Drug Formularies: Purpose, Intent, and Challenges

What is a prescription drug formulary?

A plan's formulary (or drug list) is a list of prescription drugs approved for coverage by plan sponsors such as public and private employers, unions, government programs (e.g., Medicare and Medicaid), and retiree plans. In coordination with independent clinical experts on a pharmacy and therapeutics (P&T) committee, pharmacy benefit managers (PBMs) typically develop a recommended formulary for plan sponsors, who may customize it. P&T committee experts analyze all available data for a drug and other treatment options for the same condition or disease and develop a scientifically informed recommendation about which drugs should be included on the formulary and which could be included at the plan sponsor's discretion. Plan sponsors may accept the recommended formulary or change it.

When there are multiple drug options that are equally effective at treating a medical condition, PBMs can recommend formulary placement to encourage manufacturers to compete on price. PBMs cultivate competition among manufacturers by offering more favorable formulary placement to those that offer drug products at the lowest net cost—the cost of the drug after all discounts have been applied. Drug companies offer discounts in the form of rebates, which PBMs collect and pass through to plan sponsors at rates above 90%. Plans typically reduce cost-sharing for the less-expensive drug to encourage its use over costlier drugs that provide no additional clinical benefit.

After PBMs make recommendations, plan sponsors always make the final decision about how their formularies will be structured. PBMs do not have decision-making authority over which drugs will be on a health plan's formulary, or even where they will be placed. Plan sponsors may choose to carve drugs in or out of the formulary; may shift drugs from one tier to another; may prefer lower-cost, more heavily rebated drugs over lower list price drugs; or may even choose an open formulary rather than one that is managed to encourage patients to use lower-cost drugs when and where available. Employers and other plan sponsors need this flexibility to design their benefits because they are all different and have varied resources and patient populations.

Formularies may be updated periodically to incorporate new drugs or the latest medical evidence.

Throughout this document you will see drug pricing terms. Click or scan the QR code to access PCMA's Glossary of Drug Pricing Terms.

Why do formularies exist?

PBMs encourage use of the safest, most effective and affordable drugs for patients when designing formularies to recommend to plan sponsors. **Prescription drug formularies give patients financial incentives to use the most efficacious and cost-effective drugs.** Formularies also serve to elicit discounts from drug companies. Due in large part to these efforts by PBMs, 90% of prescriptions are filled with generics and biosimilars.[1] PBMs often support uptake of biosimilars by placing these drugs on preferable tiers and also supporting policy proposals that bolster proliferation.

Sometimes, a brand name drug with a higher list price can maintain market share by offering deep discounts that place its overall cost below that of a lower list price drug with no rebates. This is a strategy brand name drug manufacturers typically use to undercut the first generic manufacturers they are forced to compete against. And while the shift in market share may be delayed, the reduction in plan liability demonstrates that the introduction of competition among manufacturers effectively lowers costs even in these circumstances.

What are some challenges to formulary effectiveness?

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Formularies are an effective, proven tool for managing drug costs; however, drug companies have found ways to protect their profits and promote higher-cost products. Two key tactics they use are manufacturing of authorized generics and offering prescription drug coupons.

Authorized generics are approved brand name drugs marketed without the brand name on their label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company or by another company with the brand company's permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower price than the brand name drug. By doing so, the brand manufacturer avoids paying agreed-upon rebates to public and private payers, as these agreements do not apply to the authorized generic version of the drug.

PBMs work to protect their clients from drastic cost increases by negotiating for additional rebates when manufacturers increase prices at a pace faster than inflation.

Authorized generics allow manufacturers to bypass their obligations to provide inflationary rebates, thereby safeguarding their profits from the requirements of the Inflation Reduction Act. Marketing a product as an authorized generic also impacts the cap on the total amount of rebates that Medicaid can collect from manufacturers because of the American Rescue Plan Act (ARPA). **This dynamic can result in a lower list price but a higher net price.**

Authorized generics tend to be different from regular generic drugs. Most people understand a true generic to be a copy of a brand name drug that is developed and made by a company other than the company that makes the brand name drug. This kind of traditional generic drug manufacturing arrangement lowers costs by fostering competition. A generic drug is the same as the brand name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain

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permissible differences) labeling. However, a generic drug may have certain minor differences from the brand name product, such as different inactive ingredients.[2] **Authorized generics do not capture the spirit or intent of the generic drug industry. They are instead a marketing tool designed to prop up pricing and extend a drug company's ability to maintain market share and deter true generic entry.**[3] For example, one manufacturer delayed independent generic competition by releasing four authorized generics, leading to an estimated $137 million to $449 million in excess Medicare spending from 2011 to 2020.[4]

Prescription drug coupons are marketing tools used by drug manufacturers to reduce patient cost sharing at the pharmacy for certain brand name medications. In fact, research has found that net prices are about 8% higher due to the availability of coupons.[5] Considered the least targeted form of copay assistance programs, this approach involves a drug manufacturer covering a portion of the cost-sharing obligations (i.e., copayments, coinsurance or deductibles) of commercially insured patients during a given calendar year until the patient's out-of-pocket maximum is met.[6] **These programs are prohibited when using federal health insurance, including Medicare Part D and Medicaid, because they may violate federal anti-kickback statutes.** Coupons are often processed at the point of sale at the same time as a patient's insurance claim. Removing the patient cost considerations encourages the use of more expensive drug products instead of lower-cost generics or therapeutically equivalent alternatives, raising costs for plan sponsors.[7] These offerings may come in the form of a paper coupon, a debit card, or some other arrangement that does not clearly indicate the source of payment.

Drug coupons bypass plan benefit strategies meant to encourage patients to use lower-cost products. Because they can completely subsidize a patient's cost-sharing obligations for the entire year for other drugs and services, they negate the purpose of cost-sharing in the first place—to encourage the use of the most efficacious and cost-effective drug available, thus controlling net costs and keeping plan premiums stable. The use of drug coupons can also create challenges for patients, as coupons usually expire after a year. After the coupon limit has been reached, the patient will need to either seek a different treatment or continue to purchase the drug without the savings the coupon provided.

To try to counter the negative effects of drug coupons, plan sponsors and PBMs have implemented programs to apply the coupon to the total cost of the drug through copay accumulators and maximizers. Copay accumulators are designed to allow a patient to use the value of a drug manufacturer's coupon offerings without it counting toward the patient's deductible and annual out-of-pocket maximum, thereby allowing the patient to be insulated from the cost of the drug itself, but not for their entire deductible for all health care, including that beyond the prescription drug in question. While the coupon is applied to minimize the increasing impacts of these programs on the plan costs, the patient continues to be responsible for their out-of-pocket costs under the plan. Once the coupon is exhausted, any additional payments made by the member for the drug are applied toward the deductible and other cost-sharing obligations. Copay maximizers, alternatively, are designed to lower members' initial out-of-pocket costs for higher-cost specialty medications by maximizing the application of available manufacturer copay assistance. Under this model, the total value of the coupon is applied evenly throughout the benefit year. Copay maximizers

tend to be preferred over accumulators by plan sponsors. The key difference between them is that copay maximizers typically also revise the member's cost-sharing obligations for such drugs so that the manufacturer coupon is applied evenly throughout the benefit year, meaning a member's out-of-pocket costs for that specific drug are typically $0 or a nominal amount. As such, copay maximizers primarily shift the plan's responsibility to pay for certain specialty drugs back to manufacturers, without negatively impacting the member.

A 2024 court case focused on the use of accumulators in individual and small group (fully insured) health plans in their present form and resulted in reinstation of a prior rule that allows private health plans to exclude the value of manufacturer cost-sharing support from patients' annual cost-sharing limits only if a generic equivalent is available and medically appropriate.[8] Recent CMS rulemaking has also brought a discussion of maximizers to the table.

PCMA believes policymakers should continue to allow plan sponsors the ability to curb manufacturers' efforts to prop up their profits at the expense of plan sponsors and patients through these tactics.

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7 Dafny et al. 2023. *How Do Copayment Coupons Affect Branded Drug Prices and Quantities Purchased?* https://www.nber.org/system/files/working_papers/w29735/w29735.pdf.

8 Sidley. 2024. https://www.sidley.com/en/insights/newsupdates/2024/01/courts-clarification-has-implications-for-us-pharmaceutical-manufacturer-copay.