



## 2018 CMS Web Interface

### PREV-13: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Measure Steward: CMS

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## INTRODUCTION

There are a total of 15 individual measures (including one composite consisting of two measures) included in the 2018 CMS Web Interface targeting high-cost chronic conditions, preventive care, and patient safety. The measures documents are represented individually and contain measure specific information. The corresponding coding documents are posted separately in an Excel format.

The measure documents are being provided to allow group practices and Accountable Care Organizations (ACOs) an opportunity to better understand each of the 15 individual measures included in the 2018 CMS Web Interface data submission method. Each measure document contains information necessary to submit data through the CMS Web Interface.

Narrative specifications, supporting submission documentation, and calculation flows are provided within each document. Please review all of the measure documentation in its entirety to ensure complete understanding of these measures.

## CMS WEB INTERFACE SAMPLING INFORMATION

### BENEFICIARY SAMPLING

For more information on the sampling process and methodology please refer to the 2018 CMS Web Interface Sampling Document, which will be made available during the performance year at CMS.gov.

## NARRATIVE MEASURE SPECIFICATION

### DESCRIPTION:

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

- Adults aged  $\geq 21$  years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR
- Adults aged  $\geq 21$  years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level  $\geq 190$  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

### IMPROVEMENT NOTATION:

Higher score indicates better quality.

### INITIAL POPULATION:

All patients aged 21 years and older at the beginning of the measurement period with a patient encounter during the measurement period.

### DENOMINATOR:

All patients who meet one or more of the following criteria (considered at "high risk" for cardiovascular events, under ACC/AHA guidelines):

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

### DENOMINATOR EXCLUSIONS:

Patients who have a diagnosis of pregnancy

Patients who are breastfeeding

Patients who have a diagnosis of rhabdomyolysis

### DENOMINATOR EXCEPTIONS:

Patients with adverse effect, allergy, or intolerance to statin medication

Patients with active liver disease or hepatic disease or insufficiency

Patients with end-stage renal disease (ESRD)

Patients with diabetes who have the most recent fasting or direct LDL-C laboratory test result  $< 70$  mg/dL and are not taking statin therapy

### NUMERATOR:

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

**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.

**NUMERATOR EXCLUSIONS:**

None

**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.

**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.

Some patients may not be appropriate to prescribe or use statin therapy (see exceptions and exclusions for a 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.

**GUIDANCE:**

**Denominator Guidance:** The denominator covers three distinct populations. Use the following process to prevent counting patients more than once.

**Denominator Population 1:** Patients aged  $\geq 21$  years at the beginning of the measurement period with clinical ASCVD

If YES, patient meets Denominator Population 1 risk category

If NO, screen for next risk category

**Denominator Population 2:** Patients aged  $\geq 21$  years at the beginning of the measurement period who have ever had a fasting or direct laboratory test result of LDL-C  $\geq 190$  mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia

If YES, patient meets Denominator Population 2 risk category

If NO, screen for next risk category

**Denominator Population 3:** Patients aged 40 through 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

If YES, patient meets Denominator Population 3 risk category

If NO, patient does NOT meet denominator criteria and is NOT eligible for measure inclusion

**Denominator Guidance for Encounter:**

In order for the patient to be included in the denominator, the patient must have ONE denominator-eligible visit, defined as follows:

- Outpatient encounter visit type
- Encounter performed: initial or established office visit, face-to-face interaction, preventive care services, or annual wellness visit

**LDL-C Laboratory test result options:**

The measure can be reported for all patients with a documented fasting or direct LDL-C level recorded as follows:

To meet Denominator Population 1:

There is no LDL-C result required

To meet Denominator Population 2:

If a patient has ANY previous fasting or direct laboratory result of LDL-C  $\geq$  190 mg/dL, report the highest value  $\geq$  190 mg/dL

To meet Denominator Population 3:

If a patient has more than one LDL-C result during the measurement period or during the two years before the start of the measurement period, report the highest level recorded during either time. The Denominator Exception, "Patients with diabetes who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dl and are not taking statin therapy" applies only to Denominator Population 3.

**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.

**Lifestyle modification coaching:**

A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time.

