

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

2018 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 performance 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 submitted **once per performance period** for patients seen during the performance period. This measure may be submitted by eligible clinicians who provide the services in the measure-specific denominator coding.

Measure Submission:

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 submissions; however, these codes may be submitted for those registries that utilize claims data.

THERE ARE THREE SUBMISSION 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 submitting this measure, determine if the patient meets denominator eligibility in order of each risk category.

DENOMINATOR (SUBMISSION 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 Exclusions should be active during the measurement period.

DENOMINATOR CRITERIA: (Eligible Cases):

Patients aged ≥ 21 years at the beginning of the measurement period

AND

Patient encounter during the performance period (CPT or HCPCS): 99201, 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

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

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 (SUBMISSION 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. Statin Medication Therapy List (NOTE: List does NOT include dosage) is included in the clinical recommendations.

Denominator Exceptions

Active Liver or Hepatic Disease or Insufficiency – The following codes are included in the Denominator Exception (G9781) 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, B17.9, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, K70.0, K70.9, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K71.0, K71.3, K71.4, K71.9, K71.10, K71.11, K71.2, K71.50, K71.51, K71.6, K71.7, K71.8, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.0, 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 – N18.6

Some patients may not be appropriate to prescribe or use statin therapy (see exceptions and exclusions below for the complete list).

"Statin intolerance is the inability to tolerate a dose of statin required to reduce a person's CV risk sufficiently from their baseline risk and could result from different statin related side effects including: muscle symptoms, headache, sleep disorders, dyspepsia, nausea, rash, alopecia, erectile dysfunction, gynecomastia, and/or arthritis" (Banach, et al., 2015).

Patients that experience symptoms such as these may prefer not to take or continue statin therapy and therefore may be exempt from the denominator.

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. 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 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 (SUBMISSION 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 Exclusions should be active during the measurement period.

DENOMINATOR CRITERIA: (Eligible Cases):

Patient aged ≥ 21 years at the beginning of the measurement period

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*, 99429*, G0438, G0439

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

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 (SUBMISSION 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.

Statin Medication Therapy List (NOTE: List does NOT include dosage) is included in the clinical recommendations.

Denominator Exceptions

Active Liver or Hepatic Disease or Insufficiency – The following codes are included in the Denominator Exception (G9781) 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, B17.9, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, B19.9, K70.0, K70.9, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K71.0, K71.3, K71.4, K71.9, K71.10, K71.11, K71.2, K71.50, K71.51, K71.6, K71.7, K71.8, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.0, 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 – N18.6

Some patients may not be appropriate to prescribe or use statin therapy (see exceptions and exclusions below for the complete list).

"Statin intolerance is the inability to tolerate a dose of statin required to reduce a person's CV risk sufficiently from their baseline risk and could result from different statin related side effects including: muscle symptoms, headache, sleep disorders, dyspepsia, nausea, rash, alopecia, erectile dysfunction, gynecomastia, and/or arthritis" (Banach, et al., 2015).

Patients that experience symptoms such as these may prefer not to take or continue statin therapy and therefore may be exempt from the denominator.

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. 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 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 (SUBMISSION 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 Exclusions should be active during the measurement period.*

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, E10.321, E10.3211, E10.3212, E10.3213, E10.3219, E10.329, E10.3291, E10.3292, E10.3293, E10.3299, E10.331, E10.3311, E10.3312, E10.3313, E10.3319, E10.339, E10.3391, E10.3392, E10.3393, E10.3399, E10.341, E10.3411, E10.3412, E10.3413, E10.3419, E10.349, E10.3491, E10.3492, E10.3493,

E10.3499, E10.351, 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, E10.359, 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, E11.321, E11.3211, E11.3212, E11.3213, E11.3219, E11.329, E11.3291, E11.3292, E11.3293, E11.3299, E11.331, E11.3311, E11.3312, E11.3313, E11.3319, E11.339, E11.3391, E11.3392, E11.3393, E11.3399, E11.341, E11.3411, E11.3412, E11.3413, E11.3419, E11.349, E11.3491, E11.3492, E11.3493, E11.3499, E11.351, 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, E11.359, 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, E13.321, E13.3211, E13.3212, E13.3213, E13.3219, E13.329, E13.3291, E13.3292, E13.3293, E13.3299, E13.331, E13.3311, E13.3312, E13.3313, E13.3319, E13.339, E13.3391, E13.3392, E13.3393, E13.3399, E13.341, E13.3411, E13.3412, E13.3413, E13.3419, E13.349, E13.3491, E13.3492, E13.3493, E13.3499, E13.351, 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, E13.359, 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): 99201, 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

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

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 (SUBMISSION 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.

