

# Implementation Guide

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## Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Electronic Clinical Quality Measure

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- Quality Insights of Pennsylvania
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team

## Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published <i>Implementation Guide</i> (Version 1)	
October 2019	Updated the <i>Implementation Guide</i> based on annual artifact updates (Version 2)	Updated the <i>Implementation Guide's</i> Introduction and Background content, revised the flow of the content to enhance readability, updated the evidence source, added evidence specifications and a semistructured representation of the artifact to Appendix A, and updated a small portion of the decision log.

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# Introduction

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices identified by peers that they must incorporate into daily practice. Transforming these large volumes of research into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own. The CDS Connect project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), provides an opportunity for healthcare organizations to share evidence-based knowledge expressed as clinical decision support (CDS), enabling other organizations to leverage the publicly available expressions. The ability to share CDS expressions enhances efficiency by removing the need for subsequent organizations to start CDS development from “scratch.” It also contributes to a learning health community where CDS developers and implementers collaborate and enhance the shared resources.

Each year, the CDS Connect team develops CDS artifacts (i.e., CDS logic expressions), implements one or more of the CDS artifacts in a live clinical setting, and contributes the body of work to the CDS Connect Repository to: 1) demonstrate CDS Connect infrastructure, 2) ensure that the artifact performs as expected, and 3) share lessons learned for future implementers of the CDS logic. CDS artifacts that were developed by the CDS Connect project team but not implemented in a clinical setting are clearly marked as such in the CDS Connect Repository. These artifacts contain resources that are meant to be shareable and interoperable so that implementers have a head start when developing CDS in this domain. Furthermore, CDS Connect artifacts are not “standalone” and are not intended to be completely plug-and-play (i.e., healthcare systems will need to integrate each artifact with components of their health information technology [IT] system for the artifact to work). Implementers should conduct extensive testing, including clinical testing in real-life workflows, of all artifacts. It is expected that artifacts will be customized and adapted to local clinical and IT environments.

This *Implementation Guide* provides information and guidance to individuals who are considering using this artifact. The main intent of this document is twofold: 1) to provide insight on how the logic can be used to improve patient care and 2) to provide information on how to integrate the CDS logic with a health IT system.

## Background

To facilitate AHRQ’s vision, the CDS Connect project team created 1) the CDS Connect Repository to host and share CDS artifacts; 2) the CDS Authoring Tool, which enables CDS developers to create CDS logic using Clinical Quality Language (CQL), a Health Level 7 (HL7) standard expression language; and 3) several open-source prototype tools to facilitate creating, testing, sharing, integrating, and implementing evidence-based, interoperable CDS in health IT systems. The use of CQL in CDS Connect systems and CDS development is notable because it

provides the ability to express logic that is human readable yet structured enough to process a query electronically. Furthermore, CQL is an interoperable format that eases integration with health IT systems.<sup>1</sup> CQL allows logic to be shared between CDS artifacts, and eventually with electronic clinical quality measures (eCQMs), in support of improving healthcare quality.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with over three dozen metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher and sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made while creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface for creating standards-based CDS logic using simple forms. The logic developed by the tool is expressed using HL7 Fast Healthcare Interoperability Resources (FHIR) and CQL. It empowers organizations that have limited access to software engineers with the ability to express evidence-based guidelines as accurate, tested, coded logic. Individuals who are interested in developing CDS logic expressions similar to this artifact can use the tool to develop new CDS logic in the clinical domain of their choice. The interoperable format of the logic facilitates sharing and integration with a wide range of health IT systems.

The CDS Connect team also developed several prototype tools, including one that facilitates CQL testing (CQL Testing Framework) and one that facilitates integration of the CQL code with a health IT system (CQL Services). The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. This framework allows CQL developers to identify bugs in the CDS logic early in the development cycle, when it is less costly to fix. In addition, these test cases enable developers to demonstrate the expected behavior of the CDS logic to bolster trust in the coded expressions. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to this artifact's CQL. CQL Services is an open-source service framework for exposing CQL-based logic using the HL7 CDS Hooks application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively. See the "Integration with Health Information Technology" section of this guide for how CQL Services was used for the pilot implementation of this artifact, and the 2019 *Pilot Report* for detailed findings and lessons learned related to the use of CQL Services to pilot this artifact.

