

**Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**  
– National Quality Strategy Domain: Effective Clinical Care  
– Meaningful Measure Area: Management of Chronic Conditions

**2022 COLLECTION TYPE:**  
**MIPS CLINICAL QUALITY MEASURES (CQMS)**

**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:

- All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR
- Patients aged  $\geq 20$  years who have ever had a low-density lipoprotein cholesterol (LDL-C) level  $\geq 190$  mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR
- Patients aged 40-75 years with a diagnosis of diabetes

**INSTRUCTIONS:**

This measure is to be submitted **once per measurement period** for patients seen during the measurement period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provide the services in the measure-specific denominator coding.

***NOTE:*** Patient encounters for this measure conducted via telehealth (e.g., encounters coded with GQ, GT, 95, or POS 02 modifiers) are allowable.

**Measure Submission Type:**

Measure data may be submitted by individual MIPS eligible clinicians, groups, or third-party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third-party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third-party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

**THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE\*\*:**

- 1) All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure.

**OR**

- 2) Patients aged  $\geq 20$  years at the beginning of the measurement period who have ever had a laboratory result of LDL-C  $\geq 190$  mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia.

**OR**

- 3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes.

\*\*All patients who meet one or more of the following criteria indicated above would be considered at high risk for cardiovascular events under the American College of Cardiology (ACC)/American Heart Association (AHA)/Multi-society (MS) guidelines. When submitting this measure, determine if the patient meets denominator eligibility in order of each risk category. There is only one performance rate calculated for this measure.

**DENOMINATOR (SUBMISSION CRITERIA 1):**

All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure.

**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

***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 MIPS CQMs.

**DENOMINATOR CRITERIA: (Eligible Cases):**

All patients, regardless of age

**AND**

**Patient encounter during the measurement period (CPT or HCPCS):** 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241\*, 99242\*, 99243\*, 99244\*, 99245\*, 99385\*, 99386\*, 99387\*, 99395\*, 99396\*, 99397\*, 99401\*, 99402\*, 99403\*, 99404\*, 99429\*, G0438, G0439

**AND**

**Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure:** G9662

**AND NOT**

**DENOMINATOR EXCLUSIONS:**

**Patients who have a diagnosis of pregnancy at any time during the measurement period:** G9778

**OR**

**Patients who are breastfeeding at any time during the measurement period:** G9779

**OR**

**Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period:** G9780

**NUMERATOR (SUBMISSION CRITERIA 1):**

Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period

**Definition:**

**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.

**Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage):**

<b>Generic Name</b>	<b>Brand or Trade Name</b>	<b>Medication Type, If Applicable</b>
Atorvastatin	Lipitor	Statin
Fluvastatin	Lescol XL or Lescol	Statin
Lovastatin (Mevinolin)	Mevacor or Altoprev	Statin
Pitavastatin	Livalo or Zypitamag or Nikita	Statin
Pravastatin Sodium	Pravachol	Statin
Rosuvastatin Calcium	Crestor	Statin
Simvastatin	Zocor	Statin
Amlodipine Besylate/Atorvastatin	Caduet	Fixed Dose Combination
Ezetimibe/Simvastatin	Vytorin	Fixed Dose Combination

**Denominator Exceptions**

**Active Liver or Hepatic Disease or Insufficiency** – The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B17.0, B17.10, B17.11, B17.2, B17.8, B17.9, B18.0, B18.1, B18.2, B18.8, B18.9, B19.0, B19.10, B19.11, B19.20, B19.21, B19.9, K70.0, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K70.9, K71.0, K71.10, K71.11, K71.2, K71.3, K71.4, K71.50, K71.51, K71.6, K71.7, K71.8, K71.9, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.00, K74.01, K74.02, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, O98.411, O98.412, O98.413, O98.419

**End Stage Renal Disease** – The following ICD-10-CM code is included in the Denominator Exception (G9781) to define end stage renal disease: N18.6

**Statin-Associated Muscle Symptoms (SAMS)** – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define SAMS: G72.0, G72.9, M60.9, M79.10.