Statin Medication Therapy List (NOTE: List does NOT include dosage) is included in the clinical recommendations.

Denominator Exceptions

Active Liver or Hepatic Disease or Insufficiency – The following codes are included in the Denominator Exception (G9781) 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, B17.9, B18.2, B18.8, B18.9, B19.0, B19.20, B19.21, B19.9, K70.0, K70.9, K70.10, K70.11, K70.2, K70.30, K70.31, K70.40, K70.41, K71.0, K71.3, K71.4, K71.9, K71.10, K71.11, K71.2, K71.50, K71.51, K71.6, K71.7, K71.8, K72.00, K72.01, K72.10, K72.11, K72.90, K72.91, K73.0, , K73.1, K73.2, K73.8, K73.9, K74.0, 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 – N18.6

Some patients may not be appropriate to prescribe or use statin therapy (see exceptions and exclusions below for the complete list).

"Statin intolerance is the inability to tolerate a dose of statin required to reduce a person's CV risk sufficiently from their baseline risk and could result from different statin related side effects including: muscle symptoms, headache, sleep disorders, dyspepsia, nausea, rash, alopecia, erectile dysfunction, gynecomastia, and/or arthritis" (Banach, et al., 2015).

Patients that experience symptoms such as these may prefer not to take or continue statin therapy and therefore may be exempt from the denominator.

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. 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 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 and, 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 U.S. 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 percent (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 percent 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:

1. 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)
2. 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 - Statin Medication Therapy List (NOTE: List does NOT include dosage):

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

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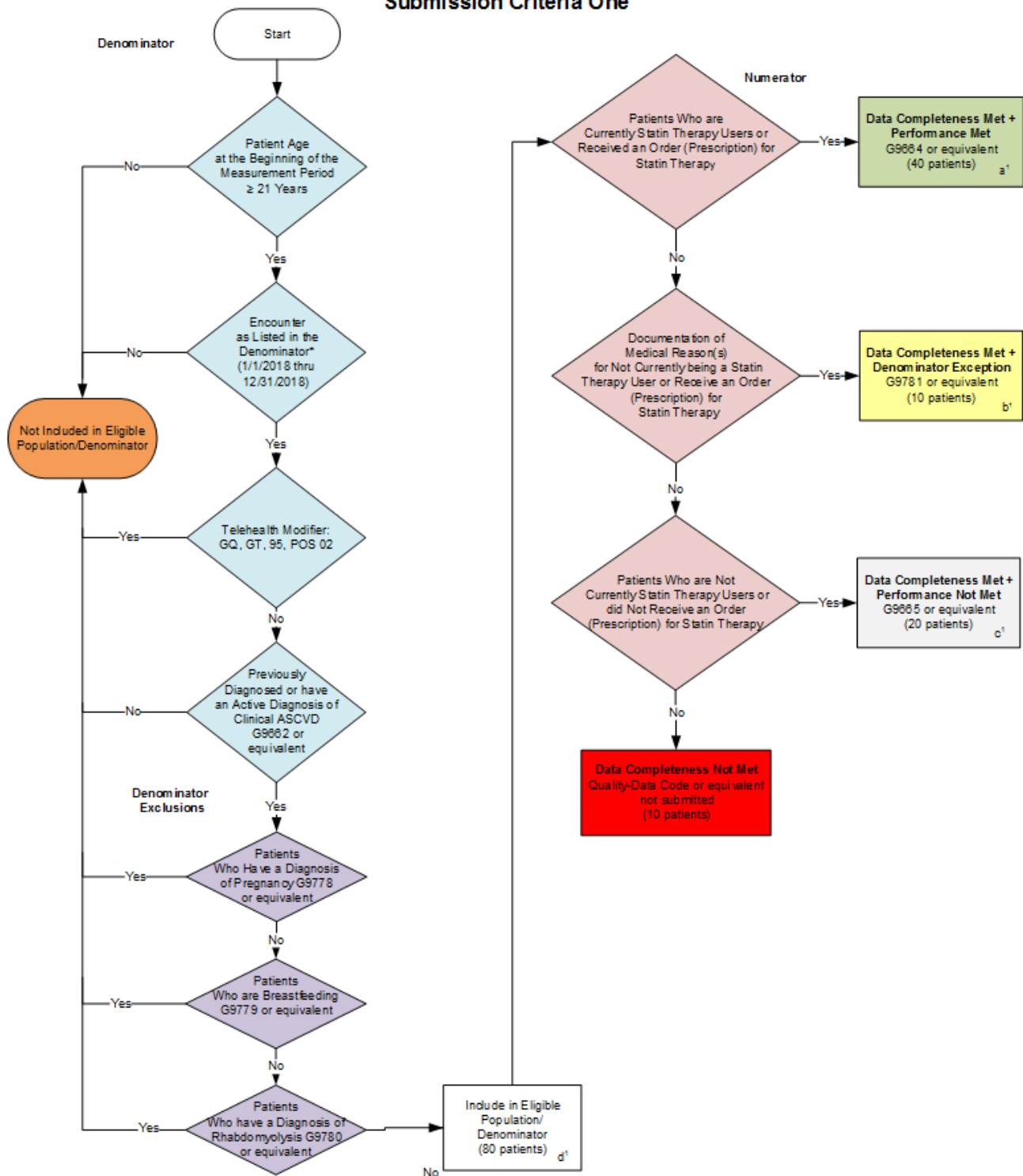
Limited proprietary coding is contained in the measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. Quality Insights, Inc. disclaims all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

