Measure #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease – National Quality Strategy Domain: Effective Clinical Care

2017 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:

• Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR
• Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR
• Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL

INSTRUCTIONS:
This measure is to be reported once per performance period for patients seen during the performance period. This measure may be reported by eligible clinicians who provide the services in the measure-specific denominator coding.

Measure Reporting:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

THERE ARE THREE REPORTING CRITERIA FOR THIS MEASURE**:

1) Patients aged ≥ 21 years at the beginning of the measurement period with clinical ASCVD diagnosis

OR

2) Patients aged ≥ 21 years at the beginning of the measurement period who have ever had a fasting or direct laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia

OR

3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes and with an LDL-C result of 70–189 mg/dL recorded as the highest fasting or direct laboratory test result in the measurement year or during the two years prior to the beginning of the measurement period

**All patients who meet one or more of the following criteria indicated above would be considered at high risk for cardiovascular events under the ACC/AHA guidelines. When reporting this measure determine if the patient meets denominator eligibility in order of each risk category.

DENOMINATOR (REPORTING CRITERIA 1):
Patients aged ≥21 years at the beginning of the measurement period with clinical ASCVD diagnosis

Definitions:
Clinical Atherosclerotic Cardiovascular Disease (ASCVD) includes
Acute Coronary Syndromes
History of Myocardial Infarction
Stable or Unstable Angina
Coronary or other Arterial Revascularization
Stroke or Transient Ischemic Attack (TIA)
Peripheral Arterial Disease of Atherosclerotic Origin

Lipoprotein Density Cholesterol (LDL-C) result - A fasting or direct LDL-C laboratory test performed and test result documented in the medical record

**DENOMINATOR NOTE:** *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for registry-based measures.*

**Denominator Criteria: (Eligible Cases):**
Patients aged ≥ 21 years at the beginning of the measurement period
AND
WITHOUT
Telehealth Modifier: GQ, GT
AND
Previously diagnosed or have an active diagnosis of Clinical ASCVD: G9662
AND NOT
**DENOMINATOR EXCLUSIONS:**
Patients who have a diagnosis of pregnancy: G9778
OR
Patients who are breastfeeding: G9779
OR
Patients who have a diagnosis of rhabdomyolysis: G9780

**NUMERATOR (REPORTING CRITERIA 1):**
Patients who are actively using or who receive an order (prescription) for statin therapy at any point during the measurement period

**Definitions:**
Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia.
Sample list of statin medications (list is NOT inclusive of all agents) is included in the clinical recommendations

**Active Liver or Hepatic Disease or Insufficiency** – The following codes are included in the Denominator Exception (G9667) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B18.0, B18.1, B19.10, B19.11, B17.0, B17.2, B17.8, B17.10, B17.11, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, K70.0, K70.9, K70.30, K70.31, K70.40, K70.41, K71.3, K71.4, K71.9, K71.10, K71.11, K71.50, K71.51, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.2, K73.8, K73.9, K74.0, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, K76.0, K76.2, K76.3, K76.7, K76.9, K76.89, O98.419, Z22.51

**NUMERATOR NOTE:** In order to meet the measure, current statin therapy use must be documented in the patient’s current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; may be called to the pharmacy. Statin medication “samples”
provided to patients can be documented as “current statin therapy” if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure.

**Numerator Options:**

**Performance Met:**
 Patients who are currently statin therapy users or received an order (prescription) for statin therapy (G9664)

**OR**

**Denominator Exception:**
 Documentation of medical reason(s) for not currently being a statin therapy user or receive an order (prescription) for statin therapy (e.g., patient with adverse effect, allergy or intolerance to statin medication therapy, patients who are receiving palliative care, patients with active liver disease or hepatic disease or insufficiency, and patients with end stage renal disease (ESRD) (G9781)

**OR**

**Performance Not Met:**
 Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy (G9665)

**DENOMINATOR (REPORTING CRITERIA 2):**
 Patients aged ≥21 years at the beginning of the measurement period who have ever had a fasting or direct laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia

**Definition:**
 Lipoprotein Density Cholesterol (LDL-C) result - A fasting or direct LDL-C laboratory test performed and test result documented in the medical record

