# Atherosclerotic Cardiovascular Disease (ASCVD) CME

GroupHealth

## November 2016


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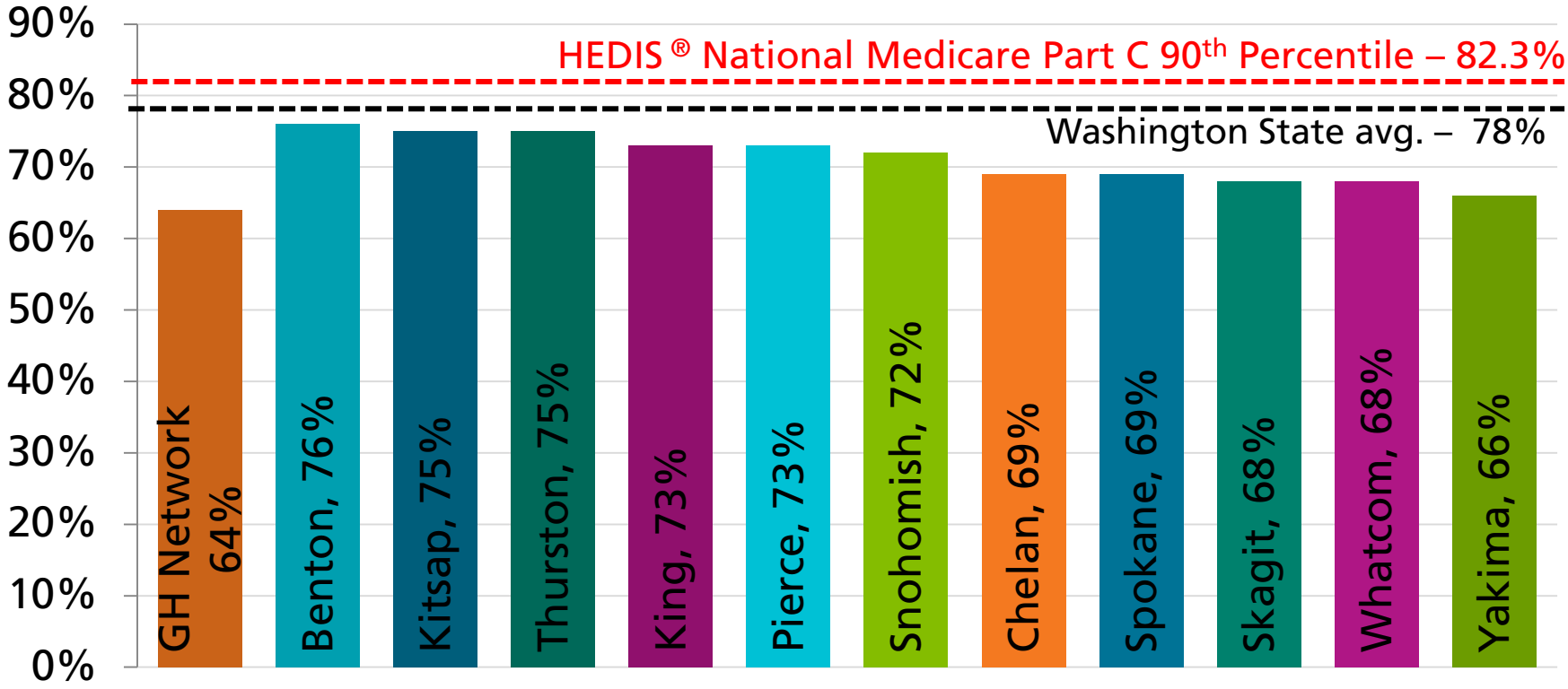
# Agenda

- Why this topic was selected
- Background
- Pharmacologic therapy
- Statin tolerance
- Targets
- Risk calculators
- HEDIS metrics

# Statin Therapy*




*Counties shown had over 200 eligible patients

*Sources: Washington State Health Alliance Community Check-up 2015-All Payers, NCQA Medicare Performance 2016, Group Health Cooperative September 2016*

# Influences

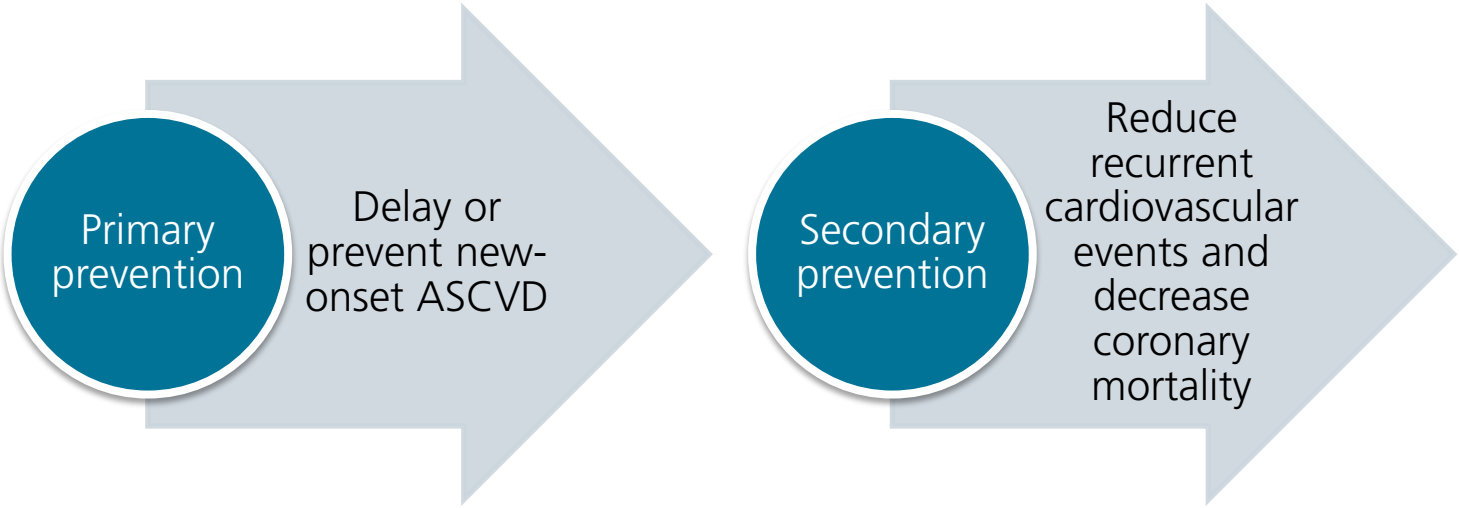
Group Health's guidelines informed by:



