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Evaluating Medication Adherence Rates Of Long-Acting Injectable (LAI) Cabotegravir Versus Daily Oral Therapies For Pre-Exposure Prophylaxis (PrEP) Of Human Immunodeficiency Virus (HIV) In A Medicaid Population

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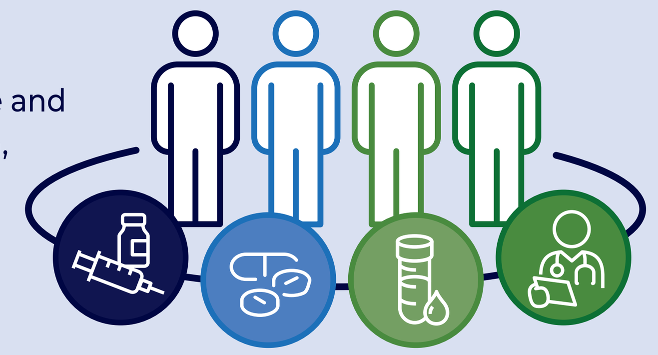
INTRODUCTION

- According to the Centers for Disease Control and Prevention (CDC), approximately 36% of the U.S. population eligible for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus (HIV) reported receiving therapy in 2022, an increase from 23% in 2019.[1]
- The Food and Drug Administration (FDA) approved emtricitabine/tenofovir disoproxil (FTC/TDF; Truvada®) as the first, daily oral medication for HIV PrEP in 2012, followed by emtricitabine/tenofovir alafenamide fumarate (FTC/TAF; Descovy®) in 2019.[2,3]
- The first long-acting injectable (LAI) therapy for HIV PrEP, cabotegravir (Apretude®), was FDA-approved in December 2021. The CDC recommends LAI therapy for patients with known or potential adherence issues, or those who prefer less frequent dosing.[4,5]
- It is currently unknown whether LAI HIV PrEP therapy is associated with higher medication adherence or persistence compared to daily oral options within a Medicaid population.

OBJECTIVE

To compare HIV PrEP medication adherence and persistence, incidence of HIV seroconversion, and HIV PrEP-related healthcare utilization and costs among Medicaid members receiving LAI cabotegravir to those receiving FTC/TAF or FTC/TDF.



METHODS

- This retrospective, claims-based, matched cohort analysis included members ≥18 years of age newly initiated on HIV PrEP therapy between August 1, 2023 and July 31, 2024.
  - Members were required to have ≥1 cabotegravir claim(s) or ≥30 total day supply of oral PrEP therapy during the study period
  - Members were divided into two mutually exclusive groups based on the HIV PrEP formulation utilized
  - Members in the daily oral PrEP group were matched 2:1 to members in the cabotegravir group based on age and sex
  - Claims data was evaluated for one-year post-treatment initiation, or until HIV seroconversion, whichever occurred first
- **Exclusion Criteria:**
  - Members with a ≥30-day gap in MassHealth coverage
  - Members with third-party liability (TPL) coverage
  - Members with an HIV diagnosis within six months prior to the enrollment period based on International Classification of Diseases, 10th revision (ICD-10) codes in medical claims or paid pharmacy claims for HIV antiretroviral medications
  - Members with HIV PrEP medication use within six months prior to their index date
  - Members with paid claims for both cabotegravir and oral PrEP during their evaluation period
- **Analysis:**
  - Statistical comparisons between groups were assessed using Mann-Whitney U tests for continuous and discrete variables, and chi-square tests for categorical variables
- **Primary Outcome:**
  - Adherence to HIV PrEP therapy was calculated using proportion of days covered (PDC)
- **Secondary Outcomes:**
  - Persistence to HIV PrEP therapy was defined as the time from initiation to the first treatment gap >60 days after accounting for day supply
  - Incidence of HIV seroconversion identified by ICD-10 codes from medical claims or paid pharmacy claims for HIV antiretrovirals
  - Number of claims for select HIV PrEP-related medical services including lab monitoring, office visits, sexually transmitted infection (STI) screenings and their associated costs, as well as gross costs for paid medication claims