**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; it 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.*

*It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list).*

*Intensity of statin therapy in primary and secondary prevention:*

*The expert panel of the 2018 ACC/AHA/MS Guidelines (Grundy et al., 2019) 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.*

Denominator Exceptions should be active during the measurement period.

**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 receiving an order (prescription) for statin therapy (e.g., patients with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice 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)

**OR**

**DENOMINATOR (SUBMISSION CRITERIA 2):**

Patients aged  $\geq 20$  years at the beginning of the measurement period who have ever had a laboratory result of LDL-C  $\geq 190$  mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia

**Definition:**

**Lipoprotein Density Cholesterol (LDL-C) result** – A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available, the direct LDL-C test result should be used.

**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 MIPS CQMs.

**DENOMINATOR CRITERIA: (Eligible Cases):**

Patient aged  $\geq 20$  years at the beginning of the measurement period

**AND**

**Patient encounter during the measurement period (CPT):** 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241\*, 99242\*, 99243\*, 99244\*, 99245\*, 99385\*, 99386\*, 99387\*, 99395\*, 99396\*, 99397\*, 99401\*, 99402\*, 99403\*, 99404\*, 99429\*, G0438, G0439

**AND**

**Any LDL-C laboratory test result  $\geq 190$  mg/dL:** G9663

**OR**

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

**AND NOT**

**DENOMINATOR EXCLUSIONS:**

**Patients who have a diagnosis of pregnancy at any time during the measurement period:** G9778

**OR**

**Patients who are breastfeeding at any time during the measurement period:** G9779

**OR**

**Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period:** G9780

**NUMERATOR (SUBMISSION CRITERIA 2):**

Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period

**Definition:**

**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.

**Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage):**

<b>Generic Name</b>	<b>Brand or Trade Name</b>	<b>Medication Type, If Applicable</b>
Atorvastatin	Lipitor	Statin
Fluvastatin	Lescol XL or Lescol	Statin
Lovastatin (Mevinolin)	Mevacor or Altoprev	Statin
Pitavastatin	Livalo or Zypitamag or Nikita	Statin
Pravastatin Sodium	Pravachol	Statin
Rosuvastatin Calcium	Crestor	Statin
Simvastatin	Zocor	Statin
Amlodipine Besylate/Atorvastatin	Caduet	Fixed Dose Combination
Ezetimibe/Simvastatin	Vytorin	Fixed Dose Combination

**Denominator Exceptions**

**Active Liver or Hepatic Disease or Insufficiency** – The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B17.0, B17.10, B17.11, B17.2, B17.8, B17.9, B18.0, B18.1, B18.2, B18.8, B18.9, B19.0, B19.10, B19.11, B19.20, B19.21, B19.9, K70.0, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K70.9, K71.0, K71.10, K71.11, K71.2, K71.3, K71.4, K71.50, K71.51, K71.6, K71.7, K71.8, K71.9, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.00, K74.01, K74.02, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, O98.411, O98.412, O98.413, O98.419

**End Stage Renal Disease** – The following ICD-10-CM code is included in the Denominator Exception (G9781) to define end stage renal disease: N18.6

**Statin-Associated Muscle Symptoms (SAMS)** – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define SAMS: G72.0, G72.9, M60.9, M79.10.

**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; it 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.*

*It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions)*

for the complete list).

*Intensity of statin therapy in primary and secondary prevention:*

*The expert panel of the 2018 ACC/AHA/MS Guidelines (Grundy et al., 2019) 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.*

*Denominator Exceptions should be active during the measurement period.*

**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 receiving an order (prescription) for statin therapy (e.g., patient with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice 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)**

**OR**

**DENOMINATOR (SUBMISSION CRITERIA 3):**

Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes.

