Pharmacy Policy Bulletin: J-0026 Coverage Outside Contract Parameters - Commercial and Healthcare Reform		
Number: J-00		Category: Prior Authorization
Line(s) of Business:		Benefit(s):
⊠ Commercial		Not Applicable
☑ Healthcare Reform		The state of the s
☐ Medicare		
Region(s):		Additional Postriction(s):
⊠ All		Additional Restriction(s): Groups with therapeutic exclusions
□ Delaware		
☐ New York		
☐ Pennsylvania		
☐ West Virginia		
Version: J-0026-025		Original Date: 12/01/2004
Effective Date: 08/18/2025		Review Date: 09/17/2025
Drugs	Products excluded from	coverage
Product(s):		
FDA-	Not applicable	
Approved		
Indication(s):		
Background:	 Consistent with corporate policy regarding benefits outside contract parameters, prescription drug benefit exclusions have been and will continue to be strictly enforced. There will be no payment for services or benefits above or outside those set forth in the benefits contract. In situations where benefits are unavailable, or when existing benefits have been exhausted, there will also be no payment. Benefit exceptions will not be reviewed as a matter of clinical necessity as there are no criteria in place to evaluate those requests. An exception to a benefit may be viewed as arbitrary or discriminatory which would be in violation of the Pennsylvania Unfair Insurance Practices Act (UIPA), Title 1 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and/or may be viewed as inconsistent with our fiduciary responsibilities under ERISA and the Department of Labor benefit claims procedure rule. These exclusions are part of the benefit package purchased by our groups, and their premiums are adjusted according to their amount of coverage purchased. Drug/Class Exclusions The following drugs and drug classes may be excluded from a group's pharmacy benefit and are not eligible for coverage regardless of the reason for use. The intent of the group is to not cover this class of medication, regardless of the condition they are being used to treat. Global Exclusions Nutritional Supplements Allergy Serums Amphetamines Antihistamines Biologicals 	

- Blood Glucose Test Monitors
- COX-2
- Diabetic Supplies
- Erythroid Stimulants
- Growth Hormone
- H2 Antagonists
- Immunization Agents
- Immunosuppressants
- Inhaler Assisted Devices
- Interferon
- Leukocyte Stimulants
- Lupron
- Misc Specialty Other
- Misc Specialty Injectable
- Misc Specialty Oral
- Needles & Syringes
- Over the Counter Drugs
- Other Managed Prior Auth
- PCSK9
- Proton Pump Inhibitors
- Psychotherapeutic Drugs
- Retin-A
- Small Network Drugs
- Vaccines
- Vitamins
- Wellbutrin

Therapy Exclusions

The following indications may be excluded from a group's pharmacy benefit. Drugs used for these indications are not eligible for coverage. If an excluded product is being used for a different FDA-approved indication, it may be eligible for coverage subject to the terms and provisions of their pharmacy benefit contract. It is the intent of the group to exclude all drugs used for the excluded indication only.

- Abortifacients
- Anti-Obesity*
- Attention Deficit Hyperactivity Disorder
- Contraceptives
- Fertility
- Hair Growth Stimulants
- Impotency
- Smoking Deterrents
- Substance Abuse Treatment

*Obesity-related conditions (e.g. cardiovascular disease, sleep apnea, etc.) may be excluded from a group's pharmacy benefit. Indications limited to overweight or obese patients (e.g. risk reduction of major cardiovascular events in overweight or obese patients, treatment of obstructive sleep apnea in obese patients) in anti-obesity medications are considered excluded indications and are not eligible for coverage outside of the anti-obesity benefit in all markets and segments except Delaware commercial fully insured and healthcare reform members For Delaware commercial fully insured and healthcare reform members, additional prior authorization criteria may apply per relevant pharmacy policies.

Approval Criteria

- I. Approval Criteria
 - A. Drug/Class Exclusions No exception will be made for products excluded by group benefits.
 - B. Therapy Exclusions

Coverage of a product within a therapy exclusion may be approved when all of the following criteria are met (1., 2., and 3.):

- 1. The product is being used for another FDA-approved indication other than the excluded indication.
- If the request is for Wegovy and the member has a Delaware Commercial fully-insured or Healthcare Reform plan, the member meets the cardiovascular risk reduction criteria in J-1388
- 3. If the request is for Zepbound and the member has a Delaware Commercial fully-insured or Healthcare Reform plan, the member meets the obstructive sleep apnea criteria in J-1388.
- **II.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- **II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans:
 - Wegovy for cardiovascular risk reduction and Zepbound for obstructive sleep apnea: If approved, up to the following authorization duration may be granted.
 - Initiation: 7 months
 - Continuation/Maintenance: 12 months
 - All others: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.