



**Response to FTC Solicitation for Public Comments on the Business Practices of Pharmacy  
Benefit Managers and Their Impact on Independent Pharmacies and Consumers**  
*Submitted May 12, 2022*

[CancerCare](#) appreciates the opportunity to offer our insights on the impact to patients of PBM practices, consolidation, and integration with insurance companies, specialty pharmacies, and providers.

CancerCare is a 78-year-old national organization that provides free professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. In 2021, our staff answered more than 49,000 calls to our helpline and provided 186,000 services to people affected by cancer. Our comments are informed by the stories we hear from our clients as they navigate the confusing, expensive, and frustrating process of accessing and paying for vital -- and sometimes life-saving -- prescription drugs.

### **Formulary Design and Rebates**

The rebate system has distorted the market. One has only to look at a publicly available formulary from any of the “big three” PBMs to see that something other than cost and efficacy are driving formulary design. For many years, insurers and PBMs steered patients towards generic or biosimilar options through their formulary tiers. Now, large PBMs are altogether excluding some generics and biosimilars from their formularies, despite their efficacy and lower list prices, in favor of brand-name drugs that supply significant rebates.

For example, Express Scripts, a PBM that handles benefits for 100 million Americans, gave preference to nine brand-name drugs and excluded their generic equivalents in a 2019 formulary change. The excluded generics included an insulin that was half the price of the brand-name and an asthma medication priced at a 70% discount to the brand-name price.<sup>i,ii</sup>

Sometimes legacy drugs offer such large rebates that newer drugs in the same class have no chance to get placed in the same formulary tier. The new drug typically ends up placed at a higher tier rate -- if it's covered at all. C

PBMs claim that rebates are passed onto patients by lowering premium costs, or through a direct pass through of a percentage of the rebate, but because rebate negotiations are secretive, it's difficult to gauge if or how savings are passed on to patients or the employers who sponsor plans. Studies suggest the direct benefits to patients may be minimal since rebates reduce PBM's cost for drugs but aren't directly passed on to patients.<sup>iii</sup> While rebates lower the cost of the drug to the PBM, they do nothing to lower patients' out-of-pocket costs since co-insurance payments are based on a drug's list price -- not the PBM's post-rebate price. A 2021 study found that changes



in net drug prices—which reflect the savings to PBMs, post-rebate—were not correlated with a reduction in patient out-of-pocket spending.

### **Formulary Exclusions**

From 2014 to 2020, the number of medications excluded by at least one of the three major PBMs expanded by about 34% each year. This means that patients are increasingly likely to discover “gaps” in their drug benefits and face significant out-of-pocket costs if they need to access a medication that is not on the formulary.<sup>iv</sup> While restrictive formularies have become a common utilization management (UM) tool, multiple studies have linked their use to increased medical costs and higher total healthcare spending.<sup>v</sup> In contrast, studies of open formularies suggest better outcomes. For example, researchers modeled scenarios under different formulary structures for patients with HIV and found that all major outcomes, including survival rates and overall treatment costs, were significantly better in the open formulary scenarios.<sup>vi</sup>

In cancer care, oral drug treatments have rapidly joined chemotherapy and biologic infusions as safe and effective cancer treatments. These drugs are usually covered as a pharmacy benefit, while infusion therapies typically fall under medical benefits. Although the oral drugs offer numerous and sometimes unique benefits, they often cost patients much more to access, due to the cost-sharing requirements in restrictive formulary designs. Especially important during the COVID-19 pandemic, oral therapies have allowed many patients to stay at home and avoid the potential virus exposure from in-person chemotherapy infusions. Oral therapies can also minimize the need for transportation and time off from work, thereby supporting increased productivity. However, unless PBMs cover oral chemotherapy agents in a way that does not disadvantage patients financially, they will have limited access to these life-saving and convenient drugs.

### **Formulary Changes and Non-medical Switching**

PBMs are increasingly making mid-year changes to their formularies, which leaves the insured, who often can only choose their health plan during open enrollment, with unexpected costs or lack of access to treatments. This can happen when PBMs negotiate lucrative new deals with drug manufacturers. Depending on negotiations, a treatment might replace another, receive a better tier placement, or be eliminated entirely from a plan’s approved formulary.

