Formulary Development and Management at CVS Caremark®

Development and management of drug formularies is an integral component of the pharmacy benefit management (PBM) services CVS Caremark provides to health plans and plan sponsors. Formularies have two primary functions: 1) to help 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. We continually monitor the pharmaceutical landscape and evolve our formulary strategy to help clients stay ahead of marketplace trends while offering members access to clinically appropriate, cost-effective medications.

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

- CVS Caremark is committed to providing a clinically appropriate formulary.
- The formulary is reviewed and approved by a committee of independent, unaffiliated clinical pharmacists and physicians.
- The prescriber always makes the ultimate determination as to the most appropriate course of therapy.

The CVS Caremark formulary development process is based on nearly three 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 P&T Committee

The P&T Committee is foundational in the formulary development process. The P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals including 18 physicians, two pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates the discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are 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 exceeds URAC standards.

CVS Caremark National Pharmacy and Therapeutics Committee Membership		
Two pharmacists, including:	**18 physicians, representing:**	
Two geriatric pharmacists	Allergy	Infectious disease
	Cardiology	Medical ethics
	Dermatology	Neurology
	Endocrinology	Pediatrics
One patient representative	Family practice	Pharmacoeconomics
	Gastroenterology	Pharmacology
	Gerontology	Psychiatry
	Hematology/oncology	Rheumatology
	Internal medicine	

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 unbiased, quality driven and evidence based. The clinical merit of the drug, not the cost, is the primary consideration of the P&T Committee.

Consideration for membership on the P&T Committee is based upon the following: active involvement in clinical practice (patient care) whether in the academic, hospital, or community setting; national recognition in their field; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees. The P&T Committee members are offered an honorarium and are reimbursed for travel/hotel expenses incurred in the process of serving on the P&T Committee.

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 Medical Officer and Vice President of Clinical Affairs. 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 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 activities are supported by the CVS Caremark Clinical Formulary Department. Clinical pharmacists in the Clinical Formulary Department prepare individual drug monographs and therapeutic class reviews following a comprehensive evaluation of peer-reviewed clinical literature. Numerous references and information resources are used in the evaluation and review of medications under consideration for formulary addition.

Formulary Development and Maintenance Process

The P&T Committee decisions are based upon scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines, and other appropriate information. CVS Caremark takes all measures to ensure the P&T Committee reviews medications from a purely clinical perspective without consideration of 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 and publications on new clinical practice trends.

In evaluating new drugs for formulary inclusion, the P&T Committee reviews 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 products are reviewed and considered for inclusion on the National 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 ensure 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 at least annually.

Review of new drugs or new indications for drugs in six classes is expedited. These classes include 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 ninety (90) days of launch/market availability. For drugs outside of these classes, the P&T Committee makes a National Formulary decision within ninety (90) days of launch/market availability and a Medicare Part D Drug List status decision within one-hundred and eighty (180) days of launch/market availability or will provide a clinical justification if this timeframe is not met. In addition, the P&T Committee will make formulary status decisions for the Managed Medicaid Drug List and Health Insurance Marketplace (Exchange) 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 (FRC)

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

- 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 the above 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 is responsive to changes in the marketplace. It is intended to offer savings to clients and members while ensuring clinically appropriate products are available to members. 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 lower-cost generic and brand-name formulary options that cover the same indications. These lower-cost generic and brand-name formulary options offer similar efficacy and safety. Since many higher-cost 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 tiering, exclusions, or closed formulary designs.

- Tiering encourages members to use preferred formulary products. Most plans apply different member cost shares between generic, preferred formulary brand products and non-preferred brand products.
- Many of our standard formularies also exclude certain products from coverage. The excluded products generally have preferred formulary alternatives available that will deliver cost savings to plan sponsors.
- Closed formularies will cover a limited number of products. Other products may be covered through an override process.

Within these formulary 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 non-preferred product at a preferred product member cost-share.

Formulary Performance

Formulary design, as noted above, is primary in achieving formulary performance. CVS Caremark also provides plan sponsors with a range of solutions that encourage the use of preferred products. 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 typically considered preferred and utilization is proactively encouraged. At that point, significant efforts are made to transition utilization to the lower-cost product. Client plan design will direct the effort and can be more restrictive and only cover the lower-cost products or be more moderate and require the member to pay the difference between the higher-cost product and the lower-cost product. Some clients may choose to no longer cover a brand-name drug if a generic is available.

Member-directed formulary education. Members are notified when a product they are using will be removed from coverage or moved to a higher tier resulting in higher member cost-share. Members receive mailings informing them in advance of the effective date of the change. Members may also receive additional notifications, such as digital communications, text messages, and/or live calls, depending on the specific change.

The CVS Caremark website, Caremark.com, in addition to providing a simple way to order prescription refills, allows the member to access information about their plan's specific drug list, pricing information and alternative drug 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 several 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 members understand and comply with their prescribed therapies by providing:
    - Refill reminders (letters, text, and digital communications) and non-adherent prompts (letters and phone calls).
    - Late to fill inquiries when members are late requesting or picking up refills.
    - Availability of automatic prescription renewals and refills and prescription synchronization to set up refills on a recurring schedule.

    - 30- to 90-day conversion promoting the convenience of fewer trips to the pharmacy.
    - Information about ways to save on prescriptions by using lower-cost options or pharmacy 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.