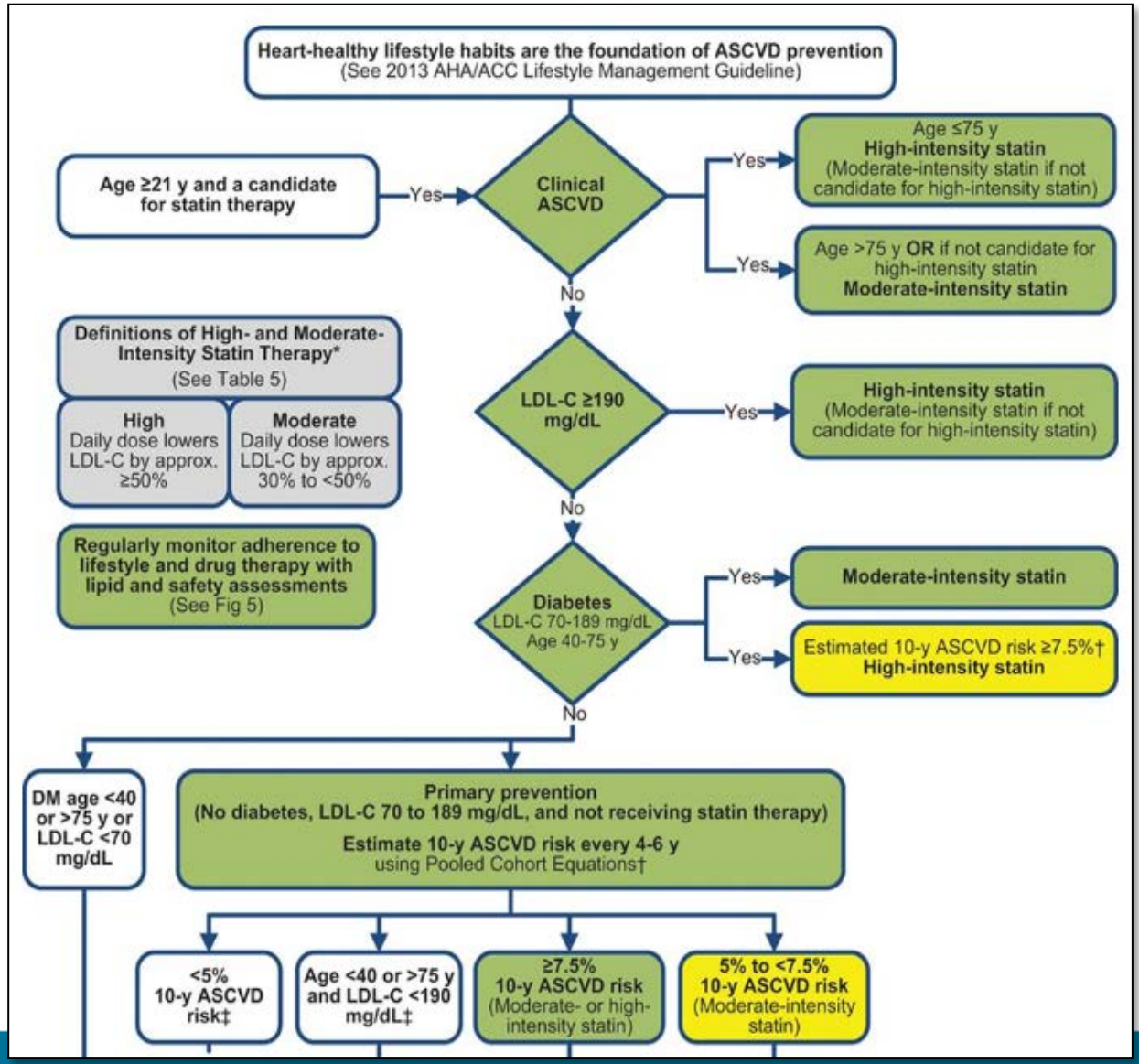

# Background

Conditions:

- Coronary heart disease (myocardial infarction, angina)
- Cerebrovascular disease (transient ischemic attack, ischemic stroke)
- Peripheral artery disease (claudication)
- Aortic atherosclerotic disease (abdominal aortic aneurysm)



# 2013 ACC/AHA Guideline



# Guideline Comparison

Provider.ghc.org > Caring for our members > Clinical Guidelines

| | GH | ACC/AHA |
|---|---|---|
| Primary Prevention | Moderate-intensity statin | Moderate to high intensity statin[¥€] |
| LDL Goal | <100 if primary prevention<br><70 if secondary prevention | None (statin intensity based on estimated risk) |
| Risk Calculator | Customized 5-year risk calculator for total ASCVD | 2013 ACC/AHA 10-year risk calculator |

[¥] High-intensity statin recommended in patients with LDL ≥190 mg/dL, diabetic patients aged 40-75 years with estimated 10-yr ASCVD risk ≥ 7.5%

[€] Moderate to high intensity statin recommended for patients without diabetes and 10-yr risk of ≥ 7.5%

# Lifestyle Modifications

## Tobacco cessation

## Mediterranean or DASH diet

- Fish consumption 2 days/week may reduce CHD mortality

## Moderation of alcohol consumption

## Physical activity

- ≥30 minutes of moderate-intensity aerobic activity ≥5 days/week
- Moderate-to-high intensity muscle-strengthening activity ≥2 days/week

## Weight management

## Blood pressure management

- Age ≤79 years, goal <140/90 mm Hg
- Age ≥80 years, goal <150/90 mm Hg

# GHC ASCVD Primary Prevention Guideline: Pharmacologic Therapy

| Population | Statin (Moderate) | Antiplatelet | ACEI |
|---|---|---|---|
| Diabetic patients | Recommended for age ≥ 40 | Use SDM | Recommended:<br>• 40-54 yr with >10% risk<br>• ≥55 yr at any risk |
| Low CVD risk (<5% over 5 yr) | Not recommended | Not recommended | Not routinely recommended in patients without diabetes |
| Moderate CVD risk (5-10% over 5 yr) | Can be considered; use SDM, hs-CRP if needed | Use SDM | |
| High CVD risk (>10% over 5 yr) | Recommended | Recommended | |
| LDL ≥ 190 mg/dL | Should be considered, use SDM | Use SDM | |

