Applicaton 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; 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; 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; 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

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.

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPIRIN</td>
<td>Pregnant Women Who Are At High Risk for Preeclampsia:</td>
<td>aspirin 81mg or less</td>
</tr>
<tr>
<td></td>
<td>The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>medication after 12 weeks of gestation in pregnant females who are at high</td>
<td></td>
</tr>
<tr>
<td></td>
<td>risk for preeclampsia.</td>
<td></td>
</tr>
<tr>
<td>TOBACCO CESSATION</td>
<td>Tobacco cessation medication is covered as a preventive service for all</td>
<td>Chantix®, bupropion, Nicotrol®, generic nicotine</td>
</tr>
<tr>
<td>MEDICATION</td>
<td>adults who use tobacco products.</td>
<td>gums and patches</td>
</tr>
<tr>
<td>FOLIC ACID</td>
<td>The USPSTF recommends that all females planning or capable of pregnancy take</td>
<td>folic acid 400 mcg to 800 mcg</td>
</tr>
<tr>
<td></td>
<td>a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.</td>
<td>(including generic prenatal vitamins with the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>above listed folic acid dose)</td>
</tr>
<tr>
<td>FLUORIDE</td>
<td>In accordance with the preventive exam age schedule set forth by American</td>
<td>fluoride up to 0.5mg for children 6 months to</td>
</tr>
<tr>
<td></td>
<td>Academy of Pediatrics (AAP)/Bright Futures, oral fluoride, up to 0.5mg, is</td>
<td>16 years of age</td>
</tr>
<tr>
<td></td>
<td>covered as a preventive service for children ages 6 months to 16 years whose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>water supply is deficient in fluoride.</td>
<td></td>
</tr>
<tr>
<td>BREAST CANCER CHEMO-</td>
<td>The USPSTF recommends that clinicians engage in shared, informed decision</td>
<td>tamoxifen 20mg</td>
</tr>
<tr>
<td>PREVENTION</td>
<td>making with individuals who are at increased risk for breast cancer about</td>
<td></td>
</tr>
<tr>
<td></td>
<td>medications to reduce their risk. For asymptomatic females 35 years or older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>without a prior diagnosis of breast cancer, ductal carcinoma in situ, or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>lobular carcinoma in situ, who are at increased risk for breast cancer and at</td>
<td></td>
</tr>
<tr>
<td></td>
<td>low risk for adverse medication effects from breast cancer chemoprevention,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>clinicians</td>
<td></td>
</tr>
</tbody>
</table>
should offer to prescribe risk-reducing medications, such as tamoxifen.

| 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) condom; (16) spermicide; (17) emergency contraception and (18) emergency contraception (Ella). |
| BOWEL PREP FOR COLONOSCOPY | The USPSTF recommends screening for colorectal cancer starting at age 45 years and continuing until age 75 years. |
| 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. |
| | 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 pharmacological class*. Reasonably equivalent therapeutic class alternatives will be considered when there are limited pharmacological class alternatives available.

A. Brand medication to preferred brand tier or
B. Generic medication to generic tier

Non-formulary Exceptions:

A medication that is non-formulary, will be covered at the appropriate level of cost share when the following is met: 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;

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:


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.

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
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.