## SUBMISSION GUIDANCE

### PATIENT CONFIRMATION

Establishing patient eligibility for reporting requires the following:

- Determine if the patient's medical record can be found
  - If you can locate the medical record select "Yes"
- OR
- If you cannot locate the medical record select "No - Medical Record Not Found"
- OR
- Determine if the patient is qualified for the sample
  - If the patient is deceased, in hospice, moved out of the country or was enrolled in HMO select "Not Qualified for Sample", select the applicable reason from the provided drop-down menu, and enter the date the patient became ineligible

### **Guidance** Patient Confirmation

*If "No – Medical Record Not Found" or "Not Qualified for Sample" is selected, the patient is completed but not confirmed. The patient will be "skipped" and another patient must be reported in their place, if available. The CMS Web Interface will automatically skip any patient for whom "No – Medical Record Not Found" or "Not Qualified for Sample" is selected in all other measures into which they have been sampled.*

*If "Not Qualified for Sample" is selected and the date is unknown, you may enter the last date of the measurement period (i.e., 12/31/2018).*

*The Measurement Period is defined as January 1 – December 31, 2018.*

#### **NOTE:**

- **In Hospice:** Select this option if the patient is not qualified for sample due to being in hospice care at any time during the measurement period (this includes non-hospice patients receiving palliative goals or comfort care)
- **Moved out of Country:** Select this option if the patient is not qualified for sample because they moved out of the country any time during the measurement period
- **Deceased:** Select this option if the patient died during the measurement period
- **HMO Enrollment:** Select this option if the patient was enrolled in an HMO at any time during the measurement period (i.e., Medicare Advantage, non-Medicare HMOs, etc.)

## SUBMISSION GUIDANCE

**DENOMINATOR CONFIRMATION, RISK CATEGORY 1**

- Determine if the patient has a diagnosis of ASCVD (active or history of) at any time up through the last day of the measurement period
  - If the patient has a diagnosis of ASCVD (active or history of) documented in the patient's medical record select "Yes"
- OR
- If you are unable to confirm the diagnosis of ASCVD (active or history of) documented in the patient's medical record select "No - Diagnosis"
- OR
- If there is a denominator exclusion for patient disqualification from the measure select "[Denominator Exclusion](#)"
- OR
- If there is an "other" CMS approved reason for patient disqualification from the measure select "No- Other CMS Approved Reason"

Denominator and Denominator Exclusion codes can be found in the 2018 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

**Guidance** **Denominator**

*If "Yes" is selected, skip to Statin Use Assessment.*

*If "No - Diagnosis" is selected, continue to Risk Category 2.*

*If "Denominator Exclusion" or "No – Other CMS Approved Reason" is selected, the patient will be "skipped" and another patient must be reported in their place, if available. The patient will only be removed from the measure for which one of these options was selected, not all CMS Web Interface measures.*

*CMS Approved Reason may only be selected when approved by CMS. To request a CMS Approved Reason, you would need to provide the patient rank, measure, and reason for request in a Quality Payment Program Service Desk inquiry. A CMS decision will be provided in the resolution of the inquiry. Patients for whom a CMS Approved Reason is selected will be "skipped" and another patient must be reported in their place, if available.*

**NOTE:**

- *Denominator Exclusion should be active during the measurement period*
- *Active Diagnosis is defined as a diagnosis that is either on the patient's problem list, a diagnosis code listed on the encounter, or is documented in a progress note indicating that the patient is being treated or managed for the disease or condition during the measurement period*

## SUBMISSION GUIDANCE

**DENOMINATOR CONFIRMATION, RISK CATEGORY 2**

- Determine if the patient has ever had a fasting or direct laboratory test result of LDL-C  $\geq$  190 mg/dL OR were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia

- If the patient has ever had a fasting or direct laboratory test result of LDL-C  $\geq$  190 mg/dL documented OR were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia select "Yes"

OR

- If the patient has never had a fasting or direct laboratory test result of LDL-C  $\geq$  190 mg/dL or has never been previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia documented select "No - Diagnosis"

OR

- If there is a denominator exclusion for patient disqualification from the measure select "[Denominator Exclusion](#)"

OR

- If there is an "other" CMS approved reason for patient disqualification from the measure select "No- Other CMS Approved Reason"

Denominator and Denominator Exclusion codes can be found in the 2018 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

### **Guidance** Denominator

*If "Yes" is selected, skip to Statin Use Assessment.*

*If "No - Diagnosis" is selected, continue to Risk Category 3.*

*If "Denominator Exclusion" or "No – Other CMS Approved Reason" is selected, the patient will be "skipped" and another patient must be reported in their place, if available. The patient will only be removed from the measure for which one of these options was selected, not all CMS Web Interface measures.*