SDM: shared decision-making
hs-CRP: high-sensitivity C-reactive protein

*Adapted from GHC ASCVD Primary Prevention Guideline Table 3*

# GHC Primary Prevention: Statin Therapy

For Primary Prevention, use ***moderate-intensity statin*** (30 to <50% LDL-lowering)

- Moderate is Simvastatin 40 mg or Atorvastatin 20 mg

**Table 4. STANDARD (moderate-intensity) statin dosing for primary prevention of ASCVD**
Standard dosing applies to patients for whom there are no concerns about their ability to tolerate moderate-intensity statin therapy.

| Line | Medication | Initial dose | Maximum dose |
|---|---|---|---|
| 1st | Simvastatin | 40 mg daily at bedtime | 40 mg [1] daily at bedtime |
| | Atorvastatin | 20 mg daily | 80 mg daily |

1. For patients already on simvastatin 80 mg daily, it is acceptable to maintain the dose if they have been taking the drug for 12 months or longer, are not taking interacting medications, are at LDL goal, and are without myopathy.

*Source: GHC ASCVD Primary Prevention Guideline*

# GHC Primary Prevention: Statin Therapy

Use reduced dosing (simva/atorva 1st, prava 2nd) if ability to tolerate moderate-intensity dose is in question

Use SDM to decide whether to change existing therapy

**Table 5. REDUCED (low-intensity) statin dosing for primary prevention of ASCVD**
Reduced dosing applies only to patients with questionable ability to tolerate moderate-intensity statin therapy, including those who are elderly/frail, have hepatic/renal impairment or untreated hypothyroidism, or are taking interacting drugs.

| Line | Medication | Initial dose | Maximum dose |
|---|---|---|---|
| 1st | Simvastatin | 10–20 mg daily at bedtime | 40 mg daily at bedtime |
| | Atorvastatin | 10 mg daily | 80 mg daily |
| 2nd | Pravastatin [1] (Alternative in cases of drug interactions or side effects) | 20–40 mg daily at bedtime | 80 mg daily at bedtime |

1. Pravastatin has about half the potency of simvastatin; however, it is less likely to interact with other medications, particularly medications that are strong CYP3A4 inhibitors.

*Source: GHC ASCVD Primary Prevention Guideline*

# Standard Pharmacologic Therapy for Secondary Prevention

| Statin (High Intensity*) | ACEI/ARB | Antiplatelet | Beta-blocker Post-MI |
|---|---|---|---|
| • Atorvastatin 80 mg daily<br>• Rosuvastatin 20-40 mg daily (2nd) | • Lisinopril 5-40 mg daily<br>• Ramipril 5-20 mg daily<br>• Losartan 25-100 mg/d in 1-2 doses (2nd) | • Aspirin 81 mg daily<br>• Clopidogrel 75 mg daily (2nd) | • Metoprolol 25-100 mg BID (EF ≥50%)<br>• Carvedilol 3.125-25 mg BID (EF <50%)<br>• Metoprolol LA 12.5-200 mg daily (EF <50%, 2nd) |

**Age >75 yr OR not candidate for high-intensity statin: use moderate-intensity statin*

Dose ranges are initial to max.

*Adapted from GHC ASCVD Secondary Prevention Guideline Tables 1a, 3, 4, and 5*

# Secondary Prevention: Statin Therapy

## Standard Dosing*

*Age >75 yr OR not candidate for high-intensity statin: use moderate-intensity statin

**Start with**
- Atorvastatin 80 mg daily

**If LDL goal not met**
- **Add** ezetimibe 10 mg daily
- **Continue** atorvastatin 80 mg daily

**If LDL goal still not met**
- **Switch statin to** rosuvastatin 40 mg daily
- **Continue** ezetimibe 10 mg daily

**If LDL goal still not met**
- **Refer to Cardiology for** PCSK9 inhibitor (alirocumab 75-150 mg SQ every 2 weeks)

# Secondary Prevention: Statin Therapy

## Standard Dosing* Alternative

*Age >75 yr OR not candidate for high-intensity statin: use moderate-intensity statin. Dose ranges are initial to max.

**Start with**

- Atorvastatin 80 mg daily

**If LDL goal not met and ~10% from target***

- **Switch to** rosuvastatin 40 mg daily

**If LDL goal still not met**

- **Add** ezetimibe 10 mg daily
- **Continue** rosuvastatin 40 mg daily **or switch to** atorvastatin 80 mg daily

**If LDL goal still not met**

- **Refer to Cardiology for** PCSK9 inhibitor (alirocumab 75-150 mg SQ every 2 weeks)

*Modified from GHC ASCVD Secondary Prevention Guideline Table 1a. IMPROVE-IT. N Engl J Med. 2015 Jun 18;372(25):2387-97. SATURN. N Engl J Med. 2011 Dec 1;365(22):2078-87.*

# Secondary Prevention: Statin Therapy Reduced Dosing

Use shared decision-making to decide whether to change existing therapy.

**Table 1b. REDUCED dosing: Statins for lowering cholesterol for secondary prevention of ASCVD**
Reduced dosing applies to patients with questionable ability to tolerate high-intensity statin therapy, including those who are frail/elderly, have hepatic/renal impairment or untreated hypothyroidism, or are taking interacting drugs.

| Line | Medication | Initial dose [1] | Maximum dose |
|---|---|---|---|
| 1st | Simvastatin | 10–40 mg daily at bedtime | 40 mg [2] daily at bedtime |
| | Atorvastatin | 10–40 mg daily | 80 mg daily |
| 2nd | Pravastatin [3] (Alternative in cases of drug interactions or side effects) | 20–40 mg daily at bedtime | 80 mg daily at bedtime |

1. Start statin at the highest dose you believe the patient will be able to tolerate. It is then very important to move the patient up from there to as close to standard high-intensity therapy as possible.
2. For patients already on simvastatin 80 mg daily, it is acceptable to maintain the dose if they have been taking the drug for 12 months or longer, are not taking interacting medications, are at LDL goal, and are without myopathy.
3. Pravastatin has about half the potency of simvastatin; however, it is less likely to interact with other medications, particularly medications that are strong CYP3A4 inhibitors.

