

**PURPOSE:**

The purpose of the Non-Formulary Management policy is to define the Aetna Better Health process of how non-formulary medications are made available for enrolled and eligible members.

**STATEMENT OF OBJECTIVE:**

The objectives of this policy are to:

- Describe the process for making non-formulary drugs available when medically necessary
- Detail the information needed and the procedures to be followed by prescribing practitioner or providers in requesting authorization for non-formulary drugs
- Describe how to apply appropriate medical criteria to the review and approval process
- State the decision and notification requirements given to the prescribing practitioner or provider, and member, as applicable
- Require monitoring of utilization of non-formulary drugs to identify possible revisions to the Aetna Better Health Formulary

**DEFINITIONS:**

Department	The Department of Human Services (DHS) of the Commonwealth of Pennsylvania.
Drug Compendia	Aetna Better Health’s accepted drug information sources, which include Food and Drug Administration (FDA)-approved drug monographs and the following medical pharmacy information sources: <ul style="list-style-type: none"><li>• American Hospital Formulary Service (AHFS) – Drug Information</li><li>• Drug Facts and Comparisons</li><li>• United States Pharmacopeia – Drug Information</li><li>• United States Pharmacopeia – Drug Information</li><li>• Clinical Pharmacology</li></ul>
Formulary	A listing of medications covered under an enrolled member’s prescription drug benefit.
HealthChoices Program	The name of Pennsylvania 1915(b) waiver program to provide mandatory managed health care to Recipients.
Immediate Need	A situation in which, in the professional judgment of the dispensing registered pharmacist and/or prescriber, the dispensing of the drug at the time when the prescription is presented is necessary to reduce or prevent the occurrence or persistence of a serious adverse health condition.
Medically Necessary/ Medical Necessity	A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards: <ul style="list-style-type: none"><li>• The service or benefit will, or is reasonably expected to, prevent</li></ul>

	<p>the onset of an illness, condition or disability.</p> <ul style="list-style-type: none"> <li>• The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.</li> <li>• The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.</li> </ul> <p>Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.</p> <p>The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.</p> <p>All such determinations must be made by qualified and trained Health Care Providers, with denials being completed by a Medical Director A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.</p> <p><sup>1</sup></p>
Non-Formulary	A drug not listed on the health plan’s formulary/ preferred drug list (formulary) as approved by the Department <sup>2</sup>
Ongoing Medication	A medication that has been previously dispensed to the member for the treatment of an illness that is chronic in nature or for an illness for which the medication is required for a length of time to complete a course of treatment, until the medication is no longer considered necessary by the physician/prescriber, and that has been used by the member without a gap in treatment. If the current prescription is for a higher dosage than previously prescribed, the prescription is for an Ongoing Medication at least to the extent of the previous dosage. When payment is authorized due to the obligation to cover pre-existing services while a Grievance or DHS Fair Hearing is pending, a request to refill that prescription, made after the Grievance or DHS Fair Hearing

<sup>1</sup> Healthchoices Agreement Section II: Definitions

<sup>2</sup> Healthchoices Agreement Section II: Definitions

	has been finally concluded in favor of Aetna Better Health, is not an Ongoing Medication. <sup>3</sup>
Prior Authorization (PA)	A determination made by Aetna Better Health to approve or deny payment for a Provider's request to provide a service or course of treatment of a specific duration and scope to a Member prior to the Provider's initiation or continuation of the requested service. <sup>4</sup>
Provider	A person, firm or corporation, enrolled in the Pennsylvania Medical Assistance (MA) Program, which provides services or supplies to Recipients <sup>5</sup> .
Quantity Level Limit	Quantity level limits are based on FDA recommended dosing and are endorsed by the Pharmacy and Therapeutics Committee. Prescriptions that exceed the established limits will be reviewed by the medical director to confirm medical necessity. Prescriptions that exceed the quantity limit will require a prior approval before the prescription is filled.
Step Therapy	A form of automated prior authorization whereby one (1) or more prerequisite medications, which may or may not be in the same drug class, must be tried first before a Step Therapy medication will be approved.