**DENOMINATOR NOTE:** *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for registry-based measures.

**Denominator Criteria: (Eligible Cases):**
 Patient aged ≥21 years at the beginning of the measurement period

**AND**

**WITHOUT**
 Telehealth Modifier: GQ, GT

**AND**
 Any fasting or direct LDL-C laboratory test result ≥ 190 mg/dL: G9663

**OR**
 History of or active diagnosis of familial or pure hypercholesterolemia: G9782

**AND NOT**

**DENOMINATOR EXCLUSIONS:**
 Patients who have a diagnosis of pregnancy: G9778

**OR**
Patients who are breastfeeding: G9779
OR
Patients who have a diagnosis of rhabdomyolysis: G9780

NUMERATOR (REPORTING CRITERIA 2):
Patients who are actively using or who receive an order (prescription) for statin therapy at any point during the measurement period

Definitions:
Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia.
Sample list of statin medications (list is NOT inclusive of all agents) is included in the clinical recommendations
Active Liver or Hepatic Disease or Insufficiency – The following codes are included in the Denominator Exception (G9667) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B18.0, B18.1, B19.10, B19.11, B17.0, B17.2, B17.8, B17.10, B17.11, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, K70.0, K70.9, K70.30, K70.31, K70.40, K70.41, K71.3, K71.4, K71.9, K71.10, K71.11, K71.50, K71.51, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.2, K73.8, K73.9, K74.0, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, K76.0, K76.2, K76.6, K76.7, K76.9, K76.89, O98.419, Z22.51

NUMERATOR NOTE: In order to meet the measure, current statin therapy use must be documented in the patient’s current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; may be called to the pharmacy. Statin medication “samples” provided to patients can be documented as “current statin therapy” if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure.

Numerator Options:
Performance Met: Patients who are currently statin therapy users or received an order (prescription) for statin therapy (G9664)
OR
Denominator Exception: Documentation of medical reason(s) for not currently being a statin therapy user or receive an order (prescription) for statin therapy (e.g., patient with adverse effect, allergy or intolerance to statin medication therapy, patients who are receiving palliative care, patients with active liver disease or hepatic disease or insufficiency, and patients with end stage renal disease (ESRD) (G9781)
OR
Performance Not Met: Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy (G9665)

DENOMINATOR (REPORTING CRITERIA 3):
Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes and with a LDL-C result of 70–189 mg/dL recorded as the highest fasting or direct laboratory test result in the measurement year or during the two years prior to the beginning of the measurement period
Definition:
Lipoprotein Density Cholesterol (LDL-C) result - A fasting or direct LDL-C laboratory test performed and test result documented in the medical record

DENOMINATOR NOTE: *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for registry-based measures.

Denominator Criteria: (Eligible Cases):
Patients aged 40 through 75 years at the beginning of the measurement period
AND
AND
Patient encounter during the performance period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99385, 99386, 99387, 99395, 99396, 99397, 99401, 99402, 99403, 99404, G0438, G0439
WITHOUT
Telehealth Modifier: GQ, GT
AND
The highest fasting or direct LDL-C laboratory test result of 70 –189 mg/dL in the measurement period or two years prior to the beginning of the measurement period: G9666
AND NOT
DENOMINATOR EXCLUSIONS:
Patients who have a diagnosis of pregnancy: G9778
OR
Patients who are breastfeeding: G9779
OR
Patients who have a diagnosis of rhabdomyolysis: G9780

NUMERATOR (REPORTING CRITERIA 3):
Patients who are actively using or who receive an order (prescription) for statin therapy at any point during the measurement period

Definitions:
Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Sample list of statin medications (list is NOT inclusive of all agents) is included in the clinical recommendations
Active Liver or Hepatic Disease or Insufficiency – The following codes are included in the Denominator Exception (G9667) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B18.0, B18.1, B19.10, B19.11, B17.0, B17.2, B17.8, B17.10, B17.11, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, K70.0, K70.9, K70.30, K70.31, K70.40, K70.41, K71.3, K71.4, K71.9, K71.10, K71.11, K71.50, K71.51, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.2, K73.8, K73.9, K74.0, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, K76.0, K76.2, K76.3, K76.7, K76.9, K76.89, O98.419, Z22.51

NUMERATOR NOTE: In order to meet the measure, current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; may be called to the pharmacy. Statin medication “samples” provided to patients can be documented as “current statin therapy” if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure.

