

Policy	<b>PHARM-MM-115</b>
Origination Date	<b>01/01/2022</b>
Reviewed/Revised Date	<b>12/18/2025</b>
Next Review Date	<b>12/18/2026</b>
Current Effective Date	<b>01/01/2026</b>
Line of Business	<b>Healthy U, Health Choice Utah</b>

## Step Therapy

<b>Purpose</b>
To outline the step-therapy process to promote appropriate, safe, and effective utilization of drugs as guided by current clinical practice guidelines. This procedure describes how the step therapy process works for medications on the Health Plan pharmacy formulary. This will apply to all lines of business unless noted in the appendix.
<b>Note:</b> N/A

<b>Definitions</b>
1. FDA: Food and Drug Administration
2. First Line Drug: medications that do not require use of another drug before coverage is considered
3. MM = Managed Medicaid
4. PBM: Pharmacy Benefit Manager
5. Second Line Drug: medications that require step therapy or use of a first line drug before coverage is considered unless medical necessity is determined
6. Step Therapy (ST): a process designed to assure that first line drugs, which have been proven to be safe and effective and that demonstrate greater value, are used before second line and potentially more costly alternatives are considered. Most brand medications with generic alternatives require ST with the generic product before the brand will be considered for authorization.

<b>Medications</b>
1. N/A
<b>Note:</b> N/A

## Policy

1. Step therapy is a process designed to assure that first line drugs, which have been proven to be safe and effective and that demonstrate greater value, are used before second line and potentially more costly alternatives are considered. Most brand medications with generic alternatives require ST through the generic product before the brand will be considered for authorization.
  - a. A point of sale edit on a second line drug claim which searches the claims adjudication system for first line drugs over a required period of time. If the first line drug(s) have been processed in the time period, the claims system may auto-approve a second line drug if all other requirements for coverage are met. If the step therapy requirement has not been met, the claim rejects for prior authorization.
2. When step therapy has not been met, a prior authorization is required.
3. Health Plans approves coverage through the prior authorization process for certain second line drugs as medically necessary when there is one of the following conditions:
  - i. Documented failure of first line drugs
  - ii. Inadequate response to first line drugs
  - iii. Contraindication according to FDA label to first line drugs
  - iv. Intolerance to first line drugs
4. If the conditions listed in C. above are not met, the request for coverage is denied.
5. Step Therapy Guidelines outline first and second line drugs along with parameters required for step therapy. These guidelines are determined and maintained by the Health Plan Pharmacy & Therapeutics Committee. The Step Therapy Guidelines are reviewed at least annually.

## Procedure

1. Step Therapy Met, Claim Auto-Adjudicates
  - a. If a member attempts to fill a drug that requires step therapy and has already met the step therapy requirement, the claim will auto-adjudicate at point-of-service.
2. Step Therapy Met, Claim Rejects
  - a. If a member attempts to fill a drug that requires step therapy and has already met the step therapy requirement, the claim may reject for several reasons:
  - b. The member is new to the Plan
  - c. The member paid out of pocket (cash) for medications that fulfill step therapy requirements