RESULTS

Table 1. Baseline Demographics

Characteristics	Cabotegravir (N=29)	Oral PrEP (N=58)	Overall (N=87)
Age, years (±SD)	34 (±12)	34 (±12)	34 (±12)
Male, n (%)	18 (62%)	36 (62%)	54 (62%)

SD=standard deviation

Figure 1. Study Cohort

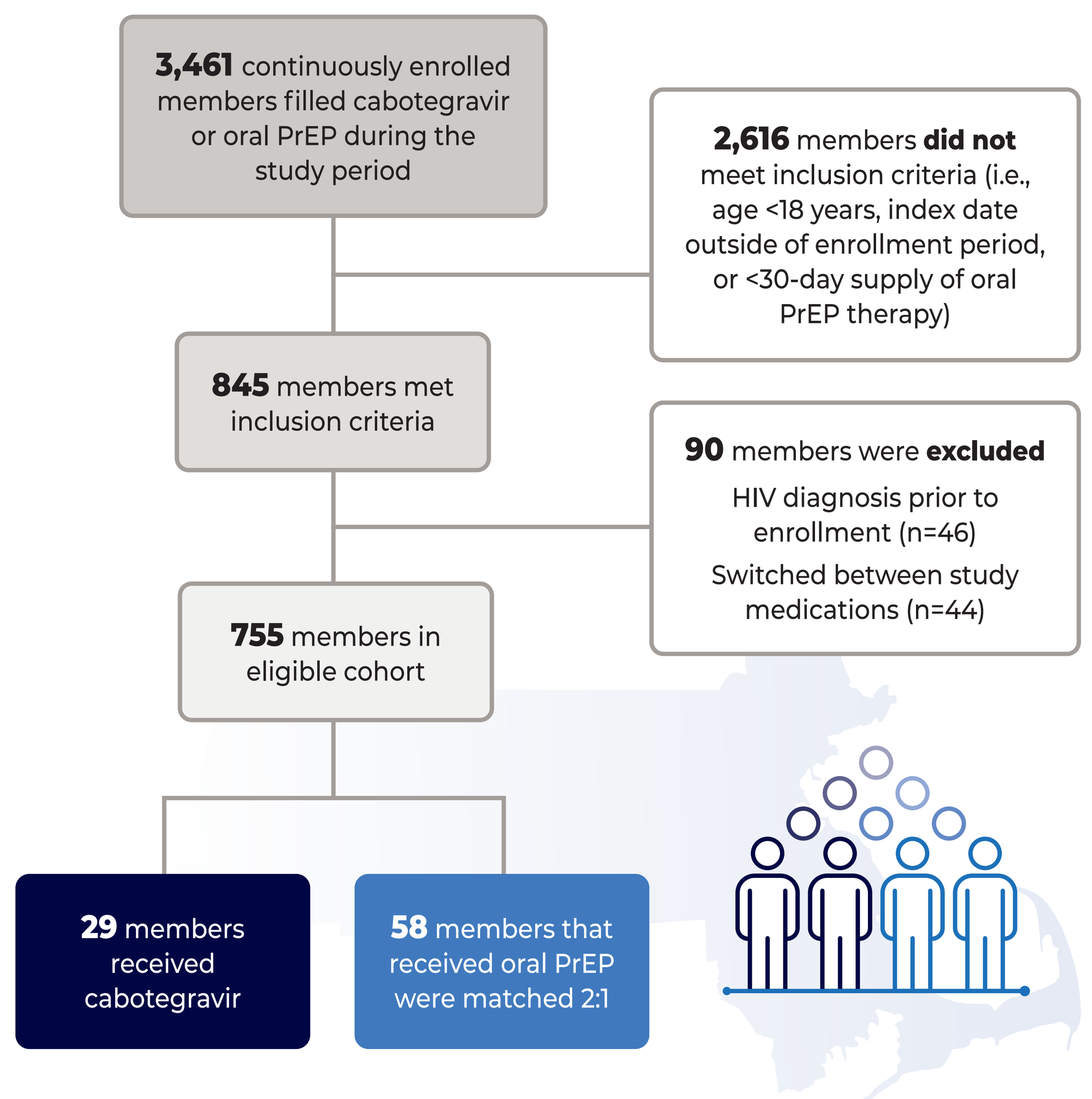


Table 2. Treatment Adherence and Incidence of HIV Seroconversion

Outcome	Cabotegravir (N=29)	Oral PrEP (N=58)	Overall (N=87)	P-value
Median PDC (IQR)	0.65 (0.08-0.92)	0.24 (0.08-0.57)	0.25 (0.08-0.78)	0.280
PDC stratified by adherence level, n (%)				