Numerator Options:
Performance Met: Patients who are currently statin therapy users or received an order (prescription) for statin therapy (G9664)

OR
Denominator Exception: Documentation of medical reason(s) for not currently being a statin therapy user or receive an order (prescription) for statin therapy (e.g., patient with adverse effect, allergy or intolerance to statin medication therapy, patients who are receiving palliative care, patients with active liver disease or hepatic disease or insufficiency, patients with end stage renal disease (ESRD) (G9781)

OR
Denominator Exception: Documentation of patients with diabetes who have a most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy (G9783)

OR
Performance Not Met: Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy (G9665)
RATIONALE:
“Cardiovascular disease (CVD) is the leading cause of death in the United States, causing approximately 1 of every 7 deaths in the United States in 2011. In 2011, stroke caused approximately 1 of every 20 deaths in the United States. For 2011, the estimated annual costs for CVD and stroke were $320.1 billion, including $195.6 billion in direct costs (hospital services, physicians and other professionals, prescribed medications, home health care, and other medical durables) and $124.5 billion in indirect costs from lost future productivity (cardiovascular and stroke premature deaths). CVD costs more than any other diagnostic group” (Mozaffarian et al., 2015).

Data collected between 2009 and 2012 indicates that more than 100 million US adults 20 years or older had total cholesterol levels equal to 200 mg/dL or more, while almost 31 million had levels 240 mg/dL or more (Mozaffarian et al., 2015). Elevated blood cholesterol is a major risk factor for CVD and statin therapy has been associated with a reduced risk of CVD. Numerous randomized trials have demonstrated that treatment with a statin reduces LDL-C, and reduces the risk of major cardiovascular events by approximately 20% (Ference, 2015).

In 2013, guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults were published (see Stone et al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: a Report of the American College of Cardiology [ACC]/American Heart Association [AHA] Task Force on Practice Guidelines). This guideline was published by an Expert Panel, which synthesized evidence from randomized controlled trials to identify people most likely to benefit from cholesterol-lowering therapy. The ACC/AHA Guideline recommendations are intended to provide a strong evidence-based foundation for the treatment of blood cholesterol for the primary and secondary prevention and treatment of Atherosclerotic Cardiovascular Disease (ASCVD) in adult men and women (21 years of age or older). The document concludes the addition of statin therapy reduces the risk of ASCVD among high-risk individuals, defined as follows: individuals with clinical ASCVD, with LDL-C >= 190 mg/dL, or with diabetes and LDL-C 70-189 mg/dL (Stone et al., 2013).

However, one study that surveyed U.S. cardiovascular practices participating in the PINNACLE registry, found that 32.4% of patients with an indication for statins under the 2013 ACC/AHA cholesterol guidelines were not currently receiving them (Maddox et al., 2014). Although, systematic evidence review found that statins are safe drugs with low incidence of conditions or diseases attributable to statin use (Law et al., 2006). Overall, the Statin Safety Expert Panel that participated in an NLA Statin Safety Task Force meeting in October 2013 reaffirms the general safety of statin therapy. The panel members concluded that for most patients requiring statin therapy, the potential benefits of statin therapy outweigh the potential risks. In general terms, the benefits of statins to prevent non-fatal myocardial infarction, revascularization, stroke, and CVD mortality, far outweighs any potential harm related to the drug (Jacobson, 2014).

CLINICAL RECOMMENDATION STATEMENTS:
This electronic clinical quality measure is intended to align with the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol (Stone et al., 2013), which indicates the use of statins as the first line of cholesterol-lowering medication therapy to lower the risk of ASCVD among at-risk populations.

Recommendations for Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults—Statin Treatment:
Secondary Prevention:
High-intensity statin therapy should be initiated or continued as first-line therapy in women and men <=75 years of age who have clinical ASCVD, unless contraindicated. (Level of Evidence A), (ACC/AHA, 2013)

In individuals with clinical ASCVD in whom high-intensity statin therapy would otherwise be used, when high-intensity statin therapy is contraindicated or when characteristics predisposing to statin-associated adverse effects are present, moderate-intensity statin should be used as the second option if tolerated (Level of Evidence A), (ACC/AHA, 2013)

Primary Prevention in Individuals >=21 Years of Age With LDL-C>=190 mg/dL:
• Adults ≥21 years of age with primary LDL–C ≥190 mg/dL should be treated with statin therapy (10-year ASCVD risk estimation is not required). (Level of Evidence B), (ACC/AHA, 2013)

Primary Prevention in Individuals With Diabetes and LDL-C 70-189 mg/dL:
• Moderate-intensity statin therapy should be initiated or continued for adults 40-75 years of age with diabetes. (Level of Evidence A), (ACC/AHA, 2013)

Intensity of statin therapy in primary and secondary prevention:
The expert panel of the 2013 ACC/AHA Guidelines (Stone et al. 2013) defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time.