Changes to formulary coverage can result in non-medical switching, which occurs when changes are made in a patient’s treatment plan that are NOT prescribed by their doctor for medical reasons.

A 2021 promotion from Cigna illustrates this well: the insurer removed a widely used psoriasis drug from most of its formularies and offered patients a \$500 debit card for agreeing to switch to a different medication.

It often takes doctors and patients months, or even years, to find the most effective medications to manage a patient’s cancer or other serious illness. When an employee loses access to a medication that has stabilized their condition, they may experience re-emerging symptoms,

negative side effects or even a relapse of their illness. For patients using biologic and biosimilar cancer therapies that are precisely tailored to the genetics of their cancer, a switch in treatments can be especially precarious. This can also happen with certain “quality of life” medications that don’t treat cancer, but rather treat medication side effects (like nausea) or long-term post-surgical effects.

While formulary changes and non-medical switches are intended to reduce costs for a health plan, costs may instead increase from extra administrative work, more doctor appointments, additional laboratory work and more hospitalizations due to adverse effects and treatment failures.<sup>vii,viii</sup> Formulary changes can also create higher out-of-pocket costs for patients, decreased work productivity and increased stress and anxiety. While some patients can make a more affordable switch, others may not have access to acceptable alternative medications and may abandon treatment altogether.

PBMs utilize additional UM tactics to restrict access to certain drugs while pushing patients toward others. Whether this is always due to rebates is impossible to quantify due to the secrecy of the system, but regardless of the rationale, the impact of UM on patients can be devastating.

### **Pre-Authorization**

Increasingly, PBMs use pre-authorization (PA) as a cost-saving measure. What started as a requirement for new, high-cost specialty medications has grown to include even established brand-name drugs and generics with no low-cost alternatives.<sup>ix</sup> For example, more than quarter of drugs covered by Medicare Part D plans required PA in 2021<sup>x</sup>; in 2007, it was just 8%.

Physicians typically can’t tell if a medication requires PA when they prescribe it: that info isn’t readily accessible, varies by health plan and changes often. Instead, physicians submit requests retrospectively, after the pharmacy flags a coverage issue.<sup>xi</sup> But that added step deters many patients from complying with their treatment plan: 37% of prescriptions flagged for PA are abandoned by patients at the pharmacy and never filled.<sup>xii</sup>

And, while almost all PBMs and health plans claim to use peer-reviewed evidence-based studies when designing their PA programs, 30% of physicians report that PA criteria are rarely or never evidence-based, and 43% report that the criteria are only sometimes supported by evidence.<sup>xiii</sup>

Treatment abandonment is one reason why PA is linked to worse health outcomes, increased hospitalizations, and higher overall medical costs when it’s applied to drugs that treat diabetes, depression, and other mental health conditions. These same serious and chronic illnesses—as well as cancer and multiple sclerosis—are now subject to PA requirements that cover entire disease states and classes of drugs under some health plans.

## Step Therapy

Step Therapy is another technique PBMs use to steer patients toward their preferred drugs. Sometimes referred to as a “fail-first” protocol, step therapy requires patients to use treatments on lower formulary tiers (usually generics or preferred drugs that provide cost-savings to the insurer or larger rebates to the PBM) before being approved for drugs in higher tiers or, in some cases, drugs not included in the formulary. Patients and their physicians must demonstrate that the required treatment has “failed” before the insurer will authorize coverage for the treatment originally prescribed.

The step therapy approach is intended to lower costs for the insurer and the patient, however “lower costs” may only apply to the PBM and insurer; for patients, step therapy can mean added out-of-pocket expenses, as well as significant burdens on their time and well-being. While encouraging the use of generic or lower-cost alternatives may sound positive, step therapy is a flawed system that can put patients at risk. Some insurers even require patients to “re-try” drugs that already failed or worsened their condition in the past. Delayed, disrupted, and denied treatment due to step therapy causes serious harm in the time-sensitive fight against cancer and other aggressive diseases. It can also cause serious side effects and major setbacks in managing chronic illnesses.

