A primer on formulary structures and strategies

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Abstract

Formularies are a tool for managing costs, optimizing patient access, and improving overall health outcomes. The general goal of formularies is to provide access to appropriate therapy while promoting effective resource utilization, which allows the managed care pharmacy organization to operate sustainably. Traditional formulary strategies have included open and closed formularies as well as tiered formularies. However, other formulary structures have emerged in support of the focus on product value. The formulary development process is primarily driven by the pharmacy and therapeutics (P&T) committee and value committee within an organization. Key considerations such as member population, regional differences, regulatory/compliance implications, and benefit design strategies may influence payers to create a customized formulary to provide additional value to their members while managing costs. With the rise of high-cost and specialty products, formularies continue to serve as an important tool for managed care pharmacy organizations. Ongoing trends, such as biosimilars, prescription digital therapeutics, and addressing health equity, will shape future strategy and management of formularies.

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Formularies are a tool used by managed care pharmacy organizations to adapt to the evolving landscape of pharmacy products. With the rise of high-cost and specialty products, formulary management has been leveraged as a strategy to manage costs, optimize patient access, and improve overall health outcomes. In 2022, gross pharmacy expenditures in the United States grew 9.4% compared with 2021, with a total spend of $633.5 billion.[1] Utilization, price, and novel products have been driving factors for this increase.[1]

A *formulary* (italicized words are defined in the Glossary) is a continually updated list of medications, products, and technologies supported by current evidence-based medicine, as well as the judgment of physicians, pharmacists, and other relevant experts in the diagnosis and treatment of disease and preservation of health. Formularies generally share an overarching goal to provide access to appropriate therapy while promoting effective resource utilization, which allows the managed care pharmacy organization to operate sustainably.[2] Further, formularies may impact both therapeutic choice and out-of-pocket costs for patients. Therefore, formulary development and management is a key competency of managed care pharmacy organizations.[3]

This primer describes the differing structures of formularies that are designed by *pharmacy benefit managers* (PBMs), *health plans*, and insurers and the related strategies. Health plans and insurers are collectively referred to as payers. Although the process for reviewing medications and

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TABLE 1 Overview and Comparison of Formulary Structures

	Formulary structures				
	Open	**Value-based**	**Tiered**	**Closed—limited brand coverage**	**Closed—generic only**
Description	Provides coverage for all products available	Accounts for product value primarily using cost-effectiveness analysis	Assigns and categorizes products into tiers	Excludes nonformulary products (brand and/or generic)	Excludes most or all brands
Relative cost to payer	High	High in short-run, low in long-run	Medium	Medium	Low
Relative cost to member	High	Medium	Medium	Medium	Low
Member product access	High	Medium	Medium	Medium	Low

related products by clinical experts has been previously described,[2] this primer describes key payer considerations and emerging trends in formulary management. Formularies used in other settings, such as hospitals and health systems, are beyond the scope of this primer.

Formulary Structures and Strategies

An ongoing formulary management strategy is essential for responding to the complex therapeutic landscape. Formularies may differ depending on the line of business (eg, commercial and Medicaid) and applicable government regulations, characteristics of their *members*, and the payer's strategy to optimize cost.

Table 1 provides a high-level comparison of the structures of formularies. Irrespective of the formulary type, medications and related products are selected for formulary coverage based on clinical review by a pharmacy and therapeutics (P&T) committee and a value committee that negotiates with the drug manufacturers for price concessions.[2] Additionally, formulary goals can be advanced through efforts to ensure appropriate medication use, such as *utilization management*. Commonly used utilization management tools include *quantity limits*, *prior authorization*, and *step therapy* and are applied at the drug level.

OPEN VS CLOSED FORMULARIES

An effective formulary allows for access to safe and clinically appropriate medications while taking into consideration population needs. Some payers offer more choices to their members, whereas others have narrowed their product options to limit higher-cost medications.

In a closed formulary, formulary exclusions are products that are not covered, and the noncoverage decision is often related to a decision to cover a competitive product in exchange for price concessions. If a provider requests an excluded product, an alternative formulary product within the same therapeutic class may be recommended to limit the member otherwise paying full retail cost for the medication. Additionally, formulary exception policies allow providers and their patients to request coverage for nonformulary medications when medically appropriate, through an *appeals* process.

An open formulary provides coverage for all products available; however, the trade-off is higher costs to the payer and potentially the member. Open formularies offer more product choice to members than closed formularies.

TIERED FORMULARIES

In tiered formularies, patient *out-of-pocket costs* depend on in which tier a specific product is categorized. Therefore, patients are incentivized to use lower-tier medication via a lower *copayment*. Although the number of tiers in a given pharmacy benefit may vary, 3-tier designs are the most common.[4] In a typical 3-tier design, tier 1 includes generic drugs, tier 2 includes preferred brand-name drugs, and tier 3 includes nonpreferred brand-name drugs.[5] With the immense growth in specialty products over the past decade, many formularies have specialty tiers to distinguish them from traditional drugs or designate them as a higher tier (eg, tier 4 or above).

The level of *rebate* provided by the manufacturer or net cost may determine preferred or nonpreferred status

TABLE 2 Examples of Payer Considerations in Formulary Development

Theme	Examples of considerations	Description
Population	Age, sex, ethnicity, social determinants of health	Makeup of each payer's membership will differ and may impact coverage decisions to ensure equitable care.
Regional	Distance to care, access to quality care, cultural differences	Access to care and unique expectations based on location (rural vs urban) can require formulary and benefit designs to accommodate patient needs.
Regulatory/ compliance	State-driven mandates, Medicare requirements, quality reporting	Federal and state mandates may affect formulary design. Payers may have financial incentives tied to specific outcomes.
Benefit design	Comprehensive coverage, carveout, medical coverage alignment, tiering, networks	Payers can create a unique benefit design by leveraging multiple vendor partners (pharmacy or medical carveout), unique patient benefits (copay vs coinsurance), and access to care (open vs narrow networks).

on the formulary. Additionally, utilization management restrictions may also affect preferred vs nonpreferred status and corresponding tier placement.

