Discriminatory Design

HIV Treatment in the Marketplace

NASTAD

The Affordable Care Act (ACA) has expanded access to medical care and prescription drug coverage for millions of Americans, revolutionizing coverage options for persons living with HIV (PLWH). Access to coverage, however, does not mean that coverage is high-quality or affordable. For PLWH, antiretroviral therapy (ARV) is the cornerstone of maintaining their HIV treatment, but too often, Qualified Health Plans (QHPs) available under the ACA fail to provide robust ARV coverage. This report analyzes the over 91,000 QHPs available on the Federally-Facilitated Marketplaces, assessing each plan's quality of ARV coverage and pricing.

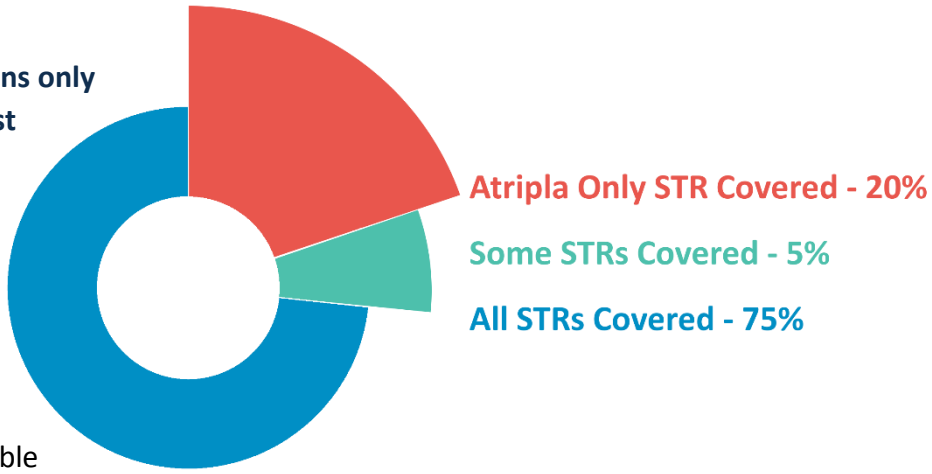
Key Findings

20% of plans only cover one single-tablet regimen, Atripla, the oldest and least-recommended regimen	One-third of plans place all covered single-tablet regimens on the specialty tier
Over 45% of Bronze plans subject all covered single-tablet regimens to co-insurance	15% of plans do not cover any HIV drugs introduced since 2013
34% of plans place Truvada, which can prevent HIV infection as Pre-Exposure Prophylaxis (PrEP), on the specialty tier	29% of plans require patients to “fail-first” on another HIV drug before taking Stribild, a leading single-tablet regimen
Cost-Sharing Reduction plans, intended to help the poor, have the same high levels of co-insurance as Silver plans	Increases in drug list prices lead to increased frequency of co-insurance at statistically significant levels

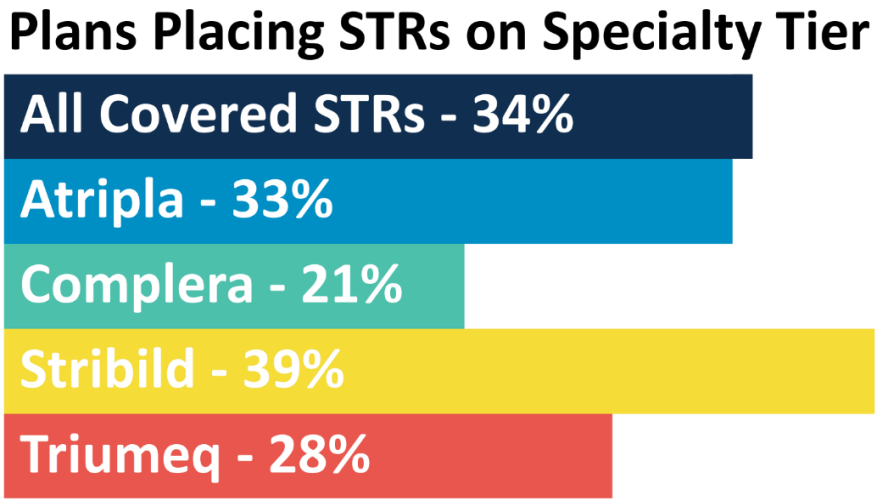
Single-Tablet Regimens

Single-tablet regimens (STRs) are the cornerstone of modern HIV treatment.[1] Too few plans, however, cover the full gamut of these critical treatments, which can discourage PLWH from enrolling in the plan.