Cancer drugs are often targets of step therapy, yet many oncology drugs do not have substitutes that are equally effective and less costly. When cancer patients don’t get the right drug at the right time, the length and severity of illness can increase.<sup>xiv</sup> One study found that breast cancer patients who endured a three-month or more delay in treatment had a 12 percent lower five-year survival rate. The uncertain process of waiting for lesser drugs to fail can take weeks or months. Additionally, step therapy has been shown to reduce the long-term effectiveness of treatment.<sup>xv</sup>

## Specialty Pharmacies

In 2020, the three largest PBMs—CVS Caremark, Express Scripts and OptumRx, all owned by health insurers—processed 85% of all prescription claims and handled drug benefits for more than 266 million Americans.<sup>xvi</sup> Insurers can require patients to fill prescriptions at a pharmacy they run, while also setting patient copay rates and out-of-pocket caps. We believe this poses a conflict of interest that acts as a disincentive for insurers and PBMs to keep costs low for patients.<sup>xvii</sup>

When PBMs require that patients use specific specialty pharmacies, it limits their choices as consumers. Further, while some specialty pharmacies offer expert personalized service, a growing number of insurer-designated pharmacies operate entirely through mail-order. Patients report difficulties refilling prescriptions, suffer long waits to reach customer service representatives and experience life-threatening shipment delays and dosage errors for critical drugs. Furthermore, the consumer advocacy group Consumer Watchdog has sued several insurance providers on behalf of patients taking HIV medications, alleging that restrictive specialty pharmacy requirements were discriminatory.

When drug manufacturers limit which pharmacies carry their specialty products, patients and their clinicians may need to coordinate with multiple pharmacies to fill their prescriptions.<sup>xviii</sup> Worse, they may discover that the drug best suited to a patient's treatment is not carried by the pharmacies in their PBM's network.<sup>xix</sup>

## **Conclusion**

We have described just some of the ways that PBM policies and practices impact cancer patients and others with serious illnesses. We appreciate the opportunity to comment on this important review and urge the FTC to take whatever steps it can to limit the damage that the greed of the PBM industry inflicts each year on the American public.