*CMS Approved Reason may only be selected when approved by CMS. To request a CMS Approved Reason, you would need to provide the patient rank, measure, and reason for request in a Quality Payment Program Service Desk inquiry. A CMS decision will be provided in the resolution of the inquiry. Patients for whom a CMS Approved Reason is selected will be "skipped" and another patient must be reported in their place, if available.*

#### **NOTES:**

- *Denominator Exclusion should be active during the measurement period*
- *If laboratory unable to calculate LDL-C value due to high triglycerides, select "No". If the test result is labeled "unreliable" and a result is provided, also select "No"*
- *Active Diagnosis is defined as a diagnosis that is either on the patient's problem list, a diagnosis code listed on the encounter, or is documented in a progress note indicating that the patient is being treated or managed for the disease or condition during the measurement period.*

## **SUBMISSION GUIDANCE**

### **DENOMINATOR CONFIRMATION, RISK CATEGORY 3**

- Determine if the patient is aged 40-75 years with Type I or Type 2 Diabetes
    - If the patient is aged 40-75 years with Type 1 or Type 2 Diabetes select "Yes"
- OR
- If the patient is not aged 40-75 years or does not have a diagnosis of Type 1 or Type 2 Diabetes select "No - Diagnosis"

Denominator codes can be found in the 2018 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

### **Guidance** Denominator

*If "Yes" is selected, continue to LDL-C.*

*If "No - Diagnosis" is selected, the patient will be "skipped" and another patient must be reported in their place, if available. The patient will only be removed from the measure for which one of these options was selected, not all CMS Web Interface measures.*

#### NOTE:

- *Diabetes diagnosis is defined as any history of diabetes, prior to or during the measurement period*

## SUBMISSION GUIDANCE

### **DENOMINATOR CONFIRMATION, RISK CATEGORY 3**

- o Determine if the patient has an LDL-C of 70-189 mg/dL during the measurement period or two years prior to the beginning of the measurement period
  - o If the patient has an LDL-C 70-189 mg/dL documented select "Yes"
- OR
- o If the patient does not have an LDL-C 70-189 mg/dL documented select "No"
- OR
- o If there is a denominator exclusion for patient disqualification from the measure select "[Denominator Exclusion](#)"
- OR
- o If there is an "other" CMS approved reason for patient disqualification from the measure select "No-Other CMS Approved Reason"

Denominator and Denominator Exclusion codes can be found in the 2018 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

### **Guidance** Denominator

*If "Yes" is selected, continue to Statin Use Assessment.*

*If "No" or "Denominator Exclusion" or "No - Other CMS Approved Reason" is selected, the patient will be "skipped" and another patient must be reported in their place, if available. The patient will only be removed from the measure for which one of these options was selected, not all CMS Web Interface measures.*

*CMS Approved Reason may only be selected when approved by CMS. To request a CMS Approved Reason, you would need to provide the patient rank, measure, and reason for request in a Quality Payment Program Service Desk inquiry. A CMS decision will be provided in the resolution of the inquiry. Patients for whom a CMS Approved Reason is selected will be "skipped" and another patient must be reported in their place, if available.*

#### NOTE:

- 
- *Denominator Exclusion* should be active during the measurement period
  - *Active Diagnosis* is defined as a diagnosis that is either on the patient's problem list, a diagnosis code listed on the encounter, or is documented in a progress note indicating that the patient is being treated or managed for the disease or condition during the measurement period
-

## SUBMISSION GUIDANCE

**NUMERATOR SUBMISSION**

- Determine if the patient was taking or prescribed statin therapy during the measurement period
  - If the patient was not taking or prescribed statin therapy select “No”
- OR
- If the patient was taking or prescribed statin therapy select “Yes”
- OR
- If the patient was not prescribed statin therapy for medical reasons select “No - [Denominator Exception](#) - Medical Reasons”

Numerator Drug, Denominator Exception and Denominator Exception Drug codes can be found in the 2018 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