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2018 Registry Flow for Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Submission Criteria One



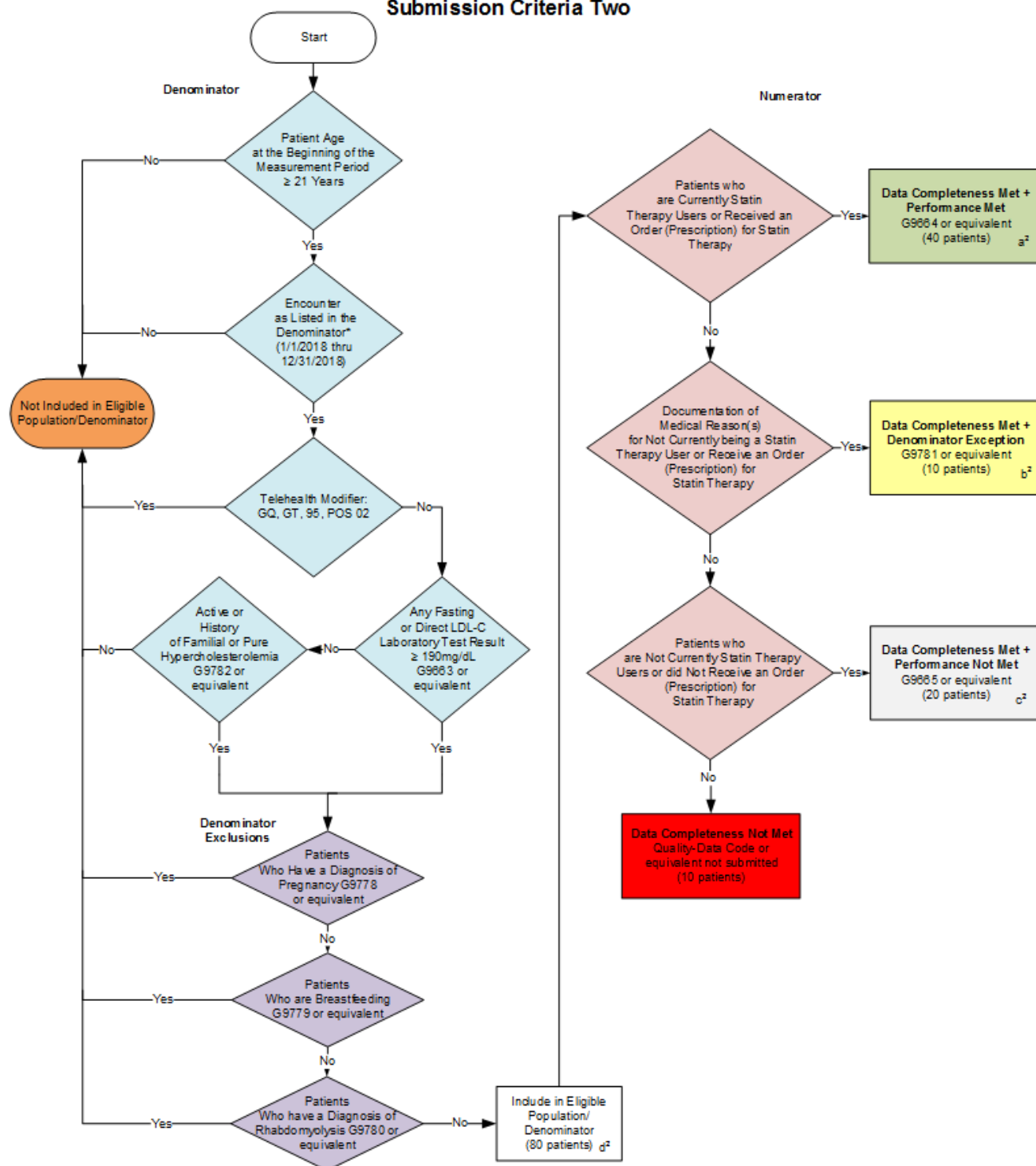
*See the posted Measure Specification for specific coding and instructions to submit this measure.

