Preventive Services Statins Zero Copay Exception-REG

Summary

Statins are a class of medications used to lower high levels of cholesterol and triglycerides in the blood and reduce the risk of cardiovascular disease. They are classified as low-intensity, moderate-intensity, or high-intensity based on their ability to lower low-density lipoprotein (LDL)-cholesterol levels. Statins work by inhibiting an enzyme in the liver that is responsible for producing cholesterol.

Table 1: Statins (hydroxymethylglutaryl-CoA reductase inhibitors) Intensity

Generic name	High intensity	Moderate intensity	Low intensity
Atorvastatin	40 to 80 mg	10 to 20 mg	
Rosuvastatin	20 to 40 mg	5 to 10 mg	
Simvastatin		20 to 40 mg	10 mg
Pravastatin		40 to 80 mg	10 to 20 mg
Lovastatin		40 to 80 mg	20 mg

Fluvastatin		80 mg daily (extended-release) or 40 mg twice daily	20 to 40 mg
Pitavastatin		1 to 4 mg	

Statin Use for the Primary Prevention of Cardiovascular Disease in Adults:

The United States Preventive Services Task Force (USPSTF) provides recommendations based on population groups and cardiovascular risk:

1. For adults aged 40 to 75 years with one (1) or more cardiovascular risk factors and an estimated 10-year cardiovascular disease (CVD) risk of 10% or greater, the USPSTF recommends initiating a statin (Grade: B). (See Definitions below for a complete list of USPSTF defined cardiovascular risk factors)
2. For adults aged 40 to 75 years with one (1) or more cardiovascular risk factors and an estimated 10-year CVD risk of 7.5% to less than 10%, the USPSTF recommends selectively offering statins for primary prevention of CVD (Grade: C).
3. The current evidence is insufficient to assess the benefits and harms of initiating a statin for the primary prevention of CVD events and mortality in adults 76 years or older.

These recommendations apply to adults 40 years or older without established CVD or signs of CVD. They do not apply to adults with a LDL cholesterol level greater than 190 mg/dL (4.92 mmol/L) or known familial hypercholesterolemia.

I. Initiate a moderate-intensity statin for those with a risk factor and a 10-year CVD risk of 10% or greater, after patient agreement.
II. For those with a risk factor and a 10-year CVD risk of 7.5% to less than 10%, selectively offer a statin considering patient values and preferences.
III. To implement these recommendations, clinicians should consider the patient's age, presence of cardiovascular risk factors, and estimated CVD risk.
    A. CVD is the leading cause of mortality in the US, making these recommendations crucial.
    B. Age is a significant risk factor for CVD.

Additional resources can be found on the Million Hearts initiative and Centers for Disease Control and Prevention websites. For the full recommendation statement, visit the USPSTF or the Journal of the American Medical Association (JAMA) website.

Preventive Services Statins Zero Copay Exception

The Plan is committed to facilitating a $0 member cost share for a brand low/moderate intensity statin or brand/generic high intensity statin when it's determined to be medically necessary for primary prevention of cardiovascular disease in adults aged 40 to 75 years. Please note that this coverage does not extend to individuals with a low-density lipoprotein cholesterol (LDL-C) level greater than 190 mg/dL (4.92 mmol/L) or known familial hypercholesterolemia, as the USPSTF recommendation does not apply

to these cases. It is also important to note that the initiation or titration to 80 mg of simvastatin is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.

Definitions

"ASCVD" refers to atherosclerotic cardiovascular disease.

"ASCVD Risk Estimator" is a peer-reviewed online calculator which uses the Pooled Cohort Equations to estimate the 10-year primary risk of ASCVD (atherosclerotic cardiovascular disease) among patients without pre-existing cardiovascular disease who are between 40 and 79 years of age.

"Cardiovascular Event" is a health incident that affects the heart or blood vessels, such as a heart attack or stroke.

