



Process: Non-Formulary Drugs and Step Therapy Exceptions

Purpose To describe the process for requesting an exception for clinically appropriate prescription medications not covered under the Formulary or that have step therapy requirements prior to receiving the requested medication. The specific process varies by the pharmacy benefits manager (PBM) under the plan.

- Definitions**
- **Formulary:** A list of medications or products that are covered under the prescription drug benefit.
 - **Non-Formulary Exception:** A request to obtain a medication that is excluded from the Formulary.
 - **Step Therapy Exception:** A request to obtain a medication that would normally require other medications to be attempted prior to coverage.
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Effective date 5/1/2019

Initiating an Exception An insured, insured's designee, or the prescriber may initiate a Non-Formulary Exception or Step Therapy Exception by contacting the applicable phone number below:

PBM	Phone Number
Wellfleet Rx/KPP (ID card BIN: 012882)	800-788-2949
Wellfleet Rx/ESI (ID Card BIN: 003858)	877-640-7948
Cigna PBM	877-228-3981

For any issues or concerns related to this process, Wellfleet may be contacted directly at 800-633-7867.

- Turnaround Times**
- Standard reviews are completed within 72 hours, except where state law or regulation requires a shorter determination window.
 - Expedited reviews are completed within 24 hours, except where state law or regulation requires a shorter determination window.
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- Reasons PBM May Allow an Exception**
- The coverage criteria for exceptions may be requested from the PBM when initiating a Non-Formulary Exception or Step Therapy Exception.



- The following are general reasons why PBMs will consider when determining whether to allow an exception:
 - The request for coverage is for an indication supported by the medical literature.
 - The insured has undergone a therapeutic trial with formulary medication alternative(s) to the non-formulary medication requested and there is documented treatment failure.
 - There is documented medical necessity of the requested medication and/or a clinical reason why the guideline criteria cannot be applied to the insured.
 - There is documented allergy or intolerance to a specified number of formulary alternatives.

Adverse Determinations and Appeals

If a Non-Formulary Exception or Step Therapy Exception is denied, the adverse determination notification letter to the insured and prescriber will include the reason for denial as well as a description of the appeals process.

Step Therapy Criteria Selection Process

Review of the Formulary, including any limitations, such as prior authorization, quantity limits, step therapy, clinical management programs or exclusions, is consistent with up-to-date evidence-based outcomes and current published, peer-reviewed medical and pharmaceutical literature. Drugs included in the Step Therapy program are considered therapeutic alternatives to each other for their respective step therapy group. Therapeutic alternatives (drug protocols with different chemical structures that are the same therapeutic or pharmacological class, and usually can be expected to have similar outcomes and adverse reaction profiles when administered in therapeutically equivalent doses) are determined from FDA approved product information and pharmaceutical compendia sources. Exceptions for indications or uses are noted in the respective clinical criteria.
