Pharmacy Policy Bulletin

Title: Formulary Exception Policy

Policy #: Rx.01.61

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:

Select Drug Formulary

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

Value Formulary

A. Non-formulary medication to be covered at the highest level of cost share. These exceptions are not eligible for tier reduction.
B. Non-preferred drug to be covered at the:
    1. Preferred brand tier if the product is a brand medication (including authorized generic/authorized brand alternative); or
    2. Generic tier if the product is generic medication
C. All other tiers are restricted to the benefit design and thus are not eligible for a tier exception.

CHIP

A. Non-preferred drug medication to be covered at the:
    1. Preferred brand tier if the product is a brand (including authorized generic/authorized brand alternative); or
    2. Generic tier if the product is generic

B. 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, or authorized brand alternatives, 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 : The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in pregnant females who are at high risk for preeclampsia.	aspirin 81mg or less
TOBACCO CESSATION MEDICATION	Tobacco cessation medication is covered as a preventive service for all adults who use tobacco products.	Chantix ®, bupropion, Nicotrol®, generic nicotine gums and patches
FOLIC ACID	The USPSTF recommends that all females 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	In accordance with the preventive exam age schedule set forth by American Academy of Pediatrics (AAP)/Bright Futures, oral fluoride, up	fluoride up to 0.5mg for children 6 months to 16 years of age

	to 0.5mg, is covered as a preventive service for children ages 6 months to 16 years whose water supply is deficient in fluoride.	
BREAST CANCER CHEMO-PREVENTION	The USPSTF recommends that clinicians engage in shared, informed decision making with individuals who are at increased risk for breast cancer about medications to reduce their risk. For asymptomatic females 35 years or older without a prior diagnosis of breast cancer, ductal carcinoma in situ, or lobular carcinoma in situ, who are at increased risk for breast cancer and at low risk for adverse medication effects from breast cancer chemoprevention, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen.	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); (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)	injection/shot, oral contraceptives, Natazia®, etonogestrel-ethinyl estradiol vaginal ring, diaphragms, sponge, cervical cap, female condom, spermicide, emergency contraceptive, Ella®. [Note: IUDs and implantable products are covered under the medical benefit. See referenced policy]
BOWEL PREP FOR COLONOSCOPY	The USPSTF recommends screening for colorectal cancer starting at age 45 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,PEG 3350 powder for solution
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
HIV PrEP	Preexposure prophylaxis (PrEP) with effective antiretroviral therapy for	emtricitabine/tenofovir disoproxil

	persons who are at high risk of HIV acquisition	fumarate 200mg-300mg, tenofovir 300mg

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 pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available.

A. Brand medication (including authorized generic/authorized brand alternative) 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 appropriate level of cost share when ONE of the following is met:

A. There is documentation of inadequate response or inability to tolerate at least three formulary alternatives in the same pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available. Safety edits (age and quantity limits) will apply to non-formulary requests; or
B. The medication is requested for the treatment of stage IV, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage IV, advanced metastatic cancer.

CHIP (IN Focus ID 10093453)

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 pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives 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.

$0 Cost-Share Override

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

**If there are fewer than three alternatives, all alternatives in the pharmacological class must be considered.*

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

Authorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

Truvada® (emtricitabine and tenofovir disoproxil fumarate), tenofovir

A. Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued Truvada® and tenofovir. Hepatic function should be monitored closely in HBV-infected patients who discontinue Truvada® and tenofovir. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Truvada® (emtricitabine and tenofovir disoproxil fumarate)

A. Truvada® used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug resistant HIV-1 variants have been identified with the use of Truvada® for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate Truvada® for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

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:

Bright Futures Period Schedule. Available at: https://www.aap.org/en-us/Documents/periodicity_schedule.pdf. Accessed September 28, 2021.

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 May 2021. AccessedSeptember 28, 2021.

Truvada® (emtricitabine and tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; June 2020. Available from: https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf. Accessed September 28, 2021.

Viread® (tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; April 2019. Available from: https://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/viread/viread_pi.pdf. Accessed September 28, 2021.

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:

Applicable age Edits Rx.01.2

Compounded Products Rx.01.134

Off-Label Use Rx.01.33

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

Opioid Policy Rx.01.197

Preventive Care Services Medical Policy 00.06.02t

Policy Version Number:	23.00
P&T Approval Date:	September 23, 2021
Policy Effective Date:	January 01, 2022
Next Required Review Date:	September 23, 2022