Table 1 - Sample (List is NOT inclusive of all agents) Statin Medication Therapy List:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand or Trade Name</th>
<th>Medication Type, If Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Lipitor</td>
<td>Statin</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol XL or Lescol</td>
<td>Statin</td>
</tr>
<tr>
<td>Lovastatin (Mevinolin)</td>
<td>Mevacor or Altoprev</td>
<td>Statin</td>
</tr>
<tr>
<td>Pitavastatin</td>
<td>Livalo</td>
<td>N/A</td>
</tr>
<tr>
<td>Pravastatin Sodium</td>
<td>Pravachol</td>
<td>Statin</td>
</tr>
<tr>
<td>Rosuvastatin Calcium</td>
<td>Crestor</td>
<td>Statin</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Zocor</td>
<td>Statin</td>
</tr>
<tr>
<td>Amlodipine Besylate/Atorvastatin Calcium</td>
<td>Caduet</td>
<td>Combination</td>
</tr>
<tr>
<td>Ezetimibe/Simvastatin</td>
<td>Vytorin</td>
<td>Combination</td>
</tr>
<tr>
<td>Niacin/Lovastatin</td>
<td>Advicor</td>
<td>Combination</td>
</tr>
<tr>
<td>Niacin/Simvastatin</td>
<td>Simcor</td>
<td>Combination</td>
</tr>
<tr>
<td>Sitagliptin/Simvastatin</td>
<td>Juvisync</td>
<td>Diabetes Combination</td>
</tr>
</tbody>
</table>

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2017 Registry Individual Measure Flow

#438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

*See the posted Measure Specification for specific coding and instructions to report this measure.

NOTE: Reporting Frequency: Patient-process
#438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

2017 Registry Individual Measure Flow

Start

Denominator

Patient Age at the Beginning of the Measurement Period ≥ 21 Years

Encounter as Listed in the Denominator* (1/1/2017 thru 12/31/2017)

Not Included in Eligible Population/Denominator

Telehealth Modifier: GQ, GT

Active or History of Familial or Pure Hypercholesterolemia G9783 or equivalent

Any Fasting or Direct LDL-C Laboratory Test Result > 190mg/dL G9683 or equivalent

Denominator Exclusions

Patients Who Have a Diagnosis of Pregnancy G9778 or equivalent

Patients Who are Breastfeeding G9776 or equivalent

Patients Who have a Diagnosis of Rhabdomyolysis G9780 or equivalent

Numerator

Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy

Documented of Medical Reason(s) for Not Currently being a Statin Therapy User or Receive as an Order (Prescription) for Statin Therapy

Data Completeness Met + Performance Met G9664 or equivalent (4 patients) a²

Data Completeness Met + Denominator Exception G9781 or equivalent (1 patient) b²

Data Completeness Met + Performance Not Met G9665 or equivalent (2 patients) c²

Data Completeness Not Met Quality Data Code or equivalent not reported (1 patient)

*See the posted Measure Specification for specific coding and instructions to report this measure.

NOTE: Reporting Frequency: Patient-Process

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2017 Registry Individual Measure Flow

#438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Start

Denominator

Patient Age 40-75 at the Beginning of the Measurement Period

Yes

No

Diagnosis of Type 1 or Type 2 Diabetes as Listed in the Denominator*

Yes

No

Encounter as Listed in the Denominator* (1/1/2017 thru 12/31/2017)

Yes

No

Telehealth Modifier: GQ, GT

Yes

No

Highest Fasting Or Direct LDL-C Laboratory Test Result of 70-189 mg/dL in the Measurement Period or Two Years Prior to the Beginning of the Measurement Period G9768 or equivalent

Yes

No

Patients Who Have a Diagnosis of Pregnancy G9778 or equivalent

Yes

No

Patients Who are Breastfeeding G9779 or equivalent

Yes

No

Patients Who have a Diagnosis of Rhabdomyolysis G9780 or equivalent

Yes

No

Not Included in Eligible Population/Denominator

Numerator

Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy

Yes

No

Documentation of Medical Reason(s) for Not Currently being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy

Yes

No

Data Completeness Met + Denominator Exception G9781 or equivalent (1 patient) b3

Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy

Yes

No

Data Completeness Met + Performance Not Met G9805 or equivalent (2 patients) c3

Data Completeness Met + Performance Met G9854 or equivalent (4 patients) a1

Include in Eligible Population/Denominator (8 patients) g1

*See the posted Measure Specification for specific coding and instructions to report this measure.