"Cardiovascular Risk Factors" are conditions or habits that increase the chances of developing cardiovascular disease. They encompass a wide range of factors, such as:

1. Age: Men aged 45 years or older and women aged 55 years or older are at higher risk.
2. Diabetes: A chronic condition that affects the body's ability to use sugar for energy and can cause damage to the blood vessels.
3. Dyslipidemia: An abnormal amount of lipids (like cholesterol and/or fat) in the blood.
4. Excessive Alcohol Use: Drinking too much alcohol can raise blood pressure and contribute to heart disease.
5. Family history of early heart disease: Heart disease in a father or brother before age 55, or in a mother or sister before age 65, can indicate a genetic predisposition to cardiovascular conditions.
6. Hypertension: High blood pressure, which can cause strain on the heart and contribute to atherosclerosis (hardening of the arteries).
7. Obesity: A body mass index (BMI) of 30 or higher, which puts strain on the heart.
8. Poor Diet: Diets high in saturated fats, trans fats, sodium, and cholesterol can raise blood cholesterol levels and contribute to heart disease.
9. Sedentary Lifestyle: Lack of physical activity can contribute to the development of heart disease.
10. Smoking: Tobacco use contributes to the buildup of plaque in the blood vessels and can lead to heart disease.

"Cholesterol" is a type of fat molecule that is essential for building cell membranes and producing hormones, but high levels of cholesterol in the blood can increase the risk of cardiovascular disease.

"Familial Hypercholesterolemia" is a genetic disorder characterized by high cholesterol levels, specifically high levels of LDL-C, in the blood.

"High-intensity statin" is a statin with LDL-lowering capacity of 50% or greater.

"Hyperlipidemia" is a condition characterized by high levels of lipids (fats) in the blood, including cholesterol and triglycerides.

"Low-density lipoprotein cholesterol (LDL-C)" is a type of cholesterol that is often referred to as "bad" cholesterol because high levels of LDL-C can increase the risk of cardiovascular disease. Statins and other medications are often used to lower LDL-C levels.

"Moderate-Intensity statin" is a statin with LDL-lowering capacity of 30-49%.

"Preventive Services Statins Zero Copay Exception" is a provision in the health plan where the member doesn't have to pay any out-of-pocket costs (copay) for statins when used for the primary prevention of cardiovascular disease.

"Primary prevention" is used to reduce the risk of future atherosclerotic cardiovascular disease (ASCVD) events.

"Secondary prevention" is used to treat existing ASCVD and to prevent it from getting worse.

"Statins" are a class of medications used to lower cholesterol levels and reduce the risk of cardiovascular disease by inhibiting an enzyme involved in cholesterol synthesis.

"Triglycerides" are a type of fat molecule that is used for energy storage in the body, but high levels of triglycerides in the blood can increase the risk of cardiovascular disease.

"U.S. Preventive Services Task Force (USPSTF) recommendations" are based on a rigorous review of existing peer-reviewed evidence and are intended to help primary care clinicians and patients decide together whether a preventive service is right for a patient's needs.

Coverage Criteria

The requested product will be covered at $0 member cost share when the following criteria are met:

1. The member is aged 40 to 75 years, and the statin is needed for primary prevention of cardiovascular disease*; AND*
2. The member has an estimated 10-year risk of a cardiovascular event of 10 percent or greater*; AND*
3. The member has ONE (1) or more cardiovascular risk factors, which may include but are not limited to the following:
    a. Age (men aged 45 years or older; women aged 55 years or older)*; and/or*
    b. Diabetes*; and/or*

c. Dyslipidemia*; and/or*
d. Family history of early heart disease (heart disease in father or brother before age 55; heart disease in mother or sister before age 65)*; and/or*
e. Hypertension*; and/or*
f. Obesity (Body Mass Index (BMI) of 30 or higher)*; and/or*
g. Smoking*; AND*

4. The member meets ALL of the following criteria:
    a. No evidence of an low-density lipoprotein cholesterol (LDL-C) level greater than 190 mg/dL (4.92 mmol/L)*; and*
    b. No evidence of familial hypercholesterolemia*; and*
    c. No evidence of existing atherosclerotic cardiovascular disease (ASCVD).

