



2020 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 10 individual measures included in the 2020 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 organizations an opportunity to better understand each of the 10 individual measures included in the 2020 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 2020 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 ≥ 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

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 ≥ 21 years at the beginning of the measurement period with clinical ASCVD diagnosis
- 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
- 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 (only applies to denominator 3)

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. Denominator Exceptions should be active during the measurement period.

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, p. 2).

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. There is only one performance rate calculated for this measure. Use the following process to prevent counting patients more than once.

Denominator Population 1: Patients aged ≥ 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 ≥ 21 years at the beginning of the measurement period who have ever had a fasting or direct laboratory test result of LDL-C ≥ 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. 2014) 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 submission 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 did not have Fee-for-Service (FFS) Medicare as their primary payer 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., 12/31/2020).

The Measurement Period is defined as January 1 – December 31, 2020.

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
 - **Non-FFS Medicare:** Select this option if the patient was enrolled in Non-FFS Medicare at any time during the measurement period (i.e., commercial payers, Medicare Advantage, Non-FFS Medicare, HMOs, etc.) This exclusion is intended to remove beneficiaries for whom Fee-for-Service Medicare is not the primary payer.
-

SUBMISSION GUIDANCE

DENOMINATOR CONFIRMATION, POPULATION 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 2020 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.

***Other CMS Approved Reason** is reserved for unique cases that are not covered by any of the above stated skip reasons. To gain CMS approval, submit a skip request by selecting Request Other CMS Approved Reason in the patient qualification question for the measure. Note that skip requests can only be submitted manually through the CMS Web Interface.*

To submit a skip request, follow these steps:

- 1. After confirming the beneficiary for the sample, scroll to the measure you would like to skip.*
- 2. When confirming if the beneficiary is qualified for the measure, select Request Other CMS Approved Reason.*
- 3. In the skip request modal, review the organization you are reporting for and provide the submitter's email address. CMS uses this email to send status updates and/or reach out if further information is needed to resolve the skip request. You also need to provide specific information about the beneficiary's condition and why it disqualifies the beneficiary from this measure. Never include Personally Identifiable Information (PII) or Protected Health Information (PHI) in the case.*

Beneficiaries remain incomplete until CMS resolves the skip request. The CMS Web Interface automatically updates the resolution of a skip request, either approved or denied. Beneficiaries for whom a CMS Approved Reason is approved are marked as Skipped and another beneficiary 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 description 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, POPULATION 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 2020 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.

Other CMS Approved Reason is reserved for unique cases that are not covered by any of the above stated skip reasons. To gain CMS approval, submit a skip request by selecting Request Other CMS Approved Reason in the patient qualification question for the measure. Note that skip requests can only be submitted manually through the CMS Web Interface.

To submit a skip request, follow these steps:

1. After confirming the beneficiary for the sample, scroll to the measure you would like to skip.
2. When confirming if the beneficiary is qualified for the measure, select Request Other CMS Approved Reason.
3. In the skip request modal, review the organization you are reporting for and provide the submitter's email address. CMS uses this email to send status updates and/or reach out if further information is needed to resolve the skip request. You also need to provide specific information about the beneficiary's condition and why it disqualifies the beneficiary from this measure. Never include Personally Identifiable Information (PII) or Protected Health Information (PHI) in the case.

Beneficiaries remain incomplete until CMS resolves the skip request. The CMS Web Interface automatically updates the resolution of a skip request, either approved or denied. Beneficiaries for whom a CMS Approved Reason is approved are marked as Skipped and another beneficiary must be reported in their place, if available.

NOTE:

- **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"
- **Previous or active Diagnosis of Familial or Pure Hypercholesterolemia** - For the purposes of the measure, a previous or current diagnosis of familial or pure hypercholesterolemia would be acceptable to satisfy the criteria in Denominator Population 2. However, in the absence of an official diagnosis, if the patient has an elevated cholesterol (i.e., LDL-C level \geq 190 mg/dl) – either historical or current – this would also satisfy the intent of the denominator eligibility criteria for Denominator Population 2.
- **Active Diagnosis** is defined as a diagnosis that is either on the patient's problem list, a diagnosis code description 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, POPULATION 3

- Determine if the patient is aged 40-75 years with Type 1 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 2020 CMS Web Interface PREV Coding Document. The Downloadable Resource Mapping Table can be located in Appendix II of this document.

