

Brand Name Medications

Policy: PHARM-013

Origination Date: 03/16/2018

Reviewed/Revised Date: 08/18/2021

Next Review Date: 08/18/2022

Current Effective Date: 09/01/2021

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 the conditions under which Brand Name Medications may be covered.

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.

Policy/Coverage

1. Prior Authorization Criteria

- A. Brand name medications for which a generic equivalent is available may be considered medically necessary if the following criteria are met:
 - i. Documentation must show an adequate trial and failure of the generic equivalent.
 - ii. If two or more manufactures are available, at least two generic options must be tried
- B. When a new generic becomes available, but the associated brand-name policy has not yet been updated, the health plan reserves the right to immediately begin preferring the generic product.
- C. Brand name medications for which a generic equivalent is not available, but other generics within the same therapeutic class are available and are considered therapeutically equivalent may be considered medically necessary if the following criteria are met:
 - i. Documentation must show an adequate trial and failure of at least 2 other generics within the same class.

D. The requesting provider must submit a letter of medical necessity stating why the brand name medication is required.

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

Date	Review, Revisions, Approvals
02/02/2018	Policy created.
03/16/2018	Policy sent to P&T Committee for review.
03/20/2018	Policy approved by P&T Committee.
02/13/2019	Policy sent to P&T Committee for annual review.
02/20/2019	Policy approved by P&T Committee.
11/26/2019	Reviewed for annual renewal. No changes.
01/22/2020	Policy reviewed and approved by P&T Committee.
04/15/2020	Added statement about right to prefer generics immediately upon release
05/20/2020	Policy reviewed and approved by P&T Committee. Effective 06.01.2020
01/27/2021	Updated Lines of Business Policy reviewed for annual review.
04/19/2021	Policy reviewed and approved by P&T Committee.

	Effective 05.01.2021
07/21/2021	Added: If two or more manufactures of the generic are available, at least two generic options must be tried
08/18/2021	Policy reviewed and approved by P&T Committee. Effective 09.01.2021

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.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from U of U Health Plans.

“University of Utah Health Plans” and its accompanying logo, and its accompanying marks are protected and registered trademarks of the provider of this Service and or University of Utah Health. Also, the content of this Service is proprietary and is protected by copyright. You may access the copyrighted content of this Service only for purposes set forth in these Conditions of Use.

© CPT Only – American Medical Association