# Pharmacy Prior Authorization and Medical Necessity

**Policy** PHARM-056

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**Current Effective Date:** 08/21/2019

**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 the conditions under which medications will be reviewed for prior authorization and medical necessity.

1. University Of Utah Health Plans requires prior authorization (prospective review of medical necessity) for select medications.
2. This policy provides the framework of review for prior authorization and for medical necessity when specific criteria are not in place.

## Definitions

1. Medically Necessary: therapy that a physician or other prescribing healthcare provider, can justify as reasonable, necessary, and/or appropriate to treat specific diagnoses for injury, diseases, cancers, 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
2. Formulary or preferred drug list: a list of medications that are covered by a health plan benefit.
3. Exception Request: a process used by Health Plans to enable a member or provider to request an exception to the formulary or pharmacy benefit.
4. 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 prescribing a particular medication in order for the drug to be covered by the health plan benefit.

5. Step Therapy (ST): a process designed to assure that first line drugs which have been proven safe and effective and that demonstrate greater value are used before second line and potentially more costly alternatives. Most brand medications with generic alternatives require ST with the generic product before the brand will be authorized.
6. Quantity Limits (QL): a limitation that is place on daily dose, days' supply, or maximum quantity. Quantity limits help assure FDA-approved doses or durations are not exceeded for the safety of the patient. Exceptions may be approved when the benefits outweigh the risks to the patient.

## Policy/Coverage

### 1. Authorization

A. Prior authorization is required on certain retail medications or medication classes in order to assure that the member is receiving the most efficacious, safe, and cost-effective regimen available through the plan. Prior authorization on retail medications may be required if a drug is determined as non-formulary, high risk/high dollar, or if the provider or member requests an exception to step therapy or quantity limitations.

B. When a PA is required under the pharmacy benefit, providers must submit a fully complete Request for Medication Prior Authorization Form for retail medications, as well as clinical documentation to support the request. Forms may be accessed on the Pharmacy Forms & Guidelines webpage located on the U of U Health Plans website. Incomplete or illegible submissions may result in a request being denied. Requests will be denied if clinical documentation is not submitted.

C. When a PA is required under the medical benefit, providers must submit a fully complete Prior Authorization request form, as well as clinical documentation to support the request. Forms may be accessed on the Forms & Guidelines webpage located on the U of U Health Plans website. Incomplete referrals or forms may result in a request being denied. Requests will be denied if clinical documentation is not submitted. Providers should request a medical necessity review at least 1 week prior to the date of service/administration (when possible) to allow University of Utah Health Plans adequate time to make a determination.

D. Authorization and denial determinations will be made on the basis of clinical criteria or medical necessity as determined by the Hierarchy of Criteria Policy. Information considered may include, but is not limited to the following: Federal and state law, Health Plan policy, FDA-approved indications, most recent clinical guidelines, and recent medical literature. Factors which affect medication adherence will also be considered. If the request is for off-label use, the Off-label Use Policy would apply.

### 2. Review for Medical Necessity

A. Medical necessity review is required on certain medications covered under the pharmacy medical and retail benefits and for formulary exception requests for pharmaceuticals not on the preferred drug list. In these cases, either an Epic Referral or a Prior Authorization form will be required. Incomplete referrals or forms may result in a request being denied. Providers should request a medical necessity review at least 1 week prior to the date of service/administration (when possible) to allow University of Utah Health Plans adequate time to make a determination. Where there are specific criteria for requested medications, authorization will be determined by those criteria. Where there are no specific criteria, a medical necessity review will determine authorization.

B. Off-Label Use Medications: The FDA requires that drugs used in the United States be both safe and effective. The label information or the package insert of a medication indicates drug use only in certain "approved" doses and routes of administration for a particular condition or disease state. The use of a drug for a disease state or condition not listed on the label, or in a dose or by a route not listed on the label, is considered to be a "non-approved", "un-labelled", or "off-label" use of the drug. A PA is required when a medication is used outside of its FDA approved route of administration, dosage, or indication. **See Off-Label Use Policy for coverage requirements.**

## 3. Requirements

A. Providers are responsible for obtaining prior authorization or a medical necessity review when required.

B. Requests are required to be clinically appropriate to type of treatment, duration of therapy, frequency of administration and effectiveness of therapy to member diagnosis, injury, and disease or cancer type.

C. The PA Form must include all, but not limited to, the following information:

i. Patient demographics, including plan name, and plan ID number.

ii. Reason for request (i.e. PA required, ST override, QL override, non-formulary, non-preferred etc.)

iii. Medication name, dose, route, duration of therapy, and start date, if applicable.

iv. Indication for treatment, including appropriate ICD-10 codes.

v. Past trials, failures, and reason therapy failed.

vi. Medical contraindications to first line therapies or alternative therapies. Please note preference to use “brand” medications over “generic” medications is not considered a medical contraindication to first line therapies.

vii. Supporting clinical documentation includes, but is not limited to, all pertinent clinic notes and medical history, diagnostic imaging and laboratory results, indication for therapy, and alternative therapies trialed. **Missing or incomplete information may result in a denial for the requested therapy or may result in a delay of the medical review and approval process.**

viii. Prescriber name, signature, DEA/NPI, office phone, office fax, office contact name, and office address.
ix. A Letter of Medical Necessity must be provided for all off-label use or QL exceptions with justification, expected outcomes, and trial duration of request therapy.