**LEGAL/CONTRACT REFERENCE:**

- Applicable federal and state laws, rules, and regulations regarding confidentiality of member information (e.g., Health Insurance Portability and Accountability Act [HIPAA])
- Current pharmacy benefits manager agreements, addenda, amendments, letters of understanding and data licensing agreements
- Federal and state laws, rules and regulations concerning the practice of pharmacy, third party administration, Medicaid, and the Department of Human Services Agreement
- Administrative services agreement
- National Committee for Quality Assurance (NCQA) Standards and Guidelines for the Accreditation of Health Plans: 2017
- Pennsylvania HealthChoices Agreement
- Pennsylvania HealthChoices Agreement Exhibit BBB Pharmacy Services

**FOCUS/DISPOSITION:** <sup>6</sup>

A participating or nonparticipating prescribing provider acting on behalf of a member is to obtain prior authorization from Aetna Better Health before prescribing or obtaining medications that are not listed in the Formulary or the member's prescription drug benefit. Aetna Better Health will

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<sup>3</sup> Healthchoices Agreement Section II: Definitions  
<sup>4</sup> Healthchoices Agreement Section II: Definitions  
<sup>5</sup> Healthhchoices Agreement Section II: Definitions  
<sup>6</sup> NCQA HP 2017 UM11

require the prescribing provider to submit the Aetna Better Health Pharmacy Prior Authorization request form and all the necessary supporting medical documentation (e.g., pertinent medical records, completed Federal Drug Administration [FDA] Med Watch form).

### **Scope**

This policy applies to Aetna Better Health members who are enrolled and eligible to receive pharmacy services on the date of service.

### **Responsibilities**

#### *Chief Medical Officer*

The Aetna Better Health chief medical officer (CMO) is responsible for directing and overseeing the management of Aetna Better Health's pharmacy services, including the policies and guidelines for monitoring members' use of non-formulary drugs. The CMO or designated medical director reviews requests for authorization of non-formulary drugs using professional judgment and/or Aetna Better Health approved guidelines (refer to the Guidelines for Coverage section).

#### *Pharmacy and Therapeutics (P&T) Committee*

The P&T Committee advises the CMO in designated areas of pharmacy management, including monitoring members' utilization of non-formulary drugs. Aetna Better Health's CMO and pharmacy director will oversee and direct the management of Aetna Better Health's formulary.

#### *Prescribing Provider/Pharmacy Provider*

The prescribing provider is responsible for submitting authorization requests for non-formulary drugs to the Pharmacy Prior Authorization unit by fax or phone and is responsible for providing medical information necessary to review the request.

Pharmacy Prior Authorization will accept drug-specific information necessary for the authorization review from the prescribing provider. Aetna Better Health will inform the member and provider of authorization approvals or denials by written notice.<sup>7</sup>

Any new drugs that are approved by the FDA will be considered through the P&T Committee review process for addition to Aetna Better Health formulary, and would be made available as a non-formulary drug, requiring PA, upon their availability in the marketplace.

#### *Pharmacy Prior Authorization*

The Pharmacy Prior Authorization unit is responsible for the operations to process and review requests for non-formulary drugs, including:

- Obtaining all information necessary for the licensed pharmacist's review from the prescribing provider and the dispensing pharmacy
- Documenting the request and decision in applicable system databases
- Notifying the requesting prescribing provider of approved authorizations

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<sup>7</sup> NCQA HP 2017 UM 11 B4

## Pharmacy Prior Authorization Unit Requirements

Pharmacy Prior Authorization is responsible for operations to process and adjudicate requests for authorization of non-formulary drugs. These operations include the following:

- Verifying that:
  - The member is eligible to receive services at the time of the request
  - The medication is a covered benefit
  - The pharmacy provider is allowable under the member's benefit plan
- Obtaining all information necessary for the pharmacist and/or medical director's review from the prescribing provider and the dispensing pharmacy
- Researching a member's pharmacy authorization history to avoid:
  - Duplicating authorization of medications the member is already receiving
  - Authorizing medications not compensable under the Medical Assistance program
  - Duplicating authorizations already documented in the system
- Assisting in informing prescribing providers of alternative drugs that are included on the formulary
- Encouraging providers to complete all information on the Aetna Better Health Pharmacy Prior Authorization request form and submit all necessary documentation (e.g., medical records)
- Presenting potential denials to the medical director for review and decision
- Documenting the request and decision in the business application system and other applicable databases
- Notifying the prescribing provider and member, as applicable, of decisions to approve or deny authorization

## Non-Formulary Pharmacy Authorization Guidelines<sup>8</sup>

### *Guidelines for Coverage*

To support routine Non-Formulary pharmacy authorization decisions, Aetna Better Health uses guidelines, based on FDA-approved indications, evidence-based clinical literature, recognized off-label use supported by peer-reviewed clinical studies, and member's benefit design, which are applied based on individual members.

