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The Economic and Health Policy Impact of a Uniform National Formulary: Equity and Policy Considerations in the U.S. Using Cystic Fibrosis Treatment with Trikafta as a Cross-Comparator

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ABSTRACT

Background: Access to essential medications is critical for an equitable healthcare system, yet the absence of a Uniform National Formulary (UNF) in the U.S. has led to disparities in drug affordability and access. Unlike New Zealand's Pharmac and Australia's PBS, which centralize price negotiations and cost-effectiveness evaluations, the U.S. relies on a fragmented system controlled by private insurers, PBMs, and Medicare Part D, resulting in inconsistent drug coverage and financial barriers. Using Trikafta (Elexacaftor/Tezacaftor/Ivacaftor) for Cystic Fibrosis (CF) as a case study, we explored how adopting elements of Pharmac and PBS could improve affordability. While the Inflation Reduction Act (IRA) of 2022 introduced Medicare drug price negotiations, Trikafta remains excluded, underscoring the need for policy reform.

Methods: We conducted a comparative policy analysis to assess the economic and health policy implications of a Uniform National Formulary (UNF) in the U.S. It examines New Zealand's Pharmac and Australia's PBS as case studies, evaluates the fragmented U.S. formulary system, and compares Cystic Fibrosis (CF) treatment accessibility, focusing on Trikafta pricing and affordability. The analysis assesses cost-sharing structures, formulary decision-making, and regulatory frameworks across the three systems. Additionally, it explores the political and equity considerations of a U.S. national formulary, analyzing policy reports, government data, and peer-reviewed research to provide evidence-based recommendations for improving drug affordability and access.

Results: We examined the economic and policy implications of a Uniform National Formulary (UNF) by comparing Trikafta access for Cystic Fibrosis (CF) patients across New Zealand (Pharmac), Australia (PBS), and the U.S. (Medicare Part D). Pharmac fully subsidizes Trikafta ($0–$5 per prescription), PBS offers fixed co-pays ($31.60, $7.70 concession), while U.S. patients pay $67–$321 under Medicare Part D. Unlike Pharmac and PBS, Medicare Part D does not negotiate drug prices, leaving CF patients with higher costs and limited access. Trikafta is not included in the IRA 2022 drug negotiations, emphasizing the need for policy reform to improve affordability and equity.

Conclusions: Disparities in drug pricing, access, and government involvement across New Zealand, Australia, and the U.S. highlight challenges in implementing a Uniform National Formulary (UNF). Pharmac and PBS negotiate lower drug prices, ensuring affordability, while the U.S. market-driven system leads to higher costs and fragmented access. The Inflation Reduction Act (IRA) of 2022 introduced Medicare drug price negotiations, but Trikafta remains excluded, underscoring the need for reform. Expanding Medicare negotiations, integrating a structured formulary, and reducing access barriers could improve affordability. Lessons from Australia and New Zealand suggest that incremental Medicare reforms could pave the way for a national formulary.

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Introduction

Access to essential medications is a cornerstone of an effective and equitable healthcare system. However, in the United States, the absence of a uniform national formulary has lead to significant disparities in medication availability, affordability, and accessibility. Unlike other nations that employ standardized drug coverage policies, where individual insurers and pharmacy benefit managers (PBMs) (entities that manage prescription drug benefits on behalf of health insurers, negotiate drug prices, and determine coverage) dictate drug formularies [1]. This lack of uniformity results in inconsistent medication coverage, financial barriers, and inequitable health outcomes, particularly for vulnerable populations such as low-income, elderly patients and those managing chronic conditions.

Recent discussions surrounding health equity and healthcare reform have revived interest in potential implementation of a national formulary to standardize medication access and reduce disparities. Countries such as New Zealand and Australia have successfully implemented centralized formularies, demonstrating their capacity to enhance patient access and streamline healthcare policy [2]. While the benefits of such systems are well-documented internationally, the feasibility of adopting a similar model in

the U.S remain subjects of debate. Our comparisons lie within reviewing New Zealand's Pharmac model (the Pharmaceutical Management Agency, a government body responsible for deciding which medicines and medical devices are publicly funded using a fixed budget) and Australia's Pharmaceutical Benefits Scheme (PBS) (a federal program that subsidizes prescription medicines to make them affordable for residents through government-negotiated pricing and co-payment structures) and how adopting certain principles from these nations, and implementing them to the US could reinforce the concepts of an equitable and effective healthcare system.

