Pharmacy Prior Authorization and Medical Necessity

Policy: PHARM-056

Origination Date: 05/09/2019

Reviewed/Revised Date: 03/05/2024

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Current Effective Date: 03/08/2024

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations University of Utah Health Plans Commercial. 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 the conditions under which medications and corresponding administration requirements will be reviewed for prior authorization and medical necessity.

1. University of Utah Health Plans (UUHP) requires prior authorization (prospective review of medical necessity) for select medications and corresponding administration requirements.
2. This policy provides the framework of review for prior authorization and for medical necessity when specific criteria are not in place.
3. Prior authorization (PA) is necessary 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.

Definitions

1. Adequate trial is defined in terms of dose and duration. An adequate trial would mean the dose of the drug is the maximum tolerated dose and the duration is sufficient to determine if a response should have been seen by that point, or in general, a trial of at least 3 months.
2. Exception Request: a process used by Health Plans to enable a member or provider to request an exception to the formulary or pharmacy benefit.
3. Formulary or preferred drug list: a list of medications that are covered by a health plan benefit. These may be subject to utilization management criteria such as prior authorization, step therapy, quantity limits, and medical necessity criteria.

4. Medically Necessary or Medical Necessity means health care services or products that a prudent health care professional would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is:
    A. In accordance with generally accepted standards of medical practice in the United States;
    B. Clinically appropriate in terms of type, frequency, extent, site, and duration;
    C. Not primarily for the convenience of the patient, physician, or other health care provider; and covered under the contract;
    D. Not more costly than an alternative drug, service(s), or supply that is at least as likely to produce equivalent therapeutic or diagnostic results to the diagnosis, injury, disease, or symptoms.

    When a medical question-of-fact exists, medical necessity shall include the most appropriate available supply or level of service for the individual in question, considering potential benefits and harms to the individual, and known to be effective.
5. Nonurgent Request (Standard, Routine): A request for medical care or services for which application of the time periods for making a decision does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.
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 prescribing a particular medication for the drug to be covered by the health plan benefit.
7. 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.
8. Specialty Medication: certain high cost, high complexity, or high touch medications. Please see **University of Utah Health Plans Specialty Medications policy** for full definition.
9. 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.
10. Urgent Request (Expedited): A request for medical care or services where application of the time frame for making routine or non-life-threatening care determinations:
    A. Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment, or
    B. Could seriously jeopardize the life, health or safety of the member or others, due to the member's psychological state, or

C. In the opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

11. Therapeutic Failure:
    A. A lack of efficacy as the unexpected failure of a drug to produce the intended effect as determined by previous scientific investigation.
    B. A drug therapeutic failure (DTF) is also defined as a failure to accomplish the goals of treatment attributable to inadequate therapy, a drug-drug interaction that results in a subtherapeutic level for a drug, or medication nonadherence.
    C. Therapeutic failure is not the same as medical necessity.

Policy/Coverage

1. Prior Authorization

A. Prior authorization is required on certain medical or 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 medications or medication-related products may be required In all but not limited to the following circumstances:
    i. A drug is categorized as specialty, high risk, or if allowed cost exceeds $1000/month
    ii. A drug does not meet step therapy or requires an exception to quantity or other limitations.
    iii. Formulary brand name products with available generic or therapeutic equivalents
    iv. Formulary generic or biosimilar products that are high-cost
    v. Non-preferred formulary products may require use of formulary preferred products first.
    vi. When a requested drug is being used off-label

B. Authorization and denial determinations will be made on the basis of clinical criteria or medical necessity as determined by the **Clinical Criteria for Review Determinations Policy**. See references for link. 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.

C. Authorization requests referencing therapeutic failure of a formulary alternative product must provide evidence that mitigation efforts have been tried for the reason for failure, that the requested medication won't have the same potential issues, and that the drug meets all other criteria for use, including medical necessity.

D. In order for administration fees to be covered by the Health Plan, the administrated medication must be approved as medically necessary. If a

medication does not meet criteria for approval, then any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will also be denied.

E. The use of samples will not be considered in the determination of a member's eligibility for coverage of a medication and/or corresponding administration codes. If a sample medication is administered, then any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will not be approved. If a medication does not meet criteria for approval, then any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will also be denied.
F. Cases of continuity of care (COC) will be reviewed according to the **Continuity of Care Policy**, according to medical necessity, and/or according to a drug-specific policy, whichever is most applicable to the case.
    i. If a member is new to the plan, the prior authorization request must meet the initial prior authorization criteria or the COC criteria.
G. Denied requests may be appealed according to the applicable Appeals Policy in the references.

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, a Prior Authorization form will be required. 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. Formulary Exceptions (non-formulary medications)

A. Retail Formulary 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.

i. 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 & Policy webpage located on the U of U Health Plans website.
ii. Failure to submit clinical documentation to support the request will result in a dismissal of the request for failing to follow filing procedures.
iii. Denied requests may be appealed according to the applicable Appeals Policy. See links in the references below.
iv. See the Formulary Exceptions Policy

B. Medical Exception requests for non-covered medications must have evidence provided to show the member has failed or has a contraindication to all covered options, that the requested therapy is superior to covered options, and that the requested therapy meets medical necessity. Where a non-covered medication is designated in the plan document as not covered, this is a benefit denial.

