LifeWise Assurance Company

PHARMACY BENEFIT COVERAGE GUIDELINE – 5.01.622

Exception Request to Utilization Management Restrictions for Washington State Fully-Insured Members

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

RELATED GUIDELINES / POLICIES:

5.01.541	Medical Necessity Exception Criteria for Closed Formulary Benefits and for Dispense as Written (DAW) Exception Reviews
5.01.549	Off-Label Use of Drugs and Biologic Agents
5.01.572	Coverage Criteria of Excluded Drugs for Essentials Formulary
5.01.607	Continuity of Coverage for Maintenance Medications

This policy ONLY applies to Washington fully-insured members.
This policy does not apply to member plans outside of Washington state or to those who enrolled in a self-insured plan.

Please contact Customer Service and
refer to the member booklet for confirmation.

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINES | CODING | RELATED INFORMATION | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

A formulary is the list of drugs that are routinely covered under your prescription drug benefit. The drugs on the formulary may require prior authorization or have limits such as quantity limits. Utilization management (UM) refers to any restrictions placed on drug coverage by your health plan. All UM requirements are overseen by an independent Pharmacy and Therapeutics (P&T) Committee, which is made of doctors and pharmacists who practice in the community. The P&T Committee reviews the medical and scientific evidence, guidelines from professional societies, and information in published medical studies when deciding whether to add any UM restrictions to a drug. However, there may be unique circumstances in which an exception to the UM restrictions are appropriate. This policy provides additional criteria for when exception requests

to the UM restrictions for a drug covered under the pharmacy benefit may be approved for Washington state fully-insured members.

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.

Coverage Guidelines

Note: For Washington state fully-insured members, utilization management (UM) exception requests will follow guidelines set forth in this policy when the Pharmacy Exception Request Form is submitted as part of request. Otherwise, the request will be reviewed following existing drug coverage criteria. (See also **Related Guidelines / Policies**).

Exception Request Type	Medical Necessity
Request for substitute drug	**A request for a substitute drug may be covered when any of the following criteria are met and documented in chart notes:** • Contraindication to the formulary drug • Previously tried another drug in the same pharmacologic class or a drug with the same mechanism of action and: • Experienced an adverse event (e.g., toxicity, allergy) **OR** • Documentation is provided the drug was not therapeutically effective • For a brand drug requested with an interchangeable generic equivalent drug available, documentation that the interchangeable generic equivalent drug has been tried and that an adverse event occurred • For a brand biological drug requested with an interchangeable biological drug available, documentation that the interchangeable biological product has been tried and that an adverse event occurred

Exception Request Type	Medical Necessity

	• Use of the formulary drug is expected to result in one of the following:
	  ○ Create a barrier to the adherence to or compliance with plan of care
	  ○ Negatively impact a comorbid condition
	  ○ Cause a clinically predictable negative drug interaction
	  ○ Decrease the ability to achieve or maintain reasonable functional ability in performing daily activities
	
	Note: Pharmacy Exception Request Form may be found on the Plan website.

Request to continue with current drug	**A request to continue with current drug may be approved when any of the following criteria are met and documented in chart notes:** • The provider has determined that changing from the currently prescribed drug to the formulary drug may cause a predictable adverse clinical outcome and documentation is provided on why an adverse clinical outcome would be expected such as: • The condition has been difficult to control (e.g., many drugs tried, multiple drugs required to control condition, etc.) • The individual had a significant adverse outcome when the condition was not controlled previously (e.g., hospitalization or frequent acute medical visits, heart attack, stroke, falls, significant limitation of functional status, undue pain and suffering, etc.) • The provider has determined that changing from the currently prescribed drug to the formulary drug may cause physical or mental harm to the individual **Note:** Pharmacy Exception Request Form may be found on the Plan website.
Request for a higher drug dosage	**A request for a higher drug dosage than allowed by a quantity limit may be covered when any of the following criteria are met and documented in chart notes:** • The provider has determined that successful clinical treatment requires a dosage that differs from the quantity allowed by plan and that clinical documentation has been submitted to plan for review

Exception Request Type	Medical Necessity
	• A medical reason exists regarding why a higher dose is required • A documented reason is provided for why less frequent dosing with a higher strength is not an option if required to use a higher strength **Note:** Pharmacy Exception Request Form may be found on the Plan website.
Request for off-label use	**Please see Policy 5.01.549 Off-Label Use of Drugs and Biologic Agents.**

Drug	Investigational
As listed	**The medications described in 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 a drug approved under this policy will be approved for 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for a drug approved under this policy will be approved for 12 months as long as chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, medication history, and any prior medication related adverse events

Coding

N/A

Related Information

Definition of Terms

Pharmacologic class: Means a group of active moieties that share scientifically documented properties and is defined on the basis of any combination of three attributes of the active moiety: (1) mechanism of action (MOA); (2) physiologic effect (PE); (3) chemical structure (CS).[1]

Benefit Application

This policy is managed through the pharmacy benefit and applies only to Washington fully-insured plan members.

References

1. Pharmacologic Class. U.S. Food & Drug Administration. **https://www.fda.gov/industry/structured-product-labeling-resources/pharmacologic-class** Accessed February 12, 2025.

History

Date	Comments
01/01/21	New policy, approved December 8, 2020 added to Prescription Drug section. This policy ONLY applies to Washington fully-insured plan members. Exception requests to utilization management restrictions have been added for requests for a substitute drug, to continue with current drug, and for a higher drug dosage. These exception requests may be considered medically necessary when criteria are met.

Date	Comments
12/01/21	Annual Review, approved November 18, 2021. No changes to policy statements.
10/01/22	Annual Review, approved September 26, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/23	Annual Review, approved May 22, 2023. No changes to policy statements.
05/01/24	Annual Review, approved April 22, 2024. No changes to policy statements.
03/01/25	Annual Review, approved February 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. 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.