Analysis of real-world prescription drug "walk-away" rates for HIV prevention therapy

A study of the impact of formulary restrictions on "walk-away" rates for commercially insured patients prescribed HIV PrEP

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Pre-exposure prophylaxis (PrEP), a highly effective HIV prevention therapy, has been recommended by the U.S. Preventive Services Task Force (USPSTF)[1] for people at high risk of contracting HIV. New therapies have expanded options for patients and providers. However, recently implemented formulary restrictions may have impacted patient access. Our analysis of real-world patients prescribed with PrEP suggests a recent increase in scripts abandoned or rejected without PrEP substitution ("walked away").

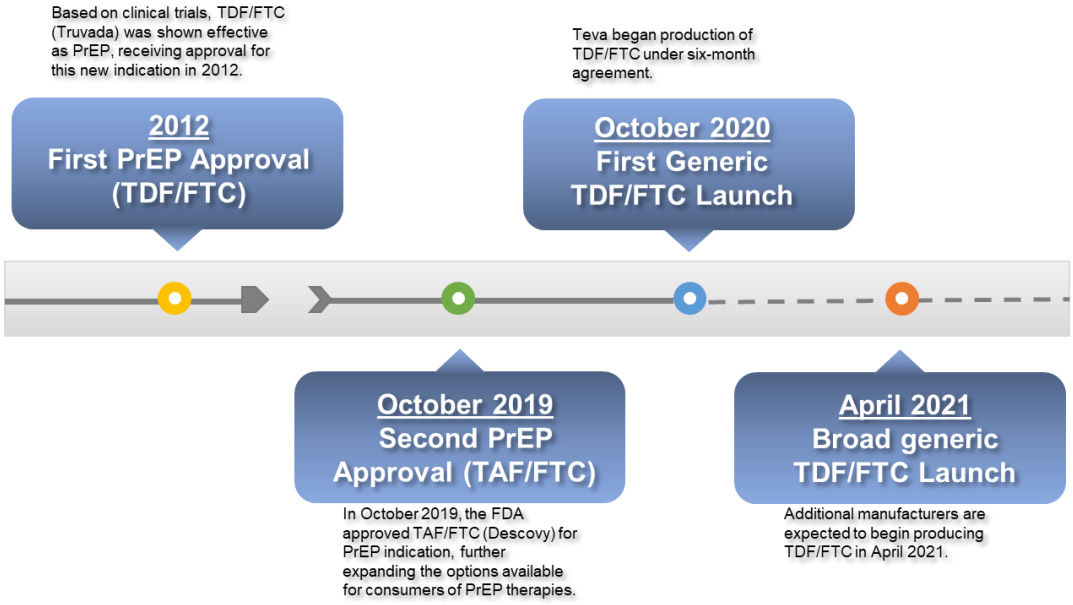
The PrEP therapy landscape

The HIV prevention medication PrEP is currently available as either of two once-daily formulations: tenofovir disoproxil fumarate with emtricitabine (TDF/FTC)—best known in the United States by the brand name Truvada—and a newer formula, tenofovir alafenamide with emtricitabine (TAF/FTC), known as Descovy.

TDF/FTC received approval from the U.S. Food and Drug Administration (FDA) to treat HIV infection in 2004 and was subsequently approved for PrEP in 2012. In October 2019, the FDA approved TAF/FTC as the second brand available for PrEP indication, further expanding the options for patients at high risk of contracting HIV. The patent for TDF/FTC was originally set to expire in September 2021, but Teva Pharmaceuticals agreed to produce the generic in the United States a year ahead of schedule, with a six-month exclusivity period beginning October 2, 2020. Other generic manufacturers are expected to follow in April 2021. Figure 1 shows a timeline of events.

[1] USPSTF (June 11, 2019). Prevention of HIV Infection: Preexposure Prophylaxis. Final Recommendation Statement. Retrieved February 2, 2021, from https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#bootstrap-panel%E2%80%945.

FIGURE 1: HIV PREVENTION THERAPY DEVELOPMENT



Consistent with the Centers for Disease Control and Prevention (CDC) recommendations,[2] patients taking PrEP require healthcare provider visits at least once every three months, including sexually transmitted infection (STI) tests, other lab work, and prescription refills. Some insurance carriers have implemented formulary restrictions for PrEP, such as quantity limits and prior authorizations which require physicians to seek approval prior to dispensing.

