Pharmacy Management Quality Drug Policy

SUBJECT: Non-Formulary Medication Exception Review Policy **POLICY NUMBER: PHARMACY-69** **EFFECTIVE DATE: 01/2014** **LAST REVIEW DATE: 01/01/2026**
If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

The closed formulary drug benefit provides high quality, cost-effective prescription drug coverage. The benefit provides coverage for most generic drugs and certain brand name medications. The Pharmacy and Therapeutics (P&T) Committee is made up of local community physicians and clinical pharmacists and is responsible for endorsing the closed formulary drug list. To determine if a drug should be covered under the closed formulary benefit, the P&T Committee completes an extensive review of the drugs in each therapeutic drug class to evaluate the clinical effectiveness, quality, and value. The drugs that are proven to be of high clinical quality as well as cost effective are selected to be covered.

It is understood there may be situations where a non-covered drug may be the only treatment option available to treat a member's condition effectively. For those select cases a physician may request a closed formulary coverage exception evaluation. This process is initiated by the prescribing physician completing a request form and submitting a letter of medical necessity along with objective supporting documentation for review. The request is reviewed within the timeframes afforded by law and the determination and rationale is communicated to the provider and member.

POLICY:

A non-formulary medication exception may be considered for coverage only when the following conditions are met (**A and B**).

A. Medical Necessity Review
   1. Coverage exception requests for non-formulary drugs will be reviewed using the corresponding prior authorization (PA) policy when one exists.
      a. The member must meet all clinical medical necessity criteria (e.g., diagnostic criteria, baseline measurements, exclusion criteria, severity thresholds, monitoring requirements, recertification criteria) outlined in the corresponding prior authorization (PA) policy, including standard-of-care treatment requirements, with the exception of any embedded therapeutic alternative requirements. Because non-formulary drug requests are reviewed under a separate coverage determination standard, the therapeutic alternative (also known as Step Therapy) requirements in the PA policy do not apply. Instead, non-formulary requests must meet the formulary-alternative failure requirements described in Section B.
      b. If no corresponding PA criteria exists, the request must meet **ONE** of the following:
         i. The requested use matches the FDA-labeled indication **OR**
         ii. The requested use meets coverage requirements in accordance with the Health Plan's

Off-Label Use of FDA Approved Drugs (Pharmacy-32)

B. Inadequate Response to Formulary Alternatives
   1. **For Commercial Closed, Exchange, and Essential Plan Formularies**:
      a. Documentation that all formulary drugs, both brand and generic (including the exact generic equivalent if available), from the same therapeutic drug category/class have been tried and failed
         i. Documentation must support at least one of the following for each of the failed products, in order to be eligible for a coverage exception:
            I. Hypersensitivity (allergic reaction)
            II. Severe, indisputable drug intolerance
            III. Clinical ineffectiveness
   2. **For Child Health Plus**:
      a. Documentation that at least two (2) formulary drugs from the same therapeutic drug category/class have been tried and failed
         i. Documentation must support at least one of the following for each of the failed products, in order to be eligible for a coverage exception:
            I. Hypersensitivity (allergic reaction)
            II. Severe, indisputable drug intolerance
            III. Clinical ineffectiveness
         ii. Coverage for a brand name product with a generic equivalent requires a trial of two (2) formulary drugs, one of which being the generic equivalent (if on formulary).

POLICY GUIDELINES:

1. This policy applies to non-formulary medication exception requests under the pharmacy benefit for Commercial, Exchange, Essential Plan, and Child Health Plus formularies. This policy **does not** apply to:
   - Medicare lines of business
   - Drugs covered under the medical benefit
2. Exception requests for drugs used for conditions deemed to be cosmetic by the Health Plan will be reviewed in accordance with the Cosmetic Drug criteria located within the Clinical Review Prior Authorization Rx Policy (Pharmacy-09)).
3. In addition to the requirements listed above, all requests for non-covered drugs will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
4. Non-formulary designation does not exempt the drug from disease-specific, drug-specific, or class-specific clinical requirements.
5. Unsupported physician statement of hypersensitivity reaction, severe drug intolerance or clinical ineffectiveness without clear clinical history, reaction and resolution will not be considered adequate documentation.
6. Approved formulary exceptions will allow a non-formulary drug (brand or generic) to be processed at the non-preferred brand copayment/coinsurance.
7. For a diagnosis of gender dysphoria, a trial of all (or 2) formulary alternatives will not be required, so long as the requested non-formulary drug is indicated or supported as part of a treatment regimen for gender dysphoria.
8. Approval of non-formulary contraceptives will require only a single trial of an AB-rated equivalent drug, unless the prescriber explains a medical need exists.
9. Clinical Review criteria related to gender dysphoria has been reviewed and approved by the New York State Office of Mental Health.