D. Additional documentation may be required and requested by the Health Plan in order to fully review the request. If requested supporting documentation is not received timely, the request may be denied. The timing required will vary depending on required turnaround times of the different authorization types. See Turnaround Times section listed under Determinations below.
E. Non-covered therapies are outlined in the plan document and a list is provided on the Health Plan website.

## 4. Exceptions (non-formulary medications)

A. Exception requests for non-formulary medications must have evidence provided to show the member has failed or has a contraindication to all formulary options, that the requested therapy is superior to formulary options, and that the requested therapy meets medical necessity. Where a non-formulary medication is designated in the plan document as not covered, this is a benefit denial.
B. Members or their representatives may request an exception to the formulary by submitting a Request for Formulary Exception Form. Forms may be accessed on the Pharmacy Forms & Guidelines webpage located on the U of U Health Plans website.
    i. The Exception Form must include all, but not limited to, the following information:
        a. Patient demographics, including plan name, and plan ID number.
        b. Reason for request (why formulary alternatives will not be used)
        c. Medication name, dose, route, duration of therapy, and start date, if applicable.
        d. Indication for treatment, including appropriate ICD-10 codes.
        e. Past trials, failures, and reason therapy failed
        f. Medical contraindications to first line therapies or alternative therapies. Please note preference to use “brand” medications over “generic” medications is not considered a medical contraindication to first line therapies.
        g. Supporting clinical documentation includes, but is not limited to, all pertinent clinic notes and medical history, diagnostic imaging and laboratory results, indication for therapy, and alternative therapies trialed. **Missing or incomplete information may result in a denial for the requested therapy or may result in a delay of the medical review and approval process.**
        h. Prescriber name, signature, DEA/NPI, office phone, office fax, office contact name, and office address.

i. A Letter of Medical Necessity must be provided for all exception requests to support the request.

C. If a non-formulary exception request is denied, member or their authorized representatives may first request an internal appeal of that decision orally (in person, telephone) or in written format (fax, mail, email).
   i. Oral appeal requests are made by calling: (801) 587-6480 option 1 or (888) 271-5870.
      a. Oral appeals will be entered into the online form by the Customer Advocate, which automatically date stamps the receipt date. The form is on the website: https://uhealthplan.utah.edu/forms.php
      b. An oral appeal request must be followed with a written, signed appeal from the person submitting the appeal within 5 business days, unless the appeal has been requested as an expedited request.
      c. If the written follow up to the oral appeal is not received within this timeframe, the appeal will be closed by a managed care coordinator.
      d. A letter is sent to the appropriate member and or/provider submitting the appeal, notifying that the appeal is closed because the written appeal was not received within the allotted timeframe.
      e. The right to appeal is still valid within the 180 calendar days from the UUHP Notice of Action (NOA).
      f. The Online Appeal Form includes the option for a MEMBER filing an Oral Appeal to give consent to a UUHP Customer Advocate, to accept the Online Appeal Form as a written appeal.
   ii. Written appeal requests are made by mailing or faxing the appeal to:
      Appeals Team
      University of Utah Health Plan
      P.O. Box 45180
      Salt Lake City, UT 84145
      Fax: 801-281-6121
      a. Appeals received via mail, in person delivery or fax, will be date stamped, with the date received.
      b. Online appeal requests are made using the online form, located on the University of Utah Health Plans website: uhealthplan.utah.edu.
   iii. If the denial of the non-formulary exception request is upheld through an internal appeal, the member or their authorized representative may request a voluntary external appeal by an Independent Review Organization (IRO).

a. A voluntary external appeal is available for issues involving medical judgment (including but not limited to those based on the Plan's requirements for Medical Necessity, appropriateness, health care setting, level of care, or effectiveness of a Covered Service); or the determination that a treatment is Investigational, but only after the member or their representative has exhausted all of the applicable non-voluntary levels of appeal, or if U of U Health Plans has failed to adhere to all claims and internal appeal requirements.
b. External appeal reviews are only available to Policyholders. Members may appoint an authorized representative, including the treating practitioner, to file an external review on the member's behalf.
c. The appeal must be requested within 180 calendar days of receipt of the notice of the prior adverse decision.
d. To request an IRO:
    1) Fully Insured or Individual Marketplace Plans: Members, or their authorized representative, may fill out the Independent Review Request Form through the Utah Department of Insurance website at www.insurance.utah.gov. They may also contact the DOI by phone at 801-538-3077 or electronically at healthappeals.uid@utah.gov .
    2) Self-Insured and Level-funded Group Plans: Members contact the U of U Health Plans Appeals Team at 801-587-6480 for assistance with filing the IRO.
e. U of U Health Plans coordinates voluntary external appeals, but the decision is made by an IRO, at no cost to the member. U of U Health Plans will provide the IRO with the appeal documentation. The IRO will make its decision and will provide the member and member's representative with its written determination within 45 calendar days after receipt of the request. U of U Health Plans will assist with coordination of care if the appeal decision is overturned.
f. A Voluntary External Appeal is the final level to determine an appeal decision and will be binding in accordance with the IRO's decision, except to the extent other remedies are available under State or Federal law.

