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Vigilant Drug Program

Thousands of prescription medications are available today and many more make their way to market each year. The U.S. Food and Drug Administration (FDA) approves approximately 50 new brand products or unique chemical entities annually.[1] However, drug manufacturers also launch numerous other new products each year that may or may not undergo formal FDA review and approval. Examples include reformulated products, new combinations and existing products repackaged in kits.

Prescription drug prices charged by manufacturers are currently under a great deal of scrutiny. Meanwhile, public and private payers are under extensive pressure to still provide well-rounded prescription drug benefits for members. As a result, careful review of every new prescription making its way to market is more critical than ever.

The OptumRx® Vigilant Drug Program is designed to do just that — to help safeguard clients and members from substantially higher-cost products that offer little to no additional value over other medication choices. When not properly managed, these products can add as much as 2 to 4 percent to a plan's overall drug expenditures.[2]

About the program

As a pharmacy care services company, OptumRx provides access to safe and effective medications while also helping to control costs for clients and members. The Vigilant Drug Program removes certain medications from coverage and drives use of lower-cost options. This helps ensure clinically appropriate medications while minimizing drug spend.

Program components

You can build an offering that's right for your organization by choosing from a number of options within the program's three categories:

1. Clinical quality strategies drive clinical appropriateness and cost savings.

- **New Drugs to Market strategy*** — Temporarily excludes newly launched products until they can be formally reviewed by the OptumRx National Pharmacy & Therapeutics (P&T) Committee. This program is a standard component of our Premium Formulary. This helps minimize member disruption and decrease financial risk until P&T review is completed on new drugs with unproven benefits.
- **Me Too strategy*** — Excludes newer, more costly medications that offer no clinical advantage over existing medications with similar chemical composition and possible generic options. Examples include unique dosage forms, combinations of two or more available medications, unique strengths, certain delivery devices and multiple product kits/packages.
- **Non-Essential strategy*** — Excludes select high-cost, non-FDA-approved products or those deemed unnecessary. Encourages use of lower-cost, FDA-approved options with established safety and effectiveness for the same condition(s).

2. Cost-saving strategies promote use of clinically equivalent, lower-cost options.

- **High-Cost Brands with Generics*** — Excludes select high-cost brand products when a lower-cost, therapeutically interchangeable generic product is available.
- **High-Cost Generics*** — Assesses generic options and excludes high-cost generic products when lower-cost alternatives are available with the same active ingredients or belong to the same drug class.
- **Medical Benefit Specialty** — Excludes high-cost specialty products exclusively administered within inpatient treatment facilities. This includes extremely expensive orphan drugs typically administered in an inpatient setting. In these cases, drug spend is best managed under the medical benefit.

* See separate information sheet for additional details on criteria.

1. U.S. Food & Drug Administration. Novel Drug Approvals for 2018. Accessed November 2018 at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm.

2. Internal OptumRx Book of Business Client Data.

optum.com/optumrx

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OptumRx is a pharmacy care services company helping clients and more than 65 million members achieve better health outcomes and lower overall costs through innovative prescription drug benefit services. Learn more at **optum.com/optumrx**.

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New Drugs to Market list criteria

The New Drugs to Market list is part of the OptumRx® Vigilant Drug Program. It excludes certain newly launched drug products, including new chemical entities, new formulations, or medication combinations not previously available. This approach helps:

- Eliminate inappropriate prescribing.
- Limit member disruption.
- Limit exposure to unnecessary drug spend.

How are drugs added to this list?

New drug products are defined as new molecular entities that fall within the scope of OptumRx Pharmacy & Therapeutics (P&T) Committee review.

- A drug will be added to this list if decided during the weekly review of the drug file.
- New drugs are maintained on the list for a maximum period of six months. At that time, the new product will be tiered according to the documented tiering decisions.
- New drugs added to the list will be placed on the highest tier of our standard formulary offering.

Products outside the OptumRx P&T Committee's scope usually will not be addressed on the New Drugs to Market list. This may include products that are typically covered under the medical benefit as a result of their administration and/or monitoring requirements.

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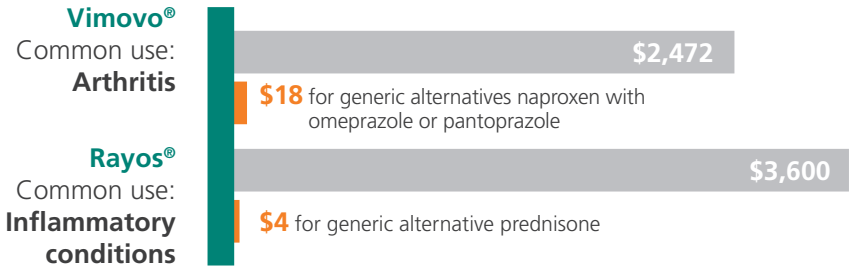
Me Too drug list criteria

The Me Too list is part of the OptumRx® Vigilant Drug Program. It excludes drugs that have chemically similar compounds and share the same mechanism of action as an existing approved chemical entity, yet offer no clinical benefit.

How are drugs added to this list?
A drug may be added to the Me Too list if it:

- Has a similar mechanism of action as an existing molecular entity.
- Has similar efficacy and safety outcomes with no significant clinical benefit over existing products.
- Is a select new combination product containing molecular entities already available as single-ingredient products.

Driving use of lower-cost options
Following are examples of clinically appropriate alternatives promoted through the Me Too drug list.