***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 MIPS CQMs.

**DENOMINATOR CRITERIA: (Eligible Cases):**

Patients aged 40 through 75 years at the beginning of the measurement period

**AND**

**Type 1 or Type 2 diabetes diagnosis (ICD-10-CM):** E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.3211, E10.3212, E10.3213, E10.3219, E10.3291, E10.3292, E10.3293, E10.3299, E10.3311, E10.3312, E10.3313, E10.3319, E10.3391, E10.3392, E10.3393, E10.3399, E10.3411, E10.3412, E10.3413, E10.3419, E10.3491, E10.3492, E10.3493, E10.3499, E10.3511, E10.3512, E10.3513, E10.3519, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E10.36, E10.37X1, E10.37X2, E10.37X3, E10.37X9, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9, E11.00, E11.01, E11.10, E11.11, E11.21, E11.22, E11.29, E11.311, E11.319, E11.3211, E11.3212, E11.3213, E11.3219, E11.3291, E11.3292, E11.3293, E11.3299, E11.3311, E11.3312, E11.3313, E11.3319, E11.3391, E11.3392, E11.3393, E11.3399, E11.3411, E11.3412, E11.3413, E11.3419, E11.3491, E11.3492, E11.3493, E11.3499, E11.3511, E11.3512, E11.3513, E11.3519,

E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E11.36, E11.37X2, E11.37X3, E11.37X9, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00, E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.3211, E13.3212, E13.3213, E13.3219, E13.3291, E13.3292, E13.3293, E13.3299, E13.3311, E13.3312, E13.3313, E13.3319, E13.3391, E13.3392, E13.3393, E13.3399, E13.3411, E13.3412, E13.3413, E13.3419, E13.3491, E13.3492, E13.3493, E13.3499, E13.3511, E13.3512, E13.3513, E13.3519, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, E13.3599, E13.36, E13.37X1, E13.37X2, E13.37X3, E13.37X9, E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9, O24.011, O24.012, O24.013, O24.019, O24.02, O24.03, O24.111, O24.112, O24.113, O24.119, O24.12, O24.13, O24.311, O24.312, O24.313, O24.319, O24.32, O24.33, O24.811, O24.812, O24.813, O24.819, O24.82, O24.83

**AND**

**Patient encounter during the performance period (CPT):**, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241\*, 99242\*, 99243\*, 99244\*, 99245\*, 99385\*, 99386\*, 99387\*, 99395\*, 99396\*, 99397\*, 99401\*, 99402\*, 99403\*, 99404\*, 99429\*, G0438, G0439

**AND NOT**

**DENOMINATOR EXCLUSIONS:**

**Patients who have a diagnosis of pregnancy at any time during the measurement period:** G9778

**OR**

**Patients who are breastfeeding at any time during the measurement period:** G9779

**OR**

**Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period:** G9780

**NUMERATOR (SUBMISSION CRITERIA 3):**

Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period

**Definition:**

**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.

**Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage):**

<b>Generic Name</b>	<b>Brand or Trade Name</b>	<b>Medication Type, If Applicable</b>
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Pravastatin Sodium	Pravachol	Statin
Rosuvastatin Calcium	Crestor	Statin
Simvastatin	Zocor	Statin
Amlodipine Besylate/Atorvastatin	Caduet	Fixed Dose Combination
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**Denominator Exceptions**

**Active Liver or Hepatic Disease or Insufficiency** – The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define liver disease: B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B17.0,

B17.10, B17.11, B17.2, B17.8, B17.9, B18.0, B18.1, B18.2, B18.8, B18.9, B19.0, B19.10, B19.11, B19.20, B19.21, B19.9, K70.0, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K70.9, K71.0, K71.10, K71.11, K71.2, K71.3, K71.4, K71.50, K71.51, K71.6, K71.7, K71.8, K71.9, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.00, K74.01, K74.02, K74.1, K74.2, K74.3, K74.4, K74.5, K74.60, K74.69, K75.4, O98.411, O98.412, O98.413, O98.419

**End Stage Renal Disease** – The following ICD-10-CM code is included in the Denominator Exception (G9781) to define end stage renal disease: N18.6

**Statin-Associated Muscle Symptoms (SAMS)** – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define SAMS: G72.0, G72.9, M60.9, M79.10.