**Guidance** Numerator**NOTE:**

- ***For mapping from the EHR when an accepted drug allergy is found, look for drug classification with a “Yc” (Yes-conditional) in the Drug EX column of the Denominator Exception Drug Codes tab. These drugs may be used as a Denominator Exception if present in the patient’s record accompanied by an appropriate conditional reason why the patient isn’t taking the drug (e.g. adverse effect, allergy, or intolerance to statin medication)***
- ***Documentation of not prescribed a statin for Denominator Exception - Medical Reason(s) relevant to Risk Category 3 ONLY: Patients with diabetes who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and not taking statin therapy. Other Denominator Exception – Medical Reason(s) are relevant to all Risk Categories***
  - ***Denominator Exception should be active during the measurement period***
  - ***Documentation of statin therapy prescribed or being taken during the measurement period cannot be completed during a telehealth encounter***

## DOCUMENTATION REQUIREMENTS

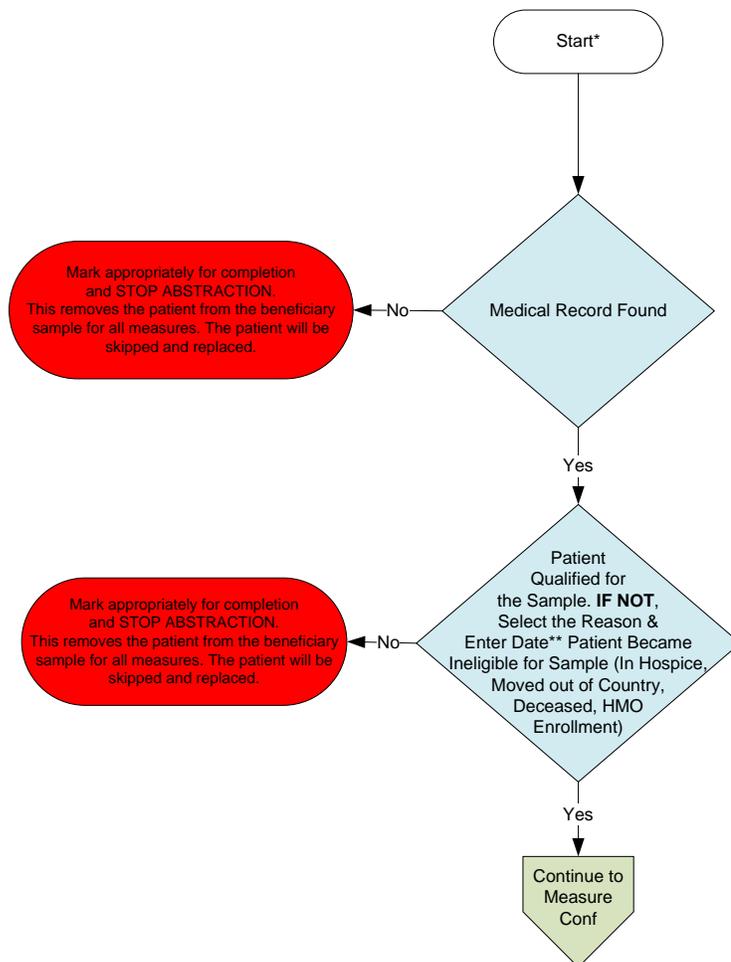
When submitting data through the CMS Web Interface, the expectation is that medical record documentation is available that supports the action reported in the CMS Web Interface i.e., medical record documentation is necessary to support the information that has been submitted.

Claims data cannot be used to confirm a diagnosis (DM, IVD, HTN, etc..) used for sampling purposes as claims are the original source of the diagnosis sampling. Claims data can be used to prepare the CMS Web Interface Excel but supporting medical record documentation will be required to substantiate what is reported in the event of an audit.

## Appendix I: Performance Calculation Flow

## Patient Confirmation Flow

For 2018, confirmation of the "Medical Record Found", or indicating the patient is "Not Qualified for Sample" with a reason of "In Hospice", "Moved out of Country", "Deceased", or "HMO Enrollment", will only need to be done **once** per patient.

