



## **ACA Prevention Copay Waiver Criteria – Individual Marketplace, Commercial**

### **CLINICAL RATIONALE**

The Affordable Care Act (ACA) requires a member-friendly mechanism for waiving the cost share for an alternative recommended product deemed medically necessary by the provider when a health care provider considers the \$0 covered product is inappropriate for an individual. Prime Therapeutics offers a standard coverage exception/cost share waiver policy that is applied across all ACA categories.

[https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\\_implementation\\_faqs12.html](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html)

[https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca\\_implementation\\_faqs26.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf)

## Breast Cancer Primary Prevention Agent ACA Copay Waiver Criteria

### OBJECTIVE

The intent of the ACA Prevention Copay Waiver Criteria is to help ensure the copay waiver, when applicable based on the member's benefit, is applied to the appropriate population as described by the United States Preventative Services Task Force (USPSTF).

### CRITERIA FOR APPROVAL

The requested breast cancer primary prevention agent will be approved when ALL of the following are met:

1. The requested breast cancer primary prevention agent is covered under the pharmacy benefit or has been approved through the coverage exception process  
**AND**
2. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary  
**AND**
3. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)  
**AND**
4. The patient is 35 years of age or over  
**AND**
5. The agent is requested for the primary prevention of breast cancer  
**AND**
6. ONE of the following:
  - a. The plan has not implemented a sex requirement  
**OR**
  - b. The plan has implemented a sex requirement **AND** ONE of the following:
    - i. The patient's sex is female  
**OR**
    - ii. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex

**Length of Approval:** 12 months

# Human Immunodeficiency Virus (HIV) Infection: Pre-exposure Prophylaxis (PrEP) ACA Prevention Copay Waiver Criteria

## OBJECTIVE

The intent of the ACA Prevention Copay Waiver Criteria is to help ensure the copay waiver, when applicable based on the member's benefit, is applied to the appropriate population as described by the United States Preventative Services Task Force (USPSTF).

## CRITERIA FOR APPROVAL

The requested HIV infection pre-exposure prophylaxis (PrEP) agent will be approved when ALL of the following are met:

1. The requested PrEP agent is covered under the pharmacy benefit or has been approved through the coverage exception process  
**AND**
2. The requested agent is being used for PrEP  
**AND**
3. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents  
**AND**
4. ONE of the following:
  - a. The requested PrEP agent is ONE of the following:
    - i. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent  
**OR**
    - ii. Tenofovir disoproxil fumarate single ingredient agent  
**OR**
    - iii. Tenofovir alafenamide and emtricitabine combination ingredient agent  
**OR**
  - b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient  
**AND**
5. The patient is at high risk of HIV infection  
**AND**
6. The patient has recently tested negative for HIV

**Length of Approval:** 12 months

## Statin ACA Prevention Copay Waiver Criteria

### OBJECTIVE

The intent of the ACA Prevention Copay Waiver Criteria is to help ensure the copay waiver, when applicable based on the member's benefit, is applied to the appropriate population as described by the United States Preventative Services Task Force (USPSTF). The USPSTF recommendation requires the calculation of Atherosclerotic Cardiovascular Disease (ASCVD) risk. The calculation requires inputting the patient's sex, age, race, high density lipoprotein (HDL) cholesterol, total cholesterol, blood pressure, whether the patient has diabetes, whether the patient is under treatment for hypertension, and whether the patient is an active smoker.<sup>1</sup>

1. American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator. Available at: <https://tools.acc.org/ASCVD-Risk-Estimator/> Accessed on 9/27/2022.

### CRITERIA FOR APPROVAL

The requested statin will be approved when ALL of the following are met:

1. The requested agent is a generic statin (MSC=Y) unless a generic statin is not available for the requested agent  
**AND**
2. The requested statin is covered under the pharmacy benefit or has been approved through the coverage exception process  
**AND**
3. The prescriber has provided information stating that the requested statin is medically necessary  
**AND**
4. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)  
**AND**
5. The patient is 40-75 years of age (inclusive)  
**AND**
6. The patient has at least one of the following risk factors:
  - a. Dyslipidemia
  - b. Diabetes
  - c. Hypertension
  - d. Smoking**AND**
7. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

**Length of Approval:** 12 months