PREMERA HMO

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PHARMACY POLICY – 5.01.572

Coverage Criteria for Excluded and Non-Formulary Drugs

Effective Date:	Apr. 1, 2025
Last Revised:	Mar. 24, 2025
Replaces:	N/A

RELATED MEDICAL/PHARMACY POLICIES:

5.01.500	Growth Hormone Therapy
5.01.503	Migraine and Cluster Headache Medications
5.01.529	Management of Opioid Therapy
5.01.541	Medical Necessity Exception Criteria for Closed Formulary Benefits and for Dispense as Written (DAW) Exception Reviews
5.01.547	Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits
5.01.549	Off-Label Use of Drugs and Biologic Agents
5.01.560	Excessively High Cost Drug Products with Lower Cost Alternatives
5.01.569	Pharmacotherapy of Type I and Type II Diabetes Mellitus
5.01.605	Medical Necessity Criteria for Pharmacy Edits

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Introduction

A formulary is a well-designed selection of drugs that meet the needs of most individuals. Formulary exclusion and non-formulary benefits normally do not provide coverage for drugs that are not included in the formulary. However, there are cases when a drug outside of the formulary may be the best therapeutic choice for an individual.

This policy outlines when a drug not included in the formulary because it is an excluded or non-formulary drug may be covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Criteria described below apply to coverage requests for excluded or non-formulary drugs in circumstances that are not specifically addressed in any other policy.

Note: Every medical necessity request submitted for an excluded or non-formulary drug requires documentation in the form of medical records/chart notes, lab work results, and other clinical information as requested by the reviewer.

Medical Necessity

Coverage of an excluded or non-formulary drug may be considered medically necessary under any of the following three circumstances:

1. An excluded or non-formulary medication that has one or more formulary alternatives:
    - Use of an excluded or non-formulary medication may be considered **medically necessary** when the prescriber has documented treatment failure, intolerance, or contraindication to at least two of the formulary alternatives.
    - Medical necessity of the excluded or non-formulary drug will be determined by medical review of the individual case circumstances. Medical necessity will be evaluated based on:
        - The drug's labeled indications, contraindications, appropriate dosing, and other clinical information contained in the label.
        - Published peer-reviewed clinical evidence from primary and tertiary medical literature sources, if the proposed use is off-label.

    Note: In cases where only one alternative is available, only that formulary agent needs to have been ineffective, not tolerated, or contraindicated.

OR

2. An excluded or non-formulary medication that has no formulary alternatives:
    - When no reasonable formulary alternative exists, medical necessity of the excluded or non-formulary drug will be determined by medical review of the individual case circumstances. Medical necessity will be evaluated based on:
        - The drug's labeled indications, contraindications, appropriate dosing, and other clinical information contained in the label.
        - Published peer-reviewed clinical evidence from primary and tertiary medical literature sources, if the proposed use is off-label.

OR

Medical Necessity
3. An excluded or non-formulary medication is brand name that has a generic equivalent available. Use of the brand product may be considered **medically necessary** with documentation of the following: ○ The prescriber is requesting the brand name drug due to a documented adverse reaction, allergy, or sensitivity to the generic equivalent and there has been treatment failure, intolerance, or contraindication to at least one other formulary alternative. **Note**: In cases where only one alternative is available, only that formulary agent needs to have been ineffective, not tolerated, or contraindicated. **OR** ○ The prescriber is requesting the brand name drug due to a documented therapeutic failure with a generic equivalent in the same therapeutic class of drugs and there has been treatment failure, intolerance, or contraindication to at least one other formulary alternative. **Note**: In cases where only one alternative is available, only that formulary agent needs to have been ineffective, not tolerated, or contraindicated. **OR** ○ The prescriber is requesting the brand name drug because transition to a generic equivalent may result in a destabilization or unnecessary risk to the individual. Note that clinical justification and medical records are also required for the review. **AND** ○ Medical necessity of the excluded or non-formulary drug will be determined by medical review of the individual case circumstances. Medical necessity will be evaluated based on: ▪ The drug's labeled indications, contraindications, appropriate dosing, and other clinical information contained in the label. ▪ Published peer-reviewed clinical evidence from primary and tertiary medical literature sources, if the proposed use is off-label.