Changes in PrEP prescriptions dispensed in 2020

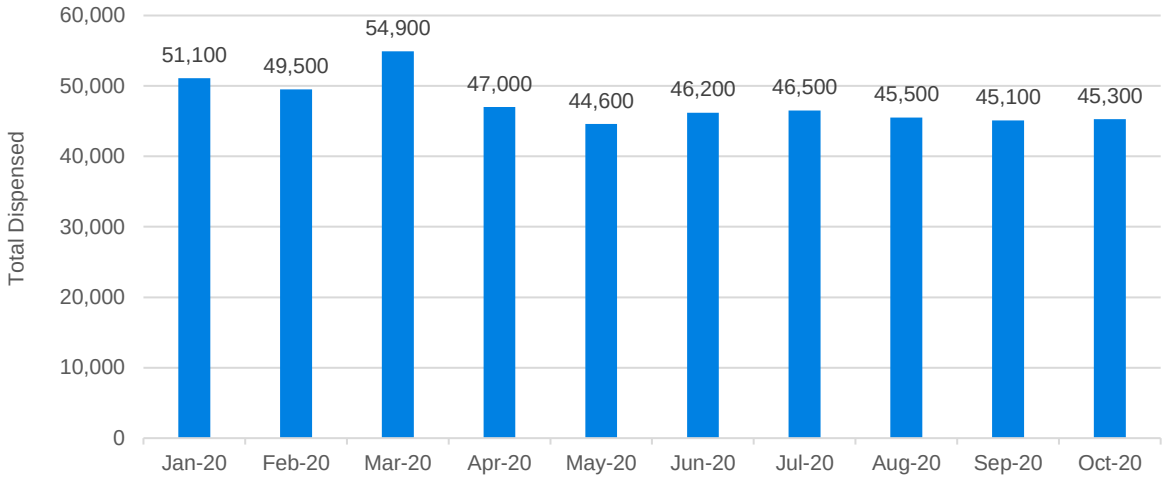
Gilead Sciences engaged Milliman to estimate the impact of insurance carrier formulary restrictions implemented by two of the largest national health insurance payers on prescription drug dispensed for HIV-PrEP therapy. To that end, we analyzed a large data set of prescription drugs dispensed nationwide from January 2020 to October 2020. We measured the rates of PrEP abandonment without substitution, often called "walk-away" rates, calculated as the rate at which prescriptions were either rejected (by the insurer) without an alternative therapy within eight weeks, or the prescription was approved but never collected from the pharmacy by the patient. We focused this analysis on patients new to PrEP therapy ("naïve" patients) and those switching PrEP therapies (from TDF/FTC to TAF/FTC or vice versa). We reviewed data from before the COVID-19 pandemic to observe the impact of the social distancing measures on PrEP use. We also compared national and carrier-specific rates of abandonment without substitution to identify differences between carriers that implemented formulary restrictions and those that did not. Figure 2 shows monthly PrEP prescriptions dispensed from January through October 2020.

[2] CDC. How can I start PrEP? Retrieved February 2, 2021, from https://www.cdc.gov/hiv/basics/prep/starting-stopping-prep.html.

THE IMPACT OF COVID-19 ON PREP USE

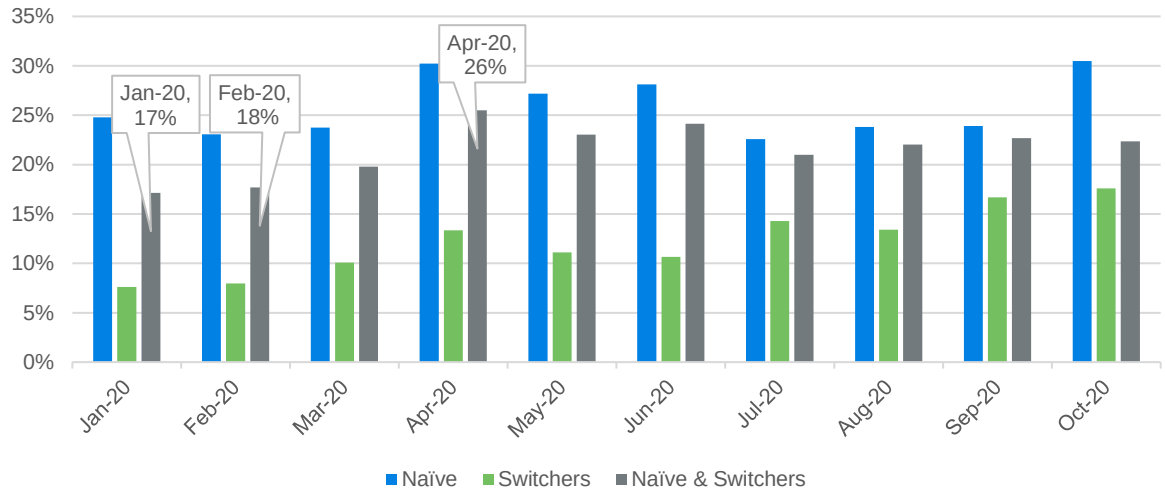
Nationwide, we observed modest reductions in patient fills for HIV PrEP therapies in 2020, potentially due to COVID-19 social distancing and physician availability.