Nationwide, **20% of plans only cover Atripla, the oldest STR with more side effects than newer treatments.** This restricted coverage means that no patient in these plans has access to any of the newer, more tolerable STRs, regardless of need.



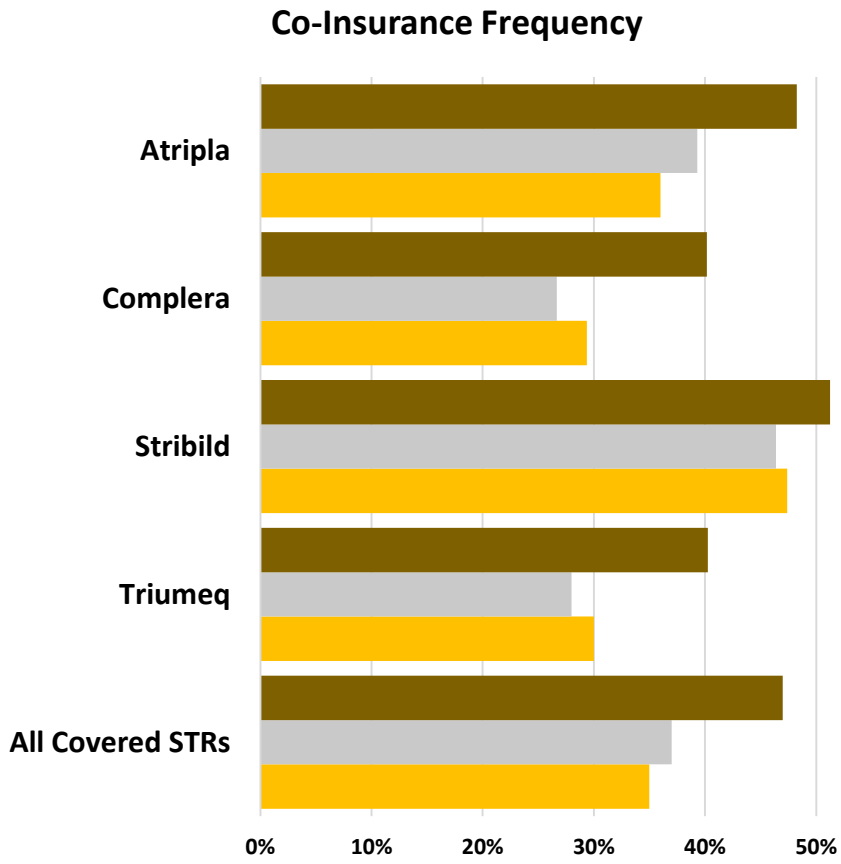
While 75% of plans cover all four STRs, plans continue to limit STR access through restrictive tiering and high cost-sharing. Thirty-four percent (34%) of plans place all covered STRs on the "Specialty" tier (these plans may not cover all four STRs). CMS has repeatedly stated that it is discriminatory to place STRs on a specialty tier to discourage PLWH from accessing these necessary drugs.[2]



[1] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.

[2] *See, e.g.*, 2016 Letter to Issuers. "For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal, such a plan design might effectively discriminate against, or discourage

Co-insurance, rather than a fixed co-payment, can strongly discourage PLWH from using an STR.



Across metal levels, plans subject covered STRs to co-insurance at high frequencies: 47% for Bronze plans, 37% for Silver plans, and 35% for Gold plans. Eighty percent (80%) of the plans with Atripla as the only covered STR use co-insurance, discouraging PLWH from enrolling in the plan by limiting drug choice and subjecting the only STR to co-insurance.