## 5. Determinations

A. Turnaround Times:
    i. Non-urgent preservice Commercial retail PA requests will be reviewed within 72 hours of receipt. Incomplete requests or request received

without all necessary supporting documentation may be denied for lack of documentation.

ii. Non-urgent preservice Medicaid and Individual Exchange retail PA requests will be reviewed within 24 hours of receipt. Incomplete requests or request received without all necessary supporting documentation may be denied for lack of documentation.

iii. Urgent or concurrent retail PA requests will be reviewed within 24 hours of receipt. The Prior Authorization Request Form must be marked as "Urgent" at the top of the form for immediate review. Incomplete requests or request received without all necessary supporting documentation may be denied for lack of documentation.

iv. Non-urgent preservice medical drug medical necessity requests will be medically reviewed and a determination will be made within 15 calendar days of receipt of all necessary supporting documentation.

v. Urgent concurrent medical drug medical necessity requests will be reviewed and a determination will be made within 24 hours of receipt of all necessary supporting documentation. Expedited requests that require immediate review must have supporting documentation provided that demonstrates immediate therapy need. The Prior Authorization Request Form must be marked as "Urgent" at the top of the form for immediate review.

vi. Urgent preservice medical drug medical necessity requests will be reviewed and a determination will be made within 72 hours of receipt of all necessary supporting documentation. Expedited requests that require immediate review must have supporting documentation provided that demonstrates immediate therapy need. The Prior Authorization Request Form must be marked as "Urgent" at the top of the form for immediate review.

vii. Post-service medical drug (medical claims) medical necessity requests will be medically reviewed and a determination will be made within 15 calendar days of receipt of all necessary supporting documentation.

B. Extending Timeframes:

i. Non-urgent preservice medical drug medical necessity requests: if the request lacks clinical documentation, Health Plans will request necessary information the member or member's representative has up to 45 calendar days to provide this information. If information is not received within this timeframe, Health Plans may extend the review period to make a determination by 15 calendar days beyond the required timeframe to submit the additional documentation.

ii. Urgent concurrent medical drug medical necessity requests: if the request lacks clinical documentation, Health Plans will request necessary information within 24 hours of the request and may make a determination within 72 hours of original receipt date.

iii. Urgent preservice medical drug medical necessity requests: if the request lacks clinical documentation, Health Plans will request necessary information within 24 hours of the request and allow at least 48 hours for the information to be submitted. Determinations on extended requests will be completed by 72 hours or the end of the timeframe given to the member.
iv. Post-service medical drug (medical claims) medical necessity requests if information is not received within the required 45 day timeframe, Health Plans may extend the review period to make a determination by 15 calendar days beyond the required timeframe to submit the additional documentation.

C. Approved therapies: Supporting clinical documentation received met all University of Utah Health Plans requirements, and authorization is granted. No further action is required for request. Letters are sent to both member and the requesting provider.
D. Denied therapies: Supporting clinical documentation received did not meet all University of Utah Health Plans requirements, and authorization is denied. Please note, University of Utah Health Plans recommends providers retain all denial letters.
    i. Denials will be communicated to the member and requesting provider in writing within the timeframes listed above.
E. Partial authorization for medical drug requests: Therapies that require a "determination of response to therapy" will receive a partial authorization. Supporting clinical documentation with response to therapy is required prior to extension of the partial authorization.
F. Exceptions: Requests will be reviewed within a timeframe according to clinical urgency as defined above.
G. Appeals: Instructions on how to appeal a determination and appeal rights are provided to the provider and members with the denial letter.
H. Approval duration may vary by the type of requested therapy. Approval expiration date will be noted on all prior authorization approval letters.

### 6. Additional Information

A. Services provided that require a prior authorization and an authorization was not approved or member was ineligible at the time of service will result in a denial for payment of claims.
B. Prior authorization is NOT a guarantee of payment of services.
C. Authorizations that are approved will be effective from the date of approval and specified time period. Retail authorizations will not be back dated.

## Lines of Business

### 1. University of Utah Health Plans

A. Healthy U
B. Commercial Groups

C. Individual Exchange

## 2. Montana/Mountain Health Co-Op

A. Commercial Groups

B. Individual Exchange

| Revision Date | Revision |
|---|---|
| 05/09/2016 | Policy created. |
| 08/29/2016 | Policy reviewed. |
| 01/25/2017 | Policy approved by P&T Committee. |
| 02/28/2018 | Policy approved by P&T Committee. |
| 04/22/2019 | Policy revised. |
| 08/21/2019 | Policy reviewed and approved by P&T Committee. |

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