

Step Therapy

Policy: PHARM-115

Origination Date: 08/04/2020

Reviewed/Revised Date: 10/26/2022

Next Review Date: 10/26/2023

Current Effective Date: 11/01/2022

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations for all members and clients of University of Utah Health Insurance Plans. Refer to the "Policy" and "Lines of Business" section for more information.
3. This Pharmacy Policy does not guarantee coverage or payment of the service. 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.

Purpose

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.

Definitions

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.

Policy/Coverage

1. Policy

- A. 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.

- i. 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.
- B. When step therapy has not been met, a prior authorization is required.
- C. 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
- D. If the conditions listed in C. above are not met, the request for coverage is denied.
- E. 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.

2. Procedure

- A. Step Therapy Met, Claim Auto-Adjudicates
 - i. 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.
- B. Step Therapy Met, Claim Rejects
 - i. 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:
 - ii. The member is new to the Plan
 - iii. The member paid out of pocket (cash) for medications that fulfill step therapy requirements
 - iv. No claims are in the claims system for medications that fulfill step therapy requirements
 - a. For example, the member received samples or was getting it through a manufacture program.
- C. 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.

- D. The PBM notifies the practitioner of the prior authorization determination.
- E. If the request is approved, an approval letter is sent to the member with a copy to the requesting provider.
- F. 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:
 - i. Information regarding the specific reason for the denial, including reference to the information upon which the decision was based.
 - ii. Appeal rights, along with an appeal rights form.
 - 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.
- G. The Prior Authorization process and notifications shall follow the time frame requirements.
- H. Step Therapy Not Met, Claims Rejects
 - i. 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.
 - a. The rejection message displayed to the pharmacy will state that step therapy is required and the medications needed to meet the step therapy.
 - ii. 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.
 - iii. If the request is approved, an approval letter is sent to the member with a copy to the requesting provider.
 - iv. 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:
 - a. Information regarding the specific reason for the denial, including reference to the information upon which the decision was based.
 - b. Appeal rights, along with an appeal rights form.
 - 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.
 - v. The Prior Authorization process and notifications shall follow the time frame requirements.
 - vi. Step therapy requirements are listed in Appendix A and will be updated as changes are made and new requirements are developed.

3. Appendix

A. Step Therapy Guidelines

- i. Available upon request in response to a relevant provider or member request.

Lines of Business

1. University of Utah Health Insurance Plans

- A. Commercial
- B. MHC

Date	Review, Revisions, Approvals
08/04/2020	Policy created
08/24/2020	Step therapy guidelines reviewed and approved by P&T Committee
09/11/2020	Policy reviewed and approved by UUHP Policy Committee.
10/23/2020	Updated step therapy guidelines REALRX_ICS/LABA
10/28/2020	Step therapy guidelines reviewed and approved by P&T Committee.
01/22/2021	Updated step therapy guidelines REALRX_ATYPICAL ANTIPSYCHOTICS REALRX_BRANDED ANTIDEPRESSANTS REALRX_OAB REALRX_ENTRESTO REALRX_GLP-1
01/26/2021	Moved to clinical policy format
01/27/2021	Policy reviewed and approved by P&T Committee. Effective 02.01.2021
05/19/2021	Updated step therapy guidelines REALRX_SOLIQUA Policy reviewed and approved by P&T Committee. Effective 06.01.2021
08/18/2021	Updated step therapy guidelines REALRX_BREXAFEMME REALRX_BRANDED ANTICONVULSANTS REALRX_ATYPICAL ANTIPSYCHOTICS
08/18/2021	Policy reviewed and approved by P&T Committee. Effective 09.01.2021
10/13/2021	Removed REALRX_ENTRESTO as a Step Therapy Requirement Updated REALRX_ATYPICAL ANTIPSYCHOTICS Policy reviewed and approved by P&T Committee at meeting. Policy effective 11.01.2021
11/16/2021	Updated step therapy guidelines: REALRX_DPP-4 NP REALRX_SGLT-2_MM
12/13/2021	Policy reviewed and approved by P&T Committee via e-vote. Policy effective 01.01.2022
01/01/2022	Removed University of Utah Health Plans (Healthy U, Healthy U Integrated) from Lines of Business to create Healthy U specific policy

03/15/2022	Updated step therapy guideline: REALRX_BRANDED ANTICONVULSANTS
03/16/2022	Policy reviewed and approved by the P&T Committee. Policy effective 04.01.2022
05/18/2022	Updated step therapy guideline: REALRX_BRANDED ANTICONVULSANTS Policy effective 06.01.22
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 REALRX_INSOMNIA effective 01.01.23

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