<ul style="list-style-type: none"> <li>d. No claims are in the claims system for medications that fulfill step therapy requirements <ul style="list-style-type: none"> <li>i. For example, the member received samples or was getting it through a manufacture program.</li> </ul> </li> </ul>
<p>3. When a member is attempting to fill a drug that requires step therapy and it rejects for any of the above reasons, the prescriber must submit a prior authorization request providing documentation as to how the member has met the step therapy. The prior authorization request is reviewed by the PBM for determination of coverage.</p>
<p>4. The PBM notifies the practitioner of the prior authorization determination.</p>
<p>5. If the request is approved, an approval letter is sent to the member with a copy to the requesting provider.</p>
<p>6. If a request is denied, a denial letter is sent to the member with a copy to the requesting provider. The denial letter will include the following:</p> <ul style="list-style-type: none"> <li>a. Information regarding the specific reason for the denial, including reference to the information upon which the decision was based.</li> <li>b. Appeal rights, along with an appeal rights form.</li> <li>c. The prescriber is also notified of the option of discussing the decision further with a Pharmacist and the number where they may be reached.</li> </ul>
<p>7. The Prior Authorization process and notifications shall follow the time frame requirements.</p>
<p>8. Step Therapy Not Met, Claims Rejects</p> <ul style="list-style-type: none"> <li>a. If a member attempts to fill a drug that requires step therapy and has not met the step therapy requirement, the claim shall reject for prior authorization due to the step therapy not being met. <ul style="list-style-type: none"> <li>i. The rejection message displayed to the pharmacy will state that step therapy is required and the medications needed to meet the step therapy.</li> </ul> </li> <li>b. Prescriber may submit a prior authorization request form for the prescribed medication stating why the member is unable to meet the step requirement with the appropriate clinical documentation and it shall be reviewed by the Clinical Pharmacy Team for determination of coverage.</li> <li>c. If the request is approved, an approval letter is sent to the member with a copy to the requesting provider.</li> <li>d. If a request is denied, a denial letter is sent to the member with a copy to the requesting provider. The denial letter will include the following: <ul style="list-style-type: none"> <li>i. Information regarding the specific reason for the denial, including reference to the information upon which the decision was based.</li> <li>ii. Appeal rights, along with an appeal rights form.</li> <li>iii. The prescriber is also notified of the option of discussing the decision further with a Pharmacist and the number where they may be reached.</li> </ul> </li> <li>e. The Prior Authorization process and notifications shall follow the time frame requirements.</li> </ul>

- f. Step therapy requirements are listed in Attachment A and will be updated as changes are made and new requirements are developed.

## Appendix/Table

1. Step Therapy Guidelines

## References

1. N/A

## Review, Revisions, Approval History

Date	Change/Approval Information
01/01/2022	Healthy U specific policy created. Separated out from PHARM-115
03/16/2022	Policy reviewed and approved by the P&T Committee. Policy effective 04.01.2022
08/24/2022	Added step therapy guideline: REALRX_INSOMNIA Policy reviewed and approved by the P&T Committee. Policy effective 09.01.2022
10/26/2022	Update step therapy guidelines reviewed and approved by P&T Committee. REALRX_GLP-1 effective 11.01.22
02/28/2023	Updated step therapy guidelines: Updated: REALRX_SGLT-2 Added: REALRX_SGLT-2_CV and REALRX_SGLT-2_DPP-4
03/15/2023	Policy reviewed and approved by P&T Committee. Policy effective 04.01.2023
10/31/2023	Updated: REALRX_DPP-4 Added: REALRX_DPP-4 NP, REALRX_ROCKLATAN and RHOPRESSA
11/08/2023	Policy reviewed and approved by P&T Committee. Policy effective 12.01.2023
07/31/2024	Added step therapy guideline: REALRX_ZOLMITRIPTAN (NASAL ONLY)
08/29/2024	Policy reviewed and approved by P&T Committee via e-vote. Policy effective 09.01.2024
01/16/2025	Updated step therapy guideline: REALRX_DIFICID
01/29/2025	Policy reviewed and approved by P&T Committee. Policy effective 02.01.2025

04/01/2025	Added: REALRX_WINLEVI
04/09/2025	Policy reviewed and approved by P&T Committee. Policy effective 05.01.2025
12/14/2025	<p><b>Clerical update:</b> formatted to new template. Updated policy number to PHARM-MM-115 to apply to both Healthy U and Health Choice lines of business.</p> <p><b>Added:</b> REALRX_DPP-4 HYB, REALRX_DPP-4 COMBO HYB, REALRX_SGLT-2 HYB, REALRX_SGLT-2 COMBO HYB, REALRX_DPP-4/SGLT-2 COMBO HYB, REALRX_SU COMBO HYB</p> <p><b>Removed:</b> REALRX_DPP-4, REALRX_DPP-4 NP, REALRX_SGLT-2, REALRX_SGLT-2_CV</p>

<b>Disclaimer</b>	
1.	The plan reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final. The plan also revises and updates Pharmacy Coverage Policies annually, or more frequently if new evidence becomes available that suggests needed revisions. Policies are subject to change in accordance with Federal and State notice requirements.
2.	Services requiring prior-authorization may not be covered, if the prior-authorization is not obtained.
3.	This Pharmacy Coverage Policy does not guarantee coverage or payment of the service. The Plan may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive.
4.	The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.
5.	Pharmacy Coverage Policies have been developed for determining coverage for plan benefits and when published are available to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a member's benefit document and in coordination with the member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs.