPT is a trademark of the American Medical Association. No fee schedules, basic units, relative values or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.</p> <p>The measure specification contains coding from LOINC® (<a href="http://loinc.org">http://loinc.org</a>). The LOINC table, LOINC codes, LOINC panels and form file, LOINC linguistic variants file, LOINC/RSNA Radiology Playbook, and LOINC/IEEE Medical</p>		
	Device Code Mapping Table are copyright © 1995–2025 Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC)		



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<b>Clinical recommendation statement</b>	<p>American Diabetes Association (2024)</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Beginning at diagnosis of complications or when there are significant changes in medical status, consider assessment for depression. Level of evidence: B</li> <li>• 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</li> </ul>
<b>Citations</b>	<p>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.” <i>Diabetes Care</i> 47(Supplement_1), S77–S110. <a href="https://doi.org/10.2337/dc24-S005">https://doi.org/10.2337/dc24-S005</a></p>
<b>Characteristics</b>	
<b>Scoring</b>	Proportion.
<b>Type</b>	Process.
<b>Product line</b>	NA.
<b>Stratification</b>	None.
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	Increased score indicates improvement.
<b>Guidance</b>	<p>This measure requires the use of an age-appropriate screening instrument. The member’s age is used to select the appropriate instrument.</p> <p>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.</p> <p><i>Example:</i> 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.</p>
<b>Definitions</b>	
<b>Depression Screening Instrument</b>	<p>A standard screening instrument that has been normalized and validated for the appropriate patient population. Eligible screening instruments with thresholds for positive findings include:</p>



	Instruments for Adults (18+ years)	Total Score LOINC Codes	Positive Finding
	Patient Health Questionnaire (PHQ-9) <sup>®</sup>	44261-6	Total score ≥10
	Patient Health Questionnaire-2 (PHQ-2) <sup>®1</sup>	55758-7	Total score ≥3
	Beck Depression Inventory-Fast Screen (BDI-FS) <sup>®1,2</sup>	89208-3	Total score ≥8
	Beck Depression Inventory (BDI-II)	89209-1	Total score ≥20
	Center for Epidemiologic Studies Depression Scale—Revised (CESD-R)	89205-9	Total score ≥17
	Duke Anxiety—Depression Scale (DUKE-AD) <sup>®2</sup>	90853-3	Total score ≥30
	Geriatric Depression Scale Short Form (GDS) <sup>1</sup>	48545-8	Total score ≥5
	Geriatric Depression Scale Long Form (GDS)	48544-1	Total score ≥10
	Edinburgh Postnatal Depression Scale (EPDS)	99046-5	Total score ≥10
	My Mood Monitor (M-3) <sup>®</sup>	71777-7	Total score ≥5
	PROMIS Depression	71965-8	Total score (T Score) ≥60
	Clinically Useful Depression Outcome Scale (CUDOS)	90221-3	Total score ≥31
	<sup>1</sup> Brief screening instrument. All other instruments are full-length. <sup>2</sup> Proprietary; may include cost or licensing requirements.		
<b>Initial population</b>	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.		
<b>Exclusions</b>	<p>Exclude patients who meet any of the following criteria:</p> <ul style="list-style-type: none"> <li>• Patients who die any time during the measurement period.</li> <li>• Patients in hospice or using hospice services (<u>Hospice Encounter Value Set</u>; <u>Hospice Intervention Value Set</u>) any time during the measurement period. This can include: <ul style="list-style-type: none"> <li>– Patients discharged from hospital (<u>Acute Inpatient Value Set</u>) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107).</li> <li>– Patients with a completed hospice care Minimum Data Set (LOINC code 45755-6; SNOMEDCT code 373066001).</li> </ul> </li> </ul>		