New Zealand is the only country with a government agency like The Pharmaceutical Management Agency (Pharmac), which was established in 1993 and negotiates with pharmaceutical companies to obtain the best prices for medications for the general population [1]. Pharmac works via deciding what medicines to fund and managing a fixed budgetary allocation for those medications [3]. While Pharmac does not approve medications, they do use national budgetary allocation to invest in making sure the New Zealand residents can access medications [3]. Furthermore, before a new medicine can receive funding, an application must be submitted, typically by pharmaceutical companies, though doctors and patients may also apply. The evaluation process begins with a review by clinical experts, including doctors, specialists, and nurses, who assess the medicine's effectiveness, safety, and impact on patient care [3]. The Pharmacology and Therapeutics Advisory Committee (PTAC) oversees this process, with input from specialist advisory groups. They compare the proposed medicine to existing treatments to determine its added value [3]. PTAC may recommend rejecting a medicine if it lacks significant benefits or poses risks. If it is effective but similar to currently funded treatments, funding may be considered only if it is cost-neutral or saves money. If deemed beneficial, the medicine is assigned a low, medium, or high funding priority. This structured approach ensures funding decisions are guided by clinical expertise, scientific evidence, and healthcare priorities, promoting equitable access to effective treatments [3].

Australia, on the other hand, has the Pharmaceutical Benefits Scheme (PBS) which was established in 1948 and is governed by the National Health Act 1953 (Commonwealth) [4]. The PBS is reported to play a crucial role in ensuring Australians have affordable and consistent access to essential medications. As part of the Australian Government's National Medicines Policy, its primary goal is to provide medications and related healthcare services that support both optimal health outcomes and economic sustainability [4].

Through this program, the government helps cover the cost of a wide range of prescription medicines for various health conditions. These medications are primarily dispensed by pharmacists and are intended for home use, making treatment more accessible and reducing financial strain on patients. Under this policy, patients contribute a co-payment for each subsidized medication, with the Australian Government covering the remaining cost [4]. In some cases, individuals may pay more than the standard co-payment, such as when opting for a specific brand over a more affordable alternative. This system ensures that essential medicines remain accessible and affordable. Currently, concession card holders pay a co-payment of $6.80, while general patients without concessions pay up to $42.50 per prescription [5]. The Closing the Gap PBS Co-Payment Program further reduces costs for eligible Aboriginal and Torres Strait Islander individuals, allowing them to either pay the concessional rate or, in some cases, receive medicines at no cost. In 2020–21, patient contributions for PBS-subsidized medications amounted to $1.4 billion, demonstrating the scheme's role in making vital treatments more affordable while supporting the healthcare system [6].

When determining which medications are covered under the Pharmaceutical Benefits Scheme (PBS), government bodies follow a cost-effectiveness approach. Pharmaceutical manufacturers must provide cost-effectiveness data, typically derived from randomized controlled trials comparing the proposed drug to an established alternative. This evidence is then reviewed by the Pharmaceutical Benefits Advisory Committee (PBAC) to assess the drug's clinical and economic value. Once a medication is approved for listing, the government sets its official price based on recommendations from the Pharmaceutical Benefits Pricing Authority (PBPA). Several factors influence this pricing decision, including PBAC's assessment of clinical and cost-effectiveness, pricing of alternative brands, comparative prices within the same therapeutic class, cost estimates from manufacturers or PBPA calculations, expected prescription volumes, and economies of scale. Additional considerations include manufacturing requirements, storage conditions, expiration dates, and international pricing benchmarks. By applying this structured evaluation process, the PBS ensures that only cost-effective medications are subsidized, balancing affordability for patients with sustainability for the healthcare system [7].

The political context surrounding the establishment of national formularies in Australia and New Zealand played a crucial role in their successful implementation. Australia's Pharmaceutical Benefits Scheme (PBS) was introduced in 1948, coinciding with the establishment of the United Kingdom's National Health Service (NHS). This period marked a global shift toward government-led healthcare initiatives in post-war nations, emphasizing social welfare expansion. At the time, pharmaceutical companies had not yet amassed the significant lobbying power they hold today, which may have facilitated the government's ability to centralize medication procurement and pricing [4,8]. New Zealand's establishment of Pharmac in 1993, by contrast, occurred in a different political climate. The early 1990s saw widespread neoliberal economic reforms in New Zealand, with market-driven healthcare policies initially prevailing. However, rising concerns over pharmaceutical expenditures led policymakers to adopt a centralized, cost-containment model. The creation of Pharmac reflected a practical approach to balancing market efficiency with government oversight, ensuring drug affordability without fully nationalizing the pharmaceutical sector. Understanding these distinct political conditions helps contextualize why these nations could implement national formularies while the U.S. continues to struggle with fragmented drug pricing policies [9-11].

