HEALTH PLANS
UNIVERSITY OF UTAH

Pharmacy Policy

Pharmacy Continuity of Care

Policy: PHARM-103

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Reviewed/Revised Date: 01/27/2021

Next Review Date: 01/27/2022

Current Effective Date: 02/01/2021

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 Plans. Refer to the "Policy" and "Lines of Business" section for more information.

Purpose

To define and provide guidance for circumstances under which the University of Utah Health Plans (UUHP) will allow continuity of care and offer coverage for a supply of a medication new members when the medication is not on the preferred drug list 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 Drug: a drug not listed on the Preferred Drug List or Formulary.
4. Orphan Drug: a medication used to treat, prevent or diagnose an orphan disease.
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, UUHP may cover a one-time, transition fill of a non-formulary drug, as well as drugs with restrictions or limits. 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.
    B. For new members to be eligible for a 30 day one-time transition fill of a non-formulary or restricted medication, one of the circumstances below must be 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.
    C. For new members to be eligible for a maximum of a 90 day one-time transition fill of a non-formulary or restricted medication while the member is transitioning to formulary/preferred agents, ALL the following must be met:
        i. The condition being treated is an 'orphan' condition as defined by the FDA
        ii. There are no alternative therapies with the same mechanism of action but alternative drugs on formulary exist to treat the condition
        iii. A change to an alternative therapy requires a visit to, or consultation with, a specialty provider
        iv. A sudden switch in therapy MAY cause serious clinical complications resulting in hospitalization or permanent harm to the member
    D. For members new or established with the plan, a benefit exception for coverage of up to 12 months may be considered when all of the following are met:

i. The therapy has been excluded from formulary and otherwise managed through an exception process
ii. No alternative therapy with same or similar mechanism of action is available
iii. Member has been on this therapy and documentation provided demonstrates all the of following:
a. Condition has remained stable or improved
b. Member has been compliant with therapy for at least the last 60 days
c. Discontinuation of the agent WILL likely cause serious harm to member resulting in hospitalization, use of other health resources or death
iv. Allowing non-formulary therapy will likely result in significant cost savings to the plan or plan sponsor.

E. For new members to the plan, non-participating providers will be allowed for continuation of care while transitioning to a participating provider to avoid a lapse in current and on-going treatment.

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

2. University of Utah Health Plans

A. Healthy U
B. Healthy U Integrated

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

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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