Implementation Guide

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

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# Introduction

The Agency for Healthcare Research and Quality (AHRQ) has elected to sponsor a project that will help to generate a systematic and replicable process for transforming patient-centered outcomes research (PCOR) findings into shareable and standards-based clinical decision support (CDS) artifacts. A CDS artifact is the template for defining how decision support is provided for a given clinical situation, often including triggers, logic, operations, recommendations and actions, and supporting evidence. A main outcome of this project will be an online Repository for storing and accessing CDS artifacts. It is hoped that this publicly available Repository will promote the usage of CDS in everyday clinical settings, and that it will serve as the linchpin for connecting high-quality CDS to the U.S. healthcare community.

## Background

The purpose of the CDS Connect Repository is to store and provide access to CDS artifacts, including text and computable versions of the decision logic; suggested trigger events; text recommendations and suggested actions; and metadata, including original evidence links, decisions made in creating the artifact, sponsoring clinical organizations, and keywords*.* It is envisioned that it may at some point become a home for user feedback and experience data as well. The CDS Connect Repository enables users to search easily for desired artifacts, to explore their contents, and to facilitate their transfer into and use in locally used electronic health records (EHRs), CDS services, and other technology tools.

The concept of a CDS repository was introduced in the HHS-sponsored Roadmap for National Action on Clinical Decision Support1 (2006). Subsequent efforts, including the CDS Consortium (2008), Advancing CDS contract (2010), National Quality Forum CDS Expert Panel (2011), Health eDecisions (2012), and the National Academy of Medicine Optimizing Strategies for CDS project, among others, have advanced the concept of shared CDS. The CDS Connect project advances the goal of shareable CDS by establishing an actual public repository of CDS that can be contributed to and consumed by many stakeholders.

With further development, additional features are projected for the Repository, including—

* making several types of CDS available (such as alerts, order sets, intelligent data presentations, relevant evidence and knowledge; tools for shared decision-making with patients).
* providing several options for displaying and using Repository information.
* allowing users to subscribe to artifact updates.
* allowing users to review and rate artifacts in the Repository and provide usage data.

These features will enhance the quality, validity, and value of the Repository, and create a climate of mutual ownership of artifacts across the CDS and EHR user community. The provenance and sponsorship of any artifact is visible and searchable in the Repository.

## Audience, Purpose, and Scope of this Implementation Guide

This document is intended to provide information about the generation, implementation, and routine operation of the USPSTF Statin Use for the Primary Prevention of Cardiovascular Disease in Adults artifact. Various audiences may find this information helpful, including:

1. **Clinicians and** **Quality Leaders** at healthcare organizations and practices who wish to implement, test, and execute CDS related to this topic in their EHRs and other health information tools.
2. **Patients and Family Caregivers** who wish to have active CDS to help them direct self-care activities or who are interested in the process of CDS development and implementation for shared decision-making more generally.
3. **CDS Developers and Informaticists** who may have suggestions, additions, or seek to add CDS artifacts on similar topics, or who want to make use of well-developed structured logic and Clinical Quality Language (CQL) in their own work.
4. **Organizations or individuals** interested in developing their own CDS artifacts, who may find this document helpful as a guideline for the process by which clinical guidelines are translated into mature clinical quality language (CQL) coded artifacts.

# Implementing and Using This Artifact

## Description and Purpose of the artifact

This artifact provides statin therapy recommendations for primary and secondary prevention of cardiovascular disease (CVD) for patients considered to be at high risk of cardiovascular events. It is a CDS rule representation of clinical guidance expressed in an electronic Clinical Quality Measure (eCQM), **CMS measure ID CMS347v1,** **“Statin Therapy for the Prevention and Treatment of Cardiovascular Disease,”** which is in part based on 2013 guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA).2

## Summary of the Clinical Statement

CMS347v1 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 ≥ 21 years with clinical ASCVD.
2. Individuals ≥ 21 years who have ever had a laboratory result of LDL-c ≥190 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-c test done in the measurement year or the two prior years, and who are not in subgroups 1 or 2.

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.

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-c 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).

Additional reference information can be found in the **Textual Metadata** section of the artifact in the CDS Connect Repository.

