



Formulary Development and Management at CVS Caremark®

Development and management of drug formularies is an integral component in the pharmacy benefit management (PBM) services CVS Caremark provides to health plans and plan sponsors. Formularies have two primary functions: 1) to help the PBM provide pharmacy care that is clinically sound and affordable for plans and their plan members; and 2) to help manage drug spend through the appropriate selection and use of drug therapy.

Underlying principles of the CVS Caremark Formulary Development and Management Process include the following:

- CVS Caremark is committed to providing a clinically appropriate formulary.
- Decisions on formulary are made by a committee of independent, unaffiliated clinical pharmacists and physicians.
- The physician always makes the ultimate prescribing determination as to the most appropriate course of therapy.

The CVS Caremark formulary development process is based on nearly two decades of experience as well as extensive clinical pharmaceutical management resources. The formulary is developed and managed through the activities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee ("P&T Committee") and Formulary Review Committee (FRC).

CVS Caremark National Pharmacy and Therapeutics Committee

The P&T Committee is foundational in the process. The P&T Committee is an external advisory body of experts from across the United States, composed of 22 independent health care professionals including 18 physicians and four pharmacists, all of whom have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing pharmacists and physicians. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians is a medical ethicist. The role of the medical ethicist is to assist in the decision-making process by facilitating the discussion, as needed, and to provide unbiased feedback with respect to the logic and appropriateness of the conclusions drawn and the decisions reached. The composition of the P&T Committee exceeds the Centers for Medicare and Medicaid Services (CMS) P&T Committee requirements for Medicare Part D sponsors and also exceeds URAC standards.

CVS Caremark National Pharmacy and Therapeutics Committee Membership		
4 pharmacists, including	18 physicians, representing	
1 academic pharmacist	Allergy	Internal medicine
1 hospital pharmacist	Cardiology	Infectious disease
2 geriatric pharmacists	Clinical pharmacology	Pediatrics
	Endocrinology	Neurology
	Family practice	Medical ethics
	Gastroenterology	Pharmacoeconomics
	Gerontology	Pharmacology
	Hematology/oncology	Psychiatry-adult/ pediatric/adolescent
		Rheumatology

1. All drugs that are legally marketed under the Federal Food Drug and Cosmetic Act (e.g., "grandfathered" drugs).

The regular voting members on the P&T Committee are not employees of CVS Caremark. The P&T Committee is charged with reviewing all drugs, including generics that are represented on the CVS Caremark approved drug lists. The approvals made are non-biased, quality driven and evidence based. The clinical merit of the drug, not the cost, is the primary consideration of the P&T Committee.

New members are included on the current P&T Committee on the basis of active involvement in clinical practice (patient care), whether in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees. The P&T Committee members are compensated for their participation with an appropriate honorarium and any travel/hotel expenses incurred in the process of serving on the P&T Committee.

The P&T Committee meets face-to-face on a quarterly basis and, as needed, on an ad hoc basis. CVS Caremark has a stringent conflict of interest policy for P&T Committee members. CVS Caremark requires each P&T Committee member to complete a Conflict of Interest Disclosure Statement annually. Completed Conflict of Interest Statements are carefully scrutinized by the CVS Caremark Chief Health Officer and Vice President of Clinical Affairs responsible for formulary development and maintenance. An objective party in the CVS Caremark Compliance Department verifies that conflict of interest requirements have been met. Through this careful review, CVS Caremark helps ensure that the P&T Committee meets or exceeds all federal and state regulatory requirements for conflict of interest, including CMS, and all industry accreditation standards, including URAC and the National Committee for Quality Assurance (NCQA).

Clinical Formulary Department

The P&T Committee functions are supported by the CVS Caremark Clinical Formulary Department. Clinical pharmacists in the Formulary Department prepare individual Drug Monographs and Therapeutic Class Reviews following a comprehensive review of available clinical literature. Numerous references and information resources are used to assist in the evaluation and review of the medications under consideration for formulary addition. These peer-reviewed resources are selected based on being accurate, reliable, current, comprehensive and well-respected.

Formulary Development and Maintenance Process

The P&T Committee bases decisions on scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines and other appropriate information. The P&T Committee reviews medications from a purely clinical perspective; it does not have access to nor does it consider any information on rebates, negotiated discounts or net costs. In alignment with this clinical perspective, the P&T Committee also reviews new drug evaluations, new U.S. Food and Drug Administration (FDA)-approved indications, new clinical line extensions and publications on new clinical practice trends.

In evaluating new drugs for formulary inclusion, the P&T Committee reviews the individual drug monographs, pivotal clinical trials accompanying the drug monographs, and therapeutic class reviews prepared by the Clinical Formulary Department. P&T Committee members share insights based on their clinical practice and the quality of published literature. FDA-approved drug products¹ are reviewed and considered for inclusion on the Formulary and standard formularies/drug lists by the P&T Committee. The P&T Committee also reviews and approves all utilization management (UM) criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling).

