

## Pharmacy Policy Bulletin

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**Title:** Formulary Exception Policy

**Policy #:** Rx.01.61

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### **▶ Intent:**

The intent of this policy is to communicate the medical necessity criteria for formulary exception requests as provided under the member's prescription drug benefit.

### **▶ Description:**

The Company utilizes a tiered cost-sharing structure for medications covered under the pharmacy benefit. Members should refer to their benefit booklet for more information.

### **Formulary Tier Exceptions**

The following tier exceptions requests will be considered:

#### **A. Select Drug Formulary**

1. Non-preferred drug to be covered at the:
  - a. Preferred brand tier if the product is a brand medication (or authorized generic); or
  - b. Generic tier if the product is generic medication
2. All other tiers are restricted to the benefit design and thus are not eligible for a tier exception

#### **B. Value Formulary**

1. Non-formulary medication to be covered at the highest level of cost share. These exceptions are not eligible for tier reduction.
2. Non-preferred drug to be covered at the:
  - a. Preferred brand tier if the product is a brand medication (or authorized generic); or

- b. Generic tier if the product is generic medication
- 3. All other tiers are restricted to the benefit design and thus are not eligible for a tier exception.

C. CHIP:

- 1. Non-preferred drug medication to be covered at the
  - a. Preferred brand tier if the product is a brand (or authorized generic); or
  - b. Generic tier if the product is generic
- 2. Brand medication to be covered at the generic benefit level

The following tiers are defined by the benefit and are not eligible for a tier exception:

- A. Specialty tier
- B. Preferred brand tier
- C. Generic tier

Authorized generics are brand name drugs that are marketed without the brand name on its label. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission. Although a Food and Drug Administration (FDA) approved drug, the authorized generic is not approved through the abbreviated new drug application process (ANDA) like a standard generic drug. For cost sharing purposes, authorized generics are treated as brand name drugs and are not eligible for coverage on the generic tier(s).

**Cost Share Exceptions for Preventive Care Services and Women's Preventive Services**

The services listed in this policy are considered preventive care services when the criteria in this policy are met, when they are identified as preventive services in the Company's benefit contracts and when they are mandated by state or federal law. This policy supports the preventative care services listed in the US Preventive Services Task Force (USPSTF) as A or B Recommendations and the Women's Preventive Services (WPS) provision of Patient Protection and Affordable Care Act (PPACA). These products are available without cost-sharing with a prescription when provided by a participating retail or mail-order pharmacy.

Based on the USPSTF recommendation the following products are available at zero-dollar cost-share. All medications refer to generic, single ingredient products unless otherwise noted.

Category	Recommendation	Medication
ASPIRIN	Low dose Aspirin for the Primary Prevention of Cardiovascular Disease and Colorectal Cancer: Preventive Medication: Individuals 50 to 59 years who have a 10 year cardiovascular risk of 10% or greater, with life expectancy of at least 10 years, without increased risk for bleeding, willing to take low-dose aspirin for at least 10 years	aspirin 81mg
	Pregnant Women Who Are At High Risk for Preeclampsia:	aspirin 81mg or less

	The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia.	
TOBACCO CESSATION MEDICATION	Tobacco cessation medication is covered as a preventive service for all adults who use tobacco products and nicotine replacement (i.e., nicotine gums and nicotine patches).	Chantix®, bupropion, Nicotrol®, generic nicotine gums and patches
FOLIC ACID	Women Planning or Capable of Pregnancy: The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	folic acid 400 mcg to 800 mcg (including generic prenatal vitamins with the above listed folic acid dose)
FLUORIDE	Children From Birth Through Age 5 Years: The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride.	fluoride up to 0.5mg for children 6 months to 60 months
BREAST CANCER CHEMO-PREVENTION	Women, Increased Risk for Breast Cancer  The USPSTF recommends that clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.	tamoxifen 20mg
CONTRACEPTIVES	The contraceptive methods for women currently identified by the FDA include: (1) sterilization surgery for women; (2) surgical sterilization implant for women; (3) implantable rod; (4) IUD copper; (5) IUD with progestin; (6) shot/injection; (7) oral contraceptives (combined pill);	injection/shot, oral contraceptives, Natazia®, Quartette®, patch, Nuvaring®, diaphragms, sponge, cervical cap, female condom, spermicide, emergency contraceptive, Ella®. [Note: other requirement may be

