

For Health or Profit?

How Insurance Companies Restrict Access to Single Source HIV/AIDS Drugs Critical to the Health of New Yorkers

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Dear Reader:

Among the many important issues facing New Yorkers today, perhaps none is more fundamental than adequate and affordable health care. This encompasses access to vital prescription drugs that are essential for treating chronic and/or life-threatening conditions. Unfortunately, decisions about the best prescription drug choices for those in need are increasingly being taken away from doctors and patients by insurance companies that too often place profits above the health of their members.

Access to single-source prescription drugs is particularly important in treating HIV/AIDS. Single-source drugs are unique in their formulation, dosage, and delivery—they have no generic equivalent because of current patent laws and are often times more expensive. The prices cause insurance companies to create policies and formularies that steer the insured toward prescription drugs that will increase their profit margins, rather than those that the doctor and patient decide are the best course of treatment. Insurance companies block access to single-source drugs through high copayments and company-approval requirements that financially burden the patient while delaying their treatment in a tangle of red tape.

The following is an investigative report showing how insurance companies in New York State restrict the use of single-source drugs treating HIV/AIDS. The report concludes with potential solutions to this problem that will ensure that medical decisions lie in the hands of our doctors and not insurance companies.

Regards,

Jeffrey D. Klein
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SECTION 1:

THE IMPORTANCE OF ACCESS

TO DRUGS TREATING

HIV/AIDS



The Impact of HIV/AIDS

- ❑ As is well-known, there is no cure or vaccine for HIV/AIDS. ¹
- ❑ AIDS has resulted in the death of 25 million people globally since the disease began in the 1980s. ²
- ❑ 33 million more people are infected with HIV/AIDS today. ³
- ❑ It is estimated that more than a million people are living with HIV in the United States. ⁴
- ❑ In NYS, 119,929 people are living with HIV or AIDS as of the end of 2007, according to the NYS Department of Health. ⁵



HIV/AIDS Drugs Extend Life

- The importance of access to a combination or cocktail of antiretroviral drugs in extending life in those with HIV/AIDS is well-established.
 - A report recently released in the Lancet Medical Journal reported that HIV patients live, on average, 13 years longer due to drug combination therapies. The report also concluded that those who are treated earlier live longer. ⁶
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NYS ADAP Program

- ❑ Fortunately, NYS Department of Health AIDS Institute offers four programs to help those infected with HIV/AIDS access life-extending prescription drugs, including ADAP (The AIDS Drug Assistance Program).⁷
 - ❑ Eligibility varies based on size of household but eligibility is capped at \$74,400 for a household of 3 with \$25,000 or less in liquid assets.⁸
 - ❑ ADAP provides assistance for the uninsured and underinsured, for example, paying for drugs completely or providing financial support with insurance premiums, deductibles and co-payments.⁹
 - ❑ For those not eligible for the program or other government programs like Medicaid, access to life-saving drugs treating HIV/AIDS can be limited by insurance company restrictions.
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SECTION 2:

RESTRICTIONS TO ACCESSING SINGLE-SOURCE DRUGS TREATING HIV/AIDS



Single-Source (Brand Name) Drugs vs. Generic Drugs

- In general, a single-source drug contains a unique active ingredient (responsible for the drug's effect), dosage, and dosage form, all of which are approved by the Food and Drug Administration (FDA) as safe and effective to treat a particular illness. Single-source drugs are under patent protection. The patent guarantees that no other pharmaceutical company may manufacture the drug until the patent expires.
- The FDA requires generic medication to contain the same active ingredient as well as the same amount of active ingredient as the brand name. Generic drugs must also be equal in safety, strength, route of administration, quality, and directions. Any manufacturer who meets these FDA requirements can market his/her generic medication and compete with the brand name drug once the patent expires.



Single-Source (Brand Name) Drugs vs. Generic Drugs Continued

- According to the FDA, generic drugs have the same effect on the body as brand name drugs do. The major difference is price.
- In 2007, the average brand name drug was 3 times the price of the average generic drug (\$119.51 vs. \$34.34).¹¹ HIV/AIDS brand name drugs typically cost much more, ranging from hundreds of dollars to over \$2,000 per month.
- Manufacturers of brand name drugs argue they must price their medications higher than generics to cover costs associated with research and development - expenses generic manufacturers do not incur.