*Source: GHC ASCVD Primary Prevention Guideline*

# Triglycerides

Labs needed for both 1° and 2° Prevention

- HbA1c
- TSH
- Protein/creatinine ratio
- Pregnancy

Other causes of ↑ TG

- Obesity
- Alcohol
- Medications (estrogen/oral contraceptives, HIV antiretrovirals, corticosteroids, cyclosporine, etc.)

Investigation/treatment required when TG>500 mg/dL (or >1000 mg/dL - use SDM)

1st line: Atorvastatin 80 mg daily
If TG still not <500 mg/dL: Add fenofibrate (preferred) or niacin IR/SR
If TG still not <500 mg/dL, add fish oil
Statin-intolerant: Gemfibrozil **monotherapy**

# LDL Targets

LDL measurement verifies that patients are:

- Taking their statin (or other LDL-lowering drug)
- Achieving the appropriate reduction in LDL

## ACC/AHA (2013) and Kaiser (2014)

- No recommendation for or against specific LDL-C or non-LDL-C targets

## National Lipid Association (2015)

- Low, Moderate, or High Risk: LDL-C <100 mg/dL
- Very High Risk*: LDL-C <70 mg/dL

*Very high risk: ASCVD or DM with ≥2 other major ASCVD risk factors or evidence of end-organ damage

## Group Health Guideline (2016)

- Primary prevention at moderate or high CVD risk: <100
- ASCVD: <70

*Source: ACC/AHA. Circulation. 2014 Jun 24;129(25 Suppl 2):S1-45.*
*National Lipid Association. J Clin Lipidol. 2015 Mar-Apr;9(2):129-69.*

# Why Lower Targets?

Larger reductions in LDL show a linear relationship with larger reductions in major vascular events

A 2010 meta-analysis found that for **every 1 mmol/L** (39 mg/dL) LDL reduction:

All-cause mortality ⬇ **10%**

Major vascular events ⬇ **22%**

*Source: Cholesterol Treatment Trialists' (CTT) Collaboration*

# How Low Is Too Low?

If a patient has achieved a very low LDL, **do not lower** the intensity of statin therapy (provided patient is tolerating therapy).

Expert opinion is that no LDL level is too low.

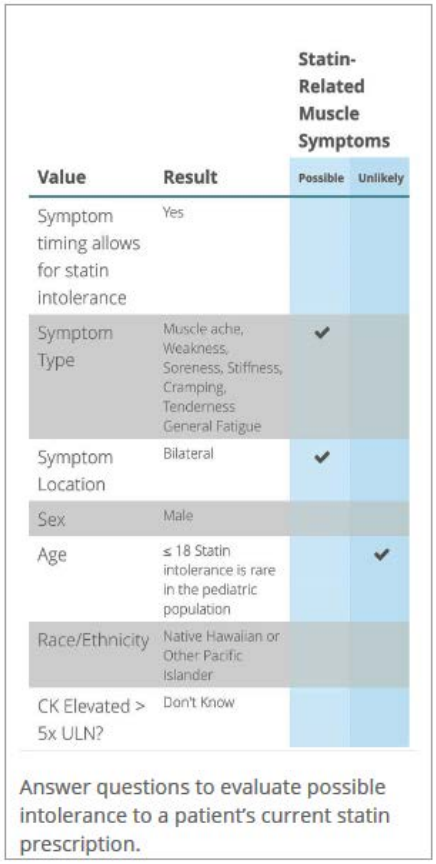
# Statin-Associated Muscle Symptoms (SAMS)

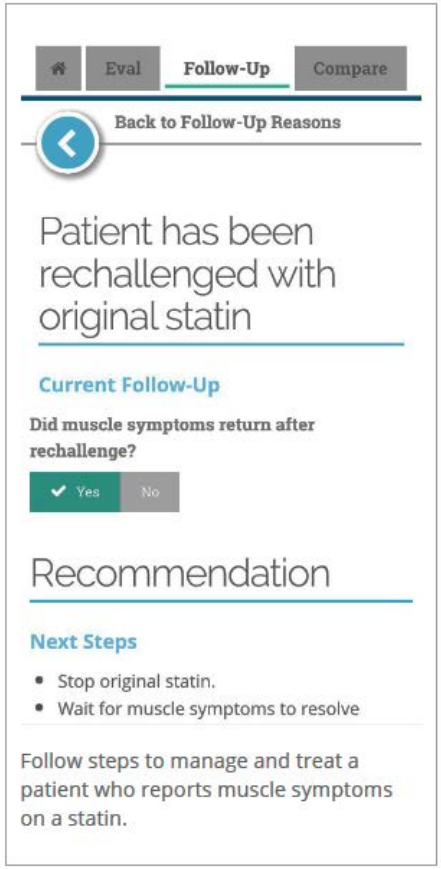
| |
|---|
| SAMS may occur with or without creatine kinase (CK) elevation |
| Pain and weakness usually symmetrical and proximal |
| Generally affect large muscle groups (thighs, buttocks, calves, back muscles) |
| Discomfort and weakness usually occur early (within 4-6 weeks after starting statin), but can occur after many years on treatment |
| Onset may occur with ↑ statin dose or initiating interacting drug |
| Appear more frequently in physically active patients |
| SAMS appear more promptly when re-exposed to the same statin |

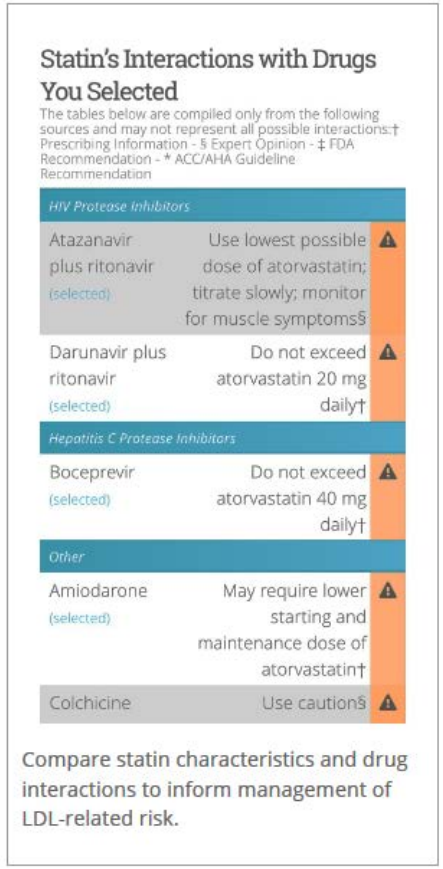
*Source: EASC Consensus Panel. Eur Heart J. 2015 May 1;36(17):1012-22.*