FIGURE 2: PRESCRIPTIONS DISPENSED FOR HIV PREVENTION THERAPY: COMMERCIAL MARKET (NATIONWIDE)



However, naïve patients and those switching PrEP medications experienced a particularly large jump in the rate of abandonment without substitution during April and May 2020. Figure 3 shows that naïve and switching commercial patients seeking PrEP abandoned their prescription without substitution 17% to 18% of the time in January and February 2020, but this rate jumped to 26% at the height of the COVID-19 pandemic.

FIGURE 3: "WALK-AWAY" RATE FOR NAÏVE AND SWITCHING PATIENTS SEEKING HIV PREVENTION THERAPY: COMMERCIAL MARKET (NATIONWIDE)



PREP COVERAGE RESTRICTIONS IN THE COMMERCIAL MARKET

One of the largest national commercial carriers ("Carrier 1") added a new formulary restriction for TAF/FTC in *May 2020*, requiring more rigorous documentation by physicians submitting each request for a new TAF/FTC PrEP prescription. A second large insurance company ("Carrier 2") implemented similar formulary restrictions for TAF/FTC in *September 2020*.

Figure 4 compares national rates for abandonment of TAF/FTC without substitution for naïve and switcher patients to those experienced by members of these two national carriers in 2020, before and after formulary restrictions. We observe that the COVID-19 pandemic appears to have impacted rates of abandonment without substitution in March and April 2020: nationwide, the rate for TAF/FTC jumped from 13% in February to 23% in April 2020, in line with the rate for all PrEP therapies (18% to 26%). In addition, our analysis suggests that rates of abandonment without substitution further spiked after formulary restrictions were added: Carrier 1 and Carrier 2 experienced rates of 39% and 31% immediately after adding formulary restrictions, respectively, up from 24% in the month prior to the new restrictions.

FIGURE 4: CHANGE IN COMMERCIAL NAÏVE AND SWITCHER "WALK-AWAY" RATE FOR TAF/FTC IN 2020

CARRIER	JANUARY	FEBRURARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER
National*	12%	13%	15%	23%	18%	*15%*	*17%*	*16%*	20%	*19%*
Carrier 1	15%	20%	20%	24%	***39%***	*34%*	*26%*	*28%*	*27%*	*25%*
Carrier 2	14%	19%	18%	19%	17%	22%	22%	24%	***31%***	31%

* National values exclude Carrier 1 and Carrier 2 "walk-away" rates once access restrictions took place for these carriers. This is May 2020 for Carrier 1 and September 2020 for Carrier 2.

Figure 5 displays the initial proportions of PrEP prescriptions, either TAF or TDF, requested in April 2020, and the proportion of prescriptions approved and dispensed, substituted with an alternative therapy and dispensed, or abandoned without substitution within eight weeks for commercial patients covered by Carrier 1. This serves as a point of comparison to May 2020, after the effective date of the carrier's new formulary restrictions. In May 2020, rates of abandonment without substitution for patients requesting TAF/FTC and all PrEP therapies increased by 16 percentage points and two percentage points, respectively. By comparison, Carrier 2, which did not implement restrictions until later in the year, observed a decrease in the rate of abandonment without substitution in May 2020, consistent with national average trends.