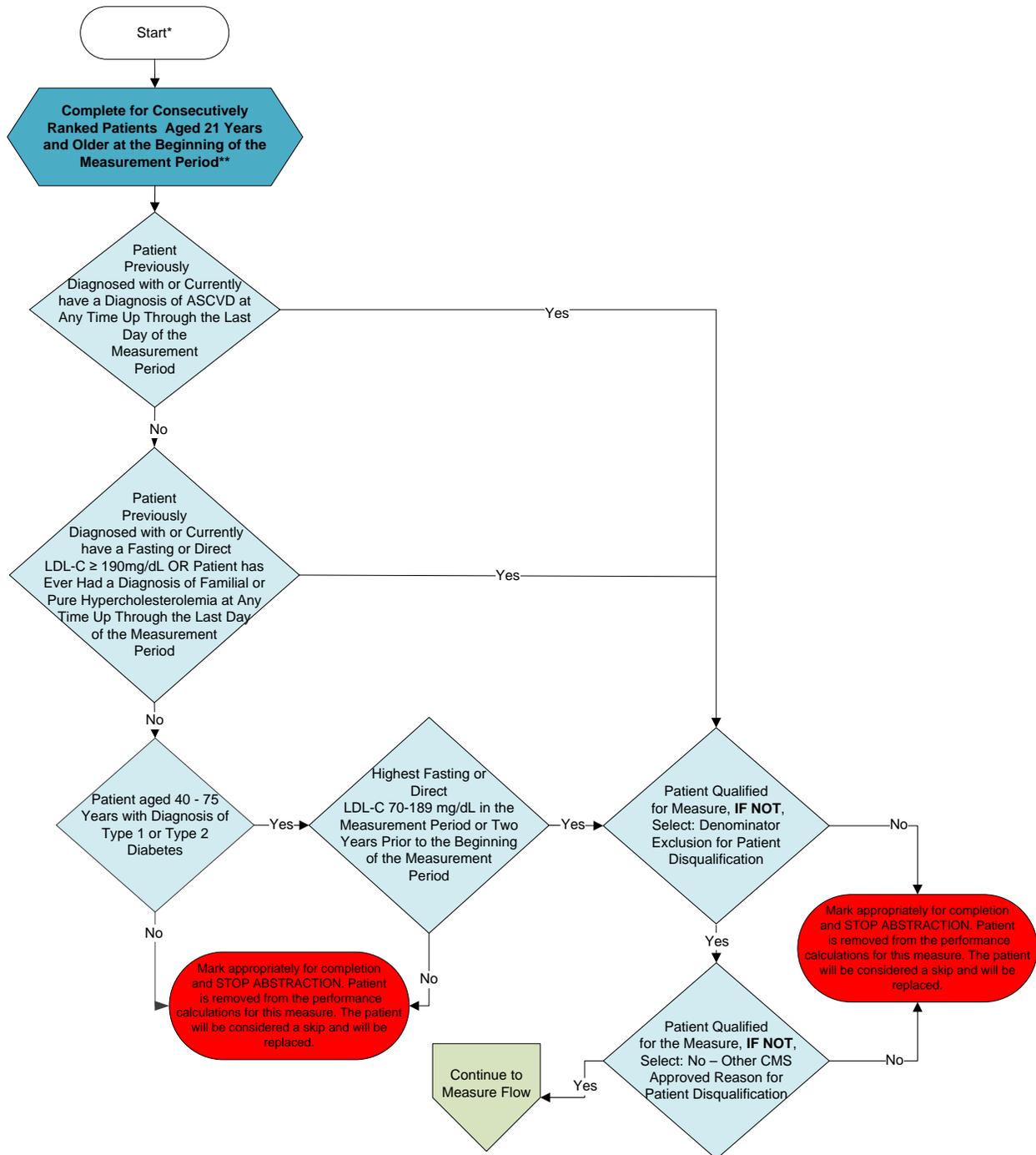


\*See the Measure Submission Document for further instructions on how to submit this measure

\*\*If date is unknown, enter 12/31/2018

## Measure Confirmation Flow for PREV-13

For 2018, measure specific reasons a patient is "Not Confirmed" or excluded for "Denominator Exclusion" or "Other CMS Approved Reason" will need to be done for each measure where the patient appears.