# American College of Cardiology Statin Intolerance App

Determine if myalgia symptoms are related to statin
http://www.acc.org/statinintoleranceapp

# If Patient *Appears* Intolerant to Statins

**Consider decreasing dose**

(can also use alternate day or 1-2x/week dosing regimen with atorvastatin or rosuvastatin)

If patient is still intolerant, **use SDM** to determine whether to switch statin. Consider consult with Cardiology.

Supplementation

- GHC ASCVD Guideline: Consider Coenzyme Q10. Evidence is conflicting, although some studies suggest benefit.
- Effectiveness of vitamin D for SAMS also controversial
- EASC does not recommend either CoQ10 or vitamin D

*Adapted from GHC ASCVD Guidelines and EASC Consensus Panel. Eur Heart J. 2015 May 1;36(17): 1012-22.*

# Definition of Statin Intolerance

Inability to tolerate at least 2 statins due to objectionable symptoms (real or perceived) or abnormal labs

| 1 statin at lowest starting daily dose | Another statin at any daily dose |
|---|---|

↓

Symptoms are temporally related to statin treatment and reversible upon discontinuation but reproducible by re-challenge

↓

Other known causes excluded

Hypothyroidism, interacting drugs, concurrent illnesses, significant changes in physical activity/exercise, underlying muscle disease

↓

Lowest starting statin daily dose defined as:

| rosuvastatin 5 mg | atorvastatin 10 mg | simvastatin 10 mg | lovastatin 20 mg | pravastatin 40 mg | fluvastatin 40 mg | pitavastatin 2 mg |
|---|---|---|---|---|---|---|

*Source: National Lipid Association Statin Intolerance Panel. J Clin Lipidol. 2014 May-Jun;8(3Suppl): S72-81.*

# If Patient *Still* Intolerant or Contraindications: Primary Prevention

**Patients not at high risk**

**Stop the statin** and do not prescribe further medications.

**High risk patients**

If not able to achieve an LDL <100 mg,

**stop the statin and consider prescribing ezetimibe**.

| **High risk based on:** |
| --- |
| 5-year risk >10% based on GHC CVD risk calculator, *or* |
| 10-year risk ≥7.5% based on ACC/AHA risk calculator, *or* |
| Patient aged 40 or older with diabetes, *or* |
| Any patient with LDL ≥190 mg/dL |

# If Patient *Still* Intolerant or Contraindications: Secondary Prevention

Start with

- Ezetimibe 10 mg daily

If LDL goal not met

- **Continue** ezetimibe 10 mg daily **and add one of the following:**
  - Niacin IR 100 mg BID-1000 mg TID
  - Niacin SR (Slo-Niacin) 250 mg-1000mg BID
  - Gemfibrozil 600 mg BID
  - Cholestyramine resin 4 g 1-2x/day to 24 g divided 1-6x/day

If LDL goal still not met

- **Refer to Cardiology for** PCSK9 inhibitor (alirocumab 75-150 mg SQ every 2 weeks)

Adapted from GHC ASCVD Secondary Prevention Guideline Table 2. Dose ranges are initial to max.