## **Scope, Purpose, and Audience of This Implementation Guide**

This document provides information about the development and implementation of the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) eCQM artifact, referred to as the "*Statin Use eCQM*" artifact in this document. Various audiences may find this information helpful, including:

1. **Clinicians and Quality Leaders** at healthcare organizations and primary care practices who wish to implement, test, and execute CDS related to this topic in their health IT tools
2. **Healthcare Systems** interested in promoting patient experience beyond traditional brick-and-mortar care to facilitate patient engagement and a patient's ability to manage their health, while enabling value-based care and quality
3. **Employers and Payers** who want to manage their cost and quality through patient-facing CDS and health management tools
4. **CDS Developers and Informaticists** who may use components of this CDS logic as a foundation for other preventive health CDS, or who want to use well-developed structured logic and CQL in their own work
5. **Organizations or Individuals** interested in developing their own patient-facing CDS artifacts, who may find this document helpful as a resource for the process by which clinical guidelines are translated into mature CQL artifacts

## Implementing and Using This Artifact

### Artifact Description

This artifact provides statin therapy recommendations for primary and secondary prevention of CVD for patients considered to be at high risk of cardiovascular events. It is a CDS logic representation of clinical guidance expressed in a CMS eCQM, (i.e., CMS measure identification (ID) CMS347v3, “Statin Therapy for the Prevention and Treatment of Cardiovascular Disease”)<sup>2</sup> which is in part based on 2013 Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Disease (ASCVD) Risk in Adults from the American College of Cardiology (ACC) and the American Heart Association (AHA).<sup>3</sup>

### Preventive Health Scenarios Supported by This Artifact

This artifact transforms the eCQM into clinical decision support by presenting it as a screening artifact. It checks a patient's record to see if they meet the denominator criteria for any of the subgroups; if they do, are not excluded or excepted, and are not already on a statin, the clinician is presented with a recommendation to consider ordering a statin drug. Thus, the CDS encourages compliance with the eCQM. However, the CDS diverges from a component of the eCQM logic in one key aspect; the eCQM provides reasonable exclusions and exceptions for withholding a statin in unique patient cases, but a patient may not *need* to be excepted from statin therapy if the case is mild or resolved (e.g., resolved hepatitis A, mild liver disease that does not cause cirrhosis). Decisions made during artifact development to transform eCQM logic into CDS logic are highlighted in the [Guideline Translation Summary](#) section of this document and detailed in [Appendix A](#).

In the clinical scenarios listed below, the decision logic and recommendations are expressed as an Event-Condition-Action alert (a common alert, reacting to a specific event). Note, each scenario is populated with a fictitious patient name and health data to provide context to the scenario.

- 1. Any time a patient's record is opened by a clinician's direct action**
  - a. Dr. Alfa is going through the records of his patients to be seen this afternoon, and is currently reviewing the record of Ms. Bravo, a scheduled patient. When the record is opened in the electronic health record (EHR), the CDS logic described herein executes to determine whether to recommend that Ms. Bravo begin taking statins. The relevant recommendations could appear immediately in a box on the EHR screen for the clinician's review and action or could be posted to a "to-do" list visible in the patient's record.
- 2. As automatic surveillance prior to the start of a clinician encounter** (particularly in a primary care, cardiology, geriatric, or internal medicine practice)
  - a. Ms. Bravo arrives for a scheduled appointment and is registered into the encounter. This registration automatically triggers the CDS logic of this artifact. Recommendations are made available as a message to the clinician's Inbox or a "to-do" item in the patient's record.
- 3. As automatic surveillance run at a fixed time the night before the practice opens each day**
  - a. Dr. Charlie's practice automatically runs a review each evening on all patients to be seen the following day. This review sets up face-sheets and requests charts for the intake personnel to use the next day. As part of this review, the computer scans each patient for a number of health maintenance gaps, including using this CDS artifact to check for appropriate use of statins. When the CDS logic determines that a patient merits a statin recommendation, the recommendation is made available via an Inbox message to the provider or a "to-do" item on the patient's chart. The recommendation can also be printed as part of the patient's visit face-sheet.

