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PHARMACY BENEFIT COVERAGE GUIDELINE – 5.01.541

Medical Necessity Exception Criteria for Dispense as Written (DAW) Exception Reviews

Effective Date:	Apr. 1, 2025	RELATED GUIDELINES / POLICIES:
Last Revised:	Mar. 24, 2025	5.01.547 Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits
Replaces:	N/A	5.01.605 Medical Necessity Criteria for Pharmacy Edits

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Introduction

Dispense as written (DAW) refers to member contract provisions requiring that a member pay the difference between the prescription price of a generic drug and the corresponding multisource brand drug when the brand is dispensed. This applies only in situations where the U.S. Food and Drug Administration (FDA) has reviewed evidence documenting that the generic product is bioequivalent to the corresponding brand. Such products are assigned an "AB" rating by the FDA, as published in the Orange Book. Even when FDA has rated a generic drug as AB equivalent, there may be rare cases where an individual does not receive the same benefit from the generic, or experiences side effects or an allergic reaction to the generic. Often, but not always, in such cases an alternative drug may be appropriate.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Coverage Guidelines

Drug	Medical Necessity
Brand name drug that has a generic equivalent	**Coverage of a brand name drug that has a generic equivalent (dispense as written [DAW]) without requiring the member to pay the difference in cost between the brand and the generic may be considered medically necessary when medical records are submitted documenting any of the following:** • The prescriber is requesting the brand name drug due to a DOCUMENTED adverse reaction, allergy, or sensitivity to a generic equivalent **OR** • The prescriber is requesting the brand name drug due to a DOCUMENTED therapeutic failure with the generic equivalent **OR** • The prescriber is requesting the brand name drug because transitioning to a generic equivalent may result in a destabilization or unnecessary risk to the individual. **Note:** When an exception to the DAW rule is approved based on medical necessity, the member must still pay the appropriate prescription copay or coinsurance for the brand product, according to the member's formulary benefit. Other applicable benefit requirements, such as step therapy edits, are not waived by this exception and must be reviewed separately.

Drug	Investigational
As listed	**The medications subject to this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for all drugs subject to this policy may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for all drugs subject to this policy may be approved up to 12 months.**

Coding

N/A

Related Information

This policy applies only to pharmacy benefits containing the dispense as written (DAW) requirement (see **Definition of Terms** below).

Definition of Terms

Dispense as written (DAW): DAW refers to member contract provisions requiring that a member pay the difference between the prescription price of a generic drug and the corresponding multisource brand drug when the brand is dispensed. This applies only in situations where the FDA has reviewed evidence documenting that the generic product is bioequivalent to the corresponding brand (i.e., both products deliver approximately the same amount of active drug to the blood stream with similar concentration/time profiles). Such products are assigned an "AB" rating by the FDA, as published in the Orange Book.

Even when FDA has rated a generic drug as AB equivalent, there may be rare cases where an individual does not receive the same benefit from the generic, or experiences side effects or an allergic reaction to the generic. Often, but not always, in such cases an alternative drug may be appropriate.

Generic equivalent: When the original patent on a brand name drug expires, other manufacturers may produce generic versions. A generic equivalent is a generic that has been approved by the FDA, based on pharmacokinetic studies that demonstrate delivery of similar amounts of the active ingredient(s) to the blood stream of healthy volunteers, with comparable concentration-time profiles. Generic equivalence evaluations are published by the FDA in the Orange Book.

Benefit Application

This policy is managed through the pharmacy benefit.

References

1. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available at **http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm** Accessed March 10, 2025.
2. U. S. Food and Drug Administration. Development & Approval Process (Drugs). Available at **http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm** Accessed March 10, 2025.

History

Date	Comments
06/12/12	New policy, add to Prescription Drug section.
07/13/12	A link to the FDA MedWatch form was added to the Policy Guidelines section.
03/11/13	Replace policy. Criteria for medical necessity of using a multisource brand in lieu of a generic were added. Policy title expanded to include "and for Dispense as Written (DAW) Exception Reviews".
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
09/09/13	Replace policy. Policy Guidelines section updated to better clarify when nonformulary drugs may be considered medically necessary for both labeled and nonlabeled indications; information on how to obtain FDA watch site added. Description section updated with definition of label as it applies to prescription drugs. Reference #2 added; #3 renumbered.
12/18/13	Update Related Policies. Change title to 5.01.547.
11/20/14	Annual Review. Covered to Benefit Coverage Guideline template; no change in coverage.
05/12/15	Annual Review. Coverage guideline section updated documentation requirements for coverage of brand name drugs with a generic equivalent and Coverage of a brand name drug that has a generic equivalent (dispense as written [DAW]). No change to policy statements.

Date	Comments
12/08/15	Interim update. Updates made to documentation requirements for non-formulary drugs.
01/01/17	Annual Review, approved December 13, 2016. No updates made to the existing policy criteria.
09/01/17	Annual Review, approved August 22, 2017. No updates made to the existing policy criteria.
11/01/18	Annual Review, approved October 26, 2018. No updates made to the existing policy criteria.
07/01/19	Annual Review, approved June 4, 2019. Updates made to clarify criteria applied to non-formulary drugs.
10/01/20	Annual Review, approved September 1, 2020. No changes to policy statement.
10/01/21	Annual Review, approved September 23, 2021. No changes to policy statement.
06/01/22	Annual Review, approved May 23, 2022. No changes to policy statements.
06/01/23	Annual Review, approved May 22, 2023. No changes to policy statements. Changed "patient" to "individual" throughout the policy for standardization.
08/01/24	Annual Review, approved July 8, 2024. No changes to policy statements.
01/01/25	Interim Review, approved December 23, 2024. Removed medical necessity exception criteria for non-formulary drugs from policy 5.01.541. Coverage criteria for non-formulary drugs has been moved to policy 5.01.572 Coverage Criteria for Excluded and Non-Formulary Drugs.
04/01/25	Annual Review, approved March 24, 2025. Clarified that non-formulary exception review authorizations and all other review authorizations for all drugs subject to this policy may be approved up to 12 months. Clarified that the medications subject to this policy are subject to the product's FDA dosage and administration prescribing information.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.