# Cardiovascular Risk Calculators

Consider calculators as risk ***estimators***

Interpret results using clinical judgment


Use tool as a starting point for discussion with patients

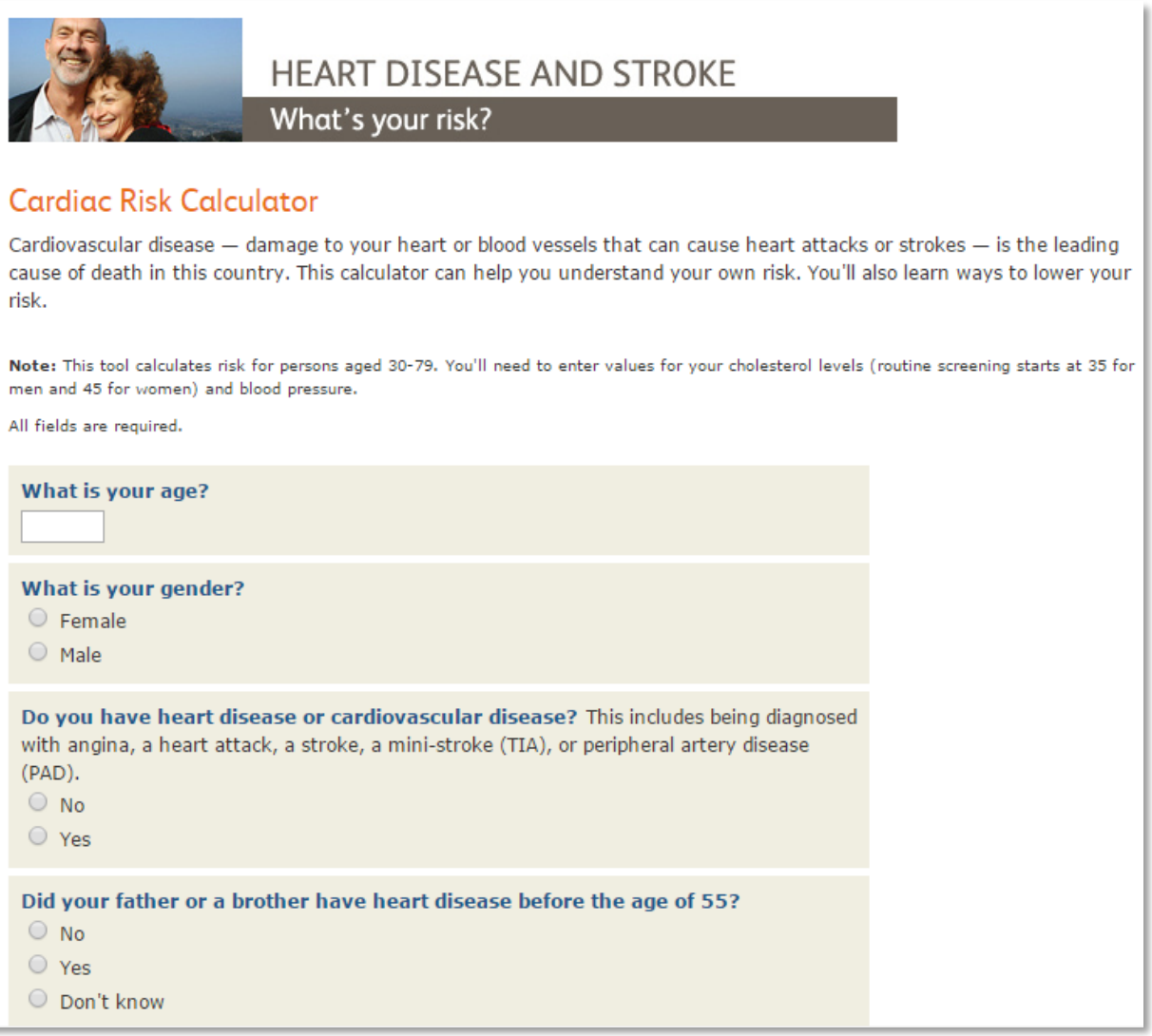
Use shared decision-making

# Group Health Risk Calculator

Customized version of the Framingham CVD risk calculator

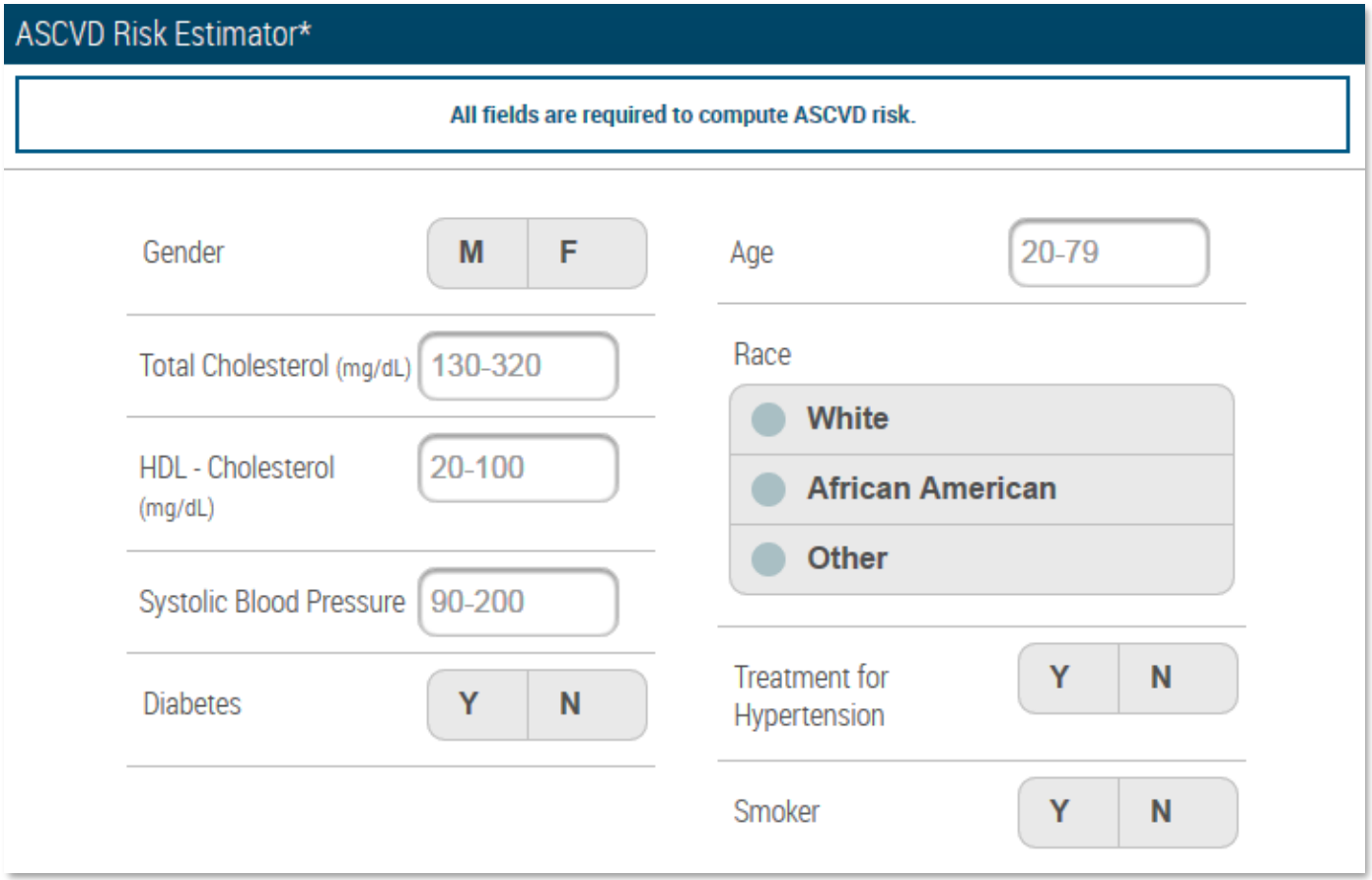
Approximates absolute 5-year risk of ASCVD and CHF