In recent years, the United States has been successful in passing legislation to help reduce prescription drugs costs as well as insurance premiums. The Affordable Care Act (ACA) was signed by President Obama on March 23,2010 aiming to make changes in healthcare regulations. Not only did this expand Medicaid eligibility to more Americans it also protected patients with preexisting conditions. Before insurances were able to assign premiums or even deny acceptance based on someone's medical history. As a result, a person with a chronic condition would experience barriers to accessing the care they need [11,12]. It is estimated that a breast cancer patient could pay up to an additional $27,330 for coverage per year [13]. At the time, this

was regarded as a significant policy achievement and a step forward in governmental medical insurance reform. Unfortunately, this bill did not include any universal formulary like the other two countries and with vastly different political ideologies shifting every couple of years, there is a threat to the progress made with the ACA.

Currently, the United States government is considering reductions to public health organizations such as the FDA to save money and eliminate fraud, waste and abuse. On March 27 th , 2025, 3,500 FDA workers were laid off. This major change in the company may have major effects on drug costs. The FDA is pivotal for getting new drugs to the market after years of clinical development [14]. Essential companies try to recoup costs with high initial copays for the first couple of years the drug is out. If this process gets delayed because of company restructuring, drug companies may be more inclined to increase initial prices thereby increasing copays. The FDA is also responsible for initiating black box warnings (severe adverse drug reaction disclaimers) and drug recalls. These changes may be headed in the direction of potentially hurting the consumer, hiking drug costs, and increasing emergency room visits, a far cry from 2010.

In contrast to centralized formulary systems like those in New Zealand (Pharmac) and Australia (PBS), the United States employs a privatized and decentralized drug formulary system. A formulary, or preferred drug list, is a continually updated collection of medications and related products, evaluated based on evidence-based medicine and the expertise of physicians, pharmacists, and other healthcare professionals [15]. The primary goal of this system is to promote the use of safe, effective, and cost-efficient medications. Unlike government-run systems, the U.S. formulary landscape is fragmented, with private insurers, pharmacy benefit managers (PBMs), and government programs (e.g., Medicare, Medicaid, VA) each maintaining separate formularies. These formularies are typically managed by Pharmacy & Therapeutics (P&T) Committees, which assess drugs based on clinical effectiveness, safety, and cost. These committees determine which drugs are covered, their placement within the formulary, and any access restrictions such as prior authorization, step therapy, or quantity limits [16].

Most U.S. formularies operate using a tiered cost-sharing system, where generic drugs (Tier 1) have the lowest co-payments, preferred brand-name drugs (Tier 2) require moderate co-pays, and non-preferred brand-name drugs (Tier 3) involve higher out-of-pocket costs. Specialty medications (Tier 4 or 5) are often the most expensive, creating financial barriers for patients [17]. Unlike Australia and New Zealand, where drug prices are government-regulated, the U.S. government does not directly control drug pricing, except for programs like Medicaid and the VA. Instead, PBMs and insurers negotiate rebates and discounts with pharmaceutical manufacturers, but these cost savings are often not directly passed on to patients, contributing to high medication expenses. However, drug pricing reforms are underway. The Medicare Drug Price Negotiation Program, introduced through the Inflation Reduction Act (IRA) of 2022, grants Medicare the ability to negotiate drug prices directly with manufacturers [18,19]. While this marks a significant policy shift, its implementation is gradual. According to KFF, by 2028, Medicare will negotiate prices for up to 15 drugs covered under Part D or Part B, with an additional 20 drugs eligible for negotiation in 2029 and subsequent years [20]. Over time, the number of drugs subject to negotiated pricing will gradually increase, potentially reducing costs for Medicare beneficiaries. However, the slow rollout means that substantial system-wide pricing relief will take years to materialize.

This results in inconsistent medication access and varying out-of-pocket costs for patients. This relies on a market-driven model, where competition, manufacturer pricing strategies, and insurer decisions dictate which drugs are covered and at what cost. This often results in higher drug prices and access disparities.

The intention of this paper lies within the lines of exploring the policy and equity considerations of implementing a uniform national formulary within the United States. By examining its potential impact on drug accessibility, regulatory oversight, and disparities in care, this research aims to contribute to the ongoing discourse on healthcare reform and medication equity in the U.S healthcare system.