## Primary Use Cases

This artifact transforms the eCQM into clinical decision support by interpreting it as a screening artifact. A patient is checked 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, a recommendation to consider ordering a statin drug is delivered. Thus, the CDS encourages compliance with the eCQM. However, the CDS diverges from one 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 (i.e., resolved Hepatitis A, mild liver disease that does not cause cirrhosis). Decisions made during artifact development to transform eCQM logic and use cases into CDS logic and use cases are highlighted in Section 3 and detailed in Appendix B.

In the primary use case, the decision logic and recommendations are intended for use by providers delivering care in an outpatient setting, supplied as an Event-Condition-Action alert (a common alert, reacting to a specific event). Typical scenarios include:

1. **Any time a patient’s record is opened by a clinician’s direct action**

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 EHR, the CDS logic described herein executes to determine whether to recommend that Ms. Bravo begin taking statins. The relevant recommendations and suggested actions (RSAs) 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.

1. **As automatic surveillance prior to the start of a clinician encounter (**particularly in a primary care, cardiology, geriatric, or internal medicine practice)

Ms. Bravo arrives for a scheduled appointment and is registered into the encounter. This registration automatically triggers the CDS logic of this artifact. RSAs are made available as a message to the clinician’s Inbox or a To-Do item in the patient’s record.

1. **As automatic surveillance run at a fixed time the night before the practice opens each day**

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 RSAs 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.

## Additional Use Cases

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

1. **Population health:** Inclusion in a requested or periodic screening scan of an entire patient panel or population.

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. RSAs 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.

1. **Patient self-care/family caregivers can use the artifact as part of self-assessment or health maintenance programs:**

Mr. Delta runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. RSAs 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.

1. **Data-driven screening:** The recommendations could change when relevant data changes, including a new LDL/HDL result; new diagnosis of diabetes; new diagnosis of ASCVD.

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. RSAs are made available as a message to the provider’s general In-Box and also to the To-Do section of the patient chart.

## Recommendations and Suggested Actions

The recommendations, warnings, and interventions provided by this CDS artifact can be found in detail under **“Potential Intervention(s) and Action(s)” in the Semi-Structured Representation section of the artifact**. In summary, they include:

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-c in the last 3 years (for subgroup 3, diabetics age 40-75) or has not had an LDL-c ever (for subgroup 2).
   1. 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 for 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:
   1. Patient has known adverse reactions to statins.
   2. Patient is likely to have adverse reactions to statins.
   3. Patient has understood the recommendation but elects not to take a statin.
   4. Lab results are incorrect.
   5. Patient has an exclusion or exception that was not inferred by the CDS logic.

# Guideline Interpretation and Clinical Decisions

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. In addition, the CDS Connect Cholesterol Management Work Group worked to clarify exclusions, inclusions, and parameters specified in the guideline statement; specified in the original reference describing the guideline; or deemed to be otherwise important to the proper application of the guideline as CDS. Decisions outlined in Appendix B explain, in detail, how source content text was interpreted and representations were defined during artifact creation.

Some of the more meaningful interpretations and decisions there include:

1. The eCQM specifies a ‘measurement period’ of a year and calls for (subpopulation 3) the determination of highest LDL-c 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 ACC/AHA guidance does discuss differing levels of statins that apply to certain subgroups. We have 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 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.

# Artifact Manifest

The Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (eCQM) artifact is comprised of eight distinct files listed in Table 1 below.