A Conflict of Interest?

- If the best medication for a patient has a generic equivalent, the latter should clearly be prescribed in order to save costs for the entire health care system. However, if a single-source drug still has patent protection, generic prescriptions are not an option.
- The problem arises with drugs that treat specific conditions like HIV/AIDS. While some of these drugs have less expensive generic equivalents, others are only available as the more expensive brand name drug. Health insurance companies want to control costs while physicians want to treat their patients with the most effective and safe medications, whether they be brand name or generic.



A Conflict of Interest? (Cont.)

- Central to the argument of this presentation is what is referred to as **heterogeneity of response**. This phenomenon is well-documented and basically means that medicine is very individualized, so that depending on the type of medication to treat a particular illness no two patients will respond the same. In some cases, even medications of the same type will affect patients differently.
- Insurance companies, however, restrict access to many single-source drugs through what are called “cost-containment strategies.” These are meant to encourage or even force physicians to prescribe drugs that, in their professional opinion, are not the safest or most effective drugs for a particular patient. Depending on the illness and the patient, certain single-source drugs may be the only effective treatment available; yet they cannot be prescribed because of insurance company restrictions.



Cost Containment Strategies

- **Formularies** are lists issued by HMOs that indicate the prescription drugs they cover as well as the associated patient co-payments.
- **Tier-based formularies** are the most common. They work by placing medications on different tiers, where the co-payments rise with every following tier. For example:

TIER 1 -- \$10 co-payment (generic brand)
TIER 2 -- \$25 co-payment (preferred brand)
TIER 3 -- \$45 co-payment (non-preferred brand)

- Tier-based formularies are intended to encourage generic use and compliance with the insurance company's formulary through increasing patient out-of-pocket costs for using non-preferred brand-name drugs. In other words, high co-payments are intended to discourage the use of non-preferred single-source drugs.



Cost Containment Strategies (Cont.)

- **Expensive Co-Payments (\$\$):** typically drugs on the third tier of a three-tier formulary are single-source drugs, or non-preferred brand drugs. These drugs have the highest co-payments, thereby discouraging the purchase of and limiting access to these medications.
- **Prior Authorization (PA):** requires approval by the insurance company before a drug will be covered. PA is intended to limit the use of certain drugs to only those patients who meet specific medical requirements.
- **Exclusion (E):** excludes certain medication from the formulary, which is therefore not covered.
- **Quantity Limitation (QL):** limits the amount of medication or number of prescriptions that can be purchased at one time. QLs are intended to ensure physicians and patients are following specific medication guidelines.
- **Mandatory Mail Order (MM):** only provides coverage for the drug when it is purchased through the insurer's designated mail-order pharmacy.



SECTION 2:

INVESTIGATORY METHODS



Investigatory Methods

- In order to determine the degree to which insurance companies in New York State (NYS) restrict access to single-source drugs treating HIV/AIDS, we:
 1. Identified the insurance companies offering prescription drug benefits through the NYS Department of Insurance.
 2. Analyzed their three-tier formularies of randomly selected insurance companies to determine the coverage restrictions for HIV/AIDS drugs.



Insurance Companies Surveyed

The following NYS health insurance companies were randomly selected and surveyed to determine their restrictions on single-source HIV/AIDS medications:

Aetna Health, Inc.

Capital District Physicians' Health Plan, Inc.

CIGNA HealthCare of New York, Inc.

Connecticare of New York, Inc.

Empire HealthChoice HMO, Inc. d/b/a Empire BlueCross BlueShield HMO

Excellus Health Plan, Inc.

GHI

Health Insurance Plan of Greater NY, Inc.

Health Net of New York, Inc.

HealthNow New York, Inc.

Independent Health Association, Inc.

MVP Health Plan, Inc



Medications Investigated

- The following medications were investigated to determine restrictions placed on single-source drugs treating HIV/AIDS:
 - Atripla
 - Combivir
 - Epivir
 - Epzicom
 - Fuzeon
 - Kaletra
 - Norvir
 - Isentress
 - Reyataz
 - Selzentry
 - Sustiva
 - Trizivir
 - Truvada
 - Viracept
 - Ziagen
- These single-source medications were chosen based on the ExpressScripts 2007 Drug Trend Report,² or based on their unique active ingredients and/or dosage forms.



SECTION 3:

FINDINGS & IMPLICATIONS



HIV/AIDS Medication Restrictions

		NEW YORK INSURANCE COMPANIES											
		Aetna	CDPHP	Cigna	Connecticare	Empire	Excellus	GHI	HIP	Health Net	Health Now	Independent	MVP
HIV/AIDS DRUGS	Atripla	\$\$		\$\$	\$\$	E	QL			QL	?		?
	Combivir						MM		\$\$?
	Epivir						MM		\$\$ (tablet)			QL	?
	Epzicom	\$\$			\$\$		MM		\$\$?
	Fuzeon	\$\$		PA	\$\$, PA		\$\$, MM		\$\$, PA		?	PA, MM	MM
	Kaletra						MM						?
	Norvir						MM						?
	Isentress	\$\$				E	?	?		\$\$			MM
	Reyataz						MM		\$\$	QL			?
	Selzentry	\$\$			\$\$	E	?			\$\$	PA		MM
	Sustiva						MM						?
	Trizivir	\$\$					MM						?
	Truvada				\$\$	E	MM	?	\$\$?
	Viracept						MM						?
Ziagen						MM		\$\$ (tablet)				?	

Restrictions Key

\$\$ - highest co-payment

PA - prior authorization required

E - excludes certain medication from the formulary, which therefore is not covered

? - not on formulary, unclear if covered

MM - mandatory mail order

QL - quantity provided at one time is limited

- Aetna formulary sampled was the Non-Medicare three-tier open formulary
- GHI formulary sampled was the 2009 GHI Pharmacy Services Formulary I
- Excellus formulary sampled was the Non-Medicare three-tier open formulary
- HIP formulary restrictions varied by dosage and mode of delivery (tablet, capsule, oral solution, etc.). HIP was identified as placing restrictions on single-source HIV/AIDS drugs if most doses and modes of delivery were restricted.



Restrictions by HMOs

HMO	Drugs Restricted/ Total Drugs Investigated*	% of Drugs Restricted of Total Investigated	# of Investigated Drugs With No Information Available
Excellus	13/13	100%	2
MVP	3/3	100%	12
Aetna	6/15	40%	0
Connecticare	5/15	33%	0
Empire	4/15	27%	0
Health Net	4/15	27%	0

- figure for total drugs investigated differs as some insurance companies do not have relevant information available for all drugs. If no information was available, the drug was not included in total drugs investigated.



Restrictions by Drug

Rank	Drug	Disease/ Therapeutic Area	Total Restrictions	# of Companies Restricting	Percentage of Companies Restricting
1	Fuzeon	HIV/AIDS	11	7 of 11	64%
2	Atripla	HIV/AIDS	6	6 of 10	60%
3	Isentress	HIV/AIDS	4	4 of 10	40%
4	Truvada	HIV/AIDS	4	4 of 10	40%
5	Epzicom	HIV/AIDS	4	4 of 11	36%

- figures for restrictions of drugs differs as some insurance companies do not have relevant information available for all drugs. If no information was available, the drug was not included as part of those restricted by insurance companies.



HIV/AIDS Medications

- According to a report on HIV/AIDS drug adherence published by the Committee on Oversight and Government Reform, “research shows that if patients are not highly adherent [in taking medications], the medicines stop working and the virus becomes resistant. As a consequence, it may become difficult to treat either the patient or any others to whom the virus might be transmitted with existing drugs. For both individual patients and the epidemic overall, therefore, it is extremely important to promote effective adherence, continuity of care, and follow-up for patients.”¹²
- “Adherence” in this context can be considered “taking medication regularly.” Any restrictions on HIV/AIDS medications placed by insurance companies could, therefore, potentially lead to non-adherence.



Concerns with High Co-Payments (Tier 3)

- There is a growing body of literature that suggests raising out-of-pocket costs through the use of a 3-tier formulary results in increased use of inpatient and emergency medical services for patients with chronic diseases.⁷ This finding suggest that patients may try to avoid high co-payments by not taking their prescribed medication, which in turn makes them more ill.
- One study analyzing the link between rising co-payments and prescription drug use found that adherence among the lowest income populations (< \$30k/year) for medications used to treat diabetes and heart failure significantly decreased when co-payments were increased by only 10%.¹³
- Of particular concern are the traditionally poorer African-American and Hispanic American populations, which display higher rates of chronic diseases, including HIV/AIDS. ¹⁴



Concerns with Other Types of Restrictions

- Prior authorization and step therapy are very time-consuming and burdensome, for both physicians and pharmacists. In both cases, the time it takes for healthcare professionals to fill out forms is valuable time taken away from patients.
- In the worst-case scenario, a physician may decide against prescribing a medication that requires prior authorization or step therapy as the paperwork and time needed to complete the process are too burdensome. Physicians have years of training; it is disturbing that their prescribing may be dictated by insurance company restrictions rather than their medical expertise.



SECTION 4: Solutions



Solutions- S2938A

- **Empowering Physicians**

- When an insurer has required that a member take a generic alternative to a brand-name patented drug prescribed by their doctor, and the alternative is not deemed as having an equivalent impact on the member by the member's prescribing physician and is not deemed an A-rated generically and therapeutically equivalent product as determined by the FDA, the insurer shall pay for and make available the brand-name patented drug originally prescribed by the member's doctor.

- **Controlling Expensive Co-Payments**

- Co-payment or co-insurance costs with respect to a prescribed drug not exceed the cost of the drug to the insurance provider.
 - An out-of-pocket cap be established for pharmacy costs on covered prescription drugs.
 - Maximum co-payment and co-insurance amounts be limited so they shall not exceed ten times the dollar value of the lowest co-payment and co-insurance amount whose cost is above zero dollars.
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Solutions- S2938A

- **Limiting Insurers' Restrictions on Access to Prescription Drugs**

- In cases where step therapy is required prior to a patient accessing a brand name patented prescription drug, the patient can receive the brand name patented prescription drug prescribed by their doctor if the patient tries one alternative medication and the patient's doctor determines that the single source therapy remains medically necessary.
- Once submitted to the State Insurance Department, plans may not remove or make changes to the drug formulary mid-year except in instances where an A-rated generically and therapeutically equivalent product as determined by the FDA becomes available, the drug is recalled by the Food and Drug Administration, or significant new safety information becomes available.
- A patient receiving coverage for a drug on an insurer's existing formulary shall not be denied coverage upon a change in the formulary if his or her physician determines that drug to be medically necessary.



Report Limitations

- Some of the formularies we accessed did not include information about their coverage of some of the HIV/AIDS drugs surveyed. Therefore, it is unclear what kind of restrictions these insurance companies place on these medications. Furthermore, available formularies we surveyed may be tailored to fit specific plans offered by insurance companies.
- Only NY insurance companies randomly selected were surveyed in this study. Therefore, we do not know the extent to which all insurance companies in NY or nationwide restrict access to HIV/AIDS single-source drugs.
- The practice of medicine is ever changing as new studies emerge. Some of these studies demonstrate that certain single-source drugs are not as safe and/or effective as was previously thought. Therefore, it may be unfair to insurance companies to criticize them for placing harsh restrictions on drugs such as this when strong evidence is available that raises serious doubt about the supposed benefits of the higher-cost single-source drugs.¹⁵



Conclusions

- Prescription drug spending is currently about ten percent of national health expenditures. As such, insurance companies have to try to control the costs of prescription drugs, not just for the sake of their own profits, but also to keep premiums affordable to all NYS citizens enrolled in their plans.
- Therefore, it may not be reasonable or fair to force insurance companies to remove their restrictions on expensive single-source drugs. The challenge is to determine which restrictions are beneficial to both patients and the health care system, and to what degree they represent the insurance company interests.



Closing Statement

- We created this report to advocate for the use of all available prescription drugs to best serve the health of NYS patients enrolled in these insurance companies. While we understand that restrictions on HIV/AIDS single-source medications are sometimes necessary, this report finds that too often, insurance companies are using these restrictions in ways that run counter to the health and well-being of the NYS population they serve.



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