https://www.ghc.org/html/public/tools/heart/



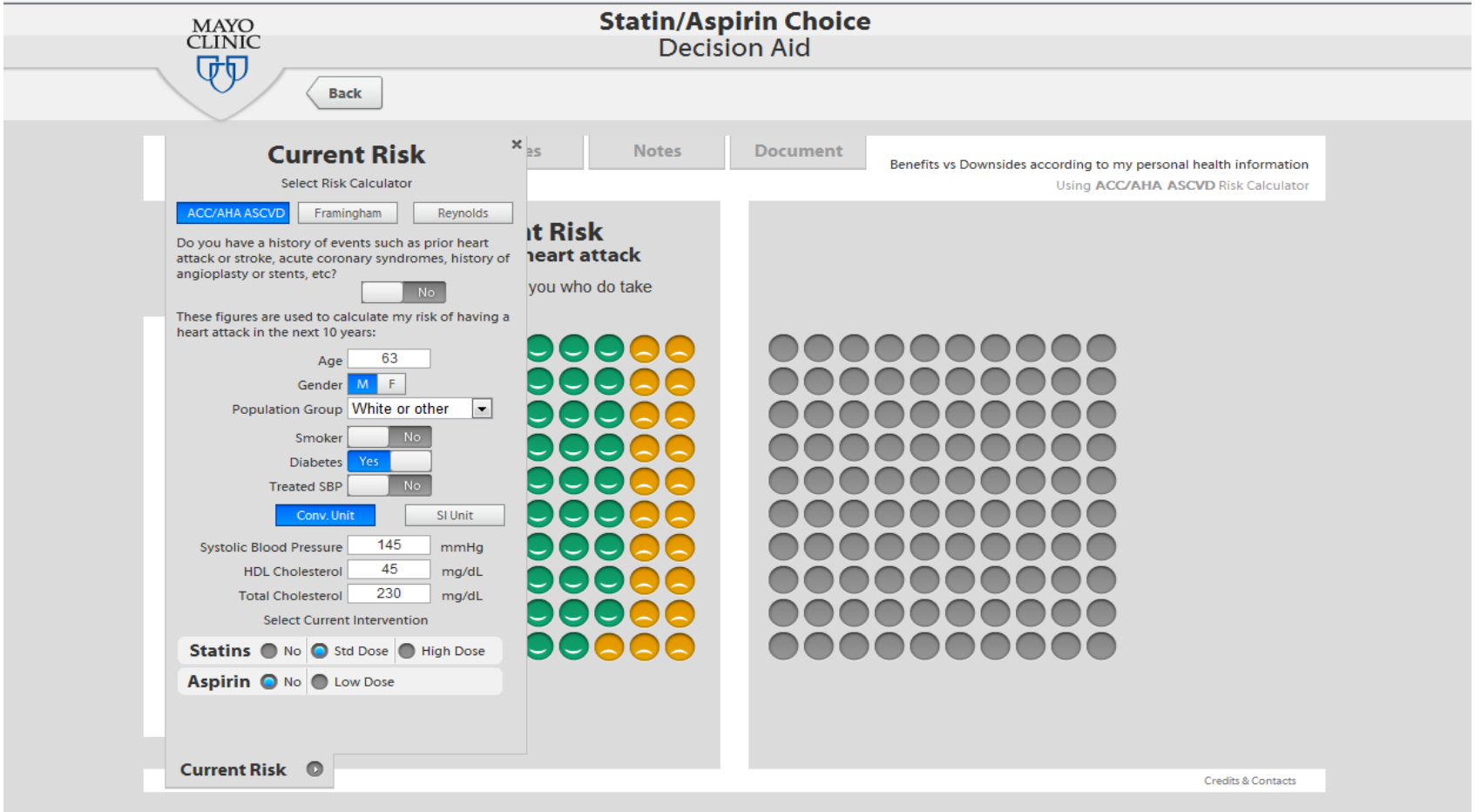
# 2013 ACC/AHA Risk Calculator

Assesses absolute 10-year risk of CVD and stroke
http://tools.acc.org/ASCVD-Risk-Estimator/



# Mayo Clinic Decision Aid

http://statindecisionaid.mayoclinic.org/index.php/statin/index



# Group Health Formulary Drug Price Comparison

| Medication | AWP (30-day supply) | GH formulary status |
|---|---|---|
| Atorvastatin 80 mg tablets | $173 | Formulary |
| Rosuvastatin 40 mg tablets | $268 | Formulary, Step therapy |
| Ezetimibe 10 mg tablets | $343 | Formulary, prior auth |
| Alirocumab 75 mg syringes | $1344 | Non-formulary, prior auth |

*Source: Group Health Formulary, November 2016*

# Retail Generic 30-day Discounts

Conversation indicates cost is barrier → Encourage mail-order Rx → 90-day fill

Retailers offer discounted cash-only purchases for generics

- May not be moderate/high intensity as defined by HEDIS
- Doesn't allow for monitoring or treat-to-target
- Claims not submitted to health plan (not reflected in performance rates)

Similar problems exist when offering drug samples to patients

| | |
|---|---|
| ***Walgreens $5***<br>• *Lovastatin 10/20/40 mg*<br>• *Pravastatin 10/20/40/80 mg*<br>• *Simvastatin 5/10/20/40/80 mg* | ***Rite-Aid $9.99***<br>• *Lovastatin 10/20/40 mg*<br>• *Pravastatin 10/20/40/80 mg*<br>• *Simvastatin 5/10/20/40/80 mg* |
| ***Walmart $4***<br>• *Lovastatin 10/20 mg* | ***Target $4***<br>• *Lovastatin 10/20 mg*<br>• *Pravastatin 10/20/40 mg* |

# New HEDIS ASCVD Measures
## Introduced 2016

**Initiation**: At least **one statin medication dispensed** during time period

**Adherence**: **Remain** on statin for at least 80% of treatment period

### Population

Males age 21–75 and females age 40–75 identified as having ischemic vascular disease (IVD) in the last two years via:

- IVD event (AMI, CABG, PCI) or
- Two or more events where IVD is diagnosed in an office visit or inpatient/emergency room setting

### Exclusions

- Pregnancy
- In vitro fertilization
- Dispensed at least 1 prescription for clomiphene
- ESRD
- Cirrhosis
- Myalgia, myositis, myopathy, or rhabdomyolysis

*Source: HEDIS 2017 Technical Specifications*

# Exclusion Codes for Statin Myopathy

Value Set: Muscular Pain and Disease

| Definition | Coding |
|---|---|
| Drug-induced myopathy | ICD10: G72.0 |
| Myopathy due to other toxic agents | ICD10: G72.2 |
| Myopathy, unspecified | ICD10: G72.9 |
| Rhabdomyolysis | ICD10: M62.82 |
| Myalgia | ICD10: M79.1 |
| Toxic myopathy | ICD9: 359.4 |
| Myopathy NOS | ICD9: 359.9 |
| Rhabdomyolysis | ICD9: 728.88 |
| Myalgia and myositis NOS | ICD9: 729.1 |