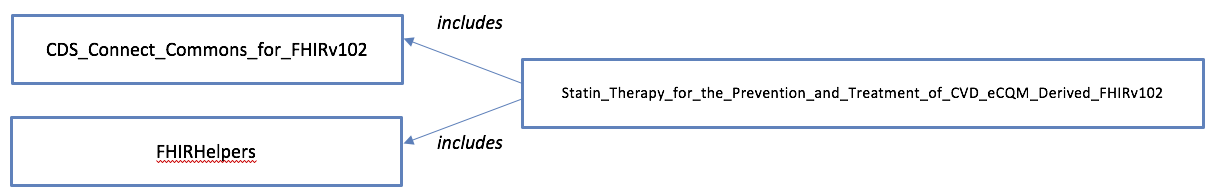
Table : Artifact Manifest

| Filename | Purpose | Author(s) |
| --- | --- | --- |
| Statin\_Therapy\_for\_the\_Prevention\_and\_Treatment\_of\_CVD\_eCQM\_Derived\_FHIRv102.cql | CQL representation of the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (eCQM) | Rute Martins, Chris Moesel, Sharon Sebastian |
| Statin\_Therapy\_for\_the\_Prevention\_and\_Treatment\_of\_CVD\_eCQM\_Derived\_FHIRv102.json | JSON representation of the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (eCQM) | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Commons\_for\_FHIRv102.cql | Common CQL functions that may be called by CDS Connect artifacts | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Commons\_for\_FHIRv102.json | JSON representation of common CQL functions that may be called by CDS Connect artifacts | Rute Martins, Chris Moesel, Sharon Sebastian |
| FHIRHelpers.cql | Common CQL functions used to convert CQL data elements to FHIR and back again | Rute Martins, Chris Moesel, Sharon Sebastian |
| FHIRHelpers.json | JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again | Rute Martins, Chris Moesel, Sharon Sebastian |

## Artifact Relationship Diagram

CQL developers are encouraged to refactor commonly used functions into their own files. The diagram in Figure 1 shows the relationships between the files included in this artifact. In this case, the Statin\_Therapy\_for\_the\_Prevention\_and\_Treatment\_of\_CVD\_eCQM\_Derived\_FHIRv102 file includes several libraries.When implementing this artifact, please ensure that all files are present and the filenames have not been modified.

Figure : Artifact Relationship Diagram

****

# Testing

The Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (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. A selection of the test data used for this artifact is included in Appendix A. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

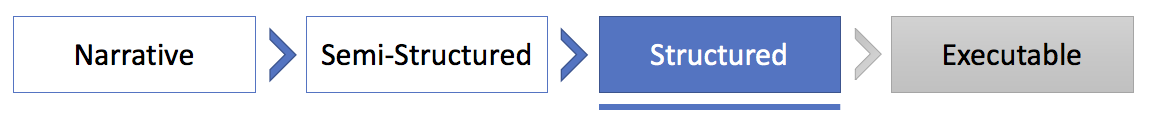
# Implementation Checklist

Boxwala et al.3 developed a multi-layered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts. The framework defines four “layers” of representation:

1. **Narrative** text created by a guideline or CQM developer (e.g., the recommendation statement described as a sentence).
2. **Semi-structured** text that describes the recommendations for implementation as CDS, often created by clinical subject matter experts. It serves as a common understanding of the clinical intent as the artifact is translated in to 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.

This artifact is a **structured** representation of medical knowledge that contains code files that represent the source content (e.g., recommendation statement).

Figure : CDS Artifact Maturity Process



Prior to incorporating this artifact in a production setting, implementers should consider the following items:

* 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 “clinical considerations” section of this document (including the decision log in Appendix B) 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 successfully incorporated into a clinical IT system. At the time of publication, many COTS EHR 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 EHR 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 a pilot setting, developers have worked around existing EHR 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 RESTful web service designed to accept requests for CQL execution and to respond with the calculated results, and
  + modifications to the EHR system such that it will
    - trigger RESTful events to call the CQL execution engine,
    - interpret the response,
    - and reflect the CQL-generated recommendations and suggested actions in the EHR 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.
* Documentation and training materials for clinical staff should 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 in the event that functionality does not meet expectations.

# Potential Reuse Scenarios

CQL code within this artifact was developed to enact a particular 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 and FHIRHelpers libraries included in the artifact define commonly used functions in CQL files and are not specific to the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (eCQM) artifact. They are expected to be used with any other CQL file that could benefit from those functions.
* Selected code blocks from Statin\_Therapy\_for\_the\_Prevention\_and\_Treatment\_of\_CVD\_eCQM\_Derived\_FHIRv102 could be copied and reused in other CQL files. For example, some have expressed interest in the definition of pregnancy (based on the existence of either a condition code or observation code).

