

Formulary Exceptions

Policy: PHARM-CHIP-151

Origination Date: 07/01/2024

Reviewed/Revised Date:

Next Review Date: 04/19/2023

Current Effective Date: 07/01/2024

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations for Healthy U CHIP. Refer to the "Policy" and "Lines of Business" section for more information.
3. Services requiring prior-authorization may not be covered, if the prior-authorization is not obtained.
4. 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

Healthy U Medicaid (Healthy U) uses a formulary medication list that is established, reviewed, and approved by our Pharmacy and Therapeutics (P&T) Committee and the regulatory bodies in the state in which Healthy U functions. The formularies for each line of business are reviewed at least annually. New to market drugs are evaluated at least quarterly for formulary placement based on clinical necessity, evidence-based literature and guidelines, the cost in relation to other existing clinical drug alternatives on the formulary, and overall safety to our members.

This policy intends to encourage the appropriate selection of medications for therapy according to product labeling, clinical guidelines, and/or clinical studies, as well as to encourage the use of formulary agents.

Definitions

1. Formulary: A list of medications that are covered under the pharmacy benefit.
2. Formulary Exception: Request by a healthcare provider to cover a medication due to medical necessity that is not included in the health plan's formulary.
3. Non-Formulary Drug: a retail drug not covered on the Formulary as part of the pharmacy benefit.

Medications

Medications listed on the Health Plan formulary that are indicated for a member's condition

must be tried and failed before medications excluded from the formulary may be considered, unless documentation indicates a medical necessity as outlined in this policy.

Policy/Coverage

1. Prior Authorization Criteria

Healthy U consider coverage of a non-formulary medication as medically necessary when the following criteria have been met for situations as listed below. This policy will not supersede drug-specific criteria approved by our P&T Committee with respect to prior authorization, quantity limits, other utilization management criteria, nor drug or therapeutic category benefit exclusions.

- A. The indication for use of the requested medication is approved by the FDA, AND
- B. Documentation of one of the following:
 - i. Evidence provided to show the member has failed or has a contraindication to all FDA-indicated formulary and/or guideline recommended options, OR
 - ii. That the requested therapy has clinically significant superior efficacy for the member condition compared to formulary options, (as evidenced by randomized, controlled, clinical trials and applicable clinical guidelines); OR
 - iii. The requested medication meets medical necessity and is the only treatment option for the member's condition; AND
- C. Drug specific criteria takes precedence over the medical necessity for the Formulary Exceptions Policy.
- D. For combination products: A clinical reason supported by chart notes why the member is unable to take the active ingredients of the combination product separately as individually prescribed medications must be provided, AND
- E. For long-acting formulations: A clinical reason supported by chart notes why the member is unable to use the immediate-release formulation of the formulary drug must be provided.
- F. Formulary exception requests must be submitted on a formulary exception form with chart notes and clinical documentation supporting medical necessity.
- G. Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be immediately reflected in this policy.
- H. The start date and duration of formulary alternatives must be provided.
- I. There must be paid claims if the member was enrolled with Healthy U when treated with the formulary alternatives.
- J. Non-adherence to formulations requiring multiple daily doses does not guarantee the member will meet the requirements of medical necessity. Chart notes must be provided on the member's physical or mental characteristics to determine if the member meets the requirements of medical necessity.
- K. Documented diagnoses must be confirmed by medical records, which need to be supplied with the formulary exception request. These medical records may

include, but are not limited to test reports, chart notes from provider’s office, or hospital admission notes.

- L. For the process to submit a request, see the University of Utah Health Plans Retail Pharmacy Formulary Exceptions Policy.

2. Re-Authorization Criteria

- A. Evaluate continued need based on the following:
 - i. If new generics or new biosimilars became available since the first authorization, has the member tried these according to the Brand Name Medications Policy or the Biosimilar Policy
 - ii. If there are new formulary products since the first approval that have not been tried and may be more appropriate for the member
 - iii. Determine if the original authorization and any subsequent renewals were done appropriately, according to criteria.
- B. The member shows a positive clinical response to therapy.
- C. Pharmacy claims show the member is adherent to the regimen.
- D. For members new to the plan, clinical documentation must demonstrate adherence.

3. Dosage

- A. Dosing must be in accordance with US Food and Drug Administration (FDA) approved package insert.
 - i. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for any dose outside of the Food and Drug (FDA) package insert listed in this policy. For a list of Health Plan-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

4. Exclusions/Contraindications

- A. The prior use of samples will not be considered in the determination of a member’s eligibility for coverage for a non-formulary medication.

5. Approval Duration

- A. Initial Authorization: 12 months
- B. Re-Authorization: 12 months

Lines of Business

1. University of Utah Health Plans

- A. Healthy U CHIP

References:

- 1. Policy: University of Utah Health Plans Retail Pharmacy Formulary Exceptions
- 2. NCQA UM Standards- UM 11: Procedures for Pharmaceutical Management, Element E: Considering Exceptions

Date	Review, Revisions, Approvals
07/01/2024	Healthy U CHIP policy created. Separated out from PHARM-HU-151

Disclaimer:

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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