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Analysis of Drug Formulary Exclusions from the Patient's Perspective

Robert Popovian*[1], Anne M. Sydor[2] and Peter Pitts[3]

1 Chief Science Policy Officer, Global Healthy Living Foundation Senior Health Policy Fellow, Progressive Policy Institute and Visting Health Policy Fellow, Pioneer Institute, United States

2 Research Consultant, Global Healthy Living Foundation, United States

3 Cofounder, Center for Medicine in the Public Interest, United States

***Corresponding author:**
Robert Popovian

rpopovian@ghlf.org

Chief Science Policy Officer, Global Healthy Living Foundation Senior Health Policy Fellow, Progressive Policy Institute and Visting Health Policy Fellow, Pioneer Institute, United States

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Abstract

Objective: Pharmacy benefit management companies (PBMs) often determine medication reimbursement with formularies, which were initially intended to ensure use of the least-costly still effective medication. Today, formularies are designed to maximise concessions (ie, rebates and fees) from PBMs through the biopharmaceutical industry. Exclusions may no longer benefit patients by controlling costs, but rather serve to enhance the ability to drive the amount gained through rebate contracting. In this brief report, we evaluate excluded drugs on the only national formulary that is publicly available in the US from the perspective of whether or not the exlusion benefits patients.

Methods: We analysed exclusions of the 2022 national formulary of the second-largest PBM in the US that is publicly available. We categorised substitutions as equivalent (same active agent used) vs. therapeutic (different active agent). We evaluated each exclusion by potential clinical or economic outcomes from a patient perspective.

Results: Close to half (46%) of the 563 exclusions had questionable clinical or financial benefits to patients, requiring prescribers to choose treatments that may have adverse financial or medical outcomes for their patients.

Conclusions: Because patient co-pays and deductibles are based on retail prices, some formulary exclusions force patients to pay substantially more for a preferred drug than an excluded drug or use a medication with questionable medical benefit for their condition. Further research is needed to understand how many patients are affected by such exclusions.

Keywords: Formulary; Pharmacy Benefits Management; Benefits; Formulary Exclusions; Insurance Policy; Prescription Drug Policy; Equivalent Substitution; Nonequivalent substitution

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Introduction

Prescription biopharmaceutical benefits allow consumers covered by an insurance company on behalf of a plan sponsor to access needed prescription medications. A plan sponsor refers to an employer, the federal or state government, individual consumers, and others who purchase health insurance. The plan sponsors are the actual payers in the healthcare marketplace in the United States.

Biopharmaceutical benefits are typically managed through pharmacy benefit management (PBM) companies on behalf of their clients, the plan sponsors. Due to consolidation, three of the largest PBMs, CVS Health (Caremark), Cigna (Express Scripts and Ascent Health Services), and United Health (OptumRx) process more than 75% of retail prescriptions [1]. The three largest PBMs also control 62% of specialty medicines dispensed in the United States [2]. Over the last several years, the three PBMs have either acquired or have been acquired by insurance companies [3].

The PBMs develop formularies, a list of medicines that will be paid for by the plan sponsor. The initial intent of formularies was to incentivize the use of the least costly medication that was also safe and effective for a particular medical condition [4]. The PBMs eventually introduced tiered formularies with a promise that patients would have unabated access to medicines if they were willing to pay more out-of-pocket costs for drugs placed in higher tiers [5]. Drugs with superior efficacy and safety and low prices would be preferred, with patients getting the best deals using their insurance benefits [6]. Formularies are also evaluated

and updated annually and during the plan year, and changes are made based on contractual agreements.

Today, formularies are, at least in part, built to maximize higher rebates and fees paid by the biopharmaceutical companies to PBMs in exchange for the coverage of certain medicines [6-8]. As such, PBMs are incentivized to cover higher-priced drugs because the amount of rebates and fees are based upon medicine's retail price. PBMs pass on some unverified percentage of rebates and fees back to the plan sponsors, and keep the balance as profit [8, 9].

It is generally understood that rather than placing drugs on higher cost-sharing tiers, PBMs have begun excluding medicines from formularies to gain further leverage in contract negotiations with biopharmaceutical manufacturers. Excluding a drug means that the insurer will not cover any portion of the cost and the patient must cover the full cost, which presents an insurmountable financial barrier for many patients. The practice of excluding medicines may at times transpire when a patient is stable on a medication, which can force a patient to switch from successful treatment to one that may be less effective. This tactical shift is the latest salvo in PBMs' efforts to gain more rebates and fees from the biopharmaceutical industry [10].

