MHC Non-Formulary Drug Coverage Policy

Overview

MHC uses a formulary medication list that is established, reviewed, and approved by our Pharmacy and Therapeutics (P&T) Committee, and the regulatory bodies in each state in which MHC functions. The formulary is reviewed on a quarterly basis, and new to market drugs are evaluated for formulary placement based on clinical necessity, the cost in relation to other existing clinical drug alternatives on the formulary, and overall safety to our members.

This policy intends to encourage the appropriate selection of members for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage the use of formulary agents. The Non-Formulary Drug Coverage Policy is a guideline for determining health care coverage for our members with benefit plans covering prescription drugs. This Pharmacy Policy statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

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

Definitions

• **Clinical Judgment**: Decisions made within the scope of the expertise of a pharmacist following the review of subjective and objective medical data for a member. A pharmacist can use Clinical Judgment for a benefit determination for an exception request for a Non-Formulary Drug. If the request is outside the scope of a pharmacist's expertise, a benefit determination will be made in collaboration with a medical director.
• **Drug**: A medication or substance which induces a physiologic effect on the body of a member (i.e., medication, agent, drug therapy, treatment, product, biosimilar drugs, etc.).
• **Formulary Drug List**: A list of prescription drugs that includes a group of selected generic and brand-name drugs that are covered by MHC.
• **Non-Formulary Drug**: a drug not on the Formulary Drug List.

Policy

MHC may approve the use of non-formulary medications and consider their use as medically necessary when the following criteria have been met for situations as listed below. This policy will not supersede drug-specific criteria developed and approved by our P&T Committee with respect to prior authorization, quantity limits, other utilization management criteria, nor drug or therapeutic category benefit exclusions. Prior authorization requests must be submitted for each non-formulary medication with chart notes and clinical documentation supporting medical necessity.

CRITERIA

I. The indication for use of the requested medication is approved by the FDA, **AND**
II. The dose of medication requested is based on FDA-Approved labeling for the age and indication, **AND**
III. Documentation of one of the following:

   A. Trial and failure of at least two (2) formulary or lower-cost alternatives, when available, and each trial has been 90 days in length, **OR**
   B. Contraindication or intolerance of ALL other formulary medications based on the member's diagnosis, medical conditions or other medication therapies; **AND**

IV. For Combination Products: A clinical reason supported by chart notes why the member is unable to take the active ingredients of the combination product separately as individually prescribed medications must be provided, **AND**
V. For long Acting Formulations: A clinical reason supported by chart notes why the member is unable to use the immediate-release formulation of the formulary drug must be provided.
VI. Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be immediately reflected in this policy.

Notes: • Drug specific criteria takes precedence over the Medical Necessity for Non-Formulary Medications Policy. • The start date and duration of a trial must be provided. • There must be paid claims if the member was enrolled with MHC during the trial with the formulary alternative. • Non-adherence to formulations requiring multiple daily doses does not guarantee the member will meet the requirements of medical necessity. Chart notes should be provided on the member's physical or mental characteristics to determine if the member meets the requirements of medical necessity. • Documented diagnoses must be confirmed by portions of the individual's medical record which need to be supplied with the prior authorization requests. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.

Guidelines

MHC provides the following processes that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescribers, as appropriate) to request and gain access to clinically appropriate drugs not covered by the MHC drug formulary. In the event that an exception request is granted, MHC will treat the excepted drug(s) as an essential health benefit, including counting any cost-sharing towards the plan's annual limitation on cost-sharing.

Standard exception request

MHC will make determinations on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescribers, as appropriate) of its coverage determination no later than 72 hours following receipt of the request. Incomplete requests or requests received without the necessary supporting documentation may be denied for lack of documentation.

If MHC grants a standard exception request, coverage of the non-formulary drug will be for the duration of the prescription, including refills, but not to exceed 12-months in duration.

Expedited exception request

Urgent request circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

MHC will make its coverage determination on an expedited review request based on the urgent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescribers, as appropriate) of its coverage determination no later than 24-hours following receipt of the request. Urgent requests must be clearly marked with "*Urgent*" on any form or document requesting such and the urgent request must have supporting documentation that demonstrates the immediate or urgent therapy need. Incomplete requests or requests received without the necessary supporting documentation may be denied for lack of documentation.

If MHC grants an exception based on urgent circumstances, coverage of the non-formulary drug will be for the duration of the exigency, but not to exceed 12-months in duration.

External exception request review

If MHC denies a request for a standard exception or for an expedited exception, MHC will use its process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescribers) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization (IRO).

MHC will make its determination on the external exception request (IRO) and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request.

If MHC grants an external exception review (IRO) of a standard exception request, MHC will provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

How to request Non-Formulary Drug Coverage

Providers must submit a request for coverage of non-formulary medications using the Formulary Exception Request Form available at www.mountainhealth.coop or by calling the MHC prescription drug benefits call center at 1-855-885-7695 to obtain the form.

Resources

45 CFR § 156.122 – Prescription Drug Benefits

Policy update/revision history

10/2019	Implementation of policy
4/2021	Changed website URL, company logo, and call center phone number