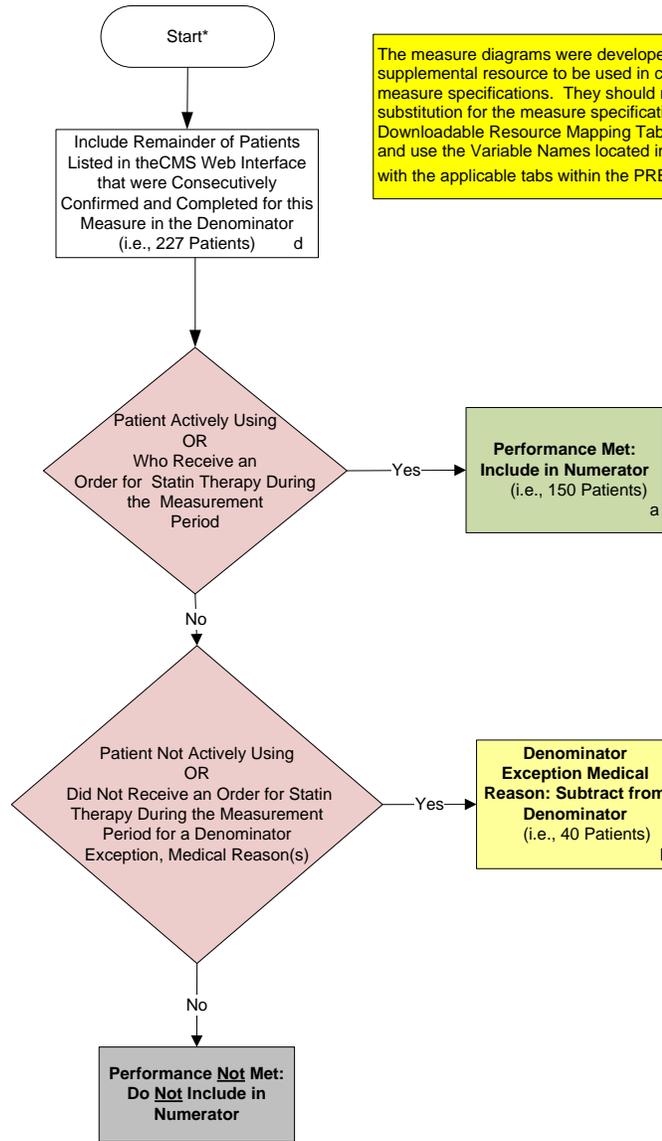


\*See the Measure Submission Document for further instructions on how to submit this measure

\*\*Further information regarding patient selection for specific disease and patient care measures can be found in the CMS Web Interface Sampling Methodology Document. For patients who have the incorrect date of birth listed, a change of the patient date of birth by the abstractor may result in the patient no longer qualifying for the PREV-13 measure. If this is the case, the system will automatically remove the patient from the measure requirements.

\*\*\*"Other CMS Approved Reason" may only be selected if you have received an approval from CMS in the resolution of a requested Quality Payment Program Service Desk Inquiry at qpp@cms.hhs.gov

### Measure Flow for PREV-13



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 as a substitution for the measure specification. For Downloadable Resource Mapping Table, go to Appendix II and use the Variable Names located in the appendix along with the applicable tabs within the PREV Coding Document.

**SAMPLE CALCULATION:**

**Performance Rate=**  

$$\frac{\text{Performance Met (a=150 Patients)}}{\text{Denominator (d=227 Patients) - Denominator Exception (b= 40 Patients) }} = \frac{150 \text{ Patients}}{187 \text{ Patients}} = 80.21\%$$

CALCULATION MAY CHANGE PENDING PERFORMANCE MET ABOVE

\*See the Measure Submission Document for further instructions on how to submit this measure

### Patient Confirmation Flow

For 2018, confirmation of the "Medical Record Found", or indicating the patient is "Not Qualified for Sample" with a reason of "In Hospice", "Moved out of Country", "Deceased", or "HMO Enrollment", will only need to be done **once** per patient. Refer to the Measure Submission Document for further instructions.

1. Start Patient Confirmation Flow.
2. Check to determine if Medical Record can be found.
  - a. If no, Medical Record not found, mark appropriately for completion and stop abstraction. This removes the patient from the beneficiary sample for all measures. The patient will be skipped and replaced. Stop processing.
  - b. If yes, Medical Record found, continue processing.
3. Check to determine if Patient Qualified for the sample.
  - a. If no, the patient does not qualify for the sample, select the reason why and enter the date (if date is unknown, enter 12/31/2018) the patient became ineligible for sample. For example; In Hospice, Moved out of Country, Deceased, HMO Enrollment. Mark appropriately for completion and stop abstraction. This removes the patient from the beneficiary sample for all measures. The patient will be skipped and replaced. Stop processing.
  - b. If yes, the patient does qualify for the sample; continue to the Measure Confirmation Flow for PREV-13.

### Measure Confirmation Flow for PREV-13

For 2018, measure specific reasons a patient is “Not Confirmed” or excluded for “Denominator Exclusion” or “Other CMS Approved Reason” will need to be done for each measure where the patient appears. Refer to the Measure Submission Document for further instructions.