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 36 months at a $0 member cost share.</u>

Appendix

Reduction in Risk of Cardiovascular Events

<u>General Recommendation</u>

1. The American Heart Association (AHA)/American College of Cardiology (ACC) cholesterol management guideline recommends statins as first-line therapy for reducing the risk of atherosclerotic cardiovascular disease (ASCVD) in adults.
2. Evidence shows that statins substantially reduce low-density lipoprotein (LDL)-cholesterol concentrations and associated ASCVD risk.
3. The maximum tolerated statin intensity should be used to achieve optimum ASCVD benefits.
4. The ACC/AHA guideline recommends statin therapy for primary prevention of CVD in the following populations:
    a. Those 40-75 years with an LDL-cholesterol ≥70 - <190 mg/dl without Diabetes Mellitus and 10-year ASCVD risk of 5- <7.5%: consider a risk discussion" "if risk enhancers present then risk discussion regarding moderate-intensity statin therapy." (Class IIb)
    b. Those 40-75 years with an LDL-cholesterol ≥70 - <190 mg/dl without Diabetes Mellitus and 10-year ASCVD risk of ≥7.5% - <20%: consider a risk discussion: "If risk estimate + risk enhancers favor statin, initiate moderate-intensity statin to reduce LCL-C by 30-49%" (Class I)
    c. Those 40-75 years with an LDL-cholesterol ≥70 - <190 mg/dl without Diabetes Mellitus and 10-year ASCVD risk of ≥20%: consider a risk discussion: "Initiate statin to reduce LDL-C by ≥50%." (Class I)
    d. In those with LDL-C ≥190 mg/dl (≥4.9 mmol/L): "No risk assessment; High intensity statin." (Class I)
    e. In those with Diabetes mellitus and age 40-75 years: "Moderate intensity statin." (Class I)

f. In those with Diabetes Mellitus and age 40-75 years: "Risk assessment to consider high intensity statin." (Class IIa)
g. In those 20-39 years: "To encourage lifestyle to reduce ASCV risk; consider statin if family history [of] premature ASCVD and LDL-C ≥160 mg/dl (≥4.1 mmol/L)."

5. ACA/AHA guidelines define "risk enhancers" as the following:
    a. Family history of premature ASCVD
    b. Persistent elevated LDL-C ≥160 mg/dl (≥4.1 mmol/L)
    c. Chronic kidney disease
    d. Metabolic syndrome
    e. Conditions specific to women (e.g., preeclampsia, premature menopause)
    f. Inflammatory disease (especially rheumatoid arthritis, psoriasis, HIV)
    g. Ethnicity (e.g., South Asian ancestry)
    h. Lipid biomarkers:
        i. Persistently elevated triglycerides (≥175 mg/dl, (≥2.0 mmol/L))
    i. In selected individuals if measured:
        i. High-sensitivity C-reactive protein (hs-CRP) ≤2.0 mg/L
        ii. Lp(a) levels > 50 mg/dl or >125 nmol/L
        iii. apoB ≥130 mg/dl
        iv. Ankle-brachial index (ABI) <0.9

<u>Primary Prevention with Statins</u>

1. Statins are used with diet and lifestyle modifications in those without clinical evidence of coronary heart disease but with an increased risk of cardiovascular disease.
2. High-risk individuals are identified by age, high-sensitivity C-reactive protein concentrations, and additional cardiovascular disease risk factors (see Definitions above).
3. A shared decision-making approach between the member and clinician is recommended when considering statin therapy for primary prevention.
4. Statin therapy in high-risk individuals has been shown to reduce the risk of major cardiovascular events.