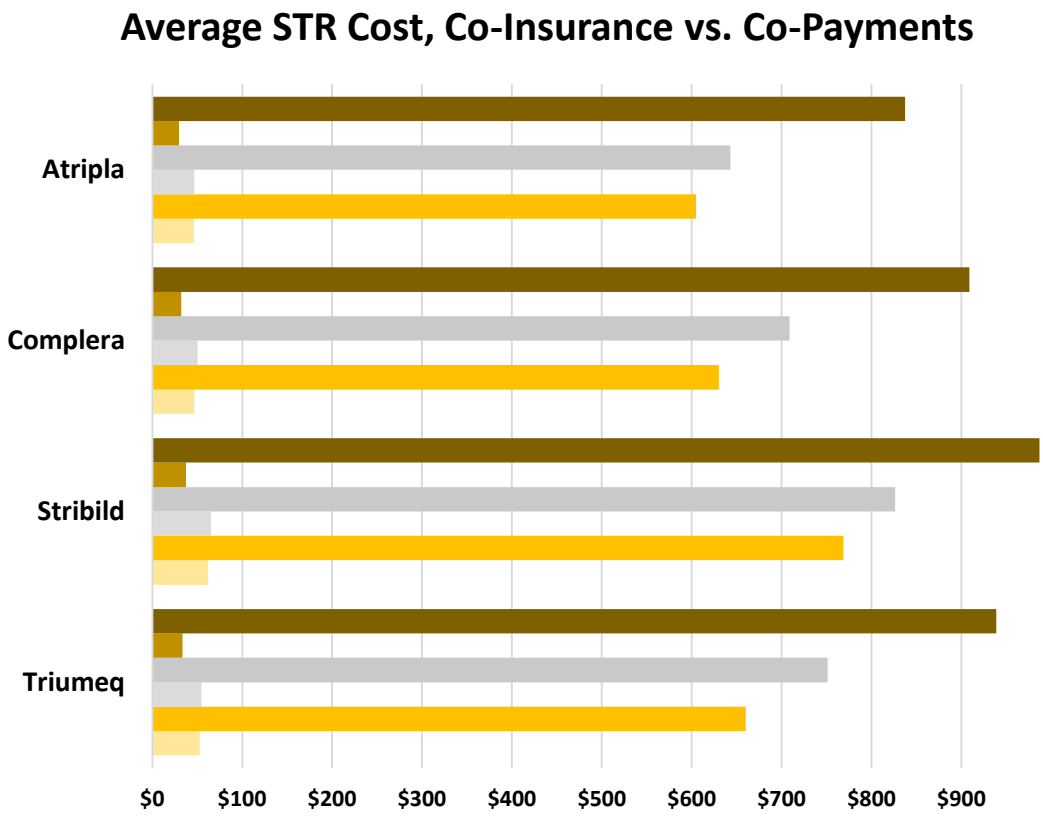
Co-Insurance can cost 28 times as much as a co-payment.

Co-insurance drastically raises costs to patients. For STRs in Bronze plans, co-insurance resulted in monthly costs that were, on average, 28 times the cost of co-payments. The ratio falls for Silver and Gold plans, but only to 14 and 13 times as expensive, respectively.

Payers further restrict access to STRs through utilization management. To access Stribild, the market leading STR, patients in 29% of plans are required to "fail first" on other drugs before they are able to access Stribild under step therapy requirements. This is higher than the step therapy rate for Sovaldi, the blockbuster Hepatitis C treatment, which is subject to step therapy in 24% of plans (another Hepatitis C treatment, Viekira Pak, has a 37% step therapy rate).

---

enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those chronic conditions." https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf



New Drugs

Fifteen percent (15%) of plans cover no drugs approved since 2013.

Long-term PLWH must often change medications to continue effectively suppressing HIV and new medications may be what is needed for them to again suppress their virus. Plans, however, have an incentive to avoid covering new medications to discriminate against patients who need them, as these patients may be sicker on average. Six new HIV treatments were released between 2013 and October 2015; drugs released after October 2015 are not included in the analysis because formularies were finalized for November 1, 2015 release. For each of these drugs, non-coverage rates range from 21-31%. For drugs approved after 2014, 17% of plans do not cover any of the drugs; for the two drugs released in 2015, 27% of plans do not cover either drug.