1. Start Measure Confirmation Flow for PREV-13. Complete for consecutively ranked patients aged 21 years and older at the beginning of the measurement period. Further information regarding patient selection for specific disease and patient care measures can be found in the CMS Web Interface Sampling Methodology Document. For patients who have the incorrect date of birth listed, a change of the patient date of birth by the abstractor may result in the patient no longer qualifying for the PREV-13 measure. If this is the case, the system will automatically remove the patient from the measure requirements.
2. Check to determine if the patient has a diagnosis of ASCVD (active or history of) at any time up through the last day of the measurement period.
  - a. If no, the patient does not have a diagnosis of ASCVD (active or history of) at any time up through the last day of the measurement period, continue processing.
  - b. If yes, the patient does have a diagnosis of ASCVD (active or history of) at any time up through the last day of the measurement period, continue processing and proceed to step 6.
3. Check to determine if the patient has ever had a fasting or direct LDL-C greater than or equal to 190 mg/dL OR has ever had a diagnosis of familial or pure hypercholesterolemia (active or history of) at any time up through the last day of the measurement period.
  - a. If no, the patient has not ever had a fasting or direct LDL-C greater than or equal to 190 mg/dL OR has ever had a diagnosis of familial or pure hypercholesterolemia (active or history of) at any time up through the last day of the measurement period, continue processing.
  - b. If yes, the patient has ever had a fasting or direct LDL-C greater than or equal to 190 mg/dL OR has ever had a diagnosis of familial or pure hypercholesterolemia (active or history of) at any time up through the last day of the measurement period, continue processing and proceed to step 6.
4. Check to determine if the patient is aged 40-75 years with a diagnosis of Type 1 or Type 2 diabetes.
  - a. If no, the patient is not aged 40-75 years or does not have a diagnosis of Type 1 or Type 2 diabetes, mark appropriately for completion and stop abstraction. Patient is removed from the performance calculations for this measure. The patient will be skipped and replaced. Stop processing.
  - b. If yes, the patient is aged 40-75 years with a diagnosis of Type 1 or Type 2 diabetes, continue processing.
5. Check to determine if highest fasting or direct LDL-C is 70-189 mg/dL in the measurement period or two years prior to the beginning of the measurement period.
  - a. If no, the highest fasting or direct LDL-C is not 70-189 mg/dL in the measurement period or two years prior to the beginning of the measurement period, mark appropriately for completion and stop abstraction. Patient is removed from the performance calculations for this measure. The patient will be skipped and replaced. Stop processing.
  - b. If yes, the highest fasting or direct LDL-C is 70-189 mg/dL in the measurement period or two years prior to the beginning of the measurement period, continue processing.
6. Check to determine if the patient qualifies for the measure (Denominator Exclusion).
  - a. If no, the patient does not qualify for the measure select: Denominator Exclusion for patient disqualification. Mark appropriately for completion and stop abstraction. Patient is removed from

the performance calculations for this measure. The patient will be skipped and replaced. Stop processing.

- b. If yes, the patient does qualify for the measure, continue processing.
7. Check to determine if the patient qualifies for the measure (Other CMS Approved Reason).
    - a. If no, the patient does not qualify for the measure select: No – Other CMS Approved Reason for patient disqualification. Mark appropriately for completion and stop abstraction. Patient is removed from the performance calculations for this measure. The patient will be skipped and replaced. “Other CMS Approved Reason” may only be selected if you have received an approval from CMS in the resolution of a requested Quality Payment Program Service Desk Inquiry at [QPP@cms.hhs.gov](mailto:QPP@cms.hhs.gov) . Stop processing.
    - b. If yes, the patient does qualify for the measure, continue to the PREV-13 measure flow.

### Measure Flow for PREV-13

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 as a substitution for the measure specifications. For Downloadable Resource Mapping Table, go to Appendix II and use the Variable Names located in the appendix along with the applicable tabs within the PREV Coding Document.