Drug	Investigational
Excluded or non-formulary drugs or biologic agents	**Excluded or non-formulary drugs or biologic agents that are considered investigational or experimental are not covered because the safety and/or efficacy cannot be established after reviewing the published scientific literature.**

Drug	Investigational
	The medications subject to this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for all drugs subject to this policy may be approved up to 12 months unless noted otherwise.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for all drugs subject to this policy may be approved up to 12 months unless noted otherwise.**

Coding

N/A

Related Information

This policy applies only to formulary exclusion or non-formulary drugs. As used in this policy, "formulary" refers to the applicable formulary list specified in a member's contract. The policy does not apply to other benefit designs. This policy is managed by the pharmacy benefit.

Definition of Terms

Formulary: A formulary is a list of drugs approved by the Pharmacy and Therapeutics Committee (P&T) for routine use. A well-designed formulary should provide adequate drug selection to meet the treatment needs of most individuals; however, there will always be exceptional cases where a nonformulary drug may be the best therapeutic choice.

Formulary alternative: A formulary alternative is a drug that is not generically equivalent to the reference product but is expected to produce similar treatment outcomes in the majority of individuals with a certain condition. Formulary alternatives may be either brand name or generic drugs.

Formulary drug: A formulary drug (also known as a preferred drug) is a drug that is on the formulary list. Drugs that are not on the list are referred to as excluded or non-formulary drugs.

Generic equivalent: When the original patent on a brand name drug expires, other manufacturers may produce generic versions. A generic equivalent is a generic that has been approved by the FDA, based on pharmacokinetic studies that demonstrate delivery of similar amounts of the active ingredient(s) to the blood stream of healthy volunteers, with comparable concentration-time profiles. Generic equivalence evaluations are published by the FDA in the Orange Book.

Label: Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the U.S. The label includes indications, contraindications, recommended dosing, warnings, precautions, side effects, drug interactions and information on safety in pregnancy and other special populations. The drug's pharmacology, pharmacokinetics, and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application.

This prescribing information is included as a package insert with the product and is available on the manufacturer's website.

Lack of a formulary alternative: Occasionally, a drug may not have a suitable formulary alternative. This occurs when a product has recently been approved by the FDA and is pending formulary review, or when the Pharmacy and Therapeutics committee believes the potential risks generally outweigh the demonstrated clinical benefits of the drug. In such cases, it may be appropriate to use the drug in certain individual individuals, despite its lack of formulary status.

References

1. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available at **http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm** Accessed March 9, 2025.
2. U. S. Food and Drug Administration. Development & Approval Process (Drugs). Available at **http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm** Accessed March 9, 2025.

History

Date	Comments
04/01/17	New policy, approved March 14, 2017. Add to Prescription Drug section. This policy addresses medical necessity criteria for the Essentials Formulary Benefit.
01/01/18	Interim Review, approved December 20, 2017. Updated targeted drug list.
05/01/18	Annual Review, approved April 3, 2018. Table of drugs and associated medical policies removed.
05/01/19	Annual Review, approved April 18, 2019. No change to policy statement.
03/01/20	Annual Review, approved February 20, 2020. Updated policy documenting that investigational or experimental drug or biologic agents are not covered.
12/01/21	Annual Review, approved November 18, 2021. No changes to policy statement.
01/01/23	Annual Review, approved December 12, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/23	Annual Review, approved February 14, 2023. Changed title from Coverage Criteria of Excluded Drugs for Essentials Formulary to Coverage Criteria for Excluded Drugs. Removed reference to the Essentials formulary within policy.
08/01/24	Annual Review, approved July 8, 2024. No changes to policy statements.
01/01/25	Interim Review, approved December 10, 2024. Changed title from “Coverage Criteria for Excluded Drugs” to “Coverage Criteria for Excluded and Non-Formulary Drugs.” Updated coverage criteria to include non-formulary drugs.
04/01/25	Annual Review, approved March 24, 2025. Clarified that non-formulary exception review authorizations and all other review authorizations for all drugs subject to this policy may be approved up to 12 months unless noted otherwise. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to

the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.