*Source: HEDIS 2017 Technical Specifications*

# HEDIS Definition: Statin Initiation

***Received Statin Therapy***

Patients with IVD who were dispensed at least one **high** or **moderate-intensity statin** medication during the measurement year.

| Description | Statin Medications | |
|---|---|---|
| High-intensity statin therapy | Atorvastatin 40-80 mg<br>Amlodipine-atorvastatin 40-80 mg<br>Ezetimibe-atorvastatin 40-80 mg | Rosuvastatin 20-40 mg<br>Simvastatin 80 mg<br>Ezetimibe-simvastatin 80 mg |
| Moderate-intensity statin therapy | Atorvastatin 10-20 mg<br>Amlodipine-atorvastatin 10-20 mg<br>Ezetimibe-atorvastatin 10-20 mg<br>Rosuvastatin 5-10 mg<br>Simvastatin 20-40 mg<br>Ezetimibe-simvastatin 20-40 mg<br>Niacin-simvastatin 20-40 mg | Sitagliptin-simvastatin 20-40 mg*<br>Pravastatin 40-80 mg<br>Lovastatin 40 mg<br>Niacin-lovastatin 40 mg<br>Fluvastatin XL 80 mg<br>Fluvastatin 40 mg bid<br>Pitavastatin* 2-4 mg |

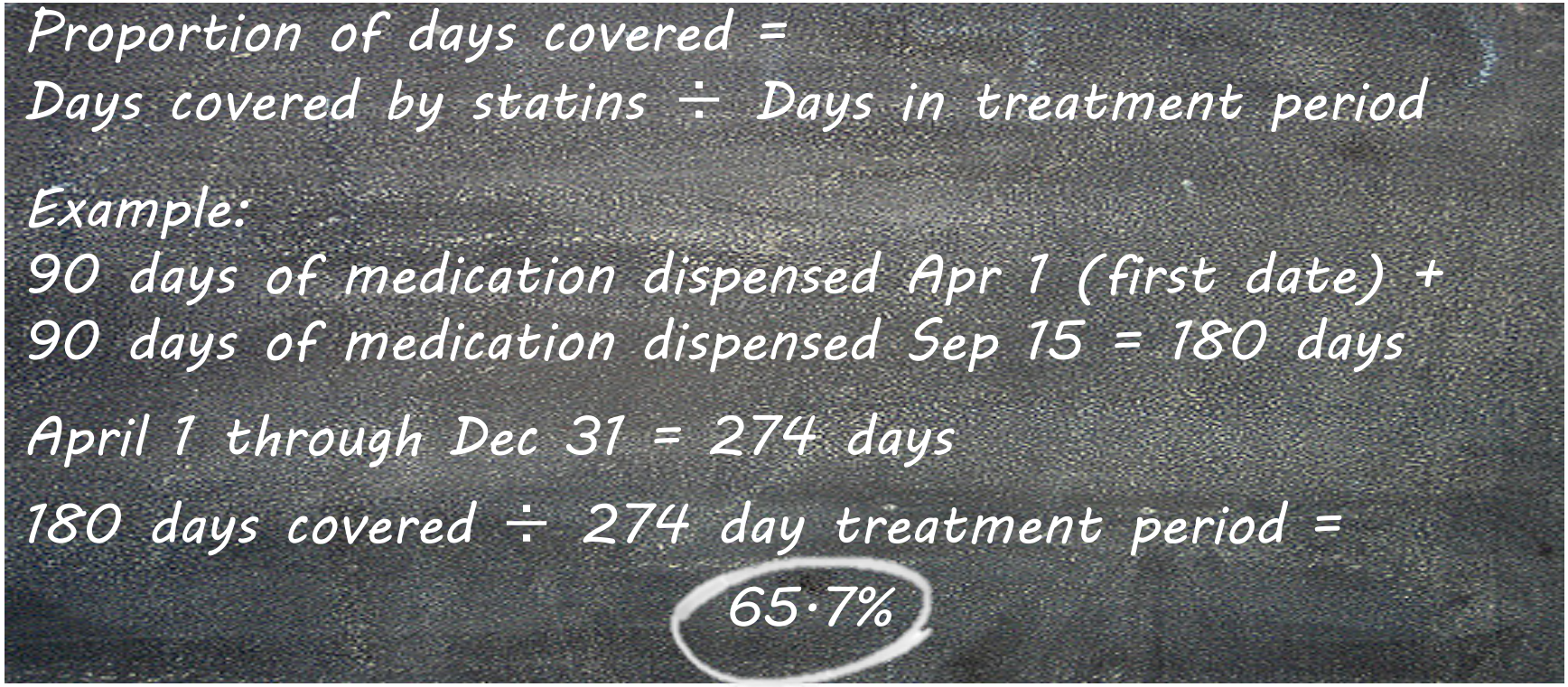
**Non-formulary at Group Health*

*Source: HEDIS 2017 Technical Specifications*

# HEDIS Definition: Statin Adherence

***Statin Adherence 80%***

Members with IVD who remained on a high or moderate-intensity statin medication for at least **80% of the treatment period.**




*Source: HEDIS 2017 Technical Specifications*

# Statin Adherence Strategies

## Patient Engagement Conversations

- Determine root cause
- Utilize Cardiac Risk tools
- Employ shared decision-making

## Cost

- Use generics: atorvastatin and rosuvastatin
- May have a reduced cost benefit via GH mail-order

## Intolerance

- Try different statin, lowering dose, or alternating days of therapy
- ACC intolerance app
- Consider CoQ10

## Convenience

- 90 day supply at mail order

# Tools

**Provider.ghc.org**

- HEDIS® Insight:  Provider Communications > HEDIS® Insight
- Clinical guidelines:  Caring For Our Members > Guidelines
- Patient education:  Caring For Our Members > Patient Health Education
- Newsletters:  Provider Communications
- Drug Formulary, Clinician Prescribing Tools: Caring For Our Members > Pharmacy
- Cardiac Risk Calculator: https://www.ghc.org/html/public/tools/heart/

**Care Gap Report:** Ask your Provider Services Consultant for regular patient lists for your practice.

# Thank you!

GroupHealth®