

Pharmacy Continuity of Care

Policy: PHARM-103

Origination Date: 11/13/2020

Reviewed/Revised Date: 05/18/2023

Next Review Date: 05/18/2024

Current Effective Date: 05/22/2023

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 define and provide guidance for circumstances under which the University of Utah Health Plans (U of U Health Plans) will allow continuity of care and offer coverage for a supply of a medication for new members within the first 90 days of enrollment when the medication is not covered on the formulary or if it has coverage restrictions.

Definitions

1. Exception Request: a process used by Health Plans to enable a member or provider to request an exception to the formulary or pharmacy benefit.
2. Medically Necessary: therapy that a prescribing healthcare provider can justify as reasonable, necessary, and/or appropriate to treat specific diagnoses for injury, diseases, and their associated symptoms, based on evidence-based clinical standards of care.
 - A. Not mainly for convenience of the member, that of the provider, or other health care provider; and
 - B. Not more costly than an alternative drug, service(s), or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of illness, injury, disease, or symptoms
3. Non-formulary Therapy: a drug or product not listed on the Health Plan Formulary and not covered by the pharmacy benefit unless a formulary exception is approved by the Plan.
4. Orphan Drug: a medication used to treat, prevent or diagnose an orphan disease as defined by the U.S. Food and Drug Administration (FDA).

5. Preferred Drug List (PDL) or Formulary: a list of medications that are covered by the Health Plan pharmacy benefit.
6. Prior Authorization (PA): a process used by health plans to assure drug benefits are administered as designed, that members receive medications that are safe and effective for the condition being treated, and that the medications used have the greatest value. Prior Authorizations require the prescriber to receive pre-approval for coverage of a particular medication in order for the drug to be covered by the health plan benefit.
7. Quantity Limits (QL): a limitation that is placed on daily dose, days' supply, or maximum quantity of a drug over a defined period of time. Quantity limits help assure FDA-approved doses or durations are not exceeded for the safety of the member. Exceptions may be considered when the benefits outweigh the risks to the member.
8. 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 through the generic product before the brand may be considered for authorization.

Policy/Coverage

1. Coverage Criteria

- A. During the first 90 days of enrollment, U of U Health Plans may cover transition fills of a non-formulary drug, as well as drugs with restrictions or limits.
- B. This transition supply is intended for the member's immediate needs to be met, while allowing enough time to work with the provider to prescribe a medication that is on the preferred drug list or to submit a prior authorization request.
- C. Transition fills will not exceed a 90 day supply.
- D. New members are not eligible for a transition fill of a non-formulary or restricted medication if ALL of the circumstances are met:
 - i. There are alternative agents on formulary with a same or similar mechanism of action
 - ii. The change to a new agent does not require a provider visit
 - iii. Member's disease state is stable or not so fragile that transition to a formulary or preferred agent will not cause the member to experience serious clinical complications.
- E. New members may be eligible for up to 90 days coverage of a non-formulary or restricted medication while the member is transitioning to formulary/preferred agents if ALL the following are met:
 - i. A change to an alternative therapy requires one of the following:
 - a. A visit or consultation with a new or specialty provider
 - b. The condition being treated is an 'orphan' condition as defined by Orphanet or the National Organization for Rare Disorders (NORD)

- ii. Treatment is a recognized treatment option supported by medical literature and/or NORD
 - iii. There are no alternative therapies with the same mechanism of action on the formulary, but there are drugs on formulary that are acceptable alternatives to treat the condition
 - iv. Discontinuation of the agent WILL likely cause serious harm to member resulting in hospitalization, use of other health resources or death
- F. Members may be eligible for full coverage for up to 12 months when all of the following are met:
- i. The provider has submitted a prior authorization (formulary medications) or formulary exception (non-formulary medications) request
 - ii. Requested therapy/dose/product has been approved by the FDA to treat the member condition or is recognized as safe and effective based on medical literature
 - iii. Medical necessity has been demonstrated by:
 - a. Member meets Health Plan criteria, if available
 - b. No alternative therapy with same or similar mechanism of action is available on formulary
 - c. No alternative therapy with same or similar efficacy is on formulary
 - d. Member has been on this therapy/dose/product and documentation provided demonstrates all the of following:
 - 1. Condition has remained stable or improved
 - 2. Member has been adherent to therapy for at least the last 60 days
 - 3. Discontinuation of the agent WILL likely cause serious harm to member resulting in hospitalization, use of other health resources or death
 - iv. A different non-formulary medication would not be more cost effective
 - v. Allowing a formulary exception will likely result in significant cost savings to the plan
- G. To avoid a lapse in current and on-going treatment, non-participating providers will be allowed for continuation of care for up to 90 days while transitioning the member to a participating provider.
- H. Exceptions may be made on a case by case basis according to medical necessity.

2. 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.
- ii. Accurate member information is necessary for the Health Plan to approve the requested dose and frequency. If the member’s dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Health Plan for a new approval based on those changes as part of the precertification process. The Health Plan reserves the right to conduct post-payment review and audit procedures for any submitted claims.

3. Exclusions/Contraindications

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

Lines of Business

1. University of Utah Health Insurance Plans

- A. Commercial
- B. MHC

References:

1. <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases>

Date	Review, Revisions, Approvals
11/13/2020	Policy created.
01/27/2021	Policy reviewed and approved by P&T Committee. Effective 02.01.2021
12/20/2021	Completed annual review of policy.
01/01/2022	Removed University of Utah Health Plans (Healthy U, Healthy U Integrated) from Lines of Business to create Healthy U specific policy
01/19/2022	Policy reviewed and approved by P&T Committee. Effective 02.01.2022
05/18/2023	Added and updated definitions Clarified abbreviations Clarified Policy Coverage 1D to when to apply a transition fill Clarified Policy Coverage 1E for when new members are eligible for a transition fill Clarified Policy Coverage 1F for when new members are eligible for longer than a transition fill Clarified Policy Coverage 1G for non-participating providers Added Policy Coverage 1H
05/18/2023	Policy reviewed and approved by P&T Committee via e-vote. Policy effective 05/22/2023

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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