The three largest PBMs announce their formularies and what medications are excluded annually. Multiple analyses have quantified the number of exclusions and the types of medicines excluded. Such research has demonstrated the exponential growth in the number of exclusions from less than 50 to well over 500 in the last decade [11, 12]. To our knowledge, however, there is no research evaluating whether the exclusions are clinically sound or financially beneficial from a patient's perspective.

Purpose of the Study

The purpose of our study is to evaluate the impact on patients' clinical and financial outcomes based on formulary exclusions of the Express Scripts (ESI) 2022 National Preferred formulary. We chose ESI because it is the second-largest PBM in the United States, and ESI provides a publicly available national preferred formulary exclusion list annually [13].

Methodology

We first categorized each exclusion as an equivalent substitution, a therapeutic substitution, or excluded without an alternative substitution.

Equivalent substitutions were defined as

• Brand, generic or biosimilar medicine is excluded in favor of a preferred generic or biosimilar medication containing the same active ingredient,

• Brand medicine is excluded in favor of another brand medicine that has the same active ingredient,

• Generic or biosimilar medicine is excluded in favor of a brand name medicine containing the same active ingredient, and

• Brand, biosimilar, or generic medicine is excluded in favor of a different formulation with the same active ingredient.

A therapeutic substitution was defined as

• Brand, biosimilar, or generic medicine is excluded in favor of another brand or generic drug that does not contain the same active ingredient.

No alternative substitution was defined as

• Brand, biosimilar, or generic medicine is excluded without any alternative recommended by the formulary.

We then categorized each exclusion based on the potential clinical or economic outcome from a patient perspective.

A clinical outcome was defined as

• The formulary includes the medicine with the same active ingredient and formulation in the form of a brand name, generic, or biosimilar medicine as an excluded drug.

An economic outcome was defined as

• An alternative to an excluded drug is an equivalent substitution with a generic or biosimilar that has a similar active ingredient and formulation and thus is presumed cheaper than the excluded brand medication.

Based on the above definitions, we could only categorize exclusions as having clear or questionable economic benefits. Exclusions could not be classified as having negative economic consequences since insurance companies, PBMs, and biopharmaceutical companies do not openly share the net prices paid for individual medications.

A medical benefit to the patient for a biopharmaceutical other than what was prescribed cannot be recognized without knowing why the particular excluded drug was prescribed. Thus, any substitution other than a generic or biosimilar biopharmaceutical substitution with a similar active ingredient and formulation was categorized as having questionable medical benefit.

Results

There are 563 excluded medications in the Express Scripts 2022 National Preferred Formulary Table 1. Approximately two-thirds (68.6%) are equivalent substitutions. The rest are therapeutic substitutions (29.8%), or no preferred alternative was recommended (1.6%). Of the 386 equivalent substitutions, 293 (76.1%) brand medicines were excluded in favor of a generic or biosimilar medicine, or biosimilar favored for another biosimilar (**Tables 1 and 2**).

Another 30 (7.8%) brand medicines were excluded in favor of another brand medicine with the same active generic or biosimilar ingredient. There were 5 (1.3%) generic or biosimilar medicines excluded in favor of a brand-name medicine. Finally, 58 (15.1%) brand, biosimilar, or generic drugs were excluded in favor of a different formulation with the same active ingredient.

Table 3 shows the equivalent substitutions categorized by whether the excluded medicine and preferred alternative are brand or generic. This level of detail was necessary to further classify exclusions as being of clear vs. questionable economic benefit. Without net prices paid for individual medications, we do

Table 1: Type of Substitution Required by Preferred Alternative.

Substitution	Number (%)
Equivalent substitution	386 (68.6%)
Therapeutic substitution	168 (29.8%)
No substitution	9 (1.6%)

Table 2: Type of Equivalent Substitutions (n=386).

	Number (%)
Brand, generic, or biosimilar medicine is excluded in favor of a preferred generic or biosimilar medication containing the same active ingredient	293 (76.1%)
Brand medicine is excluded in favor of another brand medicine that has the same active generic ingredient	30 (7.8%)
Generic or biosimilar medicine is excluded in favor of a brand name medicine with the same active ingredient	5 (1.3%)
Brand, biosimilar, or generic medicine is excluded in favor of a different formulation with the same active ingredient	58 (15.1%)

Table 3: Equivalent Substitutions (n=386) Categorized by Class Excluded and Substituted.

Excluded	Preferred alternative	Number (%)
Brand-name	Generic or biosimilar	273 (70.9%)
	Brand-name	30 (7.8%)
Generic or biosimilar	Generic or biosimilar	20 (5.2%)
	Brand-name	5 (1.3%)
Formulation substitutions		58 (15.1%)

not know if the generic-to-generic or brand-to-brand substitution is more or less cost-effective.

