

PHARMACY COVERAGE GUIDELINE

Cost-Share Waiver Exception Policy for Preventive Medications

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 precertification is available at 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.

Criteria:

- **Criteria for initial therapy:** An exception request for cost-share waiver on a preventive medication may be considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
 1. A diagnosis and treatment plan are submitted that provides the rationale for the exception request for a waived member cost share.
 2. Evidence that the U.S. Preventive Services Task Force recommendation grade of A or B is applicable to the individual.
 3. There are no benefit or contract exclusions that apply.

Initial approval duration: 12 months

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- **Criteria for continuation of coverage (renewal request):** An exception request for cost-share waiver on a preventive medication is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. U.S. Preventive Services Task Force recommendation grade of A or B is applicable.
2. There are no benefit or contract exclusions that apply.
3. Individual has been adherent with the medication.

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:

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

Description:

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 of 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. 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 precertification 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.

Definitions:

Guidance Regarding Preventive Medications as defined by the plan:

View resources for Prescription Drug Coverage Information and Formularies on azblue.com/pharmacy for a current listing of preventive medications.

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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.

Grade Definitions after July 2012:

Grade	Definition	Suggestion for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Levels of Certainty Regarding Net Benefit:

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: <ul style="list-style-type: none"> • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: <ul style="list-style-type: none"> • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes More information may allow estimation of effects on health outcomes.



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The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Resources:

[Task Force Resources | United States Preventive Services Taskforce \(uspreventiveservicestaskforce.org\)](https://www.uspreventiveservicestaskforce.org/). Current as of June 2021. Accessed September 06, 2021.

List of USPSTF A & B Recommendations <https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations>. Accessed September 06, 2021.

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