## **Preventive Health Scenarios Supported With Customization of the Coded Expression**

Additional preventive health scenarios make use of the decision logic and recommendations in this artifact, but may require adjustments for a different workflow, type of user, or mode of operation. Example scenarios include:

- 1. Population health:** Inclusion in a requested or periodic screening scan of an entire patient panel or population.
  - a. Dr. Charlie's practice is running a quarterly quality screen to find patients in need of various health maintenance and promotion services. The CDS logic is run as a report for all patients in the practice. Recommendations for appropriate patients appear on each patient's individual "to-do" list and are also compiled into an overall report that can be addressed by population health or care management workers.

2. **Patient self-care/family caregivers can use the artifact as part of self-assessment or health maintenance programs:**
  - a. Mr. Delta runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. Recommendations can be compiled into a list and presented immediately with the assessment results or can be delivered as a secure message to the patient on a self-care website.
3. **Data-driven screening:** The recommendations could change when relevant data changes, including new low density lipoprotein (LDL) high density lipoprotein (HDL) results; new diagnosis of diabetes; new diagnosis of ASCVD.
  - a. Ms. Epsilon, a patient, had a new cholesterol blood test panel done as part of a recent visit; when the test is run, this CDS logic runs to see if any change in recommendations is called for. In this case, the LDL has gone up to 195, whereas her previous high was 155; the guideline thus recommends that she be placed on a statin if she has not already been taking one. Recommendations are made available as a message to the provider’s general Inbox and also to the “to-do” section of the patient chart.

## CDS Interventions and Suggested Actions

The CDS logic that generates the display of CDS interventions and suggested actions is pictured in the Artifact Semistructured Logic section of [Appendix A](#). At a very high level, the inclusion and exclusion logic generate the following interventions and suggested actions:

1. Recommendations for statin use in patients meeting any of the subpopulations, considering shared decision making with the patient. Different messages are delivered to patients in each of the three subgroups.
2. Notification message when insufficient data is available to process the CDS logic—in particular, if the patient has not had an LDL result in the last 3 years (for subgroup 3, diabetics age 40-75) or has not had an LDL result ever (for subgroup 2).
  - a. The eCQM applies to all patients greater than age 21, and thus implies that all patients over that age should have a lipoprotein panel. Practically, many practices may not be in the habit of testing patients on the younger end of this range, which would generate many insufficient-data messages. The age range for the eCQM was carefully considered by the eCQM development group, and we have reproduced it as specified.
3. Suggested action: order a statin medication.
4. Suggested action: document any new medications being used.
5. Reference link to the eCQM specification.
6. Educational interventions: links to relevant recommendation statements, original references to the guideline, shared decision making tools, and patient education tools.
7. Exception: Document why the provider and patient have decided on a management strategy differing from the recommendation.
8. Suggested exceptions could include:
  - a. Patient has known adverse reactions to statins.
  - b. Patient is likely to have adverse reactions to statins.
  - c. Patient understood the recommendation but elects not to take a statin.
  - d. Lab results are incorrect.

- e. Patient has an exclusion or exception that was not inferred by the CDS logic.

## Guideline Interpretation and Clinical Decisions

### Evidence Source for Artifact Development

CMS347v3 measures the number of patients at high risk for cardiovascular events (the denominator) who receive an order for statins or who are using statins (the numerator). The denominator is defined in three subgroups:

1. Individuals  $\geq 21$  years with clinical ASCVD.
2. Individuals  $\geq 21$  years who have ever had a fasting or direct laboratory result of LDL  $\geq 190$  milligrams/deciliter (mg/dL), or who have a previous or active diagnosis of familial or pure hypercholesterolemia, and who are not in subgroup 1.
3. Individuals 40 to 75 years of age with Type 1 or Types 2 diabetes, and with a value of 70-189 mg/dL for the highest LDL test done in the measurement year or the two prior years, and who are not in subgroups 1 or 2.<sup>2</sup>

Individuals who are pregnant, breastfeeding, or have a diagnosis of rhabdomyolysis are excluded—that is, they are not counted in the denominator or numerator when determining performance on the measure.<sup>2</sup>

Individuals with allergy or intolerance to statin medications, who are receiving palliative care, who have hepatic disease or insufficiency, who have end-stage renal disease, and whose most recent LDL result is  $<70$  mg/dL are excepted—that is, they are counted in the denominator only if they are also included in the numerator (i.e., if they are on a statin).<sup>2</sup>

Additional reference information can be found in the textual metadata section of the artifact in the CDS Connect Repository.