NOTE: Reporting Frequency: Patient Process

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2017 Registry Individual Measure Flow  
#438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

**SAMPLE CALCULATION:**

**Data Completeness**
\[
\text{Data Completeness} = \frac{\text{Performance Met (a^1 + a^2 + a^3 = 12 patients)}}{\text{Eligible Population}} + \frac{\text{Denominator Exception (b^1 + b^2 + b^3 + b^4 = 3 patient)}}{\text{Denominator}} + \frac{\text{Performance Not Met (c^1 + c^2 + c^3 = 6 patients)}}{\text{21 patients}} = 21 \text{ patients} = 87.50\%
\]

\[
\text{12 patients} + 24 \text{ patients} = 36 \text{ patients}
\]

**Performance Rate**
\[
\text{Performance Rate} = \frac{\text{Performance Met (a^1 + a^2 + a^3 = 12 patients)}}{\text{Data Completeness Numerator (21 patients) - Denominator Exception (b^1 + b^2 + b^3 + b^4 = 3 patients)}} = \frac{12 \text{ patients}}{18 \text{ patients}} = 66.66\%
\]

*See the posted Measure Specification for specific coding and instructions to report this measure.*

**NOTE:** Reporting Frequency: Patient-process

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.
2017 Registry Individual Measure Flow

#438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure.

**Reporting Criteria One:**

1. Start with Denominator

2. Check Patient Age:
   a. If the Age is greater than or equal to 21 years of age at the beginning of the measurement period and equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If the Age is greater than or equal to 21 years of age at the beginning of the measurement period and equals Yes during the measurement period, proceed to Check Current Encounter Performed.

3. Check Encounter Performed:
   a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Encounter as Listed in the Denominator equals Yes, proceed to Check Telehealth Modifier: GQ, GT.

4. Check Telehealth Modifier: GQ, GT:
   a. If Telehealth Modifier: GQ, GT equals No, proceed to Check Previously Diagnosed or have an Active Diagnosis of Clinical ASCVD.
   b. If Telehealth Modifier: GQ, GT equals Yes, do not include in Eligible Patient Population. Stop Processing.

5. Check Previously Diagnosed or have an Active Diagnosis of Clinical ASCVD:
   a. If Previously Diagnosed or have an Active Diagnosis of Clinical ASCVD equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Previously Diagnosed or have an Active Diagnosis of Clinical ASCVD equals Yes, proceed to Check Patients Who Have a Diagnosis of Pregnancy.

6. Check Patients Who Have a Diagnosis of Pregnancy:
   a. If Patients Who Have a Diagnosis of Pregnancy equals No, proceed to Check Patients Who are Breastfeeding
   b. If Patients Who Have a Diagnosis of Pregnancy equals Yes, do not include in Eligible Patient Population. Stop Processing.

7. Check Patients Who are Breastfeeding:
   a. If Patients Who are Breastfeeding equals No, proceed to Check Patients Who have a Diagnosis of Rhabdomyolysis.
   b. If Patients Who are Breastfeeding equals Yes, do not include in Eligible Patient Population. Stop Processing.

8. Check Patients Who have a Diagnosis of Rhabdomyolysis:
   a. If Patients Who have a Diagnosis of Rhabdomyolysis equals No, include in the Eligible Patient Population.
b. If Patients Who have a Diagnosis of Rhabdomyolysis equals Yes, do not include in Eligible Patient Population. Stop Processing.

9. Denominator Population:
   a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d1 equals 8 patients in the sample calculation.

10. Start Numerator

11. Check Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy:
   a. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Met.
   b. Data Completeness Met and Performance Met letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a1 equals 4 patients in Sample Calculation.
   c. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals No, proceed to Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.

12. Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.
   a. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Denominator Exception.
   b. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b1 equals 1 patient in the Sample Calculation.
   c. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals No, proceed to Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy.

13. Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy:
   a. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Not Met.
   b. Data Completeness Met and Performance Not Met letter is represented as Data Completeness in the Sample Calculation listed at the end of this document. Letter c1 equals 2 patients in the Sample Calculation.
   c. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals No, proceed to Data Completeness Not Met

14. Check Data Completeness Not Met
   a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not reported. 1 patient has been subtracted from the data completeness numerator in the sample calculation.
Reporting Criteria 2:

1. Start with Denominator

2. Check Patient Age:
   a. If the Age is greater than or equal to 21 years of age at the beginning of the measurement period and equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If the Age is greater than or equal to 21 years of age at the beginning of the measurement period and equals Yes during the measurement period, proceed to Check Encounter Performed.

3. Check Encounter Performed:
   a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Encounter as Listed in the Denominator equals Yes, proceed to Check Telehealth Modifier: GQ, GT.

4. Check Telehealth Modifier: GQ, GT:
   a. If Telehealth Modifier: GQ, GT equals No, proceed to Check Any Fasting or Direct LDL-C Laboratory Test Result ≥ 190mg/dL.
   b. If Telehealth Modifier: GQ, GT equals Yes, do not include in Eligible Patient Population. Stop Processing.

5. Check Any Fasting or Direct LDL-C Laboratory Test Result ≥ 190mg/dL:
   a. If Any Fasting or Direct LDL-C Laboratory Test Result ≥ 190mg/dL equals No, proceed to Check Active or Familial or Pure Hypercholesterolemia.
   b. If Any Fasting or Direct LDL-C Laboratory Test Result ≥ 190mg/dL equals Yes, proceed to Check Patients Who Have a Diagnosis of Pregnancy.

6. Check Active or History of Familial or Pure Hypercholesterolemia:
   a. If Active or History of Familial or Pure Hypercholesterolemia equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Active or History of Familial or Pure Hypercholesterolemia equals Yes, proceed to Check Patients Who Have a Diagnosis of Pregnancy.

7. Check Patients Who Have a Diagnosis of Pregnancy:
   a. If Patients Who Have a Diagnosis of Pregnancy equals No, proceed to Check Patients Who are Breastfeeding
   b. If Patients Who Have a Diagnosis of Pregnancy equals Yes, do not include in Eligible Patient Population. Stop Processing.

8. Check Patients Who are Breastfeeding:
   a. If Patients Who are Breastfeeding equals No, proceed to Check Patients Who have a Diagnosis of Rhabdomyolysis.
   b. If Patients Who are Breastfeeding equals Yes, do not include in Eligible Patient Population. Stop Processing.

9. Check Patients Who have a Diagnosis of Rhabdomyolysis:
   a. If Patients Who have a Diagnosis of Rhabdomyolysis equals No, include in the Eligible Patient Population
b. If Patients Who have a Diagnosis of Rhabdomyolysis equals Yes, do not include in Eligible Patient Population. Stop Processing.

10. Denominator Population:

a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d2 equals 8 patients in the sample calculation.

11. Start Numerator

12. Check Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy:

a. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Met.

b. Data Completeness Met and Performance Met letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a2 equals 4 patients in Sample Calculation.

c. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals No, proceed to Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.

13. Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.

a. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Denominator Exception.

b. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b2 equals 1 patient in the Sample Calculation.

c. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals No, proceed to Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy.

14. Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy:

a. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Not Met.

b. Data Completeness Met and Performance Not Met letter is represented as Data Completeness in the Sample Calculation listed at the end of this document. Letter c2 equals 2 patients in the Sample Calculation.

c. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals No, proceed to Data Completeness Not Met

15. Check Data Completeness Not Met

a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not reported. 1 patient has been subtracted from the data completeness numerator in the sample calculation.
Reporting Criteria 3:

1. Start with Denominator

2. Check Patient Age:
   a. If the Age is 40 through 75 years of age at the beginning of the measurement period and equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If the Age is 40 through 75 years of age at the beginning of the measurement period and equals Yes during the measurement period, proceed to Check Diagnosis of Type 1 or Type 2 Diabetes.

3. Check Diagnosis of Type 1 or Type 2 Diabetes:
   a. If Diagnosis of Type 1 or Type 2 Diabetes as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Diagnosis of Type 1 or Type 2 Diabetes as Listed in the Denominator equals Yes, proceed to Check Encounter Performed.

4. Check Encounter Performed:
   a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Encounter as Listed in the Denominator equals Yes, proceed to Check Telehealth Modifier: GQ, GT.