	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Patients 66 and older by the end of the measurement period, with an indication of frailty (<u>Frailty Device Value Set</u>; <u>Frailty Diagnosis Value Set</u>; <u>Frailty Encounter Value Set</u>; <u>Frailty Symptom Value Set</u>; LOINC code 98181-1) for any part of the measurement period, who also meet any of the following advanced illness criteria: <ul style="list-style-type: none"> <li>– Advanced illness (<u>Advanced Illness Value Set</u>) during a qualifying encounter (<u>Outpatient Value Set</u>; <u>Emergency Department Visit Value Set</u>; <u>Acute Inpatient Value Set</u>; <u>Nonacute Inpatient Value Set</u>) during the measurement period or the year prior to the measurement period, <b>or</b></li> <li>– Prescribed dementia medications (<u>Dementia Medications List</u>) during the measurement period or the year prior to the measurement period.</li> </ul> </li> <li>• Patients receiving palliative care (<u>Palliative Care Encounter Value Set</u>; <u>Palliative Care Intervention Value Set</u>; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period.</li> <li>• Patients with a history of bipolar disorder (<u>Bipolar Disorder Value Set</u>; <u>Other Bipolar Disorder Value Set</u>) any time during their history through the end of the year prior to the measurement period.</li> <li>• Patients with depression (<u>Depression Value Set</u>) that starts during the year prior to the measurement period.</li> </ul>
<b>Denominator</b>	Equals initial population.
<b>Numerator</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• 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.</li> </ul> <p><i>Follow-up:</i> 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:</p> <ul style="list-style-type: none"> <li>– An outpatient, telephone, e-visit or virtual check-in follow up visit (<u>Follow Up Visit Value Set</u>) with a diagnosis of depression or other behavioral health condition (<u>Depression or Other Behavioral Health Condition Value Set</u>), <b>or</b></li> <li>– A depression case management encounter (<u>Depression Case Management Encounter Value Set</u>) that documents assessment for symptoms of depression (<u>Symptoms of Depression Value Set</u>) or a diagnosis of depression or other behavioral health condition (<u>Depression or Other Behavioral Health Condition Value Set</u>), <b>or</b></li> <li>– A behavioral health encounter including assessment, therapy, collaborative care or medication management (<u>Behavioral Health Encounter Value Set</u>), <b>or</b></li> <li>– An antidepressant prescription (<u>Antidepressant Medications List</u>).</li> </ul>

	<p><b>OR</b></p> <p>Documentation of additional depression screening (refer to <a href="#">Depression Screening Instrument</a> 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 <a href="#">Depression Screening Instrument</a> definition).</p> <p><i>Example:</i> 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.</p> <p>Screening must occur by December 1 of the measurement period.</p>
<p><b>Summary of changes</b></p>	<p>1. This is a new measure.</p>
<p><b>Data elements table</b></p>	<p>NA.</p>

DRAFT

Measure title	Continuous Glucose Monitoring Utilization	Measure ID	DRP_CGD
<b>Description</b>	<p>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:</p> <ol style="list-style-type: none"> <li>1. Individuals with type 1 diabetes with evidence of CGM use during the measurement period.</li> <li>2. Individuals in the initial population <i>minus</i> denominator 1 with use of basal insulin, multiple daily injections, or continuous insulin infusion and with evidence of CGM use during the measurement period.</li> </ol>		
<b>Measurement period</b>	January 1–December 31.		
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	<p>The measure specification contains coding from LOINC® (<a href="http://loinc.org">http://loinc.org</a>). The LOINC table, LOINC codes, LOINC panels and form file, LOINC linguistic variants file, LOINC/RSNA Radiology Playbook, and LOINC/IEEE Medical Device Code Mapping Table are copyright © 1995–2025 Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and are available at no cost under the license at <a href="http://loinc.org/terms-of-use">http://loinc.org/terms-of-use</a>.</p> <p>“SNOMED” and “SNOMED CT” are registered trademarks of the International Health Terminology Standards Development Organisation (IHTSDO).</p>
<p><b>Clinical recommendation statement</b></p>	<p>American Diabetes Association (2024)</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• 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.</li> <li>• 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.</li> <li>• 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</li> <li>• Use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia. Level of evidence: A</li> </ul>
<p><b>Citations</b></p>	<p>American Diabetes Association Professional Practice Committee. 2023a. “7. Diabetes Technology: Standards of Care in Diabetes—2024.” <i>Diabetes Care</i> 47(Supplement_ 1), S126–S144. <a href="https://doi.org/10.2337/dc24-S007">https://doi.org/10.2337/dc24-S007</a></p> <p>American Diabetes Association Professional Practice Committee. 2023b. “6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2024.” <i>Diabetes Care</i> 47(Supplement_ 1), S111–S125. <a href="https://doi.org/10.2337/dc24-S006">https://doi.org/10.2337/dc24-S006</a></p>
<p><b>Characteristics</b></p>	
<p><b>Scoring</b></p>	<p>NA.</p>
<p><b>Type</b></p>	<p>Utilization.</p>
<p><b>Product line</b></p>	<p>NA.</p>