VALUE-BASED FORMULARIES

A value-based formulary assesses product value primarily using cost-effectiveness analysis, assigning products with a high assessed value (low incremental cost-effectiveness ratio) to lower copayments and products with a low assessed value (high incremental cost-effectiveness ratio) to higher copayments. Value is assessed based on the long-term benefit of treatment, such as impact on clinical parameters, quality of life, and utilization of other health care resources. Value-based formularies may use tiering to incentivize patients to use high-value products.[6] Products that are higher cost but effective can still fall in the same tier as products with reasonable costs but limited clinical value. The focus of a value-based formulary is on overall health care spend over time rather than the upfront net cost of the medication alone.[7]

Formulary Customization

Some payers develop their own formularies, whereas others hire PBMs. PBMs develop template formularies for their payer clients to select from. Although many payers will adopt one of the template formularies, others will not. Instead, these plans may choose to create a customized formulary for several compelling reasons (Table 2). Most often the aim is to further manage medication costs. By tailoring formularies, payers can create an offering that best fits the needs of the members they serve. Payers may choose to further customize the formulary to add or remove specific drugs that are expected to offer additional value in managing their population.

Although formulary customization can lead to cost savings due to a targeting strategy for a unique population of patients, there are costs associated with the process itself. These costs primarily include administrative expenses and additional resources required for decision-making and ongoing management. Administrative expenses include the cost of convening P&T committee meetings, conducting clinical evaluations, and managing the communication and negotiation processes with PBMs and drug manufacturers. These expenses can vary depending on the size and complexity of the payer and the extent of customization required.

Looking Forward

Formularies have evolved with the introduction of new therapies, higher overall pharmacy and health care costs, and the changing prevalence of diseases, There are notable themes that will continue to influence the trajectory of formulary development and management:

1. With the recent rise in the approval and launch of biosimilars in the United States, these products are increasingly included in covered tiers of formularies. However, biosimilar adoption has been slower than expected. Utilization is expected to increase over time as the net cost of biosimilar products drops in relation to the reference product and additional biosimilars enter the market.[8] This growth in uptake will increase the cost-effectiveness of biologics for members and payers alike.

2. Prescription digital therapeutics (PDTs) have emerged as innovative software-driven technology.[9] PDTs are not currently a part of the traditional drug review process. Specialized expertise and considerations are needed. Some payers are attempting to evaluate PDTs and create pathways for coverage under the pharmacy or medical benefit for members to use them. The growing focus on these technologies by payers are indicators of the need for established best practices for evaluation.[10]
3. Health equity has become a priority within the formulary development process, with areas of focus including socioeconomic status, race, ethnicity, geography, sex, and sexual orientation. Payers have begun incorporating the patient perspective to better understand both intended and unintended consequences of formulary decisions as one way to address health disparities. Ideally, formularies will allow for improved health outcomes despite differences in social determinants of health.[11]

Conclusions

Formularies remain an integral tool for managed care pharmacy organizations to provide cost-effective access to medications, products, and technologies to their members. The overall growth in high-cost and specialty therapies and subsequent rise in health care costs has underscored the importance of adept response by payers in formulary development and management. As new and innovative products continue to emerge in the complex health care landscape, stakeholders must continue to evolve their strategies and approaches for improved outcomes among the members they serve.

DISCLOSURES

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Glossary

All definitions are adapted from the AMCP Managed Care Glossary, available at https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary.

Appeals: A process used by a member to request coverage for an insurance claim that the insurer has denied.

Copay or copayment: A cost-sharing arrangement in which a health plan member pays a specified charge for a specific service, such as a fixed dollar amount for a prescription drug.

Formulary: A continually updated list of medications, products, and technologies supported by current evidence-based medicine, as well as the judgment of physicians, pharmacists, and other relevant experts in the diagnosis and treatment of disease and preservation of health.

Health plans: An organization that offers benefit products, which may include, medical, pharmacy, dental, vision, and/or chiropractic benefits, to private and public purchasers. Types of health plan models: health maintenance organization, preferred provider organization, point-of-service plan, and high-deductible health plan.

Member: A participant in a health plan; a person covered by health insurance.

Out-of-pocket costs: The portion of payments for covered health services required to be paid by the member, including copayments, coinsurance, and deductibles.

Pharmacy benefit manager: An organization that represents health insurers, self-insured employers, union health plans, and government purchasers in the selection, purchase, and distribution of pharmaceuticals; a broker of purchases between payers on behalf of patients, drug manufacturers, and pharmacies.

Prior authorization: A type of utilization management that requires health plan approval for members taking certain drugs for a claim to be covered under the terms of the medical or pharmacy benefit. Prior authorization promotes the use of medications that are safe and effective and provide the greatest value.

Quantity limit: A type of utilization management that limits the amount of medication dispensed per fill to reduce waste and overuse.

Rebate: A manufacturer price concession that occurs after drugs are purchased and involves the manufacturer returning some of the purchase price to an organization providing pharmacy benefits that is set in contractional terms. May be based on volume, market share, outcomes, or other factors.

Step therapy: A type of utilization management that requires the use of a safe, lower-cost drug first before a second drug that is usually more expensive is approved under the terms of the medical or pharmacy benefit; may be administered through a prior authorization.

Utilization management: Any number of measures used to ensure appropriate medication use, such as quantity limits, prior authorization, or step therapy.