### Guideline Translation Summary

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. Throughout the development of this artifact, the CDS Development Team engaged with eCQM subject matter experts (SMEs) to ensure that the evidence was translated appropriately and to clarify any narrative phrase in the measure that was unclear. [Appendix A](#) (the Decision Log) provides detailed information on how the eCQM and subsequent SME clarifications informed CDS development. Some of the key interpretations and decisions include:

1. The eCQM specifies a ‘measurement period’ of a year and calls for (subpopulation 3) the determination of highest LDL during the measurement year or the two prior years. As the CDS could be processed anytime during a year, this lookback time has been interpreted as 3 years prior to the processing date (current date).
2. Value sets needed to be established for computable definitions of ASCVD, end-stage renal disease, hepatic disease or failure, and pregnancy.

3. “Familial or pure hypercholesterolemia” was changed to use just the codes for familial hypercholesterolemia, based on the Cholesterol Management Work Group’s determination that terms such as pure, primary, and polygenic hypercholesterolemia are often used incorrectly.
4. Intensity of statin therapy is not specified in the eCQM, although the American College of Cardiology (ACC)/American Heart Association (AHA) guidance does discuss differing levels of statins that apply to certain subgroups. We followed the eCQM in simply recommending statins for appropriate patients, without specifying a specific dosing level.
5. The Cholesterol Workgroup, in interpreting “hepatic disease or failure,” concluded that the best computable equivalent would be a diagnosis of cirrhosis or an active diagnosis of hepatitis A or hepatitis B or a most recent alanine transaminase (ALT) result > 150 mg/dL.
6. The ACC/AHA guideline notes that the evidence for statin use in patients over age 75 is less strong. This has been turned into an additional statement on the recommendations delivered for patients in subpopulation 2.

## Technical Details Regarding Artifact Implementation

This artifact is composed of several software files written in CQL. The primary focus of these software files is to allow any organization to identify patients who may benefit from statin therapy for prevention of CVD.

The following sections provide technical details useful for those implementing this artifact in their health IT system. First, background information on CQL is provided, since it is the programming language used to write the logic for the artifact. This section is followed by a listing, or manifest, of the main CQL files included in the artifact. The relationships between these files are described, followed by a discussion on how the artifact has been tested.

### General Information About CQL

This artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7 that is currently a Standard for Trial Use (STU).<sup>4</sup> CQL expresses logic in a human-readable format that is also structured enough for electronic processing of a query. It can be used within both the CDS and eCQM domains.

The following hyperlinks provide additional information on CQL:

- [CQL Release 1 STU3](#)
- [CQL on the Electronic Clinical Quality Information \(eCQI\) Resource Center](#)
- [CQL Tools on GitHub](#)
- [CQL Execution Engine \(CoffeeScript\) on GitHub \\*](#)
- [CQL Evaluation Engine \(Java\) on GitHub \\*](#)
- [CQL Online](#)

- [CQL Runner \\*](#)

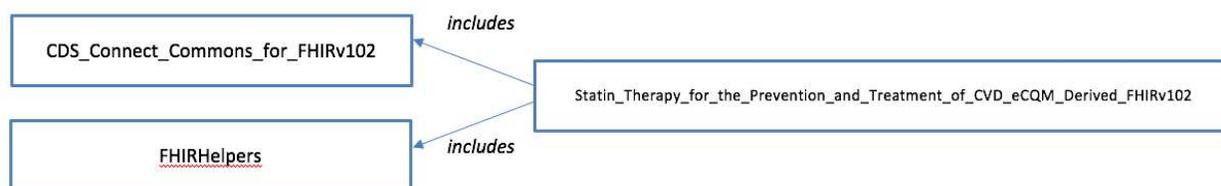
\* These websites do not support the use of Internet Explorer, and recommend using Google Chrome, Microsoft Edge, or Firefox.