Table 4 describes the therapeutic substitutions, all of which are of questionable medical benefit. In 5 cases, the more expensive brand-name drug is preferred over a generic drug that is neither therapeutically equivalent nor cost-effective. As shown in Tables 3 and 4, there are 5 equivalent substitutions and 5 therapeutic substitions (10 total) in which a brand-name medicine is favored instead of generics or authorized generics. Table 5 describes total exclusions requiring an alternative with a different active ingredient or formulation or no substitute.

Considering all the excluded medications by economic and medical benefits to the patient (Table 6), approximately half (48.49%) were of questionable economic or medical benefit (**Tables 3-6**).

Limitations

The study conducted was representative of a single plan year of formulary exclusions. Because other formularies are not publically available, it is not possible to determine if this is truly representative of formulary exclusion practices. It is important to note, however, that in 2022 the ESI National Formerly had the most number of exclusions to date.

The analysis is based on a national exclusionary formulary. Plan sponsors may adopt the formulary in its entirety or make adjustments based on their individual needs.

As discussed, beneficial vs. questionable economic outcomes could only be assumed because the actual price paid by an insurer or PBM to a biopharmaceutical company for any medication is not publicly disclosed.

Table 4: Therapeutic Substitutions (n=168) Categorized by Class Excluded and Substituted.

Excluded	Substitute	Number (%)
Brand-name	Generic	84 (50%)
Brand-name	Brand-name	67 (39.9%)
Generic	Generic	12 (7.1%)
Generic	Brand-name	5 (3.0%)

Table 5: Total Exclusions Requiring a Medicine with a Different Active Ingredient, Formulation, or No Alternative (n=235).

	Number (%)	% of all 563 exclusions
Therapeutic substitutions	168 (71.5%)	29.8%
Formulations substitutions	58 (24.7%)	10.3%
No substitution	9 (3.8%)	1.6%
Total	235 (100%)	41.7%

Table 6: Economic and Medical Benefits of Exclusion (n=563) to Patient.

Benefit?	Total (%)
Economic benefit	293 (52%)
Questionable economic benefit	35 (6.2%)
Questionable medical benefit	9 (1.6%)
Questionable economic and medical benefit	226 (40.1%)

Discussion

Overall, 42% of ESI's 2022 formulary exclusions mandate a non-therapeutically equivalent medicine based on differences in active ingredient or formulation or no therapeutic alternative. More concerning is that almost 50% of the ESI 2022 formulary exclusions have questionable benefits for the patient, potentially forcing the patient and provider to experiment with therapeutic choices that may negatively impact the patient clinically and financially. Such exclusions may also take place annually or throughout the plan year, impacting patient access to medicines.

In some cases, the exclusions violate the core principle of a "formulary," where lower-priced generics, authorized generics, or biosimilar should be preferred over equivalent brand name medicines. In 10 cases, the exclusions favor brand medicines that are significantly more expensive than the excluded generics or authorized generics. For example, insulin lispro, an authorized generic of the brand name, is excluded, and Humalog (insulin lispro) is preferred, though Eli Lilly and Company manufactures both. Such practices affirm that formularies can be used as a rebate maximization tool for PBMs since they prefer higher-priced and more highly rebated drugs instead of lower-cost generic, authorized generic, or biosimilar alternatives. Due to lack of transparency, it is a mystery how much of the rebates, fees, and other concessions gained from the biopharmaceutical industry by PBMs are passed back to the patient, government, or employer, who are the ultimate payers of the pharmaceutical benefits in the United States healthcare marketplace. Even worse, the current contracting scheme forces patients to pay their co-insurance or deductibles based on retail prices of the

covered medicine, which can be significantly greater than the excluded ones.

Within the equivalent substitution category, it is essential to note that 58 (15.1%) of equivalent substitutions may be deemed therapeutic substitution because the excluded formulation is not the same as the alternatives covered by the PBM.

Finally, in some cases, the ESI formulary excludes medicines without providing any alternatives to patients and healthcare professionals, potentially forcing patients to forgo medically necessary treatments. For example, excluded medications with no preferred option are brand-name medications, such as Viltepso (viltolarsen) for the treatment of Duchenne muscular dystrophy caused by a specific gene variation. In all 9 cases, the exclusions are the only disease-modifying treatments available for the condition treated by the excluded medication.

Conclusions

Formulary exclusions have become the norm in managing drug benefits by PBMs. They have been growing in number year over year. Although some formulary exclusions may be clinically and economically justified, a significant number require healthcare professionals to make medical decisions that may not be in the patient's best interest or aligned to current standards of care. Uniformly, such practices continue to blur the line between insurance coverage and medical practice and highlight the need to reform the drug rebating system.

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