NOTE: Submission 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.

v2

2018 Registry Flow for Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Submission Criteria Two

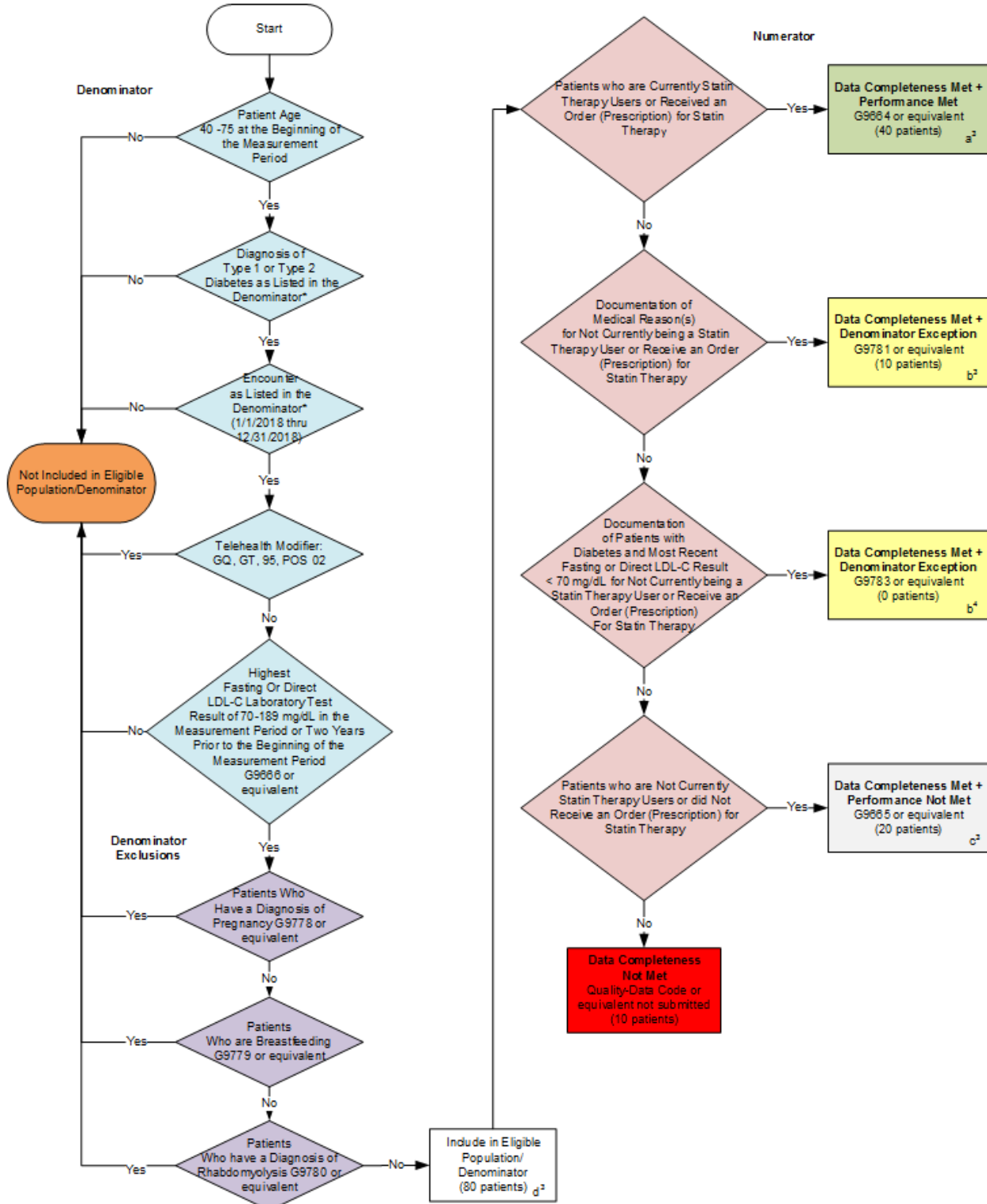


*See the posted Measure Specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Patient-Process

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**2018 Registry Flow for Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease
Submission Criteria Three**



*See the posted Measure Specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Patient Process

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2018 Registry Flow for Quality ID #438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

SAMPLE CALCULATION:

Data Completeness =

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{+a}^3\text{=120 pts)} + \text{Denominator Exception (b}^1\text{+b}^2\text{+b}^3\text{+b}^4\text{=30 pts)} + \text{Performance Not Met (c}^1\text{+c}^2\text{+c}^3\text{=60 pts)}}{\text{Eligible Population / Denominator (d}^1\text{+d}^2\text{+d}^3\text{=240 pts)}} = \frac{210 \text{ pts}}{240 \text{ pts}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{+a}^3\text{=120 pts)}}{\text{Data Completeness Numerator (210 pts) – Denominator Exception (b}^1\text{+b}^2\text{+b}^3\text{+b}^4\text{=30 pts)}} = \frac{120 \text{ pts}}{180 \text{ pts}} = 66.66\%$$

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

NOTE: Submission Frequency: Patient-process

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v2

2018 Registry Flow For Quality ID

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

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

Submission 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 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
4. Check Telehealth Modifier
 - a. If Telehealth Modifier as Listed in the Denominator equals No, proceed to check Previously Diagnosed or have an Active Diagnosis of Clinical ASCVD.
 - b. If Telehealth Modifier as Listed in the Denominator 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 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.
 - 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 40 patients in the 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 10 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.
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 20 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 submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