## Library Relationship Diagram

CQL developers are encouraged to refactor commonly used functions into separate software files called libraries.<sup>5</sup> The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. The diagram in **Figure 1** below shows the relationships between this artifact’s main library file and the three supporting libraries. As depicted in the diagram, the main CQL library references or “includes” the other three libraries.

When implementing this artifact, please ensure that all files listed in **Table 1** in the next section are present and that the filenames have not been modified. Not doing so will mean the artifact will not correctly execute since some of the artifact logic will be missing.

**Figure 1. Artifact Relationship Diagram**



## Artifact Library Manifest

As mentioned in the previous section, the *Statin Therapy eCQM* artifact is composed of several libraries. Each library is represented in two formats: 1) CQL format, and 2) JavaScript Object Notation (JSON) format. The CQL format is human readable while the JSON format is machine readable and is generated from the CQL using the CQL-to-ELM translator.<sup>6</sup> Although the two formats contain the same information, they are formatted for their different purposes. The software files that comprise the artifact are listed in **Table 1**.

**Table 1. Artifact Manifest**

Filename	Purpose
Statin_Therapy_for_the_Prevention_and_Treatment_of_CVD_eCQM_Derived_FHIRv102.cql	CQL representation of the <i>Statin Therapy eCQM</i> artifact. This file specifies the necessary logic to query relevant data, identify patients who meet the logic criteria, and return structured text that could be used in a patient-facing notification. This representation of the logic uses the HL7 standard for expressing CDS; it is considered more human-readable than other coded formats.

Filename	Purpose
Statin_Therapy_for_the_Prevention_and_Treatment_of_CVD_eCQM_Derived_FHIRv102.json	JSON representation of the artifact. This file specifies the necessary logic to query relevant data, identify patients who meet the logic criteria, and return structured text that could be used in a patient-facing notification. This representation of the logic is provided as an alternative to the CQL-expressed code, as it may be easier to parse for some IT systems.
CDS_Connect_Commons_for_FHIRv102.cql	Common CQL functions that may be called by CDS Connect artifacts
CDS_Connect_Commons_for_FHIRv102.json	JSON representation of common CQL functions that may be called by CDS Connect artifacts
FHIRHelpers.cql	Common CQL functions used to convert CQL data elements to FHIR and back again
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again

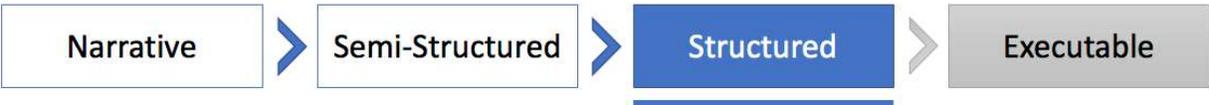
### Artifact Testing

The *Statin Therapy eCQM* artifact was tested using an automated testing framework written in Node.js. This framework accepted test cases in a .csv (Comma-separated value) file, executed the artifact against each test case, and reported the success or failure of each test case. Test cases were developed to investigate efficacy for basic expected functionality and to test the expected inclusion and exclusion criteria. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

### Implementation Checklist

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts.<sup>7</sup> The framework defines four “layers” of representation, as depicted in **Figure 2** and described here:

**Figure 2. CDS Artifact Maturity Process**



1. **Narrative** text created by a guideline or clinical quality measure (CQM) developer (e.g., the recommendation statement described as a sentence).
2. **Semistructured** text that describes the recommendation logic for implementation as CDS, often created by clinical SMEs. It serves as a common understanding of the clinical intent as the artifact is translated into a fully structured format by software engineers.
3. **Structured** code that is interpretable by a computer and includes data elements, value sets, and coded logic.
4. **Executable** code that is interpretable by a CDS system at a local level. This code will vary for each site.