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

If "No – Diagnosis or Not Aged 40-75 years" 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, POPULATION 3**

- 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
 - If the patient has an LDL-C 70-189 mg/dL documented select “Yes”
- OR**
- If the patient does not have an LDL-C 70-189 mg/dL documented select “No”
- 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 2020 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.

***Other CMS Approved Reason** is reserved for unique cases that are not covered by any of the above stated skip reasons. To gain CMS approval, submit a skip request by selecting Request Other CMS Approved Reason in the patient qualification question for the measure. Note that skip requests can only be submitted manually through the CMS Web Interface.*

To submit a skip request, follow these steps:

1. *After confirming the beneficiary for the sample, scroll to the measure you would like to skip.*
2. *When confirming if the beneficiary is qualified for the measure, select Request Other CMS Approved Reason.*
3. *In the skip request modal, review the organization you are reporting for and provide the submitter's email address. CMS uses this email to send status updates and/or reach out if further information is needed to resolve the skip request. You also need to provide specific information about the beneficiary's condition and why it disqualifies the beneficiary from this measure. Never include Personally Identifiable Information (PII) or Protected Health Information (PHI) in the case.*

Beneficiaries remain incomplete until CMS resolves the skip request. The CMS Web Interface automatically updates the resolution of a skip request, either approved or denied. Beneficiaries for whom a CMS Approved Reason is approved are marked as Skipped and another beneficiary 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 taking or prescribed statin therapy select “Yes”
- OR**
- If the patient was not taking or prescribed statin therapy select “No”
- 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 2020 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 Population 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**
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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.

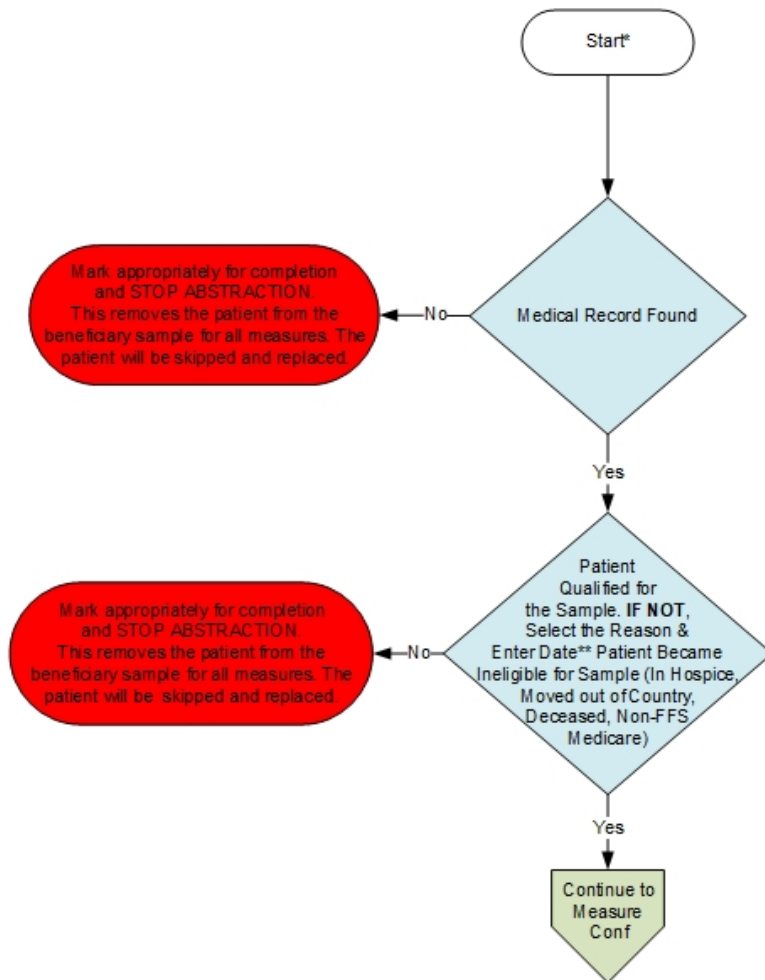
Claims data cannot be used to confirm a diagnosis (DM, HTN, etc..) used for sampling purposes as claims are the original source of the diagnosis sampling. Claims data can be used to prepare the CMS Web Interface Excel but supporting medical record documentation will be required to substantiate what is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

