Understanding the New Cholesterol Measure

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Learning Objectives

1. Identify the 3 high risk groups targeted by the new cardiovascular disease (CVD) prevention and treatment measure (PQRS #438)

2. Discuss the strengths and weaknesses of the evidence base supporting the use of statin therapy in these 3 high risk groups

3. Compare the new CVD prevention and treatment measure to prior CVD prevention, CVD treatment, and cholesterol management quality measures

4. Discuss the extent to which the new CVD prevention and treatment measure aligns with the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

5. Address the major clinical and workflow barriers to achieving high performance on the new CVD prevention and treatment measure
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 with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR

- Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL
Total number of cardiovascular disease (CVD) deaths, 1979 to 2030; observed deaths, 1979 to 2012; and conventional projections and trend-based projections, 2013 to 2030.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

• Replaced SGR (Sustainable Growth Rate)
• Move toward value-based payment
  - Establishes 2 payment pathways
    • MIPS (Merit-based Incentive Payment System)
    • APMs (Alternative Payment Models)
• MIPS
  - Payment tied to participation & performance in quality reporting programs
    - Penalties for not reporting start in 2019
    - Reporting period begins January 2017*
• APMs
  - Eligibility for 5% bonuses starts in 2019
Practice Management Significance: MIPS

• Composite quality score
  – Physician Quality Reporting System (PQRS)
  – Value-Based Payment Modifier (VBPM)
  – Meaningful Use (MU)
  – Clinical Practice Improvement Activities (CPIA)

• PQRS Measures
  – Report ≥ 9 measures covering ≥ 3 National Quality Strategy (NQS) Domains
  – NQS Domains
    • Patient safety
    • Community/population health
    • Efficiency & cost reduction
    • Effective clinical care
    • Communication & care coordination
    • Person and caregiver-centered experience and outcomes
A 48 year old woman with type 2 diabetes and fibromyalgia presents for a routine 6 month follow up visit

- Home blood sugars are well-controlled on metformin and glipizide
- Home blood pressure is well controlled on lisinopril and chlorthalidone. (Today’s office BP is 119/78)
- She has lost 20lb since exercising for 1 hour five times a week and starting a low carb diet that is also low in trans fat, saturated fat, and processed foods
- She had labs drawn a couple days before her visit and her A1C is 6.8 (down from 7.5), Total cholesterol is 204, HDL-C is 54, and LDL-C is 82.
- You congratulate her on her excellent lifestyle changes and, per the new cholesterol guidelines, you also recommend a moderate intensity statin…
Clinical Vignette

A 48 year old woman with type 2 diabetes and fibromyalgia presents for a routine 6 month follow up visit

- With a crestfallen face, she turns to you and says, “But doc, why do I need to add another medication when my cholesterol is not even high. I was hoping I would be able to cut down on the number of pills I have to take. And I’ve heard so much about muscle pain from statins. I am finally doing better in regards to my functioning with fibromyalgia – I don’t want to go backwards. And I also heard that statins can make my diabetes worse!”

- After brief discussion of potential benefits and risks of adding statin therapy, she declines.

- How would you rate the quality of this clinical encounter?
- How would the new group practice your former 4 physician practice has joined rate the quality of cardiovascular preventive care provided during this encounter?
Statin therapy for the prevention and treatment of cardiovascular disease

- PQRS Measure #438
- NQS Domain
  - Effective clinical care
- Measure Type
  - Process measure
- Measure Group
  - Cardiovascular Prevention
- Measure Steward
  - CMS
- Included as a “Preferred specialty measure” for general practice, family practice, and internal medicine
2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol

- Based on data from RCTs, systematic reviews of RCTs, and meta-analyses of RCTs with ASCVD outcomes
- Did not incorporate data from observational epidemiological studies or animal studies
- Abandoned treat to LDL-C target or lower is better strategies
• Focused on 3 clinical questions
  1. What is the evidence for LDL-C and non-HDL-C goals for the secondary prevention of ASCVD?
  2. What is the evidence for LDL-C and non-HDL-C goals for the primary prevention of ASCVD?
  3. What is the effectiveness and safety of specific cholesterol-modifying drugs in general and in selected subgroups?
Four Statin Benefit Categories