The CDS Connect team puts forward the information below as suggested “best practices” for including third-party CDS into an existing EHR system:

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization understands and agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review the [Guideline Translation Summary](#) section of this document and [Appendix A](#) (the decision log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a structured, computable CDS artifact.
- Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf health IT systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those health IT systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In many pilot settings, developers have worked around existing health IT limitations by implementing a web service wrapper around a CQL execution engine. This is a non-trivial amount of work with two primary components:
  - A CQL execution engine with a Representational State Transfer (RESTful) Web service designed to accept requests for CQL execution and to respond with the calculated results
    - CQL Services<sup>8</sup> is one possible option for this component
  - Modifications to the health IT system such that it will:
    - Trigger RESTful events to call the CQL execution engine
    - Interpret the response
    - Reflect the CQL-generated interventions and suggested actions in the health IT user interface

- After incorporation into a development environment, the artifact should be exhaustively tested against predefined test cases. Additionally, testing should be conducted to ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
- Depending on the end user that will be interacting with the CDS as well as the intervention action that is displayed, consider whether documentation and training material may need to be drafted and distributed. These training materials should include descriptions of modified functionality, directions for interacting with CDS rules (if different than in the current system), and contact information for assistance if functionality does not meet expectations.

## Potential Reuse Scenarios

CQL code within this artifact was developed to enact a clinical guideline, but there are portions of the CQL code that are expected to be useful for other purposes.

- The `CDS_Connect_Commons_for_FHIRv102`, `FHIRHelpers` and `CDS_Connect_Conversions` libraries included in the artifact define commonly used functions in CQL files and are not specific to the *Statin Use eCQM* artifact. They are expected to be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the *Statin Use eCQM* artifact could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to identify those female patients with an active pregnancy in other pertinent CDS.

## Appendix A. Decision Log

### Artifact Semistructured Logic

This artifact is derived from CMS 347v3 eCQM (i.e., CMS measure ID CMS347v3, “Statin Therapy for the Prevention and Treatment of Cardiovascular Disease”). The eCQM population statements<sup>2</sup> are as follows:

#### **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-cholesterol (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 2 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 who are receiving palliative or hospice care.

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.

The semistructured inclusion and exclusion logic derived from the eCQM population statements is as follows:

**Inclusion logic:**

Patient is  $\geq 21$  years old AND one of the following:

**Population 1:**

History of ASCVD

**Population 2:**

LDL-C  $\geq 190$  mg/dL at any point in time (fasting or direct LDL-C test)

OR familial hypercholesterolemia

AND NOT ASCVD

**Population 3:**

Patient is  $\geq 40$  and  $\leq 75$  years

AND diabetes (type 1 or 2)

AND highest LDL-C  $< 190$  mg/dL within the past 3 years (fasting or direct LDL-C test) AND MOST RECENT LDL-C  $\geq 70$  mg/dL

AND NOT LDL-C  $< 190$  mg/dL at any point in time (fasting or direct LDL-C test)

AND NOT ASCVD OR familial hypercholesterolemia

**Exclusion logic:**

Pregnancy OR pregnancy observation within the past 42 weeks

OR breastfeeding OR breastfeeding observation within the past year

- OR rhabdomyolysis
- OR adverse effect, allergy, or intolerance to statin medications
- OR hepatitis A OR hepatitis B
- OR cirrhosis OR elevated ALT > 150 (> 3 times the normal limit)
- OR ESRD
- OR receiving palliative or hospice care
- OR already receiving a statin medication

### Concept Definition Decision Log

**Table 2** defines many of the terms used in the semistructured CDS representation to provide clarity on what each logic concept means and why it was expressed as listed. These concepts were informed or derived from text in the recommendation statement.

The decisions and translations listed in this log were informed by the published eCQM, research review and supporting references. The CDS Development Team engaged with eCQM and Cholesterol Management SMEs to disambiguate narrative phrases that were unclear to ensure that the evidence was translated appropriately. This log outlines how textual phrases were translated to semistructured logic, as well as how SME and Cholesterol Management Work Group insight informed the CDS expression.