FIGURE 5: CHANGE IN COMMERCIAL DISPENSED SCRIPTS FOR NAÏVE AND SWITCHER PATIENTS BEFORE AND AFTER FORMULARY RESTRICTIONS MAY 2020, CARRIER 1

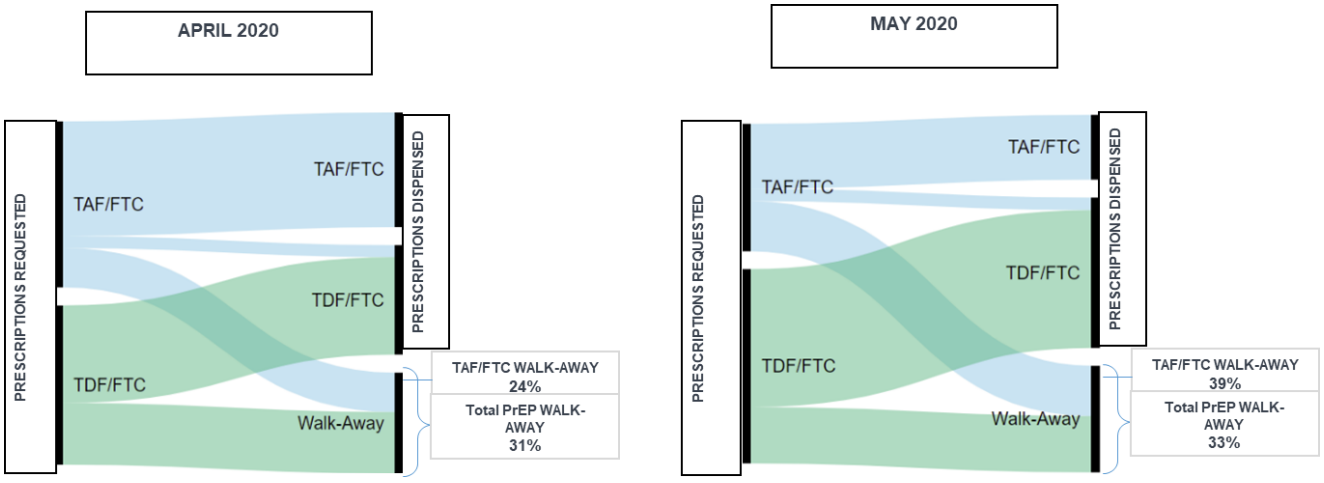
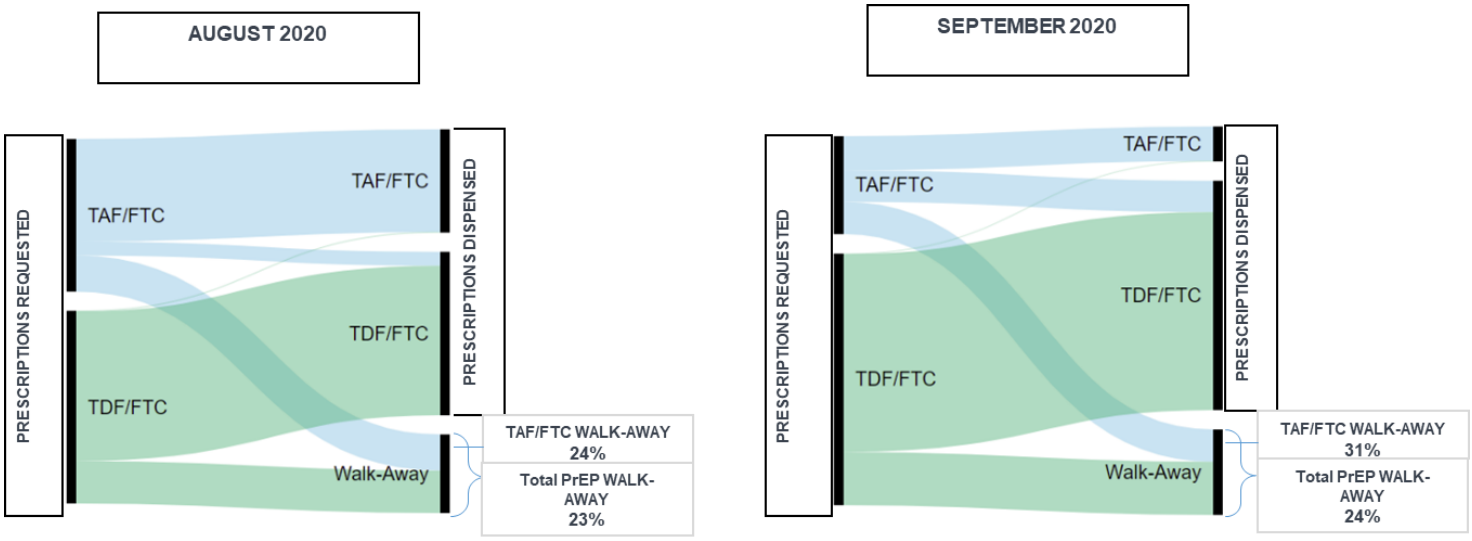