1. Secondary prevention in individuals with clinical ASCVD
2. Primary prevention in individuals with primary elevations of LDL-C ≥ 190 mg/dL
3. Primary prevention in individuals with diabetes ages 40-75 with LDL-C 70-189 mg/dL
4. Primary prevention in individuals ages 40-75 without diabetes but with estimated 10 year ASCVD risk ≥ 7.5% and LDL-C 70-189 mg/dL
Notable aspects of 2013 ACC/AHA Cholesterol Treatment Guideline

• Groups found not to benefit from statin therapy
  – Heart failure (NYHA class II-IV)
  – ESRD on maintenance hemodialysis

• Focus on the intensity of statin therapy rather than LDL-C or non HDL-C targets
Applying Classification of Recommendation and Level of Evidence.

<table>
<thead>
<tr>
<th>SIZE OF TREATMENT EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLASS I</strong> Benefit &gt;&gt; Risk</td>
</tr>
<tr>
<td>Procedure/Treatment SHOULD be performed/administered</td>
</tr>
<tr>
<td><strong>CLASS IIa</strong> Benefit &gt;&gt; Risk Additional studies with focused objectives needed IT IS REASONABLE to perform procedure/administer treatment</td>
</tr>
<tr>
<td><strong>CLASS IIb</strong> Benefit ≥ Risk Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED</td>
</tr>
<tr>
<td><strong>CLASS III</strong> No Benefit or CLASS III Harm</td>
</tr>
<tr>
<td>Procedure/Test Treatment</td>
</tr>
<tr>
<td><strong>COR III:</strong> Not Helpful No Proven Benefit</td>
</tr>
<tr>
<td><strong>COR III:</strong> Excess Cost w/ Benefit or Harmful to Patients</td>
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</tbody>
</table>

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<thead>
<tr>
<th>ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEVEL A</strong> Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses</td>
</tr>
<tr>
<td>Recommendation that procedure or treatment is useful/effective Sufficient evidence from multiple randomized trials or meta-analyses</td>
</tr>
<tr>
<td><strong>LEVEL B</strong> Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies</td>
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<tr>
<td>Recommendation that procedure or treatment is useful/effective Evidence from single randomized trial or nonrandomized studies</td>
</tr>
<tr>
<td><strong>LEVEL C</strong> Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care</td>
</tr>
<tr>
<td>Recommendation that procedure or treatment is useful/effective Only expert opinion, case studies, or standard of care</td>
</tr>
</tbody>
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| A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even when randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective. |

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
### Strength of Evidence for 2013 ACC/AHA Guideline Recommendations

<table>
<thead>
<tr>
<th>Treatment Recommendation</th>
<th>ACC/AHA Class of Recommendation (Size of Treatment Effect)</th>
<th>ACC/AHA Level of Evidence (Certainty of Treatment Effect)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High intensity statin for individuals with clinical ASCVD</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>High intensity statin for individuals with LDL-C ≥ 190 mg/dL</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Moderate intensity statin for individuals with diabetes and LDL-C 70-189 mg/dL</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Moderate or high intensity statin for individuals with 10-year ASCVD risk ≥ 7.5%</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Moderate intensity statin for individuals with 10-year ASCVD risk 5 to &lt;7.5%</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>
Denominator: Eligible patients

1. Adults aged ≥ 21 years with clinical ASCVD diagnosis; OR
2. Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR
3. Adults aged 40-75 years with type 1 or type 2 diabetes with a fasting or direct LDL-C level of 70-189 mg/dL
Anatomy of a Quality Measure: Numerator, Exceptions, and Exclusions

• **Numerator:** Targeted clinical action
  – Patients who use or have been prescribed statin therapy at any point during the measurement period

• **Denominator Exceptions**
  – Conditions that should remove a patient from the denominator of the performance rate only if the numerator criteria are not met

• **Denominator Exclusions**
  – Patients who should be removed from the measure population and denominator before determining of the numerator criteria are met
Eligible Patients Group 1: Clinical ASCVD

