Medication Policy Manual

Policy No: dru517

Topic: New to Market Drugs and Indications

Date of Origin: August 2017

Committee Approval Date: October 2, 2025

Next Review Date: 2026

Effective Date: January 1, 2026

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

The intent of the New to Market Drugs and Indications pre-authorization criteria is to ensure appropriate use of newly approved ("new-to-market") medications, as well as newly approved indications for existing medications, as outlined in Food and Drug Administration (FDA) approved product labeling while full medication policy criteria are being developed (new or updated medication policies). Appropriate use is defined as use in patients who have an FDA approved indication, would meet the inclusion/exclusion criteria for the pivotal trials, who are receiving the FDA labeled dose, and who do not have any FDA labeled contraindications.

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Policy/Criteria

Most contracts require pre-authorization approval of new to market drugs (NTMDs) and existing medications used for new indications (EMFNI) prior to coverage.

I. Continuation of therapy (COT):

NTMDs may be considered medically necessary for COT when criteria A and B below are met.

EMFNI may be considered medically necessary for COT when there is clinical documentation (such as chart notes) confirming that criteria A, B, and C below are met.

A. The patient is established on this therapy prior to current health plan membership AND the medication was covered by another health plan.

***Note**: If the diagnosis is not an FDA approved indication, written documentation of coverage must be provided, such as an approval letter or paid claim.*

AND

B. If the diagnosis is not an FDA approved indication, documentation of clinical benefit, such as disease stability as detailed in the reauthorization criteria, is provided.

AND

C. ***EMFNI only:*** There are no specific COT criteria built into the drug-specific medication policy.

PLEASE NOTE: Specific COT criteria in drug-specific medication policies take precedence over the general criteria listed in this policy.

***Please note**: Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New starts (treatment-naïve patients): **NTMDs** and **EMFNI** may be considered medically necessary for coverage when criteria A through D below are met.

A. The patient has an FDA approved indication for the requested medication.

AND

B. The patient would meet the inclusion and exclusion criteria for the pivotal trial(s) for the requested FDA approved indication, as detailed in *Appendix A*.

AND

C. The patient does not have any FDA labeled contraindications to the requested medication.

AND

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D. The quantity requested is within the manufacturer's FDA labeled maximum dose and duration.

III. Administration, Quantity Limitations, and Authorization Period

A. For the scope of this coverage policy, self-administered or provider-administered drug status will be determined by product specific labeling and prescribing information.

B. When prior authorization is approved, the requested medication may be authorized in quantities (including dose and duration) that are reasonably safe and effective based on information contained in the FDA approved labeling.

C. Authorization **shall** be reviewed at least annually (shorter, for drugs with data of uncertain safety/efficacy or in indications dictating a shorter duration of use, such as, neoadjuvant therapy), until applicable drug-specific policy has been updated and developed for **NTMDs** and **EMFNI**.

1. Clinical documentation (such as chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, such as disease stability or improvement.

2. OF NOTE: For new medications (or indications) approved under the FDA's accelerated approval regulations, continued approval for the medication/indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. If confirmatory trials fail to show clinical benefit, the coverage may be considered not medically necessary and may not be continued, per the terms of the health plan contract.

IV. New to market drugs and existing medications used for new indications are considered investigational when used for all other conditions not listed in their FDA approved prescribing information, as described in the criteria above.

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Appendix A: Sources for Determination of Inclusion and Exclusion Criteria for the Pivotal Trial
The intent is limiting coverage to requests that mirror how the drug and indication was studied in the clinical trials used for the FDA approval. The following sources will be considered for determination of inclusion and exclusion criteria for the pivotal trial: • "Section 14 Clinical Trials" of the FDA-approved product labeling • clinicaltrials.gov (based on the NCT) • The "Methods" section in the published trial (if available) • The pivotal trial protocol(s) (if available) Major considerations include the diagnostic criteria, prior therapies (line in therapy), and dosing regimen, including use of mono- or combination therapy (if applicable).

NCT = national clinical trial number

Revision History

Revision Date	Revision Summary
10/2/2025	No criteria changes with this annual review.
9/19/2024	Clarified authorization period. Removed criteria "the prescribed dose cannot be achieved using a lesser quantity of a higher strength" (criterion IID2), to be consistent with intent of policy. No changes to intent of criteria.
9/14/2023	Clarified COT criteria requirements (no change to intent of coverage criteria).
12/9/2022	Added clarity to authorization period, indicating that authorizations are 12 months unless the label indicates a shorter duration of use.
10/15/2021	Clarified authorization limit. No change to intent of policy criteria.
10/26/2020	Added continuation of therapy (COT) criteria (no change to intent of coverage criteria).
7/24/2019	• Updated criteria to add review of new indications for existing medications, in addition to newly approved medications ("new to market drugs"). • Add criteria for review of requests versus pivotal trial inclusion and exclusion criteria, to mirror the rationale for the FDA labeling.
8/17/2018	No updates to criteria on this annual review.
9/8/2017	New policy (effective 1/1/2018).

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