

## PHARMACY COVERAGE GUIDELINE

### Generic Statin Medications for Prevention Benefit Coverage with Waived Cost Share (atorvastatin, fluvastatin, fluvastatin er, lovastatin, pravastatin, rosuvastatin, and simvastatin)

#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).

#### **Criteria:**

See “Generic Statin Medications Chart” in “[Definitions](#)” section for dosing and age limitations based on USPSTF recommendations.

- **Criteria for initial therapy:** An exception request for USPSTF recommendation for generic statin medications atorvastatin, fluvastatin, fluvastatin ER, lovastatin, pravastatin, rosuvastatin, **OR** simvastatin for Prevention Benefit Coverage with Waived Cost Share is considered **medically necessary** and will be approved when **ALL** the following criteria are met:

1. Individual is 40 to 75 years of age or older

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2. Individual has medical record documentation of **NO** history of cardiovascular disease (CVD) (i.e., symptomatic coronary artery disease or ischemic stroke).
3. Individual has medical record documentation of **BOTH** of the following:
  - a. Has **ONE** or more of the following CVD risk factors:
    - i. Dyslipidemia
    - ii. Diabetes
    - iii. Hypertension
    - iv. Smoking
  - b. Has a calculated 10-year risk of a cardiovascular event of 10% or greater using the American Heart Association, American College of Cardiology ASCVD risk estimator (See resources section below for the link to this site)
4. Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
5. Individual has no benefit or contract exclusions that apply

**Initial approval duration:** 12 months

- **Criteria for continuation of coverage (renewal request):** Atorvastatin, fluvastatin, fluvastatin ER, lovastatin, pravastatin, rosuvastatin, **OR** simvastatin is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):
1. The individual continues to meet all initial criteria for use as described above
  2. Individual's condition has not progressed or worsened while on therapy.
  3. Individual has been adherent with the medication
  4. Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
  5. Individual has not developed any contraindications or other exclusions to its continued use
  6. There are no significant interacting drugs

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

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1. Off-Label Use of Non-Cancer Medications
  2. Off-Label Use of Cancer Medications
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#### **Description:**

For certain benefit plans, certain generic statin medications when prescribed for prevention, may be available at zero-member cost-share when dispensed through an in-network pharmacy. The zero-member cost-share may only apply when prior authorization is approved. Medication coverage is subject to limitations, including but not limited to medications that are used preventatively but do not qualify for waive member cost share through the prevention benefits.

The Patient Protection and Affordable Care Act (PPACA) requires that non-grandfathered group and individual health plans waive cost share for in-network preventive services, including certain preventive medications and devices in certain circumstances when these are a current published recommendation Grade A or B by the United States Preventive Services Task Force (USPSTF). This benefit option does not apply universally to grandfathered plans. The cost share waiver does not apply when an out of network or non-contracted pharmacy provider is used. Second, there are some medications and devices that can be used for both preventive care and to treat a medical condition. Cost share is waived only when the medication or device is prescribed for preventive care. Some medications covered under prevention also have prescription limitations or prior authorization requirements. The medication must be prescribed for a preventive care purpose.

Providers may submit an exception request when medication is used for prevention, but the claim is not processing under the prescription prevention benefit. However, a request is not a guarantee of coverage. Applicable benefit limitations and exclusions of the member's specific benefit plan may apply.

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#### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

#### **Guidance Regarding Preventive Medications as defined by the plan:**

Click [here](#) for a current listing of preventive medications or go to [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy), view resources for Standard Pharmacy Plans, and select Guidance Regarding Preventive Medications under the Other Forms and Resources section.

**FDA:** Food and Drug Administration

#### **Medication Product Labeling:**

Manufacturer FDA approved product information

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**U.S. Preventive Services Task Force (USPSTF):**

An independent group of national experts in prevention and evidence-based medicine that makes recommendations about clinical preventive services such as screenings, counseling services, and preventive medication.

**American College of Cardiology: ASCVD Risk Estimator:** <http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/>

- 10-year risk for ASCVD:
- Low risk (< 5%)
- Borderline risk (5% to 7.4%)
- Intermediate risk (7.5% to 19.9%)
- High risk (≥ 20%)

**Generic Statin Medications Chart:**

Generic Name	Brand Name	Form	Strength	Dosing and age limitations based on USPSTF recommendations
atorvastatin	Lipitor	oral tablet	10mg	1 daily per 30 day supply, covered age 40 and older
atorvastatin	Lipitor	oral tablet	20mg	1 daily per 30 day supply, covered age 40 and older
atorvastatin	Lipitor	oral tablet	40mg	Not applicable under preventive benefit.
atorvastatin	Lipitor	oral tablet	80mg	Not applicable under preventive benefit.
fluvastatin	Lescol	oral capsule	20mg	1 daily per 30 day supply, covered age 40 and older
fluvastatin	Lescol	oral capsule	40mg	1 daily per 30 day supply, covered age 40 and older
fluvastatin er	Lescol XL	oral capsule	80mg	1 daily per 30 day supply, covered age 40 and older
lovastatin	Mevacor	oral tablet	10mg	1 daily per 30 day supply, covered age 40 and older
lovastatin	Mevacor	oral tablet	20mg	1 daily per 30 day supply, covered age 40 and older
lovastatin	Mevacor	oral tablet	40mg	1 daily per 30 day supply, covered age 40 and older
pravastatin	Pravachol	oral tablet	10mg	1 daily per 30 day supply, covered age 40 and older
pravastatin	Pravachol	oral tablet	20mg	1 daily per 30 day supply, covered age 40 and older
pravastatin	Pravachol	oral tablet	40mg	1 daily per 30 day supply, covered age 40 and older
pravastatin	Pravachol	oral tablet	80mg	Not applicable under preventive benefit.
rosuvastatin	Crestor	oral tablet	5mg	1 daily per 30 day supply, covered age 40 and older
rosuvastatin	Crestor	oral tablet	10mg	1 daily per 30 day supply, covered age 40 and older
rosuvastatin	Crestor	oral tablet	20mg	1 daily per 30 day supply, covered age 40 and older
rosuvastatin	Crestor	oral tablet	40mg	1 daily per 30 day supply, covered age 40 and older
simvastatin	Zocor	oral tablet	5mg	1 daily per 30 day supply, covered age 40 and older
simvastatin	Zocor	oral tablet	10mg	1 daily per 30 day supply, covered age 40 and older
simvastatin	Zocor	oral tablet	20mg	1 daily per 30 day supply, covered age 40 and older
simvastatin	Zocor	oral tablet	40mg	1 daily per 30 day supply, covered age 40 and older
simvastatin	Zocor	oral tablet	80mg	Not applicable under preventive benefit. Refer to Pharmacy Coverage Guidelines for Simvastatin 80mg Products

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#### **Resources:**

U.S. Preventive Services Task Force available at <https://uspreventiveservicestaskforce.org>. Accessed April 03, 2023.

Mangione CM, Geffen D: Statin Use for the Primary Prevention of Cardiovascular Disease in Adults. US Preventive Services Task Force Recommendation Statement. 2016 JAMA August 23/30; 328 (8): 746-753. Accessed April 03, 2023.

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