**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; it 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.*

*It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list).*

*Intensity of statin therapy in primary and secondary prevention:  
The expert panel of the 2018 ACC/AHA/MS Guidelines (Grundy et al., 2019) 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.*

*Denominator Exceptions should be active during the measurement period.*

**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 receiving an order (prescription) for statin therapy (e.g., patient with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, 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)

### **RATIONALE:**

“Cardiovascular disease (CVD) is the leading cause of death in the United States, causing approximately 1 of every 3 deaths in the United States in 2015. In 2015, stroke caused approximately 1 of every 19 deaths in the United States and the estimated annual costs for CVD and stroke were \$329.7 billion, including \$199.2 billion in direct costs (hospital services, physicians and other professionals, prescribed medications, home health care, and other medical durables) and \$130.5 billion in indirect costs from lost future productivity (cardiovascular and stroke premature deaths). CVD costs more than any other diagnostic group” (Benjamin et al., 2018).

Data collected between 2011 and 2014 indicate that more than 94.6 million U.S. adults, 20 years or older had total cholesterol levels equal to 200 mg/dL or more, while almost 28.5 million had levels 240 mg/dL or more (Benjamin et al., 2018). 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 percent (Ference, 2015).

In 2018, updated guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults were published (see Grundy et al., 2019). 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/MS 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 ASCVD in patients of all ages. 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  $\geq$  190 mg/dL, or with diabetes (Grundy et al., 2019).

One study surveying U.S. cardiology, primary care, and endocrinology practices found that 1 in 4 guideline-eligible patients were not on a statin and less than half were on the recommended statin intensity. Untreated and undertreated patients had significantly higher LDL-C levels than those receiving guideline-directed statin treatment (Navar et al., 2017). In a follow-up study authored by Nanna et al., the same clinics were divided into tertiles based on the percentage of patients with guideline-recommended statin use. The researchers found that patients in the high-tertile clinics were more likely to achieve target LDL-C levels than patients at the low- or mid-tertile clinics, and this held true when patients were stratified by primary and secondary prevention (Nanna et al., 2019a).

Research also indicates that certain populations are far less likely to receive guideline-recommended statin therapy than others. A retrospective study of the National Health and Nutrition Examination Survey found that Black and Hispanic race or ethnicity, low income, lack of health insurance coverage, poor health care access, young age, and female gender are predictors of lower statin utilization (Gu et al., 2018). In particular, there is extensive evidence that women are far less likely than men to be prescribed guideline-recommended statin therapy (Zhang et al., 2016; Nanna et al., 2019b), despite research showing that female patients with cardiovascular disease derive the same or greater benefit from statin therapy as male patients with cardiovascular disease (Puri et al., 2014).

The Statin Safety Expert Panel that participated in a National Lipid Association (NLA) Statin Safety Task Force meeting in October 2013 reaffirms the general safety of statin therapy. Ultimately, 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 clinical quality measure is intended to align with the 2018 ACC/AHA/MS Guideline on the Management of Blood Cholesterol (Grundy et al., 2019), 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 Management of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults—Statin Treatment:**

### Secondary Prevention:

1. 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 a 50% or greater reduction in LDL-C levels (Class I Recommendation), (Grundy et al., 2019).
2. 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 a 30% to 49% reduction in LDL-C levels (Class I Recommendation), (Grundy et al., 2019).
3. 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 (Class IIa Recommendation), (Grundy et al., 2019).

### Primary Prevention:

1. In patients 20 to 75 years of age with an LDL-C level of 190 mg/dL or higher ( $\geq 4.9$  mmol/L), maximally tolerated statin therapy is recommended. (Class I Recommendation), (Grundy et al., 2019).
2. 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 Recommendation), (Grundy et al., 2019).

### Statin Safety and Statin-Associated Side Effects:

A clinician–patient risk discussion is recommended before initiation of statin therapy to review net clinical benefit, weighing the potential for ASCVD risk reduction against the potential for statin-associated side effects, statin–drug interactions, and safety, while emphasizing that side effects can be addressed successfully (Class I Recommendation), (Grundy et al., 2019).