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Non-Essential drug list criteria

The Non-Essential drug list and Non-Essential Patches and Creams drug list are part of the OptumRx® Vigilant Drug Program. They exclude select drugs that are not FDA approved or are considered to be non-essential treatments. These drugs offer little clinical value compared to other well-tested, FDA-approved agents.

How are drugs added to the Non-Essential drug list?
Whether a drug is new or existing, it must meet one or more of the following criteria to be on this list:

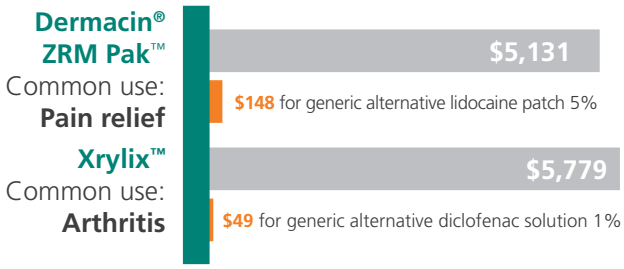
- Not FDA approved.
- Designated "non-essential non-FDA-approved" by the OptumRx Pharmacy & Therapeutics Committee.
- Select drug products approved via the FDA 510(k) pathway.

How are drugs added to the Non-Essential Patches and Creams drug list?
A drug will be added to the Non-Essential Patches and Creams drug list if it meets these criteria:

- A subset of the Non-Essential drug list that focuses on high-cost topical products (e.g., combination products and kits that combine inexpensive ingredients).
- FDA approved for only a component of the kit or combination.

The Non-Essential drug list does not include over-the-counter drugs or drugs that overlap with other standard OptumRx benefit exclusion options. In addition, OptumRx may decide not to include low-cost, highly utilized, non-FDA-approved products that have been on the market long-term without significant safety or efficacy concerns.

Driving use of lower-cost options
Following are examples of clinically appropriate alternatives promoted through the Non-Essential drug list.



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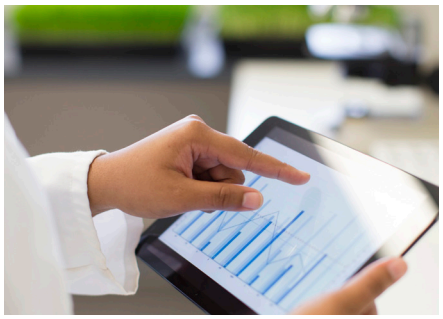
High-Cost Brands with Generics drug list criteria



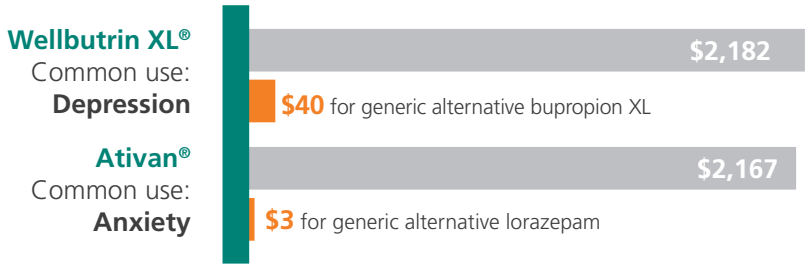
The High-Cost Brands with Generics drug list is part of the OptumRx® Vigilant Drug Program. It excludes brand drugs that are significantly higher cost than their generic equivalents.

How are drugs added to this list?
A brand product that has generics will be added to this list if it meets one or more of these criteria:

- An ingredient cost per prescription or ingredient cost per 30 days that is significantly higher than the generic equivalents or alternatives.
- A high estimated total plan paid savings based on generic conversion opportunity.

Exceptions may be made to refrain from adding specific brands if there are significant supply issues with the generics.

Driving use of lower-cost options
Following are examples of clinically appropriate alternatives promoted through the High-Cost Brands with Generics drug list.



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High-Cost Generics drug list criteria

The High-Cost Generics drug list is part of the OptumRx® Vigilant Drug Program. It excludes generic drugs that cost significantly more than other generics within the same therapeutic class.

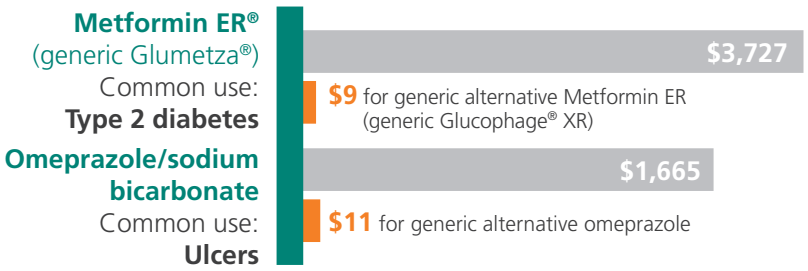
How are drugs added to this list?
A generic will be added to this list if it meets one or more of these criteria:

- A high total plan paid cost.
- A high ingredient cost per prescription or ingredient cost per 30 days with multiple lower-cost alternatives available in the same therapeutic class.

Generics within the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral and antineoplastic classes will not be targeted unless lower-cost alternatives with similar active ingredients and dosage forms are available.

Exceptions may be made to refrain from adding specific brands if there are significant supply issues with the generics.

Driving use of lower-cost options
Following are examples of clinically appropriate alternatives promoted through the High-Cost Generics drug list.



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