- Age ≥ 21 at beginning of measurement period, and
- Patient encounter during reporting period, and
- Previous or active diagnosis of clinical ASCVD
  - Acute coronary syndromes
  - History of myocardial infarction
  - Stable or unstable angina
  - Coronary or other arterial revascularization
  - Stroke or Transient ischemic attack
  - Peripheral arterial disease of atherosclerotic origin
Eligible Patients Group 2: LDL-C $\geq 190$

- Age $\geq 21$ at beginning of measurement period, and
- Patient encounter during reporting period, and
- Any fasting of direct LDL-C laboratory result $\geq 190$ mg/dL
Eligible Patients Group 3: Diabetes

• Age 40-75 at beginning of the measurement period, and
• Type 1 or Type 2 diabetes diagnosis, and
• Patient encounter during reporting period, and
• Highest fasting or direct LDL-C result 70-189 mg/dL in the measurement period or 2 years prior to beginning of the measurement period
Numerator Criteria

• “Patients who are statin therapy users during the measurement period or who receive an order (prescription) to receive statin therapy at any point during the measurement period”

• Numerator criteria
  – Performance met
    • Statin medication documented in current medication list

• Other measure considerations
  – Use of other cholesterol lowering medications does not satisfy the measure
  – Does not include any measure of adherence
Exclusion and Exception Criteria

- **Exclusions**
  - Documentation of medical reason for not being on a statin
    - Adverse effect, allergy, intolerance
    - Pregnancy, breastfeeding
    - Palliative care
    - Active liver disease or hepatic insufficiency
    - ESRD
    - Diabetes with LDL-C <70

- **Exceptions**
  - None
Measure calculation

Performance Rate =

\[
\frac{\text{Performance Met (} a_1 + a_2 + a_3 \text{)}}{\text{Eligible Population (} d_1 + d_2 + d_3 \text{) - Performance Exclusion (} b_1 + b_2 + b_3 \text{)}}
\]

\[a_1 = \text{performance met for group 1}\]
\[a_2 = \text{performance met for group 2}\]
\[a_3 = \text{performance met for group 3}\]
\[b_1 = \text{exclusion for group 1}\]
\[b_2 = \text{exclusion for group 2}\]
\[b_3 = \text{exclusion for group 3}\]
\[d_1 = \text{eligible for group 1}\]
\[d_2 = \text{eligible for group 2}\]
\[d_3 = \text{eligible for group 3}\]
Differences between Quality Measure and Clinical Guideline

• Measure does not assess intensity of statin therapy
  – Any dose of statin counts as satisfying the measure

• Measure does not target primary prevention in individuals without diabetes

• Measure does not address management of individuals over 75 or with other risk factors for ASCVD
Comparison to Prior Cholesterol-Focused Measures

- No LDL-C target
- Only counts statin therapy
- Includes multiple patient populations in a single quality measure
Measure Limitations

- No way to account for patient preference/patient refusal
- No incorporation of statin intensity
- How quickly will emerging evidence on ASCVD effects of non-statin cholesterol modifying treatments be incorporated
Workflow Limitations

• All data must be in structured fields
  – Challenging for exceptions
  • Free test documentation
  • Documentation duplication vs. clicking fatigue
Summary

1. The new cardiovascular disease (CVD) prevention and treatment measure (PQRS #438) targets 3 of the 4 groups identified in the 2013 AHA/ACC Guidelines that are most likely to benefit from statin therapy
   – Adults with clinical ASCVD
   – Adults with LDL-C ≥ 190mg/dL
   – Adults 40-75 with diabetes and LDL-C 70-189 mg/dL

2. The level of evidence supporting the 3 populations targeted by PQRS #438 is high (A or B) and based on multiple RCTs. However, there are some potential pitfalls to relying only on RCT data and focusing solely on statin therapy.

3. The new CVD prevention and treatment measure is a major departure from prior cholesterol-focused measures.

4. In most cases, clinical workflow, particularly related to documentation, will need to change in order to facilitate the best performance on this measure.
References