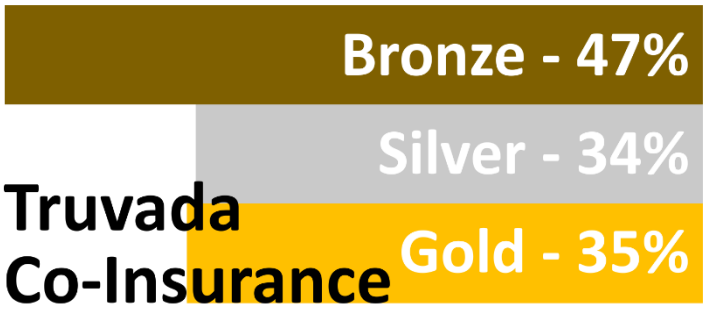
Because new drugs are often excluded from benchmark plans, there are few mechanisms to enforce coverage. State insurance authorities have few tools to require plans to cover new drugs. Failing to cover these drugs, however, discriminates against patients who may need new therapies.

Pre-Exposure Prophylaxis (PrEP)

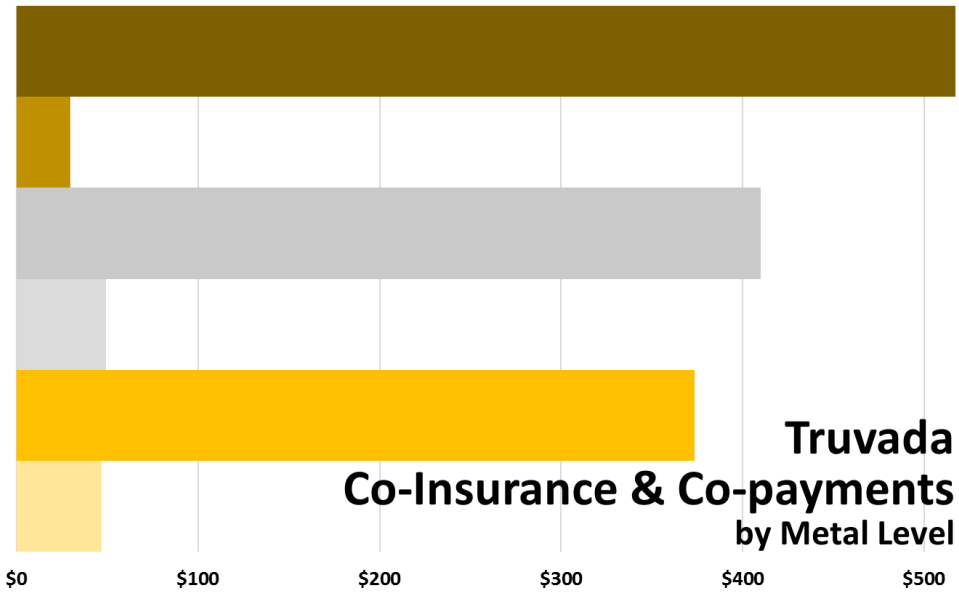
PrEP is a revolutionary advancement in HIV prevention – a once-daily pill that is nearly 100% effective at preventing HIV transmission when taken correctly.

Only one drug, Truvada, is FDA-approved for use as PrEP. Without insurance, Truvada costs over $1,400 per month, meaning insurance coverage is critical to ensuring those most at risk of HIV acquisition have access to PrEP.

Of the plans that cover PrEP, 34% place it on the specialty tier. In Alaska, Louisiana, and Maine, over 75% of plans place Truvada on the specialty tier, while 100% of Nevada plans do.



Nationwide, 39% subject Truvada to co-insurance (ranging from 34% of Silver plans to 47% of Bronze plans).



Because of these restrictions, PrEP is still unaffordable for many patients, costing over $500 per month, on average, for Bronze plans using co-insurance.

Cost-Sharing Reduction Plans

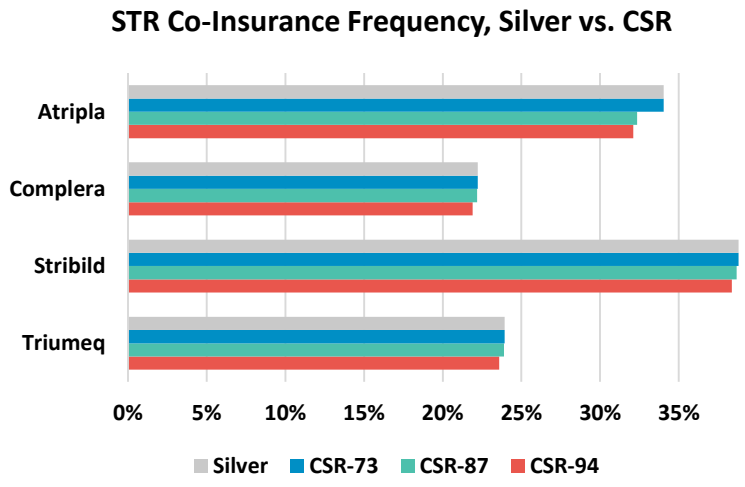
Cost-Sharing Reduction plans still discriminate by using co-insurance.

