

POLICY

New to Market Drug Policy

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The New to Market Drugs policy applies to both pharmacy and medically benefitted medications and provides Wellmark the ability to review, evaluate, and implement programs for new medications and new indications for medications to ensure members receive safe, appropriate, and quality of care of the highest value. As new medications and/or new indications are approved by the Food and Drug Administration (FDA), Wellmark carefully examines the scientific evidence and outcomes and may decide a new medication or new indication requires further evaluation to determine appropriate coverage and utilization management. The new medication or new indication for an existing medication will remain non-covered (up to 6 months) until evaluated and coverage and utilization management determinations are made.

Note: Wellmark aims to provide a more efficient review process to ensure that safe and effective treatments are available to members as early as possible, while guarding against unsafe or unproven approaches.

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New Drug Approval Process

For most benefits, there is an evaluation period before adding new, FDA-approved brand-name prescription drugs to the formulary or to medical coverage. During this time, the drug will be considered non-covered while the Wellmark Pharmacy & Therapeutics (P&T) Committee reviews the clinical evidence available and specific coverage and utilization management requirements are put in place. This evaluation period will apply to all brand-name drugs after they receive FDA approval as well as select biosimilar or generic drugs. Once the Pharmacy and Therapeutics Committee has completed its review and a coverage determination is made, Wellmark will make the required updates to formulary or medical claims coding. New to market medications will continue to be considered non-covered until the evaluation process and coding updates are completed.

All new medications that are identified as being subject to this policy will be placed on the [New-to-market drug list](#) upon FDA approval.

New Indication Process

When a new indication is approved by the FDA for an existing medication and a policy exists for that medication, this policy will hold that medication under review until either a Pharmacy & Therapeutics review is completed, or a business review is completed. If an existing medication without a policy is approved with a new FDA indication, this policy may hold that medication under review until either a Pharmacy & Therapeutics review is completed or a business review is completed. In either instance of a new FDA indication, the medication will be considered non-covered for the new indication while under review.

Individual Consideration Process

The individual consideration process applies to certain newly launched medications or newly FDA-approved indications that address an unmet medical need in the treatment of a serious or life-threatening condition when there are no significant safety and/or efficacy concerns and that have not yet undergone review by Wellmark and a utilization management strategy has not yet been put in place. Medications or new indications of medications that fall within one of the following scenarios will be eligible for the individual consideration process:

- Individual requires immediate treatment with the medication to prevent a serious deterioration of their condition and health
- Delay in treatment with the medication will jeopardize the ability of the individual to regain maximum function
- Delay in treatment with the medication will be life-threatening to the individual

Medications will be reviewed based on:

- Health plan benefits and whether the medication is a covered/reimbursable service; **and**
- Medical necessity

Medical necessity reviews for those eligible for the individual consideration process will be conducted using the following:

- Wellmark Pharmacy and Therapeutics (P&T) Committee approved drug policy; **or**
- All of the following:
 - FDA approved labeling, including but not limited to indication, patient age requirements, dosing recommendations, and contraindications; **and**
 - Clinical trial inclusion and exclusion criteria (ex., genetic testing, prior treatment experience, comorbid conditions); **and**
 - Compendia (if available); **and**
 - Current standard of care, as per evidenced based literature (if available)

Providers may send relevant clinical information for individual patients for consideration to:

Wellmark BCBS
Pharmacy Department
1331 Grand Ave
Des Moines, IA 50309

POLICY HISTORY

Policy #: 05.05.46

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Reviewed: October 2025

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