The Non-Formulary Guideline is used to evaluate authorization requests for which there are not specific guidelines. A request may be authorized if any of the following conditions are met:

- Drug is deemed to be medically necessary AND
- Three (3) formulary drugs (when available) in the same therapeutic category have been utilized for an adequate trial and have not been effective or not tolerated OR
- Formulary drugs in the same therapeutic category are contra-indicated OR
- There is no therapeutic alternative listed on the Formulary<sup>9</sup> OR

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<sup>8</sup> NCQA HP 2017 UM 11 B4-5

<sup>9</sup> NCQA HP 2017 UM11 E4-5

- Member is currently receiving medication within these drug classes<sup>10</sup>:
  - Anticonvulsants, Oral
  - Antidepressants
  - Antipsychotics
  - Cytokines and Cell Adhesion Molecules (CAM)
  - Hereditary Angioedema (HAE) medications
  - Hepatitis C agents
  - HIV medications
  - Immunosuppressives, Oral
  - Multiple Sclerosis (MS)
  - Oncology Agents, Breast Cancer
  - Pancreatic Enzymes
  - Pulmonary Arterial Hypertension (PAH)
  - Stimulants and Related Agents
  - Ulcerative Colitis Agents

The CMO or designated medical director reviews requests for non-formulary drugs using professional judgment and/or Aetna Better Health approved guidelines for medical necessity. The medical director may authorize the request if any of the above conditions are met.

Prescribing providers and members may request reconsideration of denied authorizations.

#### *Emergency, Discharge Medication Requests*

The following authorization requests will be approved:

- Aetna Better Health will authorize requested discharge medications prescribed to a member upon hospital discharge or after emergency department treatment, for a 5 day supply.

#### **Decision and Notification Standards<sup>11</sup>**

Aetna Better Health makes pharmacy authorization decisions and notifies prescribing providers, and/or members in a timely manner, according to the standards defined below unless other decision/notification time standards are required by Pennsylvania.

- Aetna Better Health makes decisions within twenty-four (24) hours of receiving the request.
- Aetna Better Health notifies requesting prescribing providers by fax, phone or electronic communication of the decisions within twenty-four (24) hours
- Aetna Better Health/Aetna Better Kids will allow pharmacists to dispense a 72-hour supply of the prescribed medication without prior authorization as per the professional

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<sup>10</sup> Pennsylvania HealthChoices Agreement. Exhibit BBB.

<sup>11</sup> NCQA HP 2017UM11 E4-5

judgment of the pharmacist. If the prescription is an ongoing medication, a 15-day supply will be allowed.<sup>12</sup>

- If an authorization is denied, Aetna Better Health gives requesting prescribing providers and members' electronic or written confirmation of the decisions with information about their appeal rights and appeal process including how to initiate an expedited appeal.<sup>13</sup>

#### **OPERATING PROTOCOL:**

##### **Systems**

- Aetna Better Health website
- Pharmacy business application system

##### **Measurement**

- Volume of requests for non-preferred drugs for addition to the Formulary
- Review new/current drugs on the Formulary, drug utilization data, and clinical and patient safety information from the pharmacy benefits manager, medical literature, or specialists as well as practitioners/providers' requests for changes in order to make recommendations about additions to the Formulary and determine whether or not action is necessary

##### **Reporting**

- Annual report to P&T Committee regarding clinical and cost efficacy
- Quarterly report to P&T Committee for review of formulary additions or deletions
- Quarterly report of formulary changes to the Department
- Summary of the activities of the P&T Committee to the Quality Management Oversight Committee

#### **INTER / INTRA DEPENDENCIES:**

##### **Internal**

- Aetna Better Health chief medical officer or designated medical director
- Aetna Better Health pharmacy director
- Information Technology (for authorization reports)
- Member Services
- Network Services
- Pharmacy and Therapeutics Committee
- Pharmacy Prior Authorization
- Quality Management Committee
- Utilization Management Committee

##### **External**

- Client

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<sup>12</sup> Pennsylvania HealthChoices Agreement: Exhibit BBB

<sup>13</sup> NCQA HP 2017 UM11 E5

- Federal and state regulators
- Members
- Participating pharmacies
- Participating prescribing providers
- Pharmacy benefits manager
- Regulatory bodies (Department)

Aetna Better Health  
Aetna Better Health Kids

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Jason Rottman  
Chief Executive Officer

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Bernard Lewin, MD  
Chief Medical Officer