The P&T Committee reviews all standard formularies annually. The review is conducted by drug class to assure that the formulary recommendations previously established are maintained and to recommend additional changes for clinical appropriateness if advisable based on newly available pharmaceutical information. In addition, the P&T Committee reviews all UM criteria annually.

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Review of new drugs or new indications for drugs in six classes is expedited. These classes include the immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals and antineoplastics. For drugs in these classes, the P&T Committee makes a National Formulary and Medicare Part D Drug List status decision within 90 days of launch/market availability. For drugs outside of these classes, the P&T Committee makes a National Formulary decision within 90 days of launch/market availability and a Medicare Part D Drug List status decision within 180 days of launch/market availability. In addition, the P&T Committee will make formulary status decisions for the Managed Medicaid Drug List and Health Exchanges Formularies within 90 days of launch/market availability of newly FDA-approved drugs, or will provide a clinical justification if this timeframe is not met.

Formulary Review Committee

The FRC is an internal CVS Caremark committee that evaluates additional factors that may affect the formulary. For example, when two or more drugs produce similar clinical results, the FRC may evaluate factors such as:

- Utilization trends
- Impact of generic drugs or drugs designated to become available over-the-counter
- Brand and generic pipeline
- Line of business
- Plan sponsor cost
- Applicable manufacturer agreement
- Potential impact on members

The FRC makes business recommendations based on such factors to the P&T Committee. It is important to note that any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary or Drug List, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation.

Formulary Management

The formulary is a dynamic tool that may be responsive to changes in the marketplace. It is intended to offer savings to clients while ensuring clinically appropriate products are available for members to use. Clients may choose to utilize CVS Caremark formularies for their plans or use them as the foundation for custom formularies.

Most drug classes have multiple generic and low-cost brand-name options that cover the same indications as more costly brand-name options in the same class. The generic and low-cost brand-name options offer similar efficacy and safety. Since many brand-name drugs do not provide clear clinical and/or financial advantages when compared to available drug options within the therapeutic class, several strategies are available to promote cost-effective use of medications ranging from tiered copayments, excluding products from coverage or having a closed plan design.

- Tiered copayments encourage members to use preferred formulary drugs. A three-tier formulary—typically with generics in the first, lowest cost tier; preferred brand-name drugs at second tier; and non-preferred brand-name drugs at the highest-cost third tier—is the option chosen by the vast majority of plan sponsors working with CVS Caremark.
- Many of our standard formularies also exclude certain products from coverage. The excluded products have alternatives available that will deliver cost savings to plan sponsors.
- Closed formularies will cover a set number of products and the others are not covered unless the claim goes through an override process.

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Within these plan designs, clients may opt to implement a formulary exception process where members, after meeting certain criteria, could have an excluded product covered, or could receive a third-tier product at a second-tier copay.

All formularies include generic drugs, and generics are typically in the lowest tier of pricing for members. Brand-name products may be considered preferred or non-preferred in the common three-tier plan design. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products.

Formulary Compliance

Plan design, as noted above, is primary in achieving formulary compliance. CVS Caremark also provides plan sponsors with a range of solutions that encourage the use of generics and preferred brand-name drugs. Many CVS Caremark clients choose a plan that requires that a cost-effective generic be used before a single-source brand in the same therapeutic class.

Promotion of generics. When an A-rated generic becomes available, it is considered preferred and proactively encouraged. At that point, significant efforts are made to transition utilization to the lower-cost generic product. Client plan design will direct the effort and can be very aggressive and only cover the generic, or be more moderate and require the member to pay the difference between the brand-name drug and the generic if the brand-name product is chosen. Some clients may no longer cover the brand-name drug if a generic is available.

Member-directed formulary education. Members are notified when a new brand-name or generic product replaces a product they are using on the formulary. They are also notified if a product they are using is removed from the drug list, which could occur due to withdrawal from the market for safety reasons. If a non-preferred product has been dispensed at a retail pharmacy due to a prescription marked "Dispense as Written," the member may also be alerted about alternative formulary product(s) that could be available at a lower copayment.

The website, Caremark.com, in addition to providing a simple way to order prescription refills, allows the member to access information about their specific drug list, pricing information and generic availability, as well as general drug and health information.

Improving Member Experience and Outcomes

CVS Caremark is focused on helping members achieve their health and wellness goals through proper understanding and utilization of their medications. There are a number of strategies used to support members in their desire for positive outcomes including:

- Helping them become knowledgeable about their plan, benefit structure and drug therapy management options
- Helping them understand and comply with their prescribed therapies by providing:
 - Adherence counseling with all new prescriptions (face-to-face at CVS Pharmacy® locations, by letter through mail service and retail network)
 - Refill reminders (letters, Interactive Voice Response [IVR], Internet) and non-adherent prompts (letters and phone calls)
 - Availability of automatic prescription renewals and refills
 - Information about ways to save on prescriptions by using lower-cost alternatives or lower-cost channels
- Coordinating with plan sponsors to promote enrollment in wellness and health management programs and offering appropriate and timely immunizations
- Making formularies readily available on Caremark.com

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