PHARMACY BENEFIT COVERAGE GUIDELINE – 5.01.541
Medical Necessity Exception Criteria for Closed Formulary Benefits and for Dispense as Written (DAW) Exception Reviews

Effective Date: Sept. 1, 2017
Last Revised: Aug. 22, 2017
Replaces: N/A

RELATED GUIDELINES / POLICIES:
5.01.547 Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits
5.01.605 Medical Necessity Criteria for Pharmacy Edits

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINES | CODING | RELATED INFORMATION | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

A formulary is the list of drugs that are routinely covered under your prescription drug benefit. The drugs on the formulary list are sometimes referred to as “preferred drugs.” All drugs on the formulary list are selected for safety, effectiveness, and value. They were selected by our independent Pharmacy and Therapeutics (P&T) Committee, which is made of doctors and pharmacists who practice in the community. The P&T Committee reviews the medical and scientific evidence, guidelines from professional societies, and information in published medical studies when deciding whether to add a drug to the formulary. There are rare situations, however, when a drug that’s not on the formulary may be needed. This policy describes when a nonformulary drug may be covered.

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.
Closed formulary benefits normally do not provide coverage for nonformulary (nonpreferred) drugs; however, in certain clinical situations, adequate pharmacotherapy may not be provided by prescribing a formulary drug.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>Nonformulary drug</td>
<td>Use of a nonformulary drug may be considered medically necessary in certain circumstances. Coverage of an appropriate nonformulary drug will be approved when the criteria in this policy are met. The following criteria apply to coverage requests for nonformulary drugs in circumstances that are not specifically addressed in any other policy. Coverage of a nonformulary drug may be considered medically necessary on closed formulary benefits under any of the following three circumstances:</td>
</tr>
</tbody>
</table>
### Drug | Medical Necessity
---|---
the generic equivalent needs to have been tried), 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 patient.
- A nonformulary medication that has one or more formulary alternatives. Use of the nonformulary medication may be considered medically necessary when the prescriber has documented treatment failure, intolerance or contraindication to at least two of the formulary alternatives in the same therapeutic class of drugs. (Note: In cases where only one alternative is available, only that formulary agent needs to have been ineffective, not tolerated or contraindicated.)
- A nonformulary medication with no formulary alternatives. When no reasonable formulary alternative exists, medical necessity of the nonformulary drug will be determined by medical review of the individual case circumstances. Medical necessity will be evaluated based on:
  - The drug’s labeled indications, contraindications, appropriate dosing and other clinical information contained in the label.
  - Published peer-reviewed clinical evidence from primary and tertiary medical literature sources, if the proposed use is off-label.

### Brand name drug that has a generic equivalent
Use 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 in certain circumstances. Coverage of a brand name drug will be approved when the criteria in this policy are met.

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
<table>
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<td></td>
<td>generic equivalent</td>
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<td></td>
<td><strong>OR</strong></td>
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<td></td>
<td>• The prescriber is requesting the brand name drug due to a DOCUMENTED therapeutic failure with the generic equivalent</td>
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<td></td>
<td><strong>OR</strong></td>
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<td></td>
<td>• The prescriber is requesting the brand name drug because transitioning to a generic equivalent may result in a destabilization or unnecessary risk to the patient.</td>
</tr>
<tr>
<td>Note:</td>
<td>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.</td>
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</tbody>
</table>

**Coding**

N/A

**Related Information**

This policy applies only to closed formulary pharmacy benefits and to pharmacy benefits containing the dispense as written (DAW) requirement (see **Definition of Terms** below). As used in this policy, “Formulary” refers to the applicable formulary list specified in a member’s contract. The policy does not apply to open benefit designs in which nonformulary drugs are covered, though in some cases at a higher tier.
Definition of Terms

**Closed formulary benefit:** A closed formulary benefit is one that routinely covers only formulary (preferred) drugs. A nonformulary drug may be covered when its use has been determined to be medically necessary after a review of the individual clinical case circumstances.

**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.

**Formulary:** A formulary is a list of drugs approved by the Pharmacy and Therapeutics Committee (P&T) for routine use. A well-designed formulary should provide adequate drug selection to meet the treatment needs of most patients; however, there will always be exceptional cases where a nonformulary drug may be the best therapeutic choice.

**Formulary alternative:** A formulary alternative is a drug that is not generically equivalent to the reference product but is expected to produce similar treatment outcomes in the majority of patients with a certain condition. Formulary alternatives may be either brand name or generic drugs.

**Formulary drug:** A formulary drug (also known as a preferred drug) is a drug that is on the formulary list. Drugs that are not on the list are referred to as nonformulary drugs.

**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.

**Label:** Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the U.S. The label includes indications, contraindications,
recommended dosing, warnings, precautions, side effects, drug interactions and information on safety in pregnancy and other special populations. The drug’s pharmacology, pharmacokinetics, and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application.

This prescribing information is included as a package insert with the product and is available on the manufacturer’s website.

**Lack of a formulary alternative:** Occasionally, a drug may not have a suitable formulary alternative. This occurs when a product has recently been approved by the FDA and is pending formulary review, or when the Pharmacy and Therapeutics committee believes the potential risks generally outweigh the demonstrated clinical benefits of the drug. In such cases, it may be appropriate to use the drug in certain individual patients, despite its lack of formulary status.

**Benefit Application**

This coverage is managed through the Pharmacy benefit.

**References**


3. This policy was reviewed by the Premera Pharmacy and Therapeutics Committee November 23, 2015.

**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/12/12</td>
<td>New policy, add to Prescription Drug section.</td>
</tr>
<tr>
<td>07/13/12</td>
<td>A link to the FDA MedWatch form was added to the Policy Guidelines section.</td>
</tr>
<tr>
<td>03/11/13</td>
<td>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”</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>07/08/13</td>
<td>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.</td>
</tr>
<tr>
<td>09/09/13</td>
<td>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.</td>
</tr>
<tr>
<td>12/18/13</td>
<td>Update Related Policies. Change title to 5.01.547.</td>
</tr>
<tr>
<td>11/20/14</td>
<td>Annual Review. Covered to Benefit Coverage Guideline template; no change in coverage.</td>
</tr>
<tr>
<td>05/12/15</td>
<td>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.</td>
</tr>
<tr>
<td>12/08/15</td>
<td>Interim update. Updates made to documentation requirements for non-formulary drugs.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Annual Review, approved December 13, 2016. No updates made to the existing policy criteria.</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Annual Review, approved August 22, 2017. No updates made to the existing policy criteria.</td>
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</tbody>
</table>

**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 customer 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). ©2017 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.
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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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