<u>Reducing Progression of Coronary Atherosclerosis</u>

1. Statins are used to slow the progression of atherosclerosis as part of a treatment strategy to lower total and LDL-cholesterol concentrations to target levels.
2. Studies have shown that statins slows the progression of atherosclerosis in those with elevated LDL-cholesterol concentrations and subclinical atherosclerosis.

<u>Secondary Prevention with Statins</u>

1. Statins are used for secondary prevention in those with established ASCVD.
2. The 2018 AHA/ACC cholesterol management guideline emphasizes lifestyle modification as the foundation of ASCVD risk reduction.

3. Those with clinical ASCVD should also be treated with a statin in conjunction with lifestyle modification to reduce LDL-cholesterol concentrations.
4. AHA/ACC recommends the use of high-intensity statin therapy.
5. This criteria does not apply to those being treated with statins for secondary prevention.

Intensity of Statin Therapy

1. The appropriate intensity of a statin should be used to reduce the risk of ASCVD and should be individualized.
2. Statins of different doses are grouped into intensity level (low, moderate or high-intensity) based on LDL-cholesterol reduction percentage from baseline.

Combination Antilipemic Therapy

1. Combination therapy with a non-statin drug may be useful in high-risk individuals who require further reduction in LDL-cholesterol concentrations.
2. If combination therapy is necessary, selection of the non-statin drug should be based on the risk and benefit profile and patient preferences.

Those with Chronic Kidney Disease

1. Studies on statin benefits in those with chronic kidney disease showed that therapy did not substantially reduce the primary composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke compared with placebo.
2. Chronic kidney disease (CKD) is considered a "risk enhancer" per the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease.
3. A secondary analysis of the JUPITER (Justification for the Use of statins in Prevention-an Intervention Trial Evaluating Rosuvastatin), which recruited n=3,267 participants with reduced kidney function, identified that those with moderate CKD experienced a 45% reduction in composite primary outcome of myocardial infarction, stroke, hospital stay for unstable angina, arterial revascularization or confirmed cardiovascular death (HR 0.55, 95% CI: 0.38-0.82, p=0.002). They also realized a 44% reduction in all-cause mortality (HR 0.56, 95% CI:0.37-0.85, p=0.005). These results were similar for those with preserved kidney function in the JUPTER study.
4. In a large cohort study of 14,828 older adult (≥65 years of age) veterans with stage 3 or 4 CKD, it was found that those who initiated a statin had a lower risk of all-cause major adverse cardiovascular events (HR 0.91, 95% CI, 0.85-0.97), compared to those who did not initiate a statin.
5. In a post-hoc analysis of the MEGA randomized controlled trial, it was found that the risk of CVD events was higher in those with moderate CKD compared to those with normal kidney function or mild CKD (35-49% higher risk). In those who initiated pravastatin with moderate CKD, the risk of coronary heart disease (CHD) was reduced by 48%, the risk of stroke was reduced by 73%, the risk of CVD was reduced by 55% and the risk of total mortality was reduced by 51%.

6. In a post-hoc analysis of the Air Force/Texas Coronary Atherosclerosis Prevention study, lovastatin was shown to significantly reduce the risk of fatal and non-fatal CVD events in those with moderate CKD (RR 0.31, 95% CI, 0.13-0.72, p=0.01) and no history of ASCVD.
7. In a multicenter international randomized controlled study of 2776 participants with CKD on hemodialysis (ages 50-80), rosuvastatin significantly reduced LDL-C, but did not significantly reduce the risk of CVD events (composite of death from CVD cause, nonfatal myocardial infarction, or nonfatal stroke) compared to placebo. Conversely, in a post-hoc analysis of the 4D (Die Deutsche Diabetes Dialyze) study, atorvastatin significantly reduced the risk of fatal and non-fatal cardiac events in those with type 2 diabetes undergoing hemodialysis (HR 0.69, 95% CI, 0.48-1.00) with the highest quartile of LDL-C (≥145 mg/dl).

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