PDC≥0.8	11 (38)	11 (19)	22 (25)	0.055
PDC<0.8	18 (62)	47 (81)	65 (75)	
Median PDC stratified by sex				
Male (n=54)	0.73	0.25	0.40	0.090
Female (n=33)	0.08	0.16	0.16	0.593
P-value	0.014	0.069	0.003	
HIV Seroconversion, n*	<11	<11	<11	NC

IQR=interquartile range, NC=not calculable
* Results that indicate a numeric value <11 have been masked to protect confidentiality.

Figure 2. Persistence to HIV PrEP Therapy

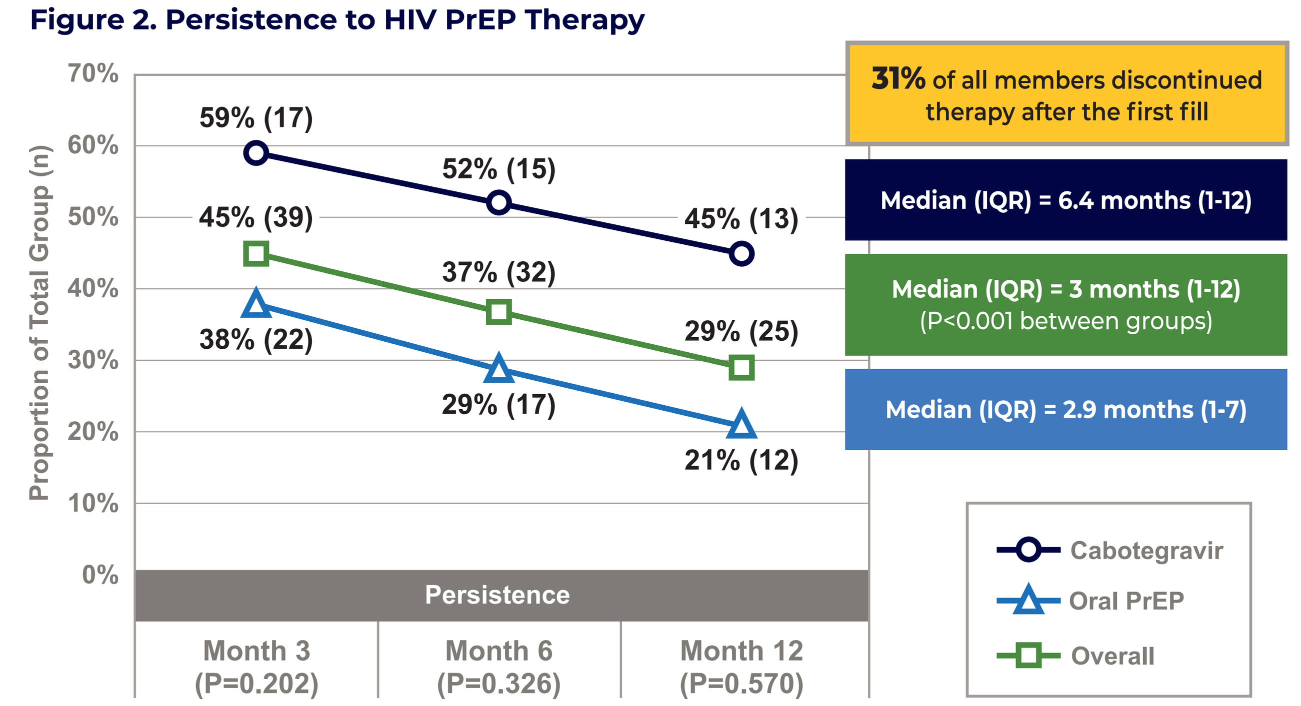


Figure 3. Median Number of Medical Services Per Member in HIV PrEP Users