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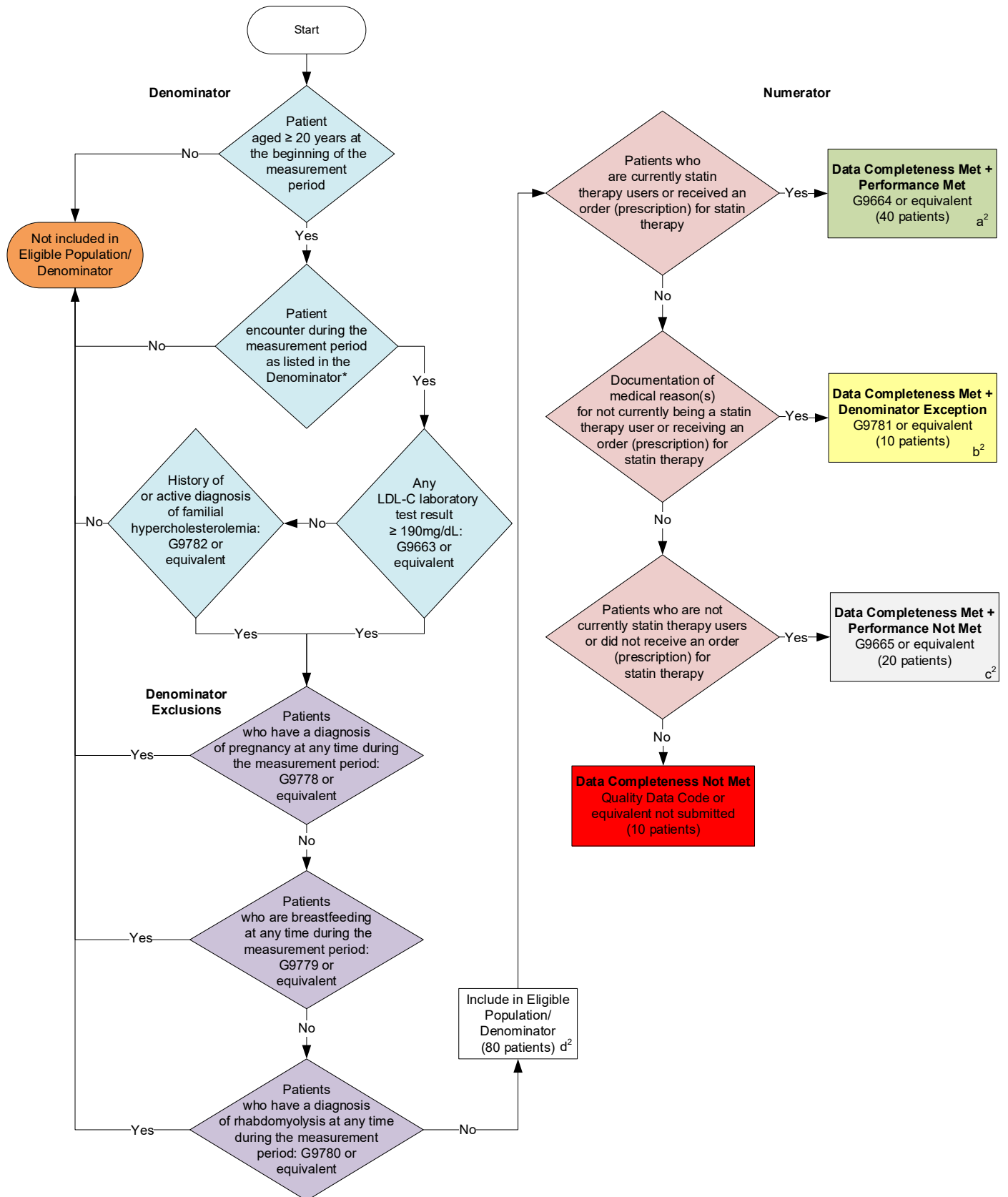
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## 2022 Clinical Quality Measure Flow for Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Submission Criteria One

