

Policy	PHARM-0001
Origination Date	10/01/2019
Reviewed/Revised Date	07/11/2025
Next Review Date	07/11/2026
Line of Business	All lines of business

Non-Formulary Drug Coverage Policy

Purpose

To define the conditions under which a non-formulary medication may be covered.

Definition

Mountain Health Co-Op 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 Mountain Health Co-Op functions. The formularies for each line of business are reviewed at least annually. New to market drugs are evaluated at least quarterly for formulary placement based on clinical necessity, evidence-based literature and guidelines, 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 medications for therapy according to product labeling, clinical guidelines, and/or clinical studies, as well as to encourage the use of formulary agents.

1. Formulary: A list of medications that are covered under the pharmacy benefit
2. Formulary Exception: Request by a healthcare provider to cover a medication due to medical necessity that is not included in the health plan's formulary.
3. Non-Formulary Drug: a retail drug not covered on Formulary as part of the pharmacy benefit.

Non-Formulary Authorization Criteria

Medications listed on the Mountain Health Co-Op formulary that are indicated for a member's condition must be tried and failed before medications excluded from the formulary may be considered, unless documentation indicates a medical necessity as outlined in this policy.

This policy will not supersede drug-specific criteria approved by our P&T Committee with respect to prior authorization, quantity limits, other utilization management criteria, or drug or therapeutic category benefit exclusions.

Mountain Health Co-Op considers coverage of a non-formulary medication as medically necessary when all of the following criteria have been met:

1. The indication for use of the requested medication is approved by the FDA, AND
2. Documentation of one of the following:
 - a. Evidence provided to show the member has failed or has a contraindication to all FDA-indicated formulary and/or guideline-recommended options, OR
 - b. That the requested therapy has clinically significant superior efficacy for the member's condition compared to formulary options (as evidenced by randomized, controlled, clinical trials and applicable clinical guidelines), OR
 - c. The requested medication meets medical necessity and is the only treatment option for the member's condition; AND
3. Drug-specific criteria takes precedence over the medical necessity for the Non-Formulary Drug Coverage Policy.
4. For combination products: A clinical reason supported by chart notes why the member is unable to take the active ingredients of the combination products separately, as individually prescribed medications must be provided, AND
5. 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.
6. Providers must submit a request for formulary exceptions using the Formulary Exception Request Form available at www.mountainhealth.coop or by calling the Mountain Health Co-Op prescription drug benefits call center at 1-855-885-7695 to obtain the form. All requests must include chart notes and clinical documentation supporting medical necessity.
7. 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.
8. The start date and duration of formulary alternatives must be provided.
9. There must be paid claims if the member was enrolled with the Health Plan when treated with the formulary alternatives.
10. Non-adherence to formulations requiring multiple daily doses does not guarantee the member will meet the requirements of medical necessity. Chart notes must be provided on the member's physical or mental characteristics to determine if the member meets the requirements of medical necessity.
11. Documented diagnoses must be confirmed by medical records, which need to be supplied with the formulary exception request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.

Renewal Authorization Criteria

1. Evaluate continued need based on the following:
 - a. If new generics or new biosimilars became available since the first authorization, has the member tried these according to the Pharmacy Benefit Manager (PBM) Brand Name Medications Policy or Biosimilar Policy.
 - b. If there are new formulary products since the first approval that have not been tried and may be more appropriate for the member.
 - c. Determine if the original authorization and any subsequent renewals were done appropriately, according to the criteria.
2. The member shows a positive clinical response to therapy.
3. Pharmacy claims show the member is adherent to the regimen.
4. For members new to the plan, clinical documentation must demonstrate adherence.

Dosage

1. Dosing must be in accordance with the US Food and Drug Administration (FDA) approved package insert.
2. For doses outside the Food and Drug Administration (FDA) package insert, the professional provider must provide supporting documentation (i.e., published peer-reviewed literature) to request coverage.
3. Accurate member information is necessary for Mountain Health Co-Op to approve the requested dose and frequency. If the member's dose, frequency, or regimen changes (based on factors such as changes in weight or incomplete therapeutic response), the provider must submit those changes to Mountain Health Co-Op for a new approval based on those changes as a new prior authorization process. Mountain Health Co-Op reserves the right to conduct post-payment reviews and audits of any submitted claims.

Exclusions/Contraindications

1. The prior use of samples will not be considered in determining a member's eligibility for coverage of this medication.
2. Contraindications per package insert.

Approval Duration

- | |
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| Initial Authorization |
| 1. 12- months |
| Re-Authorization |
| 1. 12- months |

References

1. Policy: Retail Pharmacy Formulary Exceptions
2. NCQA UM Standards- UM 11: Procedures for Pharmaceutical Management, Element E: Considering Exceptions

Review/Revision/Approval History	
Date	Description
10/2019	Policy created.
04/2021	Changed website URL, company logo, and call center phone number.
07/2025	Updated policy language, updated policy on the new company policy template.

Disclaimer
1. Policies outline coverage determinations for Mountain Health Co-Op. This Pharmacy Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan, and the member must be eligible for coverage at the time of service.
2. Additional payment guidelines may be applied that are not included in this policy. Services requiring prior authorization may not be covered if prior authorization is not obtained.
3. Policies are subject to change in accordance with State and Federal notice requirements
4. This document does not constitute medical advice and is for informational purposes only. Information should not be relied upon for the diagnosis and care of individual patients. Members should consult with their healthcare providers to obtain the necessary medical advice, care, and treatment