Appendix I: Performance Calculation Flow

Disclaimer: Refer to the measure submission document for specific coding and instructions to submit this measure.

Patient Confirmation Flow

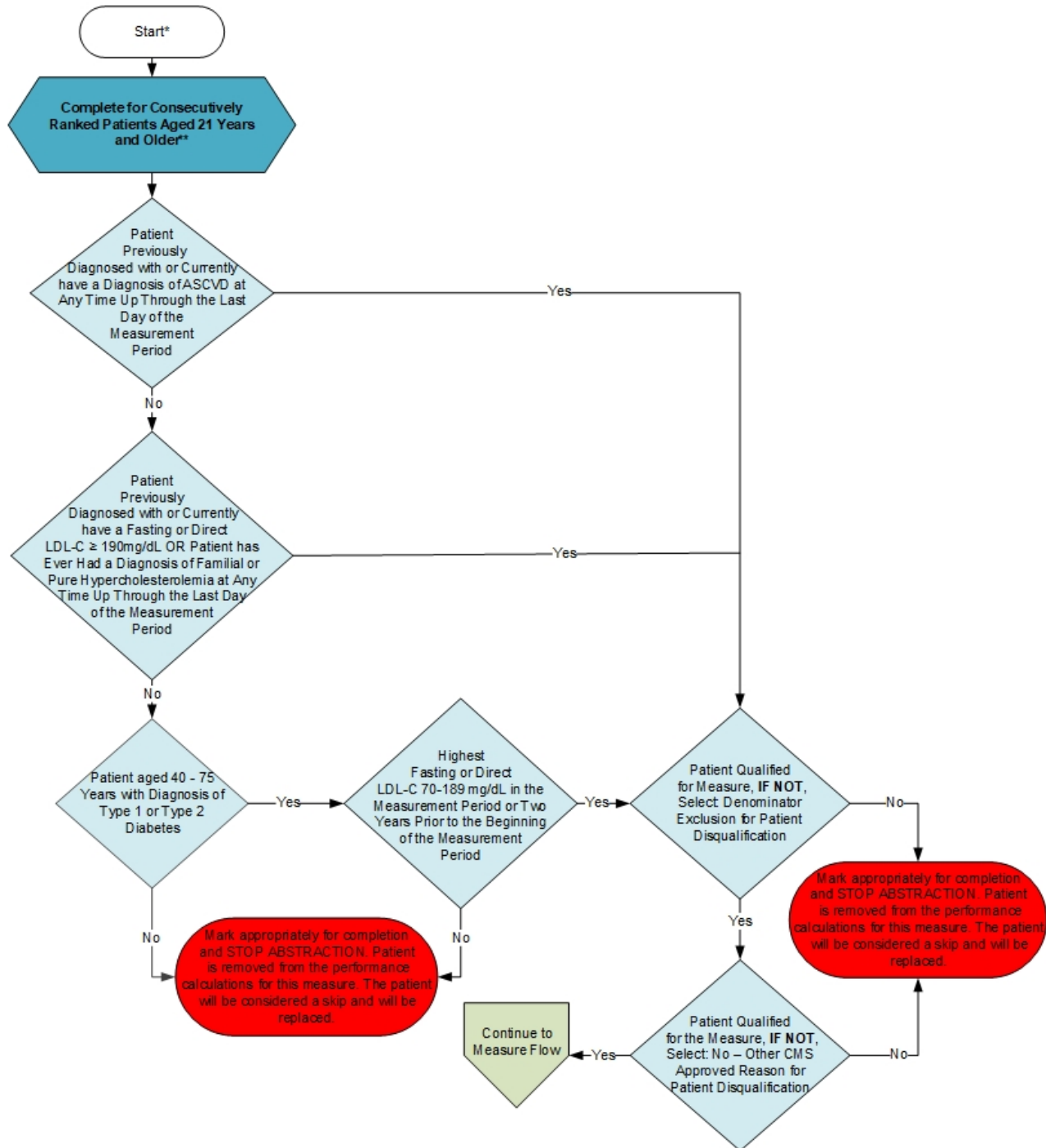
For 2020, confirmation of the "Medical Record Found", or indicating the patient is "Not Qualified for Sample" with a reason of "In Hospice", "Moved out of Country", "Deceased", or "Non-FFS Medicare", will only need to be done **once** per patient.