For terms of highlighting the disproportionate differences within these medical systems, our analysis would focus on the cross comparison of Cystic Fibrosis, which is one of the leading causes of chronic lung infection and complications due to mucus clogs the airways, affecting thousands of people across all income levels within Pharmac, PBS and a specific focus on Medicare Part D within the US [21]. CF is a chronic condition requiring lifelong medication, where the average life span for people with CF who live to adulthood is about 44 years. In the treatment of CF, Trikafta is considered a first line treatments, but coverage across the three different nations may cause an excessive restriction to access to healthcare [21].

Trikafta (elexacaftor/tezacaftor/ivacaftor) is a revolutionary drug for treating cystic fibrosis. Vertex Pharmaceuticals created the drug to target the underlying genetic mutations responsible for cystic fibrosis, rather than merely managing symptoms [22]. The U.S. Food and Drug Administration (FDA) approved Trikafta with accelerated approval on October 21, 2019, following clinical trials indicating its profound efficacy in improving lung function and slowing down disease progression. The drug was then approved for treatment in expanded age groups, further broadening its potential reach [22,23]. Despite its revolutionary potential, the high cost of Trikafta has created access barriers, particularly in a fragmented formulary system where coverage is extremely variable. The competing approaches taken by Australia's PBS and New Zealand's Pharmac, who negotiated lower drug prices and subsidies from the government, highlight the economic barriers confronted by many American patients due to the lack of centralized drug price-setting mechanisms.

Materials and Methods
We conducted a comparative policy analysis approach to evaluate the economic and health policy implications of implementing a Uniform National Formulary (UNF) in the United States. We structured our analysis around four key components: (1) Examining formulary structures in New Zealand (Pharmac) and Australia (PBS) as case studies, (2) Assessing the fragmented U.S. formulary system, with a particular focus on Medicare Part D, (3) Conducting a cross-comparison of Cystic Fibrosis (CF) treatment, focusing on Trikafta access and affordability, and (4) Identifying policy and equity considerations for adopting a standardized national formulary in the U.S.

Comparative Analysis of International Formulary Models
To understand how centralized formulary systems function, we conducted a comparative review of the Pharmac model in New Zealand and the Pharmaceutical Benefits Scheme (PBS) in Australia. Data is gathered from government reports, policy documents, and peer-reviewed studies to assess formulary

decision-making, pricing negotiations, and patient cost-sharing structures. The study evaluates the criteria used for drug funding decisions, the role of cost-effectiveness evaluations, and the impact of national price negotiations on medication affordability and access. Additionally, this section highlights how Australia and New Zealand ensure price regulation through centralized government involvement, ensuring greater access to high-cost treatments such as Trikafta for Cystic Fibrosis patients.

Evaluation of the U.S. Formulary System
This section systematically reviews the U.S. formulary system, focusing on the decentralized nature of drug coverage and its impact on access to high-cost medications such as Trikafta. The analysis includes the role of private insurers, pharmacy benefit managers (PBMs), which act as intermediaries between insurers, drug manufacturers, and pharmacies, often negotiating rebates and determining formulary placement and government programs (Medicare Part D, Medicaid, and the VA) in determining drug pricing, coverage, and patient cost-sharing. Special attention is given to Medicare Part D, as it represents the largest prescription drug program for elderly and disabled individuals in the U.S. The study explores how Part D plans establish formularies, the implications of tiered cost-sharing models, and how the lack of direct price negotiations results in significant price disparities for specialty medications such as Trikafta. The Inflation Reduction Act (IRA) of 2022 is also analyzed for its potential impact on future Medicare drug price negotiations.

Cross-Comparison: Cystic Fibrosis and Trikafta Access
To illustrate the practical implications of formulary differences, we conducted a focused cross-comparison of Trikafta, a life-saving CF treatment, across the three formulary systems. CF is a lifelong condition that significantly impacts life expectancy and quality of life, requiring consistent medication access. We recognized Trikafta as a breakthrough therapy, but coverage disparities between Pharmac, PBS, and Medicare Part D impact patient affordability and health outcomes.
The analysis evaluates:

- Cost and accessibility of Trikafta in each system (U.S. PBM-driven pricing vs. government-subsidized access in PBS and Pharmac).
- Patient out-of-pocket expenses and affordability differences across income groups.
- Prescribing and coverage restrictions, such as prior authorization requirements, step therapy, and eligibility criteria.
- Impact of formulary decisions on Cystic Fibrosis treatment adherence and long-term health outcomes.

Policy and Equity Considerations for a U.S. National Formulary
Building on the international and U.S. system comparisons, this section evaluates the feasibility and potential benefits of implementing a national formulary in the U.S. The analysis explores economic savings for the healthcare system, improvements in drug affordability, and reductions in out-of-pocket costs for patients requiring specialty medications like Trikafta. It also discusses stakeholder resistance from pharmaceutical companies, PBMs, and private insurers, along with regulatory challenges and implementation hurdles.