<b>Stratification</b>	None.
<b>Risk adjustment</b>	None.
<b>Improvement notation</b>	NA.
<b>Guidance</b>	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.
<b>Definitions</b>	
<b>CGM utilization</b>	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 <a href="#">Clinical recommendation</a> statement.
<b>Initial population</b>	Patients 18–75 years of age by the end of the measurement period who had a qualifying visit ( <a href="#">Qualifying Visit Value Set</a> ) during the measurement period, and had an ongoing or a new diagnosis of diabetes ( <a href="#">Diabetes Value Set</a> ) during the first 6 months of the measurement period.
<b>Exclusions</b>	<p>Exclude patients who meet any of the following criteria:</p> <ul style="list-style-type: none"> <li>• Patients who die any time during the measurement period.</li> <li>• Patients in hospice or using hospice services (<a href="#">Hospice Encounter Value Set</a>; <a href="#">Hospice Intervention Value Set</a>) any time during the measurement period. This can include: <ul style="list-style-type: none"> <li>– Patients discharged from hospital (<a href="#">Acute Inpatient Value Set</a>) to hospice (SNOMED CT code 428371000124100; SNOMED CT code 428361000124107).</li> <li>– Patients with a completed hospice care Minimum Data Set (LOINC code 45755-6; SNOMEDCT code 373066001).</li> </ul> </li> <li>• 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.</li> <li>• Patients 66 and older by the end of the measurement period, with an indication of frailty (<a href="#">Frailty Device Value Set</a>; <a href="#">Frailty Diagnosis Value Set</a>; <a href="#">Frailty Encounter Value Set</a>; <a href="#">Frailty Symptom Value Set</a>; LOINC code 98181-1) for any part of the measurement period, who also meet any of the following advanced illness criteria: <ul style="list-style-type: none"> <li>– Advanced illness (<a href="#">Advanced Illness Value Set</a>) during a qualifying encounter (<a href="#">Outpatient Value Set</a>; <a href="#">Emergency Department Visit Value Set</a>; <a href="#">Acute Inpatient Value Set</a>; <a href="#">Nonacute Inpatient Value Set</a>) during the measurement period or the year prior to the measurement period, <b>or</b></li> <li>– Prescribed dementia medications (<a href="#">Dementia Medications List</a>) during the measurement period or the year prior to the measurement period.</li> </ul> </li> <li>• Patients receiving palliative care (<a href="#">Palliative Care Encounter Value Set</a>; <a href="#">Palliative Care Intervention Value Set</a>; ICD-10-CM code Z51.5; LOINC code 71007-9) during the measurement period.</li> </ul>

<b>Denominator</b>	<p><b>Denominator 1: Utilization of CGM Group 1</b></p> <p>All patients from the initial population <i>with</i> a diagnosis of type 1 diabetes (<u>Type 1 Diabetes Value Set</u>).</p> <p><b>Denominator 2: Utilization of CGM Group 2</b></p> <p>All patients from the initial population <i>with</i> a diagnosis of diabetes (<u>Diabetes Value Set</u>) <i>minus</i> denominator 1, <i>with</i> at least one instance of use of basal insulin (<u>Basal Insulin Medications List</u>), multiple daily injections (<u>Basal Insulin Medications List</u>) or continuous insulin infusion (<u>Insulin Infusion Value Set</u>; <u>Presence of Insulin Pump Value Set</u>) during the first 6 months of the measurement period.</p>
<b>Numerator</b>	<p><b>Numerator 1: Utilization of CGM Group 1</b></p> <p>Patients with evidence of CGM utilization during the measurement period.</p> <p><b>Numerator 2: Utilization of CGM Group 2</b></p> <p>Patients with evidence of CGM utilization during the measurement period.</p> <p><i>Utilization:</i> One instance of CGM use within the measurement period that meets any of the following criteria:</p> <ul style="list-style-type: none"> <li>• CGM prescription, <i>or</i></li> <li>• Documentation of a CGM device (<u>Continuous Glucose Monitoring Device Value Set</u>), metric (<u>Continuous Glucose Management Value Set</u>) or Ambulatory Glucose Profile report (<u>Ambulatory Continuous Glucose Monitoring Value Set</u>).</li> </ul>
<b>Summary of changes</b>	<p>1. This is a new measure.</p>
<b>Data element tables</b>	<p>NA.</p>



## ***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<sup>®1</sup>) 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).