To make insurance affordable for people between 100-250% of the Federal Poverty Level, the ACA requires issuers to offer versions of their Silver plans that cover an actuarially higher amount of healthcare costs. Standard Silver plans are expected to cover 70% of healthcare costs, leaving 30% to the patient. CSR plans cover 73%, 87%, or 94% of average healthcare costs, depending on the patient's income bracket (CSR-73, CSR-87, and CSR-94, respectively). CSR plans are also required to have lower out-of-pocket maximums than standard Silver plans. To reduce costs to the consumer when designing a CSR plan, insurers can change deductibles or cost-sharing amounts for physician visits and drugs, as well as the out-of-pocket maximum.

Seventy-two percent (72%) of CSR-73 plans have the same cost-sharing structure as standard Silver plans, including both frequency and amount of co-insurance.

Instead of reducing patient cost-sharing for drugs, these plans use the same high frequency of co-insurance as standard Silver plans. Seventy-two (72%) of CSR-73 plans have the same cost-sharing structures for all tiers as standard Silver plans, including the same co-insurance rates and the same co-payment dollar amounts, while 42% of CSR-87 and 30% of CSR-94 plans have the same structure. Of the standard Silver plans that use co-insurance for the Specialty tier, over 99% of CSR-73 plans, 97% of CSR-87 plans, and 94% of CSR-94 plans still use co-insurance for Specialty drugs, potentially resulting in unsustainable monthly costs for patients.

STRs have the same frequency of co-insurance on CSR and standard Silver plans.

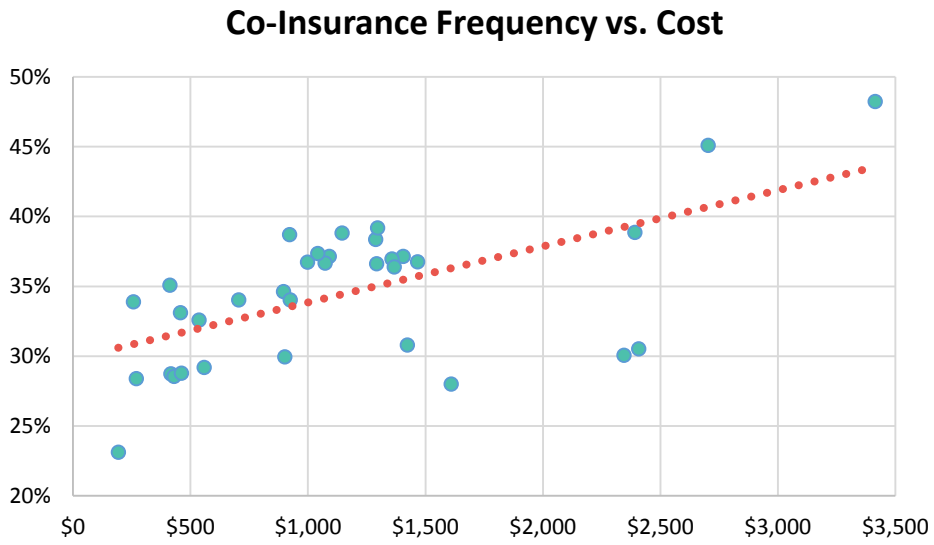


Given that CSR plans have nearly the same cost-sharing structures as standard Silver plans, it is little surprise that they have the same frequency of co-insurance for STRs. While in some cases an issuer may charge a lower co-insurance percentage for a CSR plan, the use of co-insurance still discourages PLWH from using STRs by creating high monthly payments. While PLWH on CSR plans may have to make fewer of these payments because of lower out-of-pocket expenditure limits, there is no cost relief for the first few prescriptions, which may discourage patients from filling their prescriptions at all.

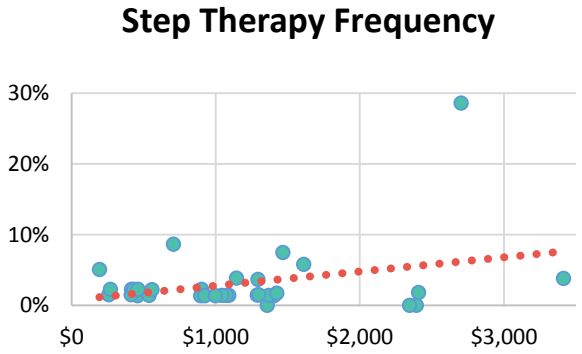
Manufacturers' Prices

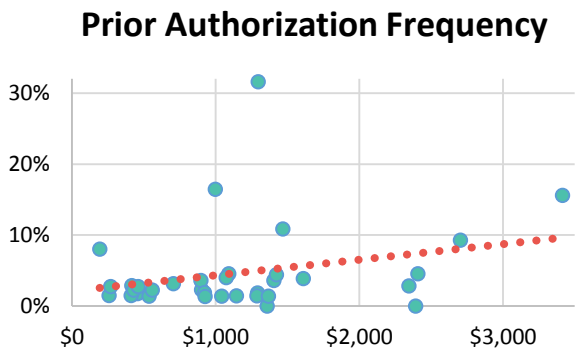
High drug costs set by manufacturers are directly linked to insurer restrictions.

Drug manufacturers continue to increase prices for existing HIV medications while raising market prices for new treatments. These high prices are directly linked to insurers' use of co-insurance, and they appear to be linked to insurers' use of step therapy and prior authorization.



Across all metal levels, the frequency of plans using co-insurance for a particular drug rises as the manufacturer's Wholesale Acquisition Cost, or list price, increases. This association is statistically significant.





Frequency of step therapy and prior authorization also increase as drug price increases, though these results are not statistically significant, as most drugs have low rates of utilization management and there is less variation to assess trends. However, the highest-priced STR, Stribild, has the highest frequency of step therapy (29%), and the most expensive HIV medication (Fuzeon) has one of the highest frequencies of prior authorization (16%).

Discussion

Insurance regulators have failed to enforce provisions that would protect PLWH from discriminatory insurance plan design.

The ACA's non-discrimination tools are useless if unenforced. One-third of plans place all covered STRs on the Specialty tier, even with CMS' guidance finding presumptive discrimination for restricted coverage of STRs.[3] Nationwide, 20% of plans only cover Atripla, the oldest and least recommended STR.

Plans continue to employ co-insurance to dissuade PLWH from accessing STRs across metal levels. While 47% of Bronze plans use co-insurance for all covered STRs, 37% of Silver and 35% of Gold plans require co-insurance as well. Even CSR plans, designed to reduce financial impact for lower-income patients, still have the same frequency of co-insurance as standard Silver plans. Plans frequently subject the market-leading and most expensive STR, Stribild, to "fail first" or step therapy requirements 29% of the time, which can cause treatment interruptions and discourage PLWH currently taking Stribild from enrolling in the plan.

Over a third of plans subject PrEP to restrictive specialty tiering, and nearly half of Bronze and over a third of Silver and Gold plans subject it to co-insurance, putting this innovative tool to prevent HIV out of reach. Similarly, 15% of plans cover none of the six HIV drugs approved since 2013, limiting options for long-term survivors or others who need new treatments.

High drug prices are directly linked to increased restrictions on drug access, yet manufacturers continue to insist that only insurers must reform their practices. While manufacturers claim to provide discounts off their list prices to insurers, higher list prices are directly linked to increased co-insurance frequency. Wholesale reform is needed in drug pricing to encourage insurers to reduce co-insurance and utilization management rates for necessary medications.

Strong action is needed from state insurance regulators and federal oversight at CMS to improve the quality of marketplace plans for PLWH. Corollary reductions in drug prices are necessary to reduce the incentive to restrict access to necessary treatments. NASTAD encourages regulators to ensure that HIV medications, particularly STRs and PrEP, remain accessible and affordable.

---

[3] 2016 Letter to Issuers. "For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen… such a plan design might effectively discriminate against, or discourage enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those chronic conditions." https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf"

Methodology

For the 2016 plan year, plans were required for the first time to provide comprehensive formulary data in a machine-readable format, allowing researchers to assess drug coverage. NASTAD compiled data on coverage of 34 brand name HIV drugs for each of the 91,080 plans offered on the federally-facilitated marketplaces. While insurers typically offer only a few plans within each state, they must determine in which geographic areas of the state they will offer a plan, and they develop separate premium rates for each area. Therefore, one overall plan design may be offered many times across a state with different premium rates. The 91,080 plans can be reduced to 4,099 unique plan designs, represented by a unique plan ID; however, NASTAD analyzes each plan offering to reflect the extent to which the plan is offered in the marketplace (e.g., one plan design offered in 10 counties versus another plan design offered in only two counties).

Of the 91,080 plans offered on the federally-facilitated marketplaces, only 67,361 had valid formulary tier data. Some plans failed to upload data; others had incomplete or wholly inaccurate data (e.g., all tiers listed as "Formulary-Drug"). Some plans had multiple formulary data files or multiple entries with different tier data for each drug; in those cases, NASTAD presumed that the drug was listed on the most-restrictive tier of the tiers listed across multiple entries. The 91,080 plans include Catastrophic, Bronze, Silver, Gold, and Platinum plans; they do not include Cost-Sharing Reduction plans, as those plans would duplicate the formulary data for Silver plans, skewing the analysis. Catastrophic (5,439) and Platinum (2,023) plans are only included in the analyses of STR and PrEP formulary coverage, specialty tiering, and utilization management, and they are not included in any analyses of cost-sharing or co-insurance except for the assessment of co-insurance frequency and utilization management by drug list price. These plans constitute less than nine percent (9%) of all plans included in the analyses. All Cost-Sharing Reduction plans were assessed separately. There were 35,693 Silver plans (27,210 with valid data), with three separate Cost-Sharing Reduction plan options for each.

To determine cost-sharing information, NASTAD crosslinked the formulary data to the plan attributes data available in the healthcare.gov 2016 QHP Landscape Data. NASTAD matched plans based on state, metal level, issuer, plan name, and plan ID. In the formulary data files, some plans included more than four tiers for their drugs; however, the QHP Landscape Data only provide information on four tiers (Generic, Preferred Brand, Non-Preferred Brand, and Specialty). NASTAD created a cross-walk to match all tier names reported in the formulary data to the Public Use File tiers, making an individualized assessment based on the reported tier names in the formulary data. Average co-insurance costs are based on each drug's Wholesale Acquisition Cost, which may result in a higher price than discounts negotiated from plans and pharmacies. Step therapy and prior authorization data were obtained through the formulary data files. Drugs approved since 2013 include Tivicay (November 2013), Triumeq (August 20/14), Vitekta (September 2014), Tybost (September 2014), Prezcobix (January 2015), and Evotaz (January 2015).

Relationships between Wholesale Acquisition Cost and frequency of co-insurance, step therapy, and prior authorization by drug were assessed using linear regression. P-values for the analyses: co-insurance ($p=3.01E-21$), step therapy ($p=0.62$), and prior authorization ($p=0.27$). Only the association between Wholesale Acquisition Cost and frequency of co-insurance is statistically significant.

Several important limitations are present, due to the datasets available. Data submitted by plans to CMS reflected formularies established prior to November 1, 2015, and may not reflect current formulary coverage. Plans that uploaded multiple versions of their formulary may have resulted in incorrect tier assignment based on conflicting data; plans with more than four tiers were condensed into four tiers to match the plan attributes available in the QHP Landscape Data.

Acknowledgments

This report was developed by the National Alliance of State & Territorial AIDS Directors (NASTAD). NASTAD represents the chief state health agency staff who have programmatic responsibility for administering HIV/AIDS and hepatitis health care, prevention, education and support service programs funded by state and federal governments.

Sean Dickson is the chief author of this report. Clear Health Analytics provided the data used for this report. Special thanks to the contributing editors, Murray Penner, Terrance Moore, Ann Lefert, Amy Killelea, and Britten Pund.

Murray C. Penner, Executive Director
DeAnn Gruber, Louisiana, Chair
July 2016