Figure 6 displays the initial proportions of PrEP prescriptions, either TAF or TDF, requested in August 2020, and the proportions of prescriptions approved and dispensed, substituted and dispensed, or abandoned without substitution for commercial patients covered by Carrier 2. In September 2020, after new restrictions were implemented, rates of abandonment without substitution for TAF/FTC patients increased by seven percentage points, or one percentage point increase across all of the carrier's commercial PrEP patients. By comparison, Carrier 1, which added those formulary restrictions earlier in the year, observed a decrease in the rate of abandonment without substitution in September 2020.

FIGURE 6: CHANGE IN COMMERCIAL DISPENSED SCRIPTS FOR NAÏVE AND SWITCHER PATIENTS BEFORE AND AFTER FORMULARY RESTRICTIONS SEPTEMBER 2020, CARRIER 2



Considerations

In its June 2019[3] memo, the USPSTF recommended coverage of PrEP as a preventive service (Category A), mandating coverage of PrEP drugs in the commercial market with no patient cost sharing as of *January 2021*. After this time, patients enrolled in the commercial health plans governed by the USPSTF rules will not pay for specified preventive prescriptions.

Formulary restrictions appear to have had an impact on rates of abandonment of PrEP therapies for naïve and switching patients. At this time, it is too early to tell whether rates for the two carriers analyzed will return to historical levels or settle at levels higher (or lower) than historical levels, and the long-term effects of these changes are unknown.

Data, methodology, and limitations

DATA SOURCES

We used the Symphony Source Healthcare Analytics (SHA) commercial claims database of HIV PrEP prescriptions through December 18, 2020. Our analysis captured only those prescriptions that offered the full "life cycle" data, with a look-forward period of 56 days. The data was not audited but was reviewed for reasonableness.

METHODOLOGY

We limited SHA claims data to HIV PrEP claims between January 2020 and December 2020 in the commercial market. We further limited the data to claims with an eight-week follow-up period to determine the ultimate outcome of the claim. The database contains claims that have been dispensed, rejected, and abandoned. The rejected claims were further divided into

[3] USPSTF Bulletin (June 11, 2019). U.S. Preventive Services Task Force Issues Final Recommendation Statements on HIV Screening and HIV Prevention. Retrieved February 2, 2021, from https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/hiv-screening-prep-final-rec-news-bulletin.pdf.

two separate categories, rejected with and without replacement, depending on whether the patient was dispensed any HIV PrEP product within eight weeks of the claim rejection. The "walk-away rate" is the sum of claims rejected without replacement and abandoned, divided by all PrEP claims submitted. We refer to this as "abandoned without replacement" throughout.

LIMITATIONS

This report was prepared for Gilead Sciences, Inc., a life sciences company that manufacturers PrEP therapies. Our findings are based on an analysis of commercially insured individuals who submitted a prescription for PrEP therapy. Results from this analysis may not be applicable to other therapeutic areas or markets. Our data does not capture individuals who did not submit their prescriptions.

The results presented herein are estimates based on the best information available as of the date of publication. Differences between our results and other analyses may arise due to variations in definitions, methodology, or data updates. At the time of this study, information was not available to investigate the impact of the increased rates of abandonment of PrEP therapies on HIV transmission rates.

Following national implementation, the coverage restrictions by the studied carriers were reversed by the state of California, with the state indicating prior authorization or step therapies could not be required for PrEP. Complete data was not available at the time of publication to assess state-level HIV PrEP prescription outcomes after this reversal.

This report represents the opinion of the authors and is not representative of the views of Milliman. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

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