**Table 2. Concept Definition Decision Log**

Location in CDS Logic	Concept	Definition and/or Rationale
All populations	"at the beginning of the measurement period"	This is an eCQM term, which does not directly apply to real-time CDS. CDS will evaluate the patient's age at the time of care. (Note: the eCQM logic looks for individuals who are 21 before January of the current calendar year, which means that they will be 21-22 during the current calendar year. For population #3 in the eCQM, individuals who turned 75 before January of the current calendar year would be 75-76 during the current calendar year. If 76 years old, they fall outside the highest ACC/AHA recommendation). Evaluating age when care is provided enables the CDS to align more directly with the ACC/AHA recommendation.

Location in CDS Logic	Concept	Definition and/or Rationale
Population 1	"clinical ASCVD"	ASCVD is defined by a grouped value set that includes diagnosis and procedure concepts that reflect signs and symptoms of the disease. It is represented as a union of eight value sets published on the Value Set Authority Center to express ASCVD "conditions" (e.g., myocardial infarction, ischemic vascular disease) and procedures that imply underlying ASCVD (e.g., coronary artery bypass grafts, percutaneous coronary interventions, carotid interventions). ASCVD is expressed as an exclusion because the interventions generated by the coded logic are only relevant to <i>preventing</i> CVD. If a patient has ASCVD, different types of treatment and counseling may be indicated. Treatments and counseling for active ASCVD are outside the of scope of this artifact.
Population 2	"who have ever had"	At any point in time. This is to accommodate scenarios where LDL was elevated prior to therapy and is now lower.
Population 2	"previously diagnosed with or currently have an active diagnosis"	Specified in CQL code with HL7 clinicalStatus and verificationStatus attributes.
Population 2	"familial or pure hypercholesterolemia"	Per the Cholesterol Management Work Group, this concept was changed to familial hypercholesterolemia only. The work group felt strongly that other classifications (i.e., pure, primary, polygenic) are misused in primary care due to poor definitions and understanding of the condition. Additionally, they felt that this data element will likely be revised during an annual update based on provider feedback.
Population 3	LDL-C result of "70-189" mg/dL	>=70 and <=189
Population 3	"as the highest...result"	In order to make populations exclusive, this is represented by 'AND highest LDL-C is <=189 mg/dL within the past 3 years.'

Location in CDS Logic	Concept	Definition and/or Rationale
Population 3	"in the measurement year or during the 2 years prior to the beginning of the measurement period"	Translated as the 'last 3 years' for CDS purposes, corresponding to those 2 years prior and up to a year since the start of the measurement period.
Denominator exclusions	Exclusions	For CDS purposes, patients meeting the listed exclusions are not provided a statin recommendation since statins are contraindicated for individuals who are pregnant, breastfeeding, or have active rhabdomyolysis.
Denominator exclusions	"Pregnancy" as an Exclusion	Based on lessons learned while piloting the statin CDS artifact in a clinical setting, pregnancy is often expressed as an observation in EHRs. Since statins are strongly contraindicated during pregnancy, an 'observation' of pregnancy has been added to the exclusions (along with a diagnosis of pregnancy) to ensure patient safety.
Denominator exclusions	"rhabdomyolysis" as an Exclusion	Per the Cholesterol Management Work Group, only "active" cases of rhabdomyolysis and the conditions in the designated value set should be excluded. Do not exclude "resolved" cases.
Denominator exceptions	Exceptions	For CDS purposes, patients meeting these exceptions are not targets for a statin recommendation, since they would not be flagged as deficient if they did not receive a statin. In most cases, the potential benefit versus harm of initiating a statin must be closely considered for patients with the listed conditions.

Location in CDS Logic	Concept	Definition and/or Rationale
Denominator exception	"...who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy"	Population 3 logic to include: AND MOST RECENT LDL-C result is $\geq 70$ mg/dL (i.e., MOST RECENT LDL-C result is not $< 70$ mg/dL).
Denominator exception	"active liver disease or hepatic disease or insufficiency"	eCQM logic represents this phrase as 3 distinct data elements: liver disease, hepatitis A, and Hepatitis B. Based on Cholesterol Management Work Group recommendation, this phrase is represented as cirrhosis, ALT > 150 (i.e., 3 times the upper normal limit), hepatitis A and hepatitis B. Note: elevated ALT is cited in the ACC/AHA guidelines as a contraindication for statins and has been used as a proxy for severe liver disease.
Denominator exception	"hepatitis A" "hepatitis B"	The Cholesterol Management Work Group had varied opinions on whether to include active/relapsed hepatitis A and B in the exclusions or express <i>all</i> liver-related conditions in one statement (i.e., cirrhosis or ALT > 150). The current representation aligns with eCQM logic (i.e., includes hepatitis A and B). Future implementers can adjust the logic to align with what would work best in their organization.