1. Start processing 2018 PREV-13 Flow for the patients that qualified for the sample in the Patient Confirmation Flow and the Measure Confirmation Flow for PREV-13. Note: Include remainder of patients listed in the CMS Web Interface that were consecutively confirmed and completed for this measure in the denominator. For the sample calculation in the flow these patients would fall into the 'd' category (eligible denominator, i.e. 227 patients).
2. Check to determine if the patient is actively using OR received an order for statin therapy during the measurement period.
  - a. If no, the patient is not actively using OR did not receive an order for statin therapy during the measurement period, continue processing.
  - b. If yes, the patient is actively using OR received an order for statin therapy during the measurement period, performance is met and the patient will be included in the numerator. For the sample calculation in the flow these patients would fall into the 'a' category (numerator, i.e. 150 patients). Stop processing.
3. Check to determine if the patient is Not actively using OR did Not receive an order for statin therapy during the measurement period for a denominator exception, medical reason(s).
  - a. If no, the patient is Not actively using OR did Not receive an order for statin therapy during the measurement period for a denominator exception, medical reason(s), performance is not met and the patient should not be included in the numerator. Stop processing.
  - b. If yes, the patient is Not actively using OR did Not receive an order for statin therapy during the measurement period for a denominator exception, medical reason(s), this is a denominator exception and the case should be subtracted from the denominator. For the sample calculation in the flow these patients would fall into the 'b' category (denominator exception, i.e. 40 patients). Stop processing.

#### Sample Calculation

Performance Rate Equals

Performance Met is category 'a' in the measure flow (150 patients)

Denominator is category 'd' in the measure flow (227 patients)

Denominator Exception is category 'b' in the measure flow (40 patients)

150 (Performance Met) divided by 187 (Denominator minus Denominator Exception) equals a performance rate of 80.21 percent

Calculation May Change Pending Performance Met

## Appendix II: Downloadable Resource Mapping Table

Each data element within this measure's denominator or numerator is defined as a pre-determined set of clinical codes. These codes can be found in the 2018 CMS Web Interface PREV Coding Document.

## \*PREV-13: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Measure Component/Excel Tab	Data Element	Variable Name	Coding System(s)
Denominator/Denominator Codes	ASCVD Diagnosis	ANGINA_CODE	I9 I10 SNM
		ATHERO_PAD_CODE	I9 I10 SNM
		CABG_CODE	I9 I10 SNM
		CAROTID_CODE	I9 I10 SNM
		IHD-CODE	I9 I10 SNM
		MI_CODE	I9 I10 SNM
		PCI_CODE	I10 SNM
		STROKE_TIA_CODE	I9 I10 SNM
	LDL-C $\geq$ 190 <u>OR</u> Hypercholesterolemia	LDL_CODE	LN <u>WITH</u> value $\geq$ 190
		HYPERCHOL_CODE	I9 I10 SNM
	Diabetes <u>AND</u> aged 40-75 <u>AND</u> LDL-C 70-189	DIABETES_DX_CODE	I9 I10 SNM <u>AND</u> Aged 40-75
		LDL_CODE	LN <u>WITH</u> value 70-189
	Denominator Exclusion/ Denominator Exclusion Codes	Exclusion	BREASTFEEDING_CODE
PREGNANCY_CODE			I10 SNM
RHABDOMYOLYSIS_CODE			I10 SNM

Numerator/Numerator Drug Codes	Statin Therapy	STATIN_DRUG_CODE	RxNorm (Drug EX=N)
Denominator Exception/ Denominator Exception Codes/Denominator Exception Drug Codes	Medical Reason	ESRD_CODE	I9 I10 SNM
		HEPATITIS_A_CODE	I10 SNM
		HEPATITIS_B_CODE	I10 SNM
		LIVER_DISEASE_CODE	I9 I10 SNM
		STATIN_ALLERGEN_CODE	RxNorm (Drug EX=Yc) <u>AND</u> documented reason for not receiving statin therapy
		Exclude patients from <b>Risk Category 3</b> with: Diabetes <u>AND</u> Most recent LDL-C < 70 mg/dL <u>AND</u> Not taking statin therapy	No coding provided

\*For EHR mapping, PREV-13 coding is considered all-inclusive.

## Appendix III: Measure Rationale and Clinical Recommendation Statements

### 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  $\geq$  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)

- 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  $\geq 21$  Years of Age With LDL-C  $\geq 190$  mg/dL:

- Adults  $\geq 21$  years of age with primary LDL-C  $\geq 190$  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.

**Statin Medication Therapy List**

Generic Name	Brand or Trade Name	Medication Type, If Applicable
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 Calcium	Caduet	Combination
Ezetimibe/Simvastatin	Vytorin	Combination

NOTE: List does NOT include dosage

## Appendix IV: Use Notices, Copyrights, and Disclaimers

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