# General Information About CQL

The Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) Electronic Clinical Quality Measure (eCQM) artifact is composed of several files, but the primary focus of the artifact is the introduction of CQL files that can be used by any healthcare organization to properly identify populations of patients that require a specific message or clinical intervention. CQL is a data standard governed by Health Level 7 (HL7) that is currently a Standard for Trial Use (STU). CQL expresses logic in a human-readable document that is also structured enough for electronic processing of a query. It can be used within both the CDS and CQM domains.

If you would like to learn more about CQL, there are a few resources (care of the [eCQI Resource Center](https://ecqi.healthit.gov/cql)) that you should review:

1. [CQL STU Release 1 at HL7](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=400)
2. [CQL Tools on GitHub](https://github.com/cqframework/clinical_quality_language)
3. [CQL Formatting and Usage Wiki](https://github.com/esacinc/CQL-Formatting-and-Usage-Wiki/wiki)
4. [CQL Online](http://cql-online.esacinc.com/)
5. [CQL Q&As on the eCQI Resource Center](https://ecqi.healthit.gov/cql/CQ-Qs%26As)

Appendix A: Test Data

In conjunction with a custom Node.js testing framework, the following data tables were used to test the USPSTF Statin Use for the Primary Prevention of CVD in Adults artifact:

Table : Statin Therapy eCQM Basic Tests

| **TestCase** | **Patient** | **age** | **ALT** | **LDL** | **issued** | **MI** | **Diabetes** | **FamilialHypercholesterolemia** | **StatinAllergy** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: Errors** | **RESULT: Recommendation** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pop 1 Recommendation | female | 39 |  | 129 |  | + |  |  |  | TRUE | FALSE | <null> | ~Consider a statin for this patient. Criterion: >=21 years old with ASCVD |
| Pop 2 Recommendation | male | 40 |  | 190 |  |  |  |  |  | TRUE | FALSE | <null> | ~Consider a statin for this patient. Criterion: >=21 years old with at least one LDL-C >=190 |
| Pop 3 Recommendation | male | 75 |  | 71 |  |  | + |  |  | TRUE | FALSE | <null> | ~Consider a statin for this patient. Criterion: 40-75 years old with diabetes and LDL-C 70-189 |
| Not Included | male | 47 |  | 75 |  |  |  |  |  | FALSE | FALSE | <null> | <null> |
| Excluded | male | 58 |  | 190 |  | + |  |  | + | TRUE | TRUE | <null> | <null> |
| Old Data Error | male | 75 |  | 71 | 7/18/10 |  | + |  |  | <null> | FALSE | ~Guidelines for recommending statins cannot be processed because the patient has not had an LDL-C result in the past three years | <null> |
| Missing Data Error | male | 75 | 50 |  |  |  | + |  |  | <null> | FALSE | ~Guidelines for recommending statins cannot be processed because the patient does not have an LDL result in their record | <null> |
| Missing Age Error | female |  | 50 | 129 |  | + |  |  |  | <null> | FALSE | ~Inadequate data to assess recommendations for statins, because patient age is missing | <null> |

Table : Statin Therapy eCQM Exclusion Tests

| **TestCase** | **Patient** | **age** | **ALT** | **LDL** | **MI** | **ECQMPregnancyCondition** | **ECQMPregnancyObservation** | **BreastfeedingCondition** | **BreastfeedingObservation** | **Rhabdomyolysis** | **StatinAllergy** | **Cirrhosis** | **HepA** | **HepB** | **ESRD** | **PalliativeCare** | **status** | **StatinStatement** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: Population1** | **RESULT: Population2** | **RESULT: Population3** | **RESULT: Errors** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Really Too Young, and Excluded | female | 20 | 50 | 129 | + | + |  |  |  |  |  |  |  |  |  |  |  |  | FALSE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Normal Pop 1 Inclusion: ASCVD | female | 39 | 150 | 129 | + |  |  |  |  |  |  |  |  |  |  |  |  |  | TRUE | FALSE | TRUE | FALSE | FALSE | <NULL> |
| Excluded: Pregancy | female | 39 |  | 129 | + | + |  |  |  |  |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Pregnancy Observation | female | 39 |  | 129 | + |  | + |  |  |  |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Breastfeeding | female | 39 |  | 129 | + |  |  | + |  |  |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Breastfeeding Observation | female | 39 |  | 129 | + |  |  |  | + |  |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Rhabdomyolysis | female | 39 |  | 129 | + |  |  |  |  | + |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Problems with Statin | female | 39 |  | 129 | + |  |  |  |  |  | + |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Cirrhosis | female | 39 |  | 129 | + |  |  |  |  |  |  | + |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Elevated ALT | female | 39 | 151 | 129 | + |  |  |  |  |  |  |  |  |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Hep A | female | 39 |  | 129 | + |  |  |  |  |  |  |  | + |  |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Hep B | female | 39 |  | 129 | + |  |  |  |  |  |  |  |  | + |  |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: ESRD | female | 39 |  | 129 | + |  |  |  |  |  |  |  |  |  | + |  |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Palliative Care Completed | female | 39 |  | 129 | + |  |  |  |  |  |  |  |  |  |  | + |  |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Palliative Care In progress | female | 39 |  | 129 | + |  |  |  |  |  |  |  |  |  |  | + | in-progress |  | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |
| Excluded: Already on Statin | female | 39 |  | 129 | + |  |  |  |  |  |  |  |  |  |  |  |  | + | TRUE | TRUE | <NULL> | <NULL> | <NULL> | <NULL> |