*See the posted measure submission document for specific coding and instructions to submit this measure.
 **If date is unknown, enter 12/31/2020

Measure Confirmation Flow for PREV-13

For 2020, 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.

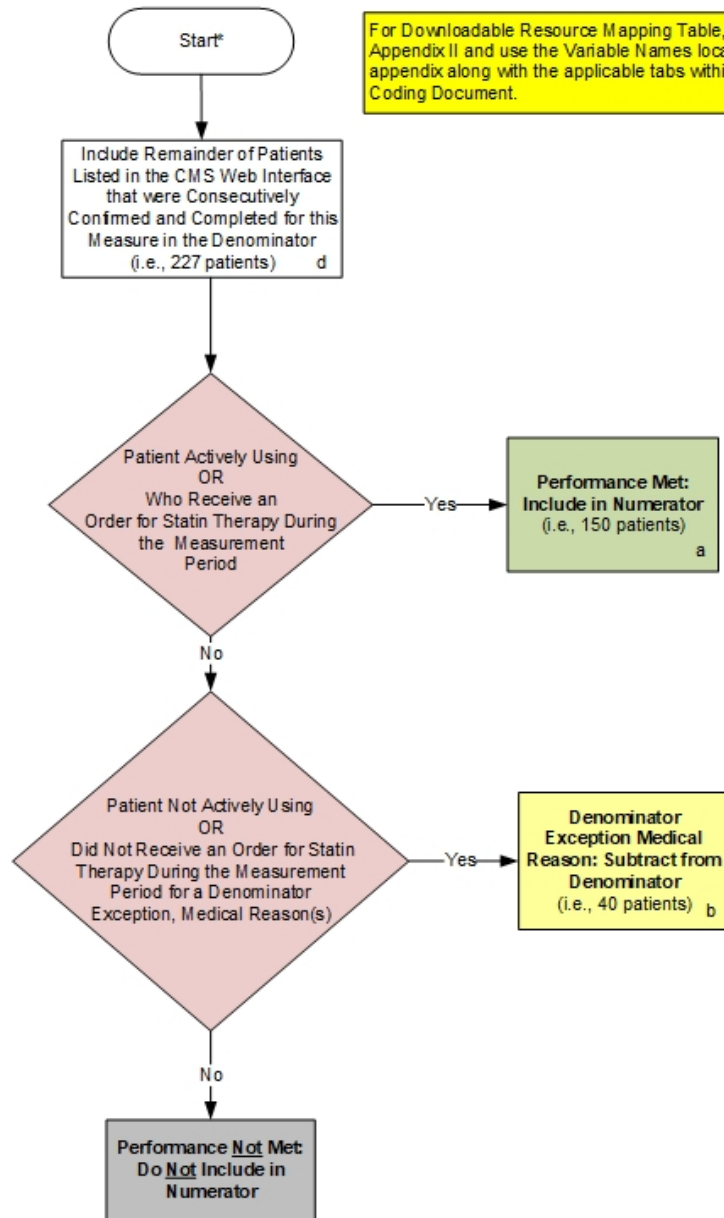


*See the posted measure submission document for specific coding and instructions to submit this measure.