5. Check Telehealth Modifier: GQ, GT:
   a. If Telehealth Modifier: GQ, GT equals No, proceed to Check Highest Fasting or Direct LDL-C Laboratory Test Result of 70-189 mg/dL in the Measurement Period or Two Years Prior to the Beginning of the Measurement Period.
   b. If Telehealth Modifier: GQ, GT equals Yes, do not include in Eligible Patient Population. Stop Processing.

6. Check Highest Fasting Or Direct LDL-C Laboratory Test Result of 70-189 mg/dL in the Measurement Period or Two Years Prior to the Beginning of the Measurement Period:
   a. If Highest Fasting Or Direct LDL-C Laboratory Test Result of 70-189 mg/dL in the Measurement Period or Two Years Prior to the Beginning of the Measurement Period equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Highest Fasting Or Direct LDL-C Laboratory Test Result of 70-189 mg/dL in the Measurement Period or Two Years Prior to the Beginning of the Measurement Period equals Yes, proceed to Check Patients Who Have a Diagnosis of Pregnancy.

7. Check Patients Who Have a Diagnosis of Pregnancy:
   a. If Patients Who Have a Diagnosis of Pregnancy equals No, proceed to Check Patients Who are Breastfeeding
   b. If Patients Who Have a Diagnosis of Pregnancy equals Yes, do not include in Eligible Patient Population. Stop Processing.

8. Check Patients Who are Breastfeeding:
   a. If Patients Who are Breastfeeding equals No, proceed to Check Patients Who have a Diagnosis of Rhabdomyolysis.
   b. If Patients Who are Breastfeeding equals Yes, do not include in Eligible Patient Population. Stop Processing.
9. Check Patients Who have a Diagnosis of Rhabdomyolysis:
   a. If Patients Who have a Diagnosis of Rhabdomyolysis equals No, include in the Eligible Patient Population
   b. If Patients Who have a Diagnosis of Rhabdomyolysis equals Yes, do not include in Eligible Patient Population. Stop Processing.

10. Denominator Population:
    a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d3 equals 8 patients in the sample calculation.

11. Start Numerator

12. Check Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy:
    a. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Met.
    b. Data Completeness Met and Performance Met letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a3 equals 4 patients in Sample Calculation.
    c. If Patients who are Currently Statin Therapy Users or Received an Order (Prescription) for Statin Therapy equals No, proceed to Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.

13. Check Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy.
    a. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Denominator Exception.
    b. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b3 equals 1 patient in the Sample Calculation.
    c. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals No, proceed to Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy.

14. Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy:
    a. If Documentation of Patients with Diabetes and Most Recent Fasting or Direct LDL-C Result < 70 mg/dL for Not Currently being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Denominator Exception.
    b. Data Completeness Met and Denominator Exception letter is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b4 equals 0 patients in the Sample Calculation.
    c. If Documentation of Medical Reason(s) for Not Currently Being a Statin Therapy User or Receive an Order (Prescription) for Statin Therapy equals No, proceed to Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy.

15. Check Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy:
a. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals Yes, include in Data Completeness Met and Performance Not Met.

b. Data Completeness Met and Performance Not Met letter is represented as Data Completeness in the Sample Calculation listed at the end of this document. Letter c3 equals 2 patients in the Sample Calculation.

c. If Patients who are Not Currently Statin Therapy Users or did Not Receive an Order (Prescription) for Statin Therapy equals No, proceed Data Completeness Not Met.

16. Check Data Completeness Not Met

a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not reported. 1 patient has been subtracted from the data completeness numerator in the sample calculation.

**SAMPLE CALCULATION:**

Data Completeness =

Performance Met \(a + a^2 + a^3 = 12\) patients \(+\) Denominator Exception \(b^1 + b^2 + b^3 = 1\) patient \(+\) Performance Not Met \(c^1 + c^2 + c^3 = 6\) patients \(= 21\) patients \(= 87.50\%\)

Eligible Population / Denominator \((d^1 + d^2 + d^3 = 24\) patients\) = 24 patients

Performance Rate =

Performance Met \(a^1 + a^2 + a^3 = 12\) patients \(= 12\) patients \(= 66.66\%\)

Data Completeness Numerator (21 patients) – Denominator Exception \(b^4 + b^5 + b^6 = 3\) patients \(= 18\) patients