Submission 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.
4. Check Telehealth Modifier:
 - a. If Telehealth Modifier as listed in the Denominator equals No, proceed to check Any Fasting or Direct LDL-C Laboratory Test Result $\geq 190\text{mg/dL}$.
 - b. If Telehealth Modifier as listed in the Denominator equals Yes, do not include in Eligible Patient Population. Stop Processing.
5. Check Any Fasting or Direct LDL-C Laboratory Test Result $\geq 190\text{mg/dL}$:
 - a. If Any Fasting or Direct LDL-C Laboratory Test Result $\geq 190\text{mg/dL}$ equals No, proceed to check Active or Familial or Pure Hypercholesterolemia.
 - b. If Any Fasting or Direct LDL-C Laboratory Test Result $\geq 190\text{mg/dL}$ 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 80 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 40 patients in the 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 10 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.
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 20 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 submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

Submission 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.
5. Check Telehealth Modifier:
 - a. If Telehealth Modifier as listed in the Denominator 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 as listed in the Denominator 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 80 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 40 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 10 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 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.
- 14. Check 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:
 - 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 20 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 submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATION:

Data Completeness =

$$\frac{\text{Performance Met (a}^1+\text{a}^2+\text{a}^3=120 \text{ pts) + Denominator Exception (b}^1+\text{b}^2+\text{b}^3+\text{b}^4=30 \text{ pts) + Performance Not Met (c}^1+\text{c}^2+\text{c}^3=60 \text{ pts)}}{\text{Eligible Population / Denominator (d}^1+\text{d}^2+\text{d}^3=240 \text{ pts)}} = \frac{210 \text{ pts}}{240 \text{ pts}} = \mathbf{87.50\%}$$

Performance Rate=

$$\frac{\text{Performance Met (a}^1+\text{a}^2+\text{a}^3=120 \text{ pts)}}{\text{Data Completeness Numerator (210 pts) – Denominator Exception (b}^1+\text{b}^2+\text{b}^3+\text{b}^4=30 \text{ pts) }} = \frac{120 \text{ pts}}{180 \text{ pts}} = \mathbf{66.66\%}$$