## Artifact Development Decision Log

The Artifact Development Team made numerous decisions while translating the eCQM and developing the structured representation of this artifact. **Table 3** provides insight on those decisions, along with where the coded representation might be expanded in the future. The table lists a “Decision Category”, which was informed by the Tso et al. journal article titled, “Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation” that outlines a methodology for knowledge translation.<sup>9</sup> It also lists the high-level “Concept” related to the entry and the “Rationale” for each decision.

**Table 3. Artifact Development Decision Log**

Decision Category	Concept	Rationale
Select guidelines	Age >75	The ACC/AHA guideline provides no evidence on benefit of statins for patients >79yrs. Per the Cholesterol Management Work Group (1) If age >75 and patient has ASCVD, add a clause to the recommendation stating that benefit has not been proven, and (2) If age > 75 and patient evaluates as true for Population 2, display the following notification: Evaluate comorbidities, safety considerations, and priorities of care before considering a statin for patients over 75 years old.
Disambiguate	Simplification of Population 3 logic related to LDL-C level	The eCQM statement excepts patients from Population 3 if most recent LDL-C <70 mg/dL, even if the highest LDL-C in the past 3 years was between 70-189. Logically this is equivalent to "highest LDL-C ≤ 189 mg/dL in last 3 years and most recent LDL-C ≥ 70 mg/dL."
Implementation guidance	Provide distinct messages for different populations	CQL coding will support the provision of distinct notification and rationale statements for each population. At this time, the recommendations align with eCQM specifications, which promote initiation of <i>any</i> intensity statin. Due to intellectual property constraints, the more specific ACC/AHA guideline recommendations are not implemented in this artifact. However, end users can adjust the notification text and the intensity of statin that is expressed in the notification prior to implementation of the artifact, if desired. The ACC/AHA guidelines are available at: <a href="http://circ.ahajournals.org/content/129/25_suppl_2/S1">http://circ.ahajournals.org/content/129/25_suppl_2/S1</a> .

Decision Category	Concept	Rationale
Deabstract	Strength of notifications	The Cholesterol Management Work Group had varied opinions on the strength of wording to use in notifications (e.g., 'start' vs. 'discuss' vs. 'consider' a statin). All felt that provider and patient discussion is important prior to initiation of a statin. Some felt that selecting a less directive verb (e.g., 'discuss' or 'consider') facilitates this shared decision making.
Add explanation related to logic constraints to ensure clinical relevance	CDS vs eCQM measurement	Original 'source' content of this artifact is an eCQM, which is scored for each patient and in aggregate. The CDS representation of the eCQM provides an intervention/recommendation/action for each patient. As such, this affects parameters such as "measurement period," "exclusion," "exception" outlined above. Recommendations are synthesized to encourage all eligible patients to be scored in the numerator of the eCQM.
Add explanation related to logic constraints	Evaluation of three distinct populations	Once a patient is in the target population (age >21) and is not excluded/excepted, the three populations (i.e., ASCVD, LDL-C >190, diabetic age 40-75 with LDL-C 70-189) will be tested in sequence. Current logic will still test each patient for each population as if the other tests had not been done -- thus, factors such as "no ASCVD" are included in tests for Populations 2 and 3, even though the patient would already have been included in Population 1 and thus would have exited the artifact.
Deabstract to ensure clinical relevance	Clinical and Verification attributes	Specific FHIR clinical attributes (e.g., "resolved," "active") and FHIR verification attributes (e.g., "presumptive," "refuted") are designated in CQL code to express the accepted status' for each condition.

## Appendix B. References

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