Pharmacy Continuity of Care

Policy: PHARM-CHIP-103

Origination Date: 07/01/2024

Reviewed/Revised Date:

Next Review Date: 05/18/2024

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

To define and provide guidance for circumstances under which the Healthy U CHIP (CHIP) 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 HU 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 HU 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 HU pharmacy benefit.
6. Prior Authorization (PA): a process used by HU 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 HU 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, HU 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 <u>not</u> 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 HU 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 HU-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

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 Plans**
    A. Healthy U CHIP

References:

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

Date	Review, Revisions, Approvals
07/01/2024	Healthy U CHIP policy created. Separated out from PHARM-HU-103