

## Preventive Services Statins Zero Copay Exception

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member’s policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member’s policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### 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 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 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).
2. For those in the same age range with an estimated 10-year CVD risk of 7.5% to less than 10%, statins should be offered selectively (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 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 is not characterized by one or more of the following:
  - a. adults with a low-density lipoprotein cholesterol (LDL-C) level greater than 190 mg/dL (4.92 mmol/L); **and/or**
  - b. known familial hypercholesterolemia; **and/or**
  - c. existing atherosclerotic cardiovascular disease.

**If the above prior authorization criteria are met, the requested product will be authorized for 12 months at a \$0 member cost share.**

## Appendix

### Reduction in Risk of Cardiovascular Events

#### General Recommendation

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.

#### Primary Prevention with Rosuvastatin

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

#### Reducing Progression of Coronary Atherosclerosis

1. Rosuvastatin is 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 rosuvastatin slows the progression of atherosclerosis in patients with elevated LDL-cholesterol concentrations and subclinical atherosclerosis.

#### Secondary Prevention with Rosuvastatin

1. Rosuvastatin is used for secondary prevention in patients with established ASCVD.
2. The 2018 AHA/ACC cholesterol management guideline emphasizes lifestyle modification as the foundation of ASCVD risk reduction.
3. Patients 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.

#### Intensity of Statin Therapy

1. The appropriate intensity of a statin should be used to reduce the risk of ASCVD.

2. Rosuvastatin at different doses is considered to be high-intensity or moderate-intensity statin based on LDL-cholesterol reduction.

### **Combination Antilipemic Therapy**

1. Combination therapy with a non-statin drug may be useful in high-risk patients 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.

### **Patients with Chronic Kidney Disease**

1. Studies on rosuvastatin's benefits in patients 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.

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### Clinical Guideline Revision / History Information

Original Date: 7/31/2023

Reviewed/Revised: 12/19/2024