Data Sources and Methodology
We utilized policy reports, government publications, peer-reviewed literature, and real-world pricing data to compare Trikafta pricing, formulary coverage, and accessibility. Comparative data from Pharmac, PBS, and the U.S. formulary system is synthesized to highlight disparities in access and affordability.

By analyzing global best practices and U.S.-specific challenges, we aim to provide evidence-based policy recommendations that promote affordability, equity, and improved access to essential medications within the U.S. healthcare system.

Results
This analysis examines the economic and policy implications of a Uniform National Formulary by comparing drug pricing, access, and equity for Cystic Fibrosis (CF) treatment across the U.S., Australia, and New Zealand. Using Trikafta (Elexacaftor/Tezacaftor/Ivacaftor) as a cross-comparator, the results highlight disparities in formulary decision-making, patient affordability, and policy-driven healthcare outcomes. The comparison of formulary systems between the United States, Australia, and New Zealand reveals significant differences in drug pricing, access, and government involvement.

In New Zealand (Pharmac) and Australia (PBS), a single national formulary ensures uniform medication coverage, whereas the U.S. operates a fragmented system, where private insurers, pharmacy benefit managers (PBMs), and government programs (Medicare, Medicaid, etc.) each maintain separate formularies. Government involvement is central to both Pharmac and PBS, where authorities negotiate directly with pharmaceutical companies to secure lower drug prices, while in the U.S., drug pricing is determined by market-driven negotiations between manufacturers and insurers, leading to significant cost variations and higher patient expenses.

Cost-sharing structures also differ widely. In Australia, patients pay a fixed co-payment amounting to $31.60 for general patients and $7.70 for concession card holders [24]. Similarly, Pharmac subsidizes the most essential medications, though certain high-cost drugs like Trikafta are restricted based on cost-effectiveness evaluations. In contrast, U.S. patients face tiered formulary structures, where out-of-pocket costs depend on insurance coverage, prior authorization requirements, and step-therapy policies, often resulting in a larger financial burden for high-risk patients.

Moreover, formulary decision-making processes differ across the three systems. Both Pharmac and PBS rely on independent advisory committees to conduct cost-effectiveness reviews before listing medications, ensuring that public funds are allocated efficiently. In the U.S., however, Pharmacy and Therapeutics (P&T) Committees operate within individual insurance plans and PBMs, which contribute to inconsistent drug coverage and variable access depending on the patient's insurance provider. Additionally, while Australia and New Zealand regulate drug prices at the national level, the U.S. allows pharmaceutical manufacturers to set initial drug prices, leading to higher costs for specialty medications such as Trikafta.

Also, in the United States, Medicare Part D plays a critical role in prescription drug coverage for seniors and disabled individuals, but its privatized structure contributes to medication access disparities. Unlike Australia's PBS and New Zealand's Pharmac, which operate under government-controlled pricing and formulary management, Medicare Part D is administered by private insurance companies, within its own formulary, tiered pricing, and cost-sharing arrangements [24,25]. This fragmentation leads to significantly variable drug access, as patients enrolled in different

Part D plans may face varying co-payments, prior authorization requirements, or even non-coverage of certain medications. Additionally, Medicare Part D does not currently negotiate drug prices at the federal level, allowing pharmaceutical companies to set high initial prices. Although the Inflation Reduction Act of 2022 introduced Medicare drug price negotiations, Trikafta is not currently included, highlighting the continued need for policy reform [26].

In contrast, PBS and Pharmac negotiate lower prices for all covered medications, ensuring that high-cost drugs remain more affordable and accessible to patients in Australia and New Zealand. The lack of centralized price regulation in Medicare Part D results in higher costs for specialty medications, greater financial burdens on elderly patients, and inconsistent access to life-saving treatments compared to government-led formulary models.

Table 1 Below Provides a Summary of the Differences Between the Pharmac, PBS, and U.S. Formulary Models

