Regence Oregon and Utah

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Medication Policy Manual

Policy No: dru694

Topic: Step Therapy Exception Criteria for Washington and Oregon Fully Insured Members

Date of Origin: January 1, 2022

Committee Approval Date: October 2, 2025

Next Review Date: 2026

Effective Date: January 1, 2026

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

This policy applies only to fully insured commercial and Exchange plans subject to Oregon, ORS 743B.602 (Step Therapy) or Washington, RCW 48.43.420 (Prescription Drug Utilization Management - Exception Request Process), WAC 284-43-2021 (Prescription drug utilization management exception and substitution process) when pre-authorization (PA) requires step therapy. Full pre-authorization criteria can be found in the individual medication coverage policies.

Policy/Criteria

I. A PA medication subject to step therapy may be pre-authorized for coverage when the following criteria, A and B below is met:

A. All non-step-therapy coverage criteria are met, as defined in the medication-specific policy.

AND

B. For an exception to step therapy requirements (of a different drug class), there is clinical documentation (such as chart notes) that at least one of the following is met:

1. The required step therapy medication is contraindicated or will cause the beneficiary to experience a clinically predictable adverse reaction (as supported by current national guidelines, compendia, standard of care, or peer-reviewed literature).

OR

2. The required step therapy medication is expected to be ineffective based on the known clinical characteristics of the beneficiary and the known characteristics of the prescription drug regimen (as supported by current national guidelines, compendia, standard of care, or peer-reviewed literature).

OR

3. Treatment with at least one of the following was discontinued due to lack of efficacy/ effectiveness, a diminished effect, or an adverse reaction:

a. The required step therapy medication

b. A drug in the same pharmacologic class as the required step therapy medication

c. A drug with the same mechanism of action as the required step therapy medication

PLEASE NOTE: Use of samples does not meet this requirement.

OR

4. The member is established on therapy (for at least 90 days) with the PA medication subject to step therapy and a change in therapy may cause clinically predictable adverse reactions, or physical or mental harm to the patient (as supported by current national guidelines, compendia, standard of care, or peer-reviewed literature).

PLEASE NOTE: Use of samples does not meet this requirement.

OR

5. The required step therapy medication is not in the best interest of the beneficiary, based on one of the following:

a. For Oregon fully-insured commercial or Exchange plans:

Documentation of medical necessity (as supported by current national guidelines, compendia, standard of care, or peer-reviewed literature).

b. For Washington fully-insured commercial or Exchange plans: documentation of medical appropriateness, including an explanation of why the provider expects that the patient's use of the prescription drug is expected to result in one of the following:

i. Create a barrier to the patient's adherence to or compliance with the patient's plan of care.

ii. Negatively impact a comorbid condition of the patient.

iii. Cause a clinically predictable negative drug interaction.

iv. Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

II. Limitations and Authorization Period

Authorization may be renewed as defined in the specific medication policy.

Cross References
Medication Policy Manual Introduction, Medication Policy Manual, Policy No. dru150

References

1. Oregon Revised Statues, Section 743b.602 (Step Therapy). 2022.
2. Revised Code of Washington, 48.43.420. (Prescription drug utilization management—Exception request process—Conditions, requirements, and time frames for approval or denial of requests—Emergency fill coverage—Notice of new policies and procedures). 2021 https://app.leg.wa.gov/rcw/default.aspx?cite=48.43.420
3. Washington Administrative Code, 284-43-21 (Prescription drug utilization management exception and substitution process). 2020. https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-2021

Revision History

Revision Date	Revision Summary
10/2/2025	No criteria changes with this annual review.
9/19/2024	No changes with this annual review.
9/14/2023	Criteria now requires all non-step therapy criteria to be met in addition to the step therapy exception criteria. Clarified that step therapy exceptions may occur if in a different drug class from the requested drug. Expanded to Washington Fully insured and Exchange members subject to RCW 48.43.420 and WAC 284-43-21 (WA ESHB 1879).
12/15/2021	New policy effective 1/1/2022.

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