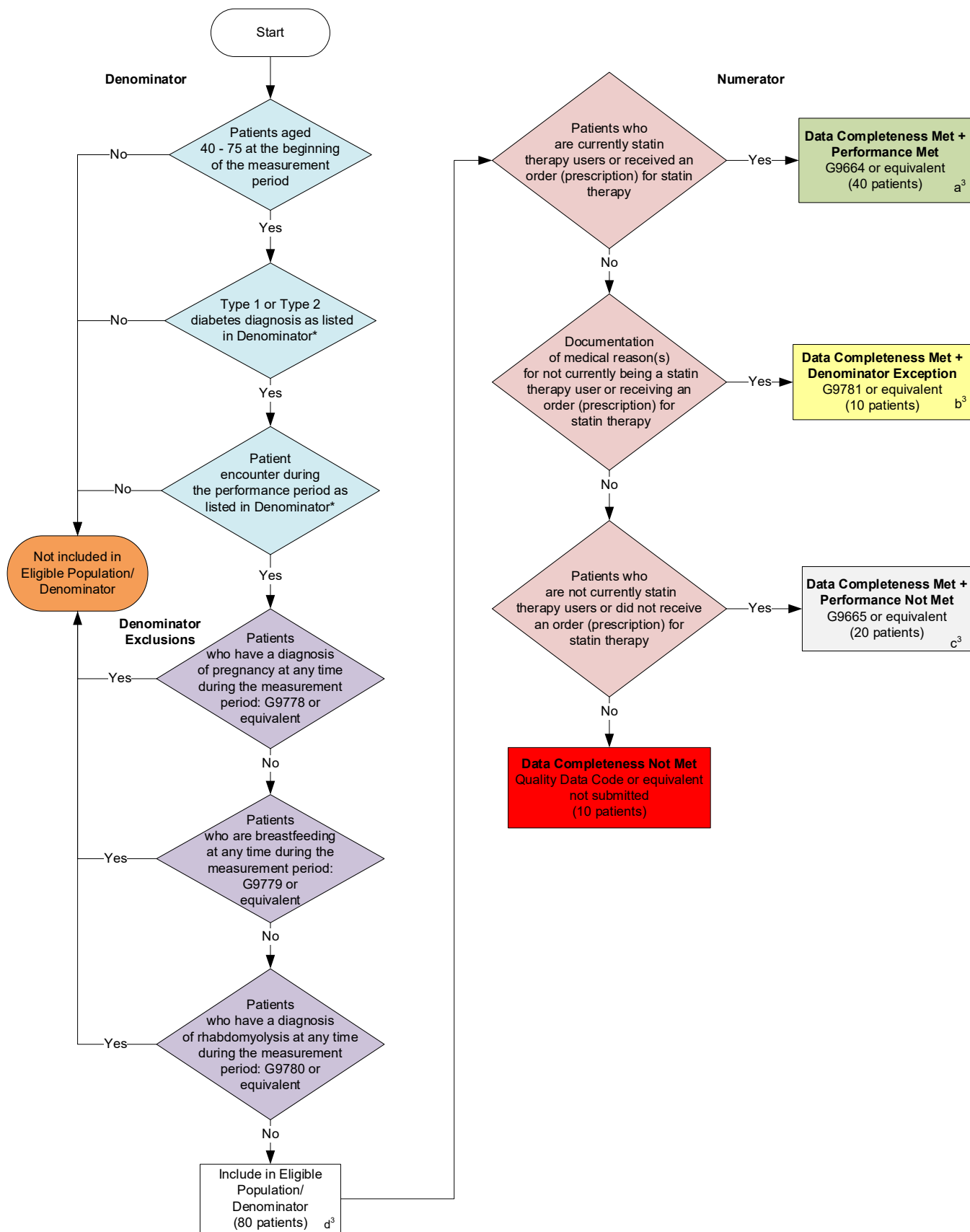
*Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.*



## Submission Criteria Two



### Submission Criteria Three



### SAMPLE CALCULATIONS

**Data Completeness=**

$$\frac{\text{Performance Met (a}^1+\text{a}^2+\text{a}^3=120 \text{ patients)} + \text{Denominator Exception (b}^1+\text{b}^2+\text{b}^3=30 \text{ patients)} + \text{Performance Not Met (c}^1+\text{c}^2+\text{c}^3=60 \text{ patients)}}{\text{Eligible Population / Denominator (d}^1+\text{d}^2+\text{d}^3=240 \text{ patients)}} = \frac{210 \text{ patients}}{240 \text{ patients}} = 87.50\%$$

**Performance Rate=**

$$\frac{\text{Performance Met (a}^1+\text{a}^2+\text{a}^3=120 \text{ patients)}}{\text{Data Completeness Numerator (210 patients) – Denominator Exception (b}^1+\text{b}^2+\text{b}^3=30 \text{ patients)}} = \frac{120 \text{ patients}}{180 \text{ patients}} = 66.67\%$$

\*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient-Process

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**2022 Clinical Quality Measure Flow Narrative For Quality ID #438:  
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**

*Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.*

**Submission Criteria One:**

1. Start with Denominator
2. All patients, regardless of age.
3. Check *Patient encounter during the performance period as listed in the Denominator\**:
  - a. If *Patient encounter during the performance period as listed in the Denominator\** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patient encounter during the performance period as listed in the Denominator\** equals Yes, proceed to check *Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure*.
4. Check *Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure*:
  - a. If *Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure* equals Yes, proceed to check *Patients who have a diagnosis of pregnancy at any time during the measurement period*.
5. Check *Patients who have a diagnosis of pregnancy at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals No, proceed to check *Patients who are breastfeeding at any time during the measurement period*.
  - b. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
6. Check *Patients who are breastfeeding at any time during the measurement period*:
  - a. If *Patients who are breastfeeding at any time during the measurement period* equals No, proceed to check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*.
  - b. If *Patients who are breastfeeding at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
7. Check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals No, include in *Eligible Population/Denominator*.
  - b. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
8. 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 d<sup>1</sup> equals 80 patients in the Sample Calculation.

9. Start Numerator
10. 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*.
    - *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 a<sup>1</sup> equals 40 patients in the Sample Calculation.
  - b. 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*.
11. 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*.
    - *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 b<sup>1</sup> equals 10 patients in the Sample Calculation.
  - b. 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*.
12. 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*.
    - *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 c<sup>1</sup> equals 20 patients in the Sample Calculation.
  - b. If *Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy* equals No, proceed to check *Data Completeness Not Met*.
13. Check *Data Completeness Not Met*.
  - If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

**Submission Criteria Two:**

1. Start with Denominator
2. Check *Patient aged greater than or equal to 20 years at the beginning of the measurement period*:
  - a. If the *Patient aged greater than or equal to 20 years at the beginning of the measurement period* equals No, do not include in *Eligible Population/Denominator*. Stop processing.



- b. If the *Patient aged greater than or equal to 20 years at the beginning of the measurement period* equals Yes, proceed to check *Patient encounter during the performance period as listed in the Denominator\**.
3. Check *Patient encounter during the performance period as listed in the Denominator\**:
  - a. If *Patient encounter during the performance period as listed in the Denominator\** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patient encounter during the performance period as listed in the Denominator\** equals Yes, proceed to check *Any LDL-C laboratory test result greater than or equal to 190mg/dL*.
4. Check *Any LDL-C laboratory test result greater than or equal to 190mg/dL*:
  - a. If *Any LDL-C laboratory test result greater than or equal to 190mg/dL* equals No, proceed to check *History of or active diagnosis of familial hypercholesterolemia*.
  - b. If *Any LDL-C laboratory test result greater than or equal to 190mg/dL* equals Yes, proceed to check *Patients who have a diagnosis of pregnancy at any time during the measurement period*.
5. Check *History of or active diagnosis of familial hypercholesterolemia*:
  - a. If *History of or active diagnosis of familial hypercholesterolemia* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *History of or active diagnosis of familial hypercholesterolemia* equals Yes, proceed to check *Patients who have a diagnosis of pregnancy at any time during the measurement period*.
6. Check *Patients who have a diagnosis of pregnancy at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals No, proceed to check *Patients who are breastfeeding at any time during the measurement period*.
  - b. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
7. Check *Patients who are breastfeeding at any time during the measurement period*:
  - a. If *Patients who are breastfeeding at any time during the measurement period* equals No, proceed to check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*.
  - b. If *Patients who are breastfeeding at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
8. Check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals No, include in *Eligible Population/Denominator*.
  - b. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. 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 d<sup>2</sup> equals 80 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*.
    - *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 a<sup>2</sup> equals 40 patients in the Sample Calculation.
  - b. 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*.
    - *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 b<sup>2</sup> equals 10 patients in the Sample Calculation.
  - b. 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*.
    - *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 c<sup>2</sup> equals 20 patients in the Sample Calculation.
  - b. If *Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy* equals No, proceed to check *Data Completeness Not Met*.
14. Check *Data Completeness Not Met*.
  - If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