REQUEST PROCESS:

1. All requests for a formulary exception are reviewed by the Excellus Pharmacy Utilization Management staff following policy guidelines and considering any unique patient specific clinical information presented. A Medical Director or peer reviewer (pharmacist for self-funded plans) completes all denials.

2. **For all lines of business except Medicare:**

   Unless otherwise discussed in the corresponding PA policy, standard approval time is one year. Exceptions to the standard timeframe may include situations where doses/treatments are limited to a certain time-period (e.g., short-term approval for bowel preps, acute antibiotic treatments, etc.)

3. **Timeframes:**

   a. Fully Insured Closed Formulary contracts:
   For non-formulary requests, Standard (non-urgent) requests for a non-formulary drug will be completed within 72 hours.
   For the expedited exceptions process, based on exigent circumstances that is defined as when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug, the health plan will make its coverage determination on such requests within no more than 24 hours after receiving them and continue to provide the drug for the duration of the exigency.

   b. Self-Funded Commercial Closed non-formulary requests:
   For non-formulary requests, standard (non-urgent) requests will be completed in 3 business days. Urgent (expedited) requests will be completed within 3 calendar days (72 hours) of receipt.

4. **Notification:**

   Each formulary exception review will include a determination letter to the member and a fax to the physician. Depending on the benefit, an attempt is also made to contact the member and the provider by phone. If the determination is a denial, an Adverse Determination letter, which includes the Notice of Determination (NOD) is sent to the member. The prescriber receives a fax of the information. If the denial is for a review for a Fully Insured Closed Formulary contract, the issued letter will indicate that the decision is the final adverse determination and will provide instructions on how to submit for external appeal if necessary.
   In the event of a denied request, the notification letter will include the following:
   - Rationale for denial.
   - Instructions on how to initiate an appeal.
     - The documentation, in letter format, contains instructions regarding how to initiate standard, expedited, and external appeals. The phone numbers for Member Services, the New York State Department of Health, and the New York Department of Insurance are included in the written notification to members. Notices of adverse determinations to Medicaid members will also include fair hearing rights, aid continuing rights, and the members' right to contact the New York State Department of Health.
   - Information on the right to obtain a copy of the review criteria.
   - Instructions on how to have prescribing physician discuss case with clinical reviewer.

5. **Lack of Medical Information:**

   If an exception request cannot be determined because of the failure to provide enough and appropriate medical information, then the provider and member are notified that the provider must produce certain requested information within 45 days for self- funded plans and Child Health Plus products. If the requested information is not provided within timeframes for consideration, the formulary exception request will be denied due to the failure to supply such information in a timely manner. The member and provider will be notified of the denial on this basis. Formulary Exceptions for Fully Insured Closed Formulary contracts will be completed within the 24- or 72-hour timeframe with the information obtainable within those timeframes. Provider outreach to collect required medical information is done by fax and by phone as appropriate.

UPDATES:

Date:	Revision:
01/01/2026	Revised
10/17/2025	Reviewed
03/06/2025	Revised
10/15/2024	Revised
11/10/2023	Reviewed
11/01/2023	Revised
04/01/2023	Revised
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02/18/2022	Revised
11/22/2021	Revised
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09/19	Revised
07/19	Revised
12/18	Revised
06/18	Revised
01/18	Revised
12/16	Revised
09/16	Revised
11/15	Revised
07/15	Revised
08/14	Revised
07/14	Revised
01/2014	Created

VIOLATIONS:

Violation of this policy may result in disciplinary action, up to and including termination for employees, termination of vendor, contractors or consultants' contracts, or dismissal for interns and volunteers. Additionally, individuals may be subject to loss of access privileges and/or civil or criminal prosecution. The Health Plan is subject to action against the Certificate of Authority and/or civil monetary penalties per New York State Department of Health regulations.

EFFECT ON PREVIOUS POLICIES:

This policy supersedes any previous policy with respect to this subject matter approved or adopted by The Lifetime Healthcare Companies or its subsidiary or affiliates to which this policy applies.

At any time and without notice, the Corporation reserves the right to amend or establish its policies, requirements, and standards.

POLICY REVIEW:
This policy is reviewed at least annually.

COMMITTEE APPROVAL HISTORY:

Date	Revision
11/13/2025	Review / P&T Committee Approval
11/21/2024	Review / P&T Committee Approval
11/30/2023	Review / P&T Committee Approval
11/17/2022	Review / P&T Committee Approval
09/16/2021	Reviewed/P&T Committee Approval
09/16/2020	P&T Committee Approval