<sup>1</sup> 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, and 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 statins 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	<p>Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted multicenter trial.</li> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis.</li> </ul> <p>Compelling nonexperimental evidence:</p> <ul style="list-style-type: none"> <li>i.e., “all or none” rule developed by the Centre for Evidence-Based Medicine at the University of Oxford.</li> </ul> <p>Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted trial at one or more institutions.</li> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis.</li> </ul>
B	<p>Supportive evidence from well-conducted cohort studies</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted prospective cohort study or registry.</li> <li>Evidence from a well-conducted meta-analysis of cohort studies.</li> </ul> <p>Supportive evidence from a well-conducted case-control study</p>
C	<p>Supportive evidence from poorly controlled or uncontrolled studies</p> <ul style="list-style-type: none"> <li>Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results.</li> <li>Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls).</li> <li>Evidence from case series or case reports.</li> </ul> <p>Conflicting evidence with the weight of evidence supporting the recommendation</p>
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: <ul style="list-style-type: none"> <li>• Is recommended.</li> <li>• Is indicated/useful/effective/beneficial.</li> <li>• Should be performed/administered/other.</li> <li>• Comparative-Effectiveness Phrases: <ul style="list-style-type: none"> <li>– Treatment/strategy A is recommended/indicated in preference to treatment B.</li> <li>– Treatment A should be chosen over treatment B.</li> </ul> </li> </ul>
Class IIa (Moderate)	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Is reasonable.</li> <li>• Can be useful/effective/beneficial.</li> <li>• Comparative-Effectiveness Phrases: <ul style="list-style-type: none"> <li>– Treatment/strategy A is probably recommended/indicated in preference to treatment B.</li> <li>– It is reasonable to choose treatment A over treatment B.</li> </ul> </li> </ul>
Class IIb (Weak)	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• May/might be reasonable.</li> <li>• May/might be considered.</li> <li>• Usefulness/effectiveness is unknown/unclear/uncertain or not well established.</li> </ul>

<b>Class</b>	<b>Recommendation</b>
Class III: No Benefit (Weak)	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Is not recommended.</li> <li>• Is not indicated/useful/effective/beneficial.</li> <li>• Should not be performed/administered/other.</li> </ul>
Class III: Harm (Strong)	Suggested phrases for writing recommendations: <ul style="list-style-type: none"> <li>• Potentially harmful.</li> <li>• Causes harm.</li> <li>• Associated with excess morbidity/mortality.</li> <li>• Should not be performed/administered/other.</li> </ul>

**Level (Quality) of Evidence**

<b>Level of Evidence</b>	<b>Recommendation</b>
A	<ul style="list-style-type: none"> <li>• High-quality evidence from more than 1 randomized control trial (RCT).</li> <li>• Meta-analyses of high-quality RCTs.</li> <li>• One or more RCTs corroborated by high-quality registry studies.</li> </ul>
B-R	<ul style="list-style-type: none"> <li>• Moderate-quality evidence from 1 or more RCTs.</li> <li>• Meta-analysis of moderate-quality RCTs.</li> </ul>
B-NR	<ul style="list-style-type: none"> <li>• Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies.</li> <li>• Meta-analysis of such studies.</li> </ul>
C-LD	<ul style="list-style-type: none"> <li>• Randomized or nonrandomized observational or registry studies with limitations of design or execution.</li> <li>• Meta-analysis of such studies.</li> <li>• Physiological or mechanistic studies in human subjects.</li> </ul>
C-EO	<ul style="list-style-type: none"> <li>• Consensus of expert opinions on clinical experience.</li> </ul>



## ***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	<p>Newly diagnosed diabetes: Assess the following:</p> <ul style="list-style-type: none"> <li>• Ability to cope with the diagnosis and follow the new treatment regimen (ex. medication, BGM, CGM, diet changes, exercise)</li> <li>• Potential psychosocial barriers to treatment and self-management (behavioral, developmental, social, economic)</li> <li>• Cultural background and practices (ex. beliefs about medicine, diabetes, dietary practices)</li> <li>• Presence of coping skills for living with the emotional impact of diabetes</li> <li>• Level of family and social support</li> <li>• Non-diabetes related life stressors</li> </ul>	1C
	Adults with Diabetes	<p>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:</p> <ul style="list-style-type: none"> <li>• Ability to follow the treatment regimen</li> <li>• Psychosocial barriers to treatment and self-management</li> <li>• Coping skills for living with the emotional impact of living with diabetes. (ex. diabetes burnout and distress: consider using PAID as a screening tool)</li> <li>• Level of family and social support (ex. assess for family conflict, diabetes police, positive and negative supports)</li> <li>• Fear of hypoglycemia: consider referral for blood glucose awareness training</li> <li>• Non-diabetes life stressors</li> <li>• Depression: consider using PHQ-9 or PHQ-2 as a screening tool</li> <li>• Anxiety</li> <li>• Disordered eating/eating disorder: consider inquiry about insulin omission or bingeing if A1c&gt;9% or recurrent DKA</li> <li>• 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.</li> </ul>	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: <ul style="list-style-type: none"> <li>Evidence from a well-conducted multicenter trial               <ul style="list-style-type: none"> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul> </li> </ul>
	Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: <ul style="list-style-type: none"> <li>Evidence from a well-conducted trial at one or more institutions               <ul style="list-style-type: none"> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul> </li> </ul>
B	Supportive evidence from well-conducted cohort studies, including: <ul style="list-style-type: none"> <li>Evidence from a well-conducted prospective cohort study or registry               <ul style="list-style-type: none"> <li>Evidence from a well-conducted meta-analysis of cohort studies</li> </ul> </li> </ul>
	Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies, including: <ul style="list-style-type: none"> <li>Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results</li> <li>Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)               <ul style="list-style-type: none"> <li>Evidence from case series or case reports</li> </ul> </li> </ul>
	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 (CGM)**