**Submission Criteria Three:**

1. Start with Denominator
2. Check *Patients aged 40 - 75 at the beginning of the measurement period*:
  - a. If *Patients aged 40 - 75 at the beginning of the measurement period* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patients aged 40 - 75 at the beginning of the measurement period* equals Yes, proceed to check *Type 1 or Type 2 diabetes diagnosis as listed in Denominator\**.

3. Check *Type 1 or Type 2 diabetes diagnosis as listed in Denominator\**:
  - a. If *Type 1 or Type 2 diabetes diagnosis as listed in Denominator\** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Type 1 or Type 2 diabetes diagnosis as listed in Denominator\** equals Yes, proceed to check *Patient encounter during the performance period as listed in Denominator\**.
4. Check *Patient encounter during the performance period as listed in Denominator\**:
  - a. If *Patient encounter during the performance period as listed in Denominator\** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
  - b. If *Patient encounter during the performance period as listed in Denominator\** equals Yes, proceed to check *Patients who have a diagnosis of pregnancy at any time during the measurement period*.
5. Check *Patients who have a diagnosis of pregnancy at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals No, proceed to check *Patients who are breastfeeding at any time during the measurement period*.
  - b. If *Patients who have a diagnosis of pregnancy at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
6. Check *Patients who are breastfeeding at any time during the measurement period*:
  - a. If *Patients who are breastfeeding at any time during the measurement period* equals No, proceed to check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*.
  - b. If *Patients who are breastfeeding at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
7. Check *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period*:
  - a. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals No, include in *Eligible Population/Denominator*.
  - b. If *Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
8. 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 d<sup>3</sup> equals 80 patients in the Sample Calculation.
9. Start Numerator
10. 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*.
    - *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 a<sup>3</sup> equals 40 patients in Sample Calculation.
  - b. 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*.

11. 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*.
    - *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 b<sup>3</sup> equals 10 patients in the Sample Calculation.
  - b. 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*.
12. 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*.
    - *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 c<sup>3</sup> equals 20 patients in the Sample Calculation.
  - b. If *Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy* equals No, proceed to check *Data Completeness Not Met*.
13. Check *Data Completeness Not Met*:
  - If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

### **Sample Calculations:**

Data Completeness equals Performance Met (a<sup>1</sup> plus a<sup>2</sup> plus a<sup>3</sup> equals 120 patients) plus Denominator Exception (b<sup>1</sup> plus b<sup>2</sup> plus b<sup>3</sup> equals 30 patients) plus Performance Not Met (c<sup>1</sup> plus c<sup>2</sup> plus c<sup>3</sup> equals 60 patients) divided by Eligible Population/Denominator (d<sup>1</sup> plus d<sup>2</sup> plus d<sup>3</sup> equals 240 patients). All equals 210 patients divided by 240 patients. All equals 87.50 percent.

Performance Rate equals Performance Met (a<sup>1</sup> plus a<sup>2</sup> plus a<sup>3</sup> equals 120 patients) divided by Data Completeness Numerator (210 patients) minus Denominator Exception (b<sup>1</sup> plus b<sup>2</sup> plus b<sup>3</sup> equals 30 patients). All equals 120 patients divided by 180 patients. All equals 66.67 percent.

\*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient-Process

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.