4. PA Submission Requirements

A. Providers, members, or authorized member representatives are responsible for obtaining prior authorization or a medical necessity review when required. Requested quantity, duration of therapy, and frequency of administration, must be appropriate for member diagnosis, injury, and disease or cancer type.
B. PA requests may be submitted by fax or online. Instructions are located on the plan website. Where available, drug-specific PA request forms are preferred over the general PA form.
C. To be reviewed, the PA form must be fully complete, and the submission must include sufficient clinical documentation to support the request. A prior authorization request will be eligible for review once a completed prior authorization form and all clinical documentation is received by the Plan. Requests will be dismissed due to failing to meet filing procedures if clinical documentation is not submitted before a timely determination must be made.
D. Failure to submit clinical documentation to support the request will result in a dismissal of the request for failing to follow filing procedures.
E. A Letter of Medical Necessity is strongly encouraged to be provided for all requests, especially those for nonformulary, off-label use, or QL exceptions with justification, expected outcomes, and trial duration of request therapy.
F. 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 the required turnaround times of the different authorization types. See Retail Pharmacy Utilization Management Timeliness policy.
G. Non-covered therapies are outlined in the plan document and a list is provided on the Health Plan website.
H. If UUHP is the secondary payer, the prior authorization determination from the primary payer is required.

5. **Determinations**

A. PA determinations will be made according to clinical criteria or based on medical necessity as determined by 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.
B. All determinations will be made in a timely manner as dictated by the clinical urgency of the therapy and based on the timeframes outlined in the Retail Pharmacy Utilization Management Timeliness policy or the Utilization Review Turnaround Times policy. See links below in the references.
C. Appropriate Reviewers: An appropriate licensed health care professional (medical provider or pharmacist) will review medical necessity denials for medications, including denials of requests for formulary exceptions based on medical necessity.
D. PA determinations will be communicated to the requesting provider and member in writing.
E. 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.
F. Denied therapies: Supporting clinical documentation received did not meet all University of Utah Health Plans requirements, and authorization is denied.
G. Partial approvals: Therapies that require a proven effectiveness for continuation or are time limited will receive a partial authorization. Supporting clinical documentation with response to therapy or justification for extension of the authorization is required prior to extension of the partial authorization.
H. Appeals: Instructions on how to appeal a determination and appeal rights are provided to the provider and members with the denial letter. See the applicable Appeals Policy for full information. See links in the references below.
I. 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 Insurance Plans

A. Commercial
B. MHC

References:

1. Policy: Clinical Criteria for Review Determinations (ADMIN-001): https://doc.uhealthplan.utah.edu/medicalpolicy/admin-001.pdf
2. Policy: Off-Label Use: https://doc.uhealthplan.utah.edu/medicalpolicy/pharmacy/pharm-049.pdf
3. Policy: University of Utah Health Plans Specialty Medications
4. Policy: Retail Pharmacy Utilization Management Timeliness: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=12825
5. Policy: Continuity of Care Policy: https://doc.uhealthplan.utah.edu/medicalpolicy/pharmacy/pharm-103.pdf
6. Policy: Appeals - MHC-Wyoming: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=12833
7. Policy: Health Plans MHC Idaho – Appeals: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=11053
8. Policy: Health Plans MHC Montana – Appeals: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=11164
9. Policy: Health Plans Commercial and Marketplace – Appeals
10. Policy: Formulary Exceptions Policy: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=12822
11. Policy: Utilization Review Turnaround Times: https://pulse.utah.edu/policies/Lists/Policies/DispForm.aspx?id=2695

Revision Date	Review, Revisions, Approvals
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.
04/29/2020	Added: - In order for administration fees to be covered by the Health Plan, the administrated medication must be approved as medically necessary. If a medication does not meet criteria for approval, then any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will also be denied. - The use of samples will not be considered in the determination of a member's eligibility for coverage of a medication and/or corresponding administration codes. If a sample medication is administered, then any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will not be approved. If a medication does not meet criteria for approval, than any corresponding administration requirements such as intravenous infusion therapy and office visits for administration will also be denied.
01/28/2021	Updated Lines of Business
01/01/2022	Removed University of Utah Health Plans (Healthy U, Healthy U Integrated) from Lines of Business to create Healthy U specific policy. Removed Medicare Advantage from University of Utah Health Insurance Plans to create Medicare Advantage specific policy.
10/20/2022	Completed annual review of policy.
10/26/2022	Policy reviewed and approved by the P&T Committee. Policy effective 11.01.2022
02/23/2024	Updated definitions Added references
03/08/2024	Policy reviewed and approved by the P&T Committee via e-vote. Policy effective 03.08.2024

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.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.