	(8) oral contraceptives (progestin only); (9) oral contraceptives extended/continuous use; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female condom; (16) spermicide; (17) emergency contraception (Plan B/Plan B One Step/Next Choice); and (18) emergency contraception (Ella)	covered under the medical benefit. See referenced policy]
BOWEL PREP FOR COLONOSCOPY	The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years.	PEG 3350- electrolyte, Gavilyte-C, Gavilyte-G, Gavilyte-N, Trilyte with flavor packets, Gavilyte-H with bisacodyl, PEG-prep
STATIN PREVENTIVE MEDICATION	The USPSTF recommends that adults without a history of cardiovascular diseases (CVD) (i.e., symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1.) they are ages 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e. dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater. Identification of dyslipidemia and calculation of 10-year CVD event risk requires universal lipids screening in adults ages 40 to 75 years.	lovastatin 10, 20, 40 mg

Certain medications have additional indications that are not addressed by the preventative care measure, such as raloxifene, or have generic alternatives, such as branded contraceptives. Thus, the plan employs medical management to administer the requirements. The policy below outlines the process by which an exception can be obtained for medications that may apply to the USPSTF recommendation or the WPS provision of the PPACA but are not coded as \$0 at the point-of-sale.

\*This policy does not apply to the Premium Formulary

**Policy:**

Tier Exceptions:

A non-preferred drug will be covered at the preferred tier for brand medications as listed below when there is documentation of inadequate response or inability to tolerate at least three preferred or generic tier alternatives in the same drug class (when available).

- A. Brand medication (or authorized generic) to preferred brand tier, or
- B. Generic medication to generic tier

Non-formulary Exceptions:

Non-formulary exceptions: A medication that is non-formulary, will be covered at the highest level of cost share when there is documentation of inadequate response or inability to tolerate at least three preferred or generic tier alternatives in the same drug class (when available). Safety edits (age and quantity limits) will apply to non-formulary requests.

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A brand medication may be covered at the generic benefit level when there is documentation of an inadequate response or inability to tolerate at least three generic alternatives in the same drug class (when available).

Compounded Products:

A non-preferred compounded product may be covered at the preferred (formulary) tier when there is an inadequate response or inability to tolerate/use all other formulary alternatives.

Note: Compounded products are specially made products to meet the needs of an individual member and are not considered generics and thus not eligible for an exception to the generic tier.

An exception to allow no-cost share is approved when:

- A. The drug is described as either a preventative medication identified by the US Preventive Services Task Force (USPSTF) or Women's Preventive Services provision of the Patient Protection and Affordable Care Act (PPACA); and if applicable
- B. For branded products, ALL of the following:
  - 1. Inadequate response or inability to tolerate the generic equivalent, if available
  - 2. Inadequate response or inability to tolerate a generic alternative
  - 3. The prescriber has provided documentation indicating the requested product is medically necessary

\*Premium Formulary: This policy does not apply to the premium formulary.

**Black Box Warning:**

N/A

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.


**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

USPSTF A and B Recommendations by Date. US Preventive Services Task Force Web Site. <https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations-by-date/>. Updated October 2018. Accessed October 31, 2018.

**Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

**Cross References:**

Age Edits Rx.01.2

Compounded Products Rx.01.134

Experimental/ Investigational Policy Rx.01.33

Quantity Level Limits for Pharmaceutical Covered under the Pharmacy Benefit Rx.01.76

Opioid Management Policy Rx.01.197

Preventive Care Services Medical Policy 00.06.02t

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<b>Policy Effective Date:</b>	January 1, 2019
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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.