Table : Statin Therapy eCQM Inclusion Tests

| **TestCase** | **Patient** | **age** | **ALT** | **LDL** | **LDL** | **issued** | **Diabetes** | **FamilialHypercholesterolemia** | **MI** | **CABG** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: Population1** | **RESULT: Population2** | **RESULT: Population3** | **RESULT: Errors** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Really Too Young | female | 20 | 50 | 129 |  |  |  |  | + |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Pop 1: ASCVD Diagnosis | female | 39 |  | 129 |  |  |  |  | + |  | TRUE | FALSE | TRUE | FALSE | FALSE | <NULL> |
| Pop 1: ASCVD Procedures | female | 39 |  | 129 |  |  |  |  |  | + | TRUE | FALSE | TRUE | FALSE | FALSE | <NULL> |
| Pop 2: Familial Hypercholesterolemia | female | 39 |  | 129 |  |  |  | + |  |  | TRUE | FALSE | FALSE | TRUE | FALSE | <NULL> |
| Pop 2: LDL >=190 Anytime | female | 39 |  | 190 | 69 | ->monthsAgo(1) |  |  |  |  | TRUE | FALSE | FALSE | TRUE | FALSE | <NULL> |
| Pop 2: Really old LDL >=190 | female | 39 |  | 135 | 190 | ->yearsAgo(10) |  |  |  |  | TRUE | FALSE | FALSE | TRUE | FALSE | <NULL> |
| Pop 3 | female | 50 |  | 129 | 75 | ->monthsAgo(2) | + |  |  |  | TRUE | FALSE | FALSE | FALSE | TRUE | <NULL> |
| Not Pop 3: Too Young | female | 39 |  | 129 |  |  | + |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Not Pop 3: Too Old | female | 76 |  | 129 |  |  | + |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Not Pop 3: Not Diabetic | female | 50 |  | 129 |  |  |  |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Not Pop 3: LDL Too Low | female | 50 |  | 69 |  |  | + |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Not Pop 3: Latest LDL Too Low | female | 50 |  | 189 | 69 | ->daysAgo(7) | + |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |
| Not Pop 3: No Risk Factors | female | 50 |  | 129 |  |  |  |  |  |  | FALSE | FALSE | <NULL> | <NULL> | <NULL> | <NULL> |

Appendix B: Decision Log

The decision log was generated per procedures published by Tso et al.,4 which incorporates and extends steps that Shiffman et al.5 outlined for translating clinical practice guidelines to CDS. Brief descriptions of the steps in this process are included in the following table:

Table : Definitions of Shiffman's Steps

| **Decision Category** | **Definition** |
| --- | --- |
| **Select Guidelines** | Choosing specific guidelines and specific recommendations within the selected guidelines to be implemented |
| **Markup** | Identifying and tagging guideline knowledge components relevant to operationalization |
| **Atomize** | The process of extracting and refining single concepts from the narrative text recommendations |
| **Deabstract** | The process of adjusting the level of generality at which a decision variable or action is described to permit operationalization |
| **Disambiguate** | The process of establishing a single semantic interpretation for a recommendation statement |
| **Build Executable Statements** | Arranging the atomized, de-abstracted, and disambiguated decision variables and actions into logical statements that can be translated readily into computable statements |
| **Verify Completeness** | The process of making sure that each recommendation provides guidance in all situations that a clinician is likely to face |
| **Add Explanation** | A facility to describe the reasoning behind recommendations |
| **Identify Origin** | Identifying a source or origin in the clinical environment for each decision variable |
| **Insert Recommendations** | Identifying an insertion point in the care process for each recommended action |
| **Define Action Type** | Categorizing guideline-recommended activities per predefined action types |
| **Define Associated Beneficial Services** | Linking action types to associated beneficial services that offer design patterns for facilitating clinical care |
| **Design User Interface** | Selecting and grouping user interface elements to best deliver CDS output |

eCQM Population Statements

**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 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 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.

Decision Logs

Table : Decisions Based on "Atomized" Components of the Population Statements

| **Presence in Statement** | **"Atomized" Word or Phrase** | **Interpretation 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. |
| Population 1 | "Clinical ASCVD" | Arteriosclerotic Cardiovascular Disease (ASCVD) is defined by a grouped value set that includes diagnosis and procedure concepts that reflect signs and symptoms of the disease:   "Procedure, Performed: PCI"   "Diagnosis: Myocardial Infarction"   "Diagnosis: Cerebrovascular disease, Stroke, TIA"   "Procedure, Performed: CABG Surgeries"   "Diagnosis: Atherosclerosis and Peripheral Arterial Disease"   "Procedure, Performed: Carotid Intervention"   "Diagnosis: Ischemic heart disease or coronary occlusion, rupture, or thrombosis"   "Diagnosis: Stable and Unstable Angina" |
| 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 Clinical Status and Verification Status 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 the 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.' |
| 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. |
| 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 >= 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 *all* 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. |

Several decisions were made outside the scope of the atomized words and phrases in the recommendation statements. These additional decisions were made based on the best available clinical knowledge and were encountered at various stages in the artifact development process.

Table : Additional Decisions

| **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:   - If age >75 and patient has ASCVD, add a clause to the recommendation stating that benefit has not been proven.   - 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 QIP statement excepts patients from Population 3 if most recent LDL-C <70 mg/dL, even if the highest LDL 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 *any* intensity statin. Due to IP 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: <http://circ.ahajournals.org/content/129/25_suppl_2/S1> |
| 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. |
| **Logic constraints to ensure clinical relevance:** | | |
| Add explanation | 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/actions 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 | 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>190, diabetic age 40-75 with LDL 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 | Clinical and Verification attributes | Specific FHIR clinical attributes (such as "resolved," "active") and FHIR verification attributes (such as "presumptive," "refuted") are designated in CQL code to express the accepted status' for each condition. |

Appendix C: Acronyms

|  |  |
| --- | --- |
| ACA | Affordable Care Act |
| AHRQ | Agency for Healthcare Research and Quality |
| CAMH | CMS Alliance to Modernize Healthcare |
| CDS | Clinical Decision Support |
| CMS | Centers for Medicare & Medicaid Services |
| COTS | Commercial Off-the-Shelf |
| CQL | Clinical Quality Language |
| CQM | Clinical Quality Measurement |
| CVD | Cardiovascular Disease |
| eCQI | Electronic Clinical Quality Information |
| EHR | Electronic Health Record |
| FAR | Federal Acquisition Regulation |
| FFRDC | Federally Funded Research and Development Center |
| FHIR | Fast Healthcare Interoperability Resources |
| HDL | High-Density Lipoprotein |
| HHS | Department of Health and Human Services |
| HIT | Health Information Technology |
| HL7 | Health Level 7 |
| IT | Information Technology |
| LDL | Low-Density Lipoprotein |
| ONC | Office of the National Coordinator for Health Information Technology |
| PCOR | Patient-Centered Outcomes Research |
| PCORI | Patient-Centered Outcomes Research Institute |
| RSAs | Recommendations and Suggested Actions |
| USPSTF | U.S. Preventive Services Task Force |

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