## **Diabetes Recognition Program**

### **Measure Workup**

#### **Topic Overview**

#### **Measure Description**

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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**

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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**

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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

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### **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/severe 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	<p>Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted multicenter trial</li> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul> <p>Compelling nonexperimental evidence</p> <ul style="list-style-type: none"> <li>i.e., “all or none” rule developed by the Centre for Evidence-Based Medicine at the University of Oxford</li> </ul> <p>Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted trial at one or more institutions</li> <li>Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul>
B	<p>Supportive evidence from well-conducted cohort studies</p> <ul style="list-style-type: none"> <li>Evidence from a well-conducted prospective cohort study or registry</li> <li>Evidence from a well-conducted meta-analysis of cohort studies</li> </ul> <p>Supportive evidence from a well-conducted case-control study</p>
C	<p>Supportive evidence from poorly controlled or uncontrolled studies</p> <ul style="list-style-type: none"> <li>Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results</li> <li>Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)</li> <li>Evidence from case series or case reports</li> </ul> <p>Conflicting evidence with the weight of evidence supporting the recommendation</p>
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

## **Notification of Changes for HEDIS<sup>®1</sup>**

**NCQA does not seek comment on the following changes.**

### **Release of Volume 2: Technical Specifications**

The *HEDIS Measurement Year 2025 Volume 2: Technical Update* will be released on March 31 as a full-text publication that includes direct edits. Organizations will now see the exact placement of updates.

This is in lieu of the memo table format referencing phrasing and edit location. Changes in the Technical Update are required for HEDIS MY 2025 reporting.

NCQA will release *HEDIS Measurement Year 2026 Volume 2: Technical Specifications for Health Plans* on August 1.

### **Measure Changes for HEDIS MY 2025 Technical Update**

*Breast Cancer Screening:* NCQA is expanding the age range from 50–74 to 40–74.

*Rationale:* This measure is based on U.S. Preventive Services Task Force (USPSTF) recommendations that expand the ages for biennial mammography screening for women 40–74 at average risk of breast cancer.

The RAND table will be removed from HEDIS Volume 2 with the release of the Technical Update. Beginning MY 2025, NCQA will use an alternative timeline and approach to distribute RAND numbers for HEDIS reporting. This information will be released in the NCQA store for purchasers of HEDIS Volume 2 in October, before production of systematic samples for hybrid reporting (November 2025, for MY 2025).

### **Measure Changes for HEDIS MY 2026**

Remove SNOMED CT codes from value sets that identify laboratory tests, imaging studies and vaccinations.

*Rationale:* This aligns HEDIS value sets with national interoperability standards.

HEDIS measure template formatting will be updated to align with FHIR<sup>®</sup> standards and enable interoperability of HEDIS measures across systems. Updating the publication format supports the transition to digital HEDIS measurement. All the information needed to calculate a HEDIS measure will remain. For information, refer to this NCQA [blog](#).

### **ECDS Reporting Changes for HEDIS MY 2026 and Beyond**

NCQA is transitioning the following measures to ECDS-only reporting for MY 2026:

- *Statin Therapy for Patients With Diabetes.*
- *Statin Therapy for Patients With Cardiovascular Disease.*

*Rationale:* The ECDS transition aligns with NCQA's digital transformation strategy. Because both measures rely primarily on administrative claims data, there is likely to be little impact on measure performance.

<sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).

NCQA will allow optional ECDS reporting for *Blood Pressure Control for Patients With Diabetes*.

*Rationale:* NCQA proposes to remove the Hybrid Method from the measure and transition to ECDS-only reporting by MY 2028. NCQA will introduce the ECDS version for optional reporting alongside the Hybrid Method in MY 2026, and will implement a 2-year transition period before removing the hybrid version. Refer to this NCQA [blog](#) for the proposed timeline.

Refer to [www.ncqa.org/ecds](http://www.ncqa.org/ecds) for updates on ECDS reporting.