**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 the CMS Web Interface updated the resolution of the skip request to be "Approved".

Measure Flow for PREV-13



SAMPLE CALCULATION:

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

CALCULATION MAY CHANGE PENDING PERFORMANCE MET ABOVE

*See the posted measure submission document for specific coding and instructions to submit this measure.

Patient Confirmation Flow

For 2020, 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 “Non-FFS Medicare”, will only need to be done **once** per patient.

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 12/31/2020) the patient became ineligible for sample. For example; In Hospice, Moved out of Country, Deceased, Non-FFS Medicare. 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 2020, 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. 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.

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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 the CMS Web Interface updated the resolution of the skip request to be “Approved”. Stop processing.
 - b. If yes, the patient does qualify for the measure, continue to the PREV-13 measure flow.

Measure Flow for PREV-13

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 2020 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:

$$\begin{array}{l} \text{Performance Rate=} \\ \text{Performance Met (a=150 patients)} \\ \text{Denominator (d=227 patients) - Denominator Exception (b=40 patients)} \end{array} = \frac{150 \text{ patients}}{187 \text{ patients}} = 80.21\%$$

CALCULATION MAY CHANGE PENDING PERFORMANCE MET ABOVE

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 2020 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
	ASCVD Diagnosis	ATHERO_PAD_CODE	I9 I10 SNM
	ASCVD Diagnosis	CABG_CODE	I9 I10 SNM
	ASCVD Diagnosis	CAROTID_CODE	I9 I10 SNM
	ASCVD Diagnosis	IHD-CODE	I9 I10 SNM
	ASCVD Diagnosis	MI_CODE	I9 I10 SNM
	ASCVD Diagnosis	PCI_CODE	I10 SNM
	ASCVD Diagnosis	STROKE_TIA_CODE	I9 I10 SNM
	LDL-C ≥ 190 <u>OR</u> Hypercholesterolemia	LDL_CODE	LN <u>WITH</u> value ≥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	I10 SNM
	Exclusion	PREGNANCY_CODE	I10 SNM
	Exclusion	RHABDOMYOLYSIS_CODE	I10

Measure Component/Excel Tab	Data Element	Variable Name	Coding System(s)
			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
	Medical Reason	HEPATITIS_A_CODE	I10 SNM
	Medical Reason	HEPATITIS_B_CODE	I10 SNM
	Medical Reason	LIVER_DISEASE_CODE	I9 I10 SNM
	Medical Reason	STATIN_ALLERGEN_CODE	RxNorm (Drug EX=Yc) <u>AND</u> documented reason for not receiving statin therapy
	Medical Reason	Exclude patients from Risk Category 3 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 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 2013, guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults were published (see Stone et al., 2014). 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., 2014).

One study that surveyed 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). 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. However, 1 in 10 people who try taking a statin will report some kind of intolerance, most commonly muscle aches. Other known low risk circumstances of statin intolerance includes side effects such as myopathy, cognitive dysfunction, increased hepatic transaminase levels, and new onset diabetes. Statin intolerance usually does not involve substantial risk for mortality or permanent disability (Guyton et al., 2014). 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 electronic clinical quality measure is intended to align with the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol (Stone et al. 2014), 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 \leq 75 years of age who have clinical ASCVD, unless contraindicated. (*Level of Evidence A*), (Stone et al., 2014)

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*), (Stone et al., 2014)

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*), (Stone et al., 2014)

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*), (Stone et al., 2014)

Intensity of statin therapy in primary and secondary prevention:

The expert panel of the 2013 ACC/AHA Guidelines (Stone et al., 2014) 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 (NOTE: List does NOT include dosage):

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	Caduet	Combination
Ezetimibe/Simvastatin	Vytorin	Combination

Appendix IV: Use Notices, Copyrights, and Disclaimers

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