- 
- <sup>i</sup> Boudreaux, Todd. “Express Scripts Won't Cover Lilly's Generic Insulin.” *Beyond Type 1*, 4 August 2021, [beyondtype1.org/express-scripts-wont-cover-generic-insulin/](https://beyondtype1.org/express-scripts-wont-cover-generic-insulin/).
- <sup>ii</sup> Herman, Bob. “Generic drugs aren't always favored.” *Axios*, 4 April 2019, [www.axios.com/generic-brand-drug-prices-express-scripts-coverage-dc62b393-a086-4179-a48b-beb27e3a847b.html](https://www.axios.com/generic-brand-drug-prices-express-scripts-coverage-dc62b393-a086-4179-a48b-beb27e3a847b.html).
- <sup>iii</sup> Rome, Benjamin N., et al. “Correlation Between Changes in Brand-Name Drug Prices and Patient Out-of-Pocket Costs.” *JAMA Network Open*, vol. 4, no. 5, 2021. *JAMA Network*, [doi.org/10.1001/jamanetworkopen.2021.8816](https://doi.org/10.1001/jamanetworkopen.2021.8816).
- <sup>iv</sup> Koziara, Katie. “Study Finds Middlemen Excluded Nearly 850 Medicines from Formularies This Year.” *PhRMA*, 17 Sept 2020, [catalyst.phrma.org/study-finds-middlemen-excluded-nearly-850-medicines-from-formularies-this-year](https://catalyst.phrma.org/study-finds-middlemen-excluded-nearly-850-medicines-from-formularies-this-year).
- <sup>v</sup> Park, Yujin, et al. “The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review.” *Journal of Managed Care + Specialty Pharmacy*, vol. 23, no. 8, 2017, pp. 893-901. *JMCP*, [doi.org/10.18553/jmcp.2017.23.8.893](https://doi.org/10.18553/jmcp.2017.23.8.893).
- <sup>vi</sup> Baumgardner, James, et al. “Modeling the Impacts of Restrictive Formularies on Patients With HIV.” *The American Journal of Managed Care*, vol. 24, no. 8, 2018, pp. SP322-328. *AJMC*, [ajmc.s3.amazonaws.com/media/pdf/AJMC\\_07\\_2018\\_PharmacyBenefits\\_SpecialIssue\\_Baumgardner%20final.pdf](https://ajmc.s3.amazonaws.com/media/pdf/AJMC_07_2018_PharmacyBenefits_SpecialIssue_Baumgardner%20final.pdf).
- <sup>vii</sup> Alliance for Patient Access. “Understanding Non-Medical Switching.” *YouTube*, uploaded by Alliance for Patient Access, 9 February 2016, [youtu.be/2I67kYOh\\_sk](https://youtu.be/2I67kYOh_sk).
- <sup>viii</sup> Dolinar, Richard, et al. “The non-medical switching of prescription medications.” *Postgraduate Medicine*, vol. 131, no. 5, 29 May 2019, PubMed.gov, National Center for Biotechnology Information, [doi.org/10.1080/00325481.2019.1618195](https://doi.org/10.1080/00325481.2019.1618195).
- <sup>ix</sup> Resneck Jr., Jack S. “Refocusing Medication Prior Authorization on Its Intended Purpose.” *JAMA*, vol. 323, no. 8, 2020, pp. 703-704.
- <sup>x</sup> Medicare Payment Advisory Commission. “Health Care Spending and the Medicare Program: A Data Book.” *Medicare Payment Advisory Commission*, July 2021, [www.medpac.gov/wp-content/uploads/2021/10/July2021\\_MedPAC\\_DataBook\\_Sec10\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec10_SEC.pdf).
- <sup>xi</sup> CoverMyMeds. “2020 Electronic Prior Authorization Report Executive Summary.” *CoverMyMeds*, 2020, [assets.ctfassets.net/2in405srp47m/4uzia8m4YQy3mBplpyBuqF/9af9cefa63bba76566aa3e8595751e45/CMM\\_36664\\_ePAExecutiveSummary\\_Digital.pdf](https://assets.ctfassets.net/2in405srp47m/4uzia8m4YQy3mBplpyBuqF/9af9cefa63bba76566aa3e8595751e45/CMM_36664_ePAExecutiveSummary_Digital.pdf).
- <sup>xii</sup> CoverMyMeds. “2019 ePA National Adoption Scorecard.” *CoverMyMeds*, 2019, [marketingbuilder.covermymeds.com/insights/scorecard/](https://marketingbuilder.covermymeds.com/insights/scorecard/).
- <sup>xiii</sup> 2021 AMA prior authorization (PA) physician survey, <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>
- <sup>xiv</sup> McCleery, John. “The Politics of Step Therapy.” *OBR Oncology*, May 2019, [obroncology.com/article/the-politics-of-step-therapy/](https://obroncology.com/article/the-politics-of-step-therapy/).
- <sup>xv</sup> Chung, Adrienne, et al. “Does A ‘One-Size-Fits-All’ Formulary Policy Make Sense?” *Health Affairs*, 2 June 2016, [www.healthaffairs.org/doi/10.1377/hblog20160602.055116/full](https://www.healthaffairs.org/doi/10.1377/hblog20160602.055116/full). Accessed 18 March 2021.
- <sup>xvi</sup> Royce, Trevor J., et al. “Impact of Pharmacy Benefit Managers on Oncology Practices and Patients.” *JCO Oncology Practice*, vol. 16, no. 5, 2020, pp. 276-284. *ASCO Publications*, [doi.org/10.1200/JOP.19.00606](https://doi.org/10.1200/JOP.19.00606).
- <sup>xvii</sup> Sukel, Kayt. “How Mergers Change Specialty Pharmacy.” *Managed Healthcare Executive*, 3 May 2019, [www.managedhealthcareexecutive.com/view/how-mergers-change-specialty-pharmacy](https://www.managedhealthcareexecutive.com/view/how-mergers-change-specialty-pharmacy).
- <sup>xviii</sup> Arquette, Sheila M. “The Evolving Role of Specialty Pharmacy.” *HomeCare*, 10 September 2019, [www.homecaremag.com/september-2019/evolving-role-specialty-pharmacy](https://www.homecaremag.com/september-2019/evolving-role-specialty-pharmacy).
- <sup>xix</sup> Thomas, Katie, and Andrew Pollack. “Specialty Pharmacies Proliferate, Along With Questions.” *The New York Times*, 15 July 2015, [www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html](https://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html).