



ACA Prevention Copay Waiver Program Summary – 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/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.¹

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