Table 1: Comparative Overview of Pharmac, PBS, and U.S. Formulary Models

Feature	Pharmac (New Zealand)	Australia (PBS)	United States
Formulary Type	Single national formulary	Single national formulary	Multiple formularies
Government Role	Direct price negotiations	Direct price negotiations	Limited, private negotiations (subject to change for Medicare Part D due to the IRA of 2022)
Pricing Strategy	Fixed budget, cost-effectiveness evaluation	Cost-effective review, price caps	Market-driven, negotiated by PBMs and insurers
Patient Cost-sharing	Low co-payments or free medications for essential drugs	Fixed co-payments	Tiered system with variable co-pays and high specialty drug costs
Access Equity	Universal access, minimal disparities	High access for general and concession patients	Unequal access based on insurance status
Regulatory Authority	Pharmac	PBAC (Pharmaceutical Benefits Advisory Committee)	P&T Committees for insurers, PBMs, Medicare, Medicaid
Drug Price Negotiations	Direct negotiations with manufacturers	Government-set pricing	PBMs and insurers negotiate, prices vary widely
Challenges	Limited funding may restrict access to some new drugs	High cost of some specialty drugs	High drug prices, fragmented coverage, patient affordability issues

Utilizing Cystic Fibrosis and Trikafta as a cross-comparator, this study visually assesses the differences in drug pricing, access, and formulary decision-making across the U.S., Australia, and New Zealand. By comparing how each formulary system determines drug coverage and affordability, this analysis highlights the equity and policy implications of a Uniform National Formulary (UNF) in the U.S.

Table 2 below depicts the cost differences of Trikafta (Elexacaftor/Tezacaftor/Ivacaftor) between New Zealand's Pharmac, Australia's PBS, and Medicare Part D in the U.S., highlighting pricing disparities, government subsidies, and patient out-of-pocket costs across the three formulary systems.

Table 2: Cost Comparison (Per Prescription) of Trikafta Across Pharmac, PBS, and Medicare Part D in the U.S

Trikafta (Per Prescription, in USD)		
New Zealand (Pharmac) [25]	**Australia (PBS) [24]**	**U.S. (Medicare Part D) [26]**
$0 - $5 (per prescription)	$31.60 (per prescription), $7.70 (concession card)	$67 - $321 (per prescription, after reaching their deductible)

The cost disparities for Trikafta (Elexacaftor/Tezacaftor/Ivacaftor) across New Zealand (Pharmac), Australia (PBS), and the United States (Medicare Part D) highlight the impact of different formulary structures on drug affordability and access. In New Zealand, patients pay between $0 and $5 per prescription, aligning with Pharmac's standardized co-payment system, where the government fully subsidizes high-cost medications to ensure widespread accessibility. This model reflects Pharmac's strict cost-effectiveness criteria and centralized drug pricing negotiations, which enable nationwide uniform pricing and affordability for essential treatments like Trikafta.

Similarly, in Australia, the Pharmaceutical Benefits Scheme (PBS) provides fixed co-payment pricing that makes Trikafta more affordable for eligible patients. Under this scheme, general patients pay $31.60 per prescription, while concession card holders pay only $7.70, significantly reducing out-of-pocket expenses. The PBS model ensures that drug pricing remains consistent across the country, with the government negotiating directly with manufacturers to lower costs [24]. As a result, CF patients in Australia face predictable and manageable medication expenses, preventing financial hardship. In stark contrast, the U.S. Medicare Part D system results in highly variable and significantly higher patient costs [26]. The cost of Trikafta under Medicare Part D ranges from $67 to $321 per prescription, depending on the specific insurance plan, deductible status, and formulary placement. Unlike Pharmac and PBS,

Medicare Part D does not directly negotiate drug prices, allowing pharmaceutical manufacturers to set high list prices that insurers and PBMs negotiate independently. This fragmented, market-driven pricing structure leads to substantial financial burdens for CF patients, particularly those with limited insurance coverage or high deductibles [24-26].

Equity concerns about U.S. access to Trikafta encompass more than the prohibitive cost and limited Medicare Part D coverage. Populations that are most likely to benefit from Trikafta, including cystic fibrosis individuals with advanced disease, are typically among the most vulnerable groups when it comes to health care access. In the United States, where private insurance coverage determines the cost of medication, those without strong health plans or who are dependent on Medicaid might have substantial financial barriers. This is especially worrisome considering that cystic fibrosis disproportionately impacts those with greater healthcare needs, and thus affordability becomes a key determinant of treatment compliance and health outcomes. While Medicare price negotiations under the Inflation Reduction Act (IRA) have potential for cost reductions, Trikafta is not on the list of negotiated drugs in the first round, rendering many patients unable to afford this life-sustaining therapy. The lack of standards aggravates these disparities because patients covered by different plans have widely divergent out-of-pocket costs. Correcting these imbalances would require not just more Medicare drug negotiations but also policy intervention to make available to all patients, insured or not, costly specialty drugs at all income levels.

Although the IRA grants limited Medicare negotiation authority, Trikafta has not yet been selected for negotiation, prolonging affordability barriers. This means that its high cost will remain a significant barrier for Medicare patients in the foreseeable future, unlike in Australia and New Zealand, where government intervention ensures affordability.

These findings emphasize how government-led formulary systems (Pharmac and PBS) provide significantly lower medication costs through centralized price negotiations and national subsidy programs, ensuring greater affordability and equitable access for all eligible patients. In contrast, the U.S. market-driven approach results in price variability, higher patient expenses, and financial barriers, which disproportionately affect those needing high-cost, life-saving treatments like Trikafta. The data suggests that adopting a Uniform National Formulary (UNF) in the U.S. could help control drug prices, ensuring that specialty medications remain accessible to all patients, regardless of income or insurance status.

Discussion

The findings of this study highlight significant disparities in drug pricing, access, and government involvement across New Zealand (Pharmac), Australia (PBS), and the United States (Medicare Part D), using Trikafta for Cystic Fibrosis as a case study. The results emphasize that government-led formulary models provide significantly lower costs and broader access to high-cost specialty drugs, while the market-driven U.S. system results in higher patient expenses and inconsistent access. However, while these differences underscore the potential benefits of a Uniform National Formulary (UNF) in the U.S., there are critical political, policy, and systemic challenges that must be addressed to assess its feasibility in the American healthcare system.

The political conditions surrounding drug policy reform in the U.S. remain highly dynamic, especially given recent shifts in American politics. Historically, efforts to regulate drug prices and centralize drug coverage have faced strong resistance from pharmaceutical manufacturers, PBMs, and private insurers, who exert significant influence over healthcare policy. Additionally, new administration policies have already reversed certain Medicare cost-saving measures, raising questions about the long-term commitment to drug price regulation. In contrast, the development of national formularies in Australia and New Zealand followed a very different political trajectory, largely due to the structure of their healthcare systems [24,25]. Both PBS and Pharmac were established within stronger public-sector healthcare frameworks, where government-led drug procurement was already a widely accepted practice. Unlike the U.S., where private insurers dominate prescription drug coverage, Australia and New Zealand had the advantage of a more centralized healthcare infrastructure, which allowed for the smoother adoption of a national formulary model.

One major policy lesson from PBS and Pharmac is that early government intervention in drug pricing played a critical role in securing lower costs and ensuring equitable access [27]. In contrast, the U.S. healthcare system has long prioritized market-based solutions, making large-scale government-led formulary reform more politically contentious. Given the current political climate, any push for a Uniform National Formulary in the U.S. would need to overcome substantial industry lobbying and political polarization, particularly in Congress and regulatory agencies.

The political journey of national formulary implementation in Australia and New Zealand offers valuable insights into the structural and policy factors that enabled their success. Both PBS and Pharmac were introduced as part of broader public health reforms, aligning with existing government-led healthcare initiatives. Several key differences between these systems and the U.S. healthcare model made the transition to a centralized formulary more feasible. Unlike the U.S., where healthcare coverage is highly privatized, both Australia and New Zealand have universal health coverage models with significant government oversight in drug procurement [24,25]. This allowed them to implement centralized formularies without disrupting large-scale private insurer operations. Additionally, both PBS and Pharmac were designed with cost-effectiveness frameworks from the outset, ensuring that government price negotiations were a fundamental part of their healthcare structure [24,25]. In contrast, the U.S. system relegates drug pricing negotiations to private PBMs and insurers, limiting the federal government's influence on direct price controls. Another major distinction is that the U.S. pharmaceutical industry wields substantial lobbying power, making it far more difficult to implement large-scale pricing reform [28]. In Australia and New Zealand, government-led healthcare decisions face less industry pushback, allowing policymakers to prioritize cost-effectiveness and public health over corporate interests.

One of the most critical developments in U.S. drug policy is the Inflation Reduction Act (IRA) of 2022, which introduced limited Medicare drug price negotiations for the first time [28]. While this is a significant step forward, the scope of price negotiations remains narrow, and Trikafta is not included among the first wave of negotiated drugs. We propose a potential policy trajectory could involve gradually incorporating negotiated drugs into a standardized Medicare formulary over time, effectively creating a national formulary model through incremental expansion. This would mirror the phased implementation approach used in Australia and New Zealand, where cost-effectiveness evaluations gradually shaped national drug coverage policies. An important

area for further research involves examining how CMS selects drugs for negotiation under the IRA. If CMS prioritizes high-cost, widely used medications, this could serve as a foundation for a future Medicare-based formulary. However, the current administration's approach to Medicare drug price negotiations remains uncertain, particularly given recent executive orders that reversed certain policy experiments aimed at reducing drug costs. To move toward a national formulary, policymakers will need to expand Medicare drug price negotiations beyond the current limitations of the IRA, establish clearer criteria for drug selection that align with public health priorities, and address resistance from pharmaceutical companies and insurance providers who stand to lose profits under a government-led formulary model.

While Medicare drug price negotiations represent a critical step toward formulary standardization, the U.S. lacks a clear legislative pathway for implementing a fully centralized national formulary. Given the current constraints, several policy approaches could be considered. By gradually integrating drugs selected for Medicare negotiation into a standardized formulary, CMS could slowly build the foundation for a national formulary without abrupt market disruptions. Additionally, some states have already begun experimenting with state-level drug pricing models, and expanding these efforts could serve as a testing ground for broader formulary integration. Studying the formulary implementation processes of PBS and Pharmac could help identify adaptable elements that fit within the existing U.S. healthcare system. Given the partisan nature of healthcare policy, building bipartisan coalitions focused on cost containment and patient affordability will be essential to advancing legislation that supports formulary integration.

The disparities in Trikafta pricing and access across New Zealand, Australia, and the U.S. illustrate the broader challenges of implementing a national formulary in a highly privatized healthcare system. While PBS and Pharmac successfully centralized drug pricing through strong public-sector involvement, the U.S. model remains fragmented, making a fully integrated formulary politically and structurally challenging. However, Medicare drug price negotiations under the IRA may provide a pathway for future formulary expansion. By studying the political and policy trajectories of PBS and Pharmac, the U.S. can identify viable strategies for expanding government-led drug coverage. Further research should focus on the evolving role of CMS in drug price negotiations, as well as the legislative and political conditions necessary for a Uniform National Formulary to gain traction in the U.S. healthcare system.

Conclusion

The disparities in drug pricing, access, and government involvement across New Zealand, Australia, and the United States underscore the challenges of implementing a Uniform National Formulary (UNF) in a highly privatized healthcare system. The comparison of Pharmac, PBS, and Medicare Part D using Trikafta for Cystic Fibrosis as a case study reveals how government-led formulary systems provide greater affordability and equitable access, while the U.S. market-driven model results in higher patient costs, fragmented coverage, and significant financial barriers. The findings highlight that centralized drug price negotiations, as seen in Australia and New Zealand, play a crucial role in reducing medication costs and improving accessibility, which is a stark contrast to the U.S., where pharmaceutical companies and PBMs largely dictate pricing structures with limited federal intervention.

While the Inflation Reduction Act (IRA) of 2022 marks a significant policy shift by allowing limited Medicare drug price negotiations, its scope remains narrow, and Trikafta is not included in the first round of negotiated drugs. However, expanding Medicare drug price negotiations over time could serve as a foundation for a national formulary, gradually bringing more high-cost medications under a standardized coverage framework. Given the recent political shifts and administrative reversals of certain cost-reduction initiatives, the feasibility of such a transformation will depend on political will, industry influence, and public advocacy for drug affordability reforms.

To move toward a national formulary model in the U.S., based on our findings, we propose several policy recommendations that emerge from this analysis. First, policymakers should strengthen Medicare drug price negotiations by broadening the list of eligible drugs and establishing clear, transparent criteria for inclusion in the negotiation process. Expanding the IRA's impact beyond select medications will increase affordability for a larger patient population and provide a precedent for formulary standardization. Second, CMS should explore integrating negotiated drugs into a structured Medicare Part D formulary, ensuring greater consistency in drug coverage and minimizing disparities across different insurance plans. Third, regulatory efforts should focus on reducing administrative barriers, such as prior authorization and step therapy requirements, which disproportionately hinder access to life-saving specialty drugs. Additionally, state-level initiatives and pilot programs could serve as testing grounds for formulary expansion, allowing for gradual implementation without disrupting existing private insurance markets.

Further research should examine the selection criteria used by CMS for Medicare price negotiations, as this will provide insights into which high-cost medications could be prioritized for inclusion in a national formulary. Additionally, comparative policy analysis should investigate the legislative and political conditions that enabled the successful implementation of PBS and Pharmac, identifying best practices that can be adapted to the U.S. healthcare landscape.

While the implementation of a Uniform National Formulary in the U.S. faces significant challenges, the incremental expansion of Medicare drug price negotiations presents a viable path forward. By leveraging lessons from Australia and New Zealand, policymakers can explore strategic reforms that balance cost containment with equitable medication access. Given the shifting political landscape and ongoing debate over Medicare drug pricing, continued evaluation of policy developments, industry resistance, and public support for formulary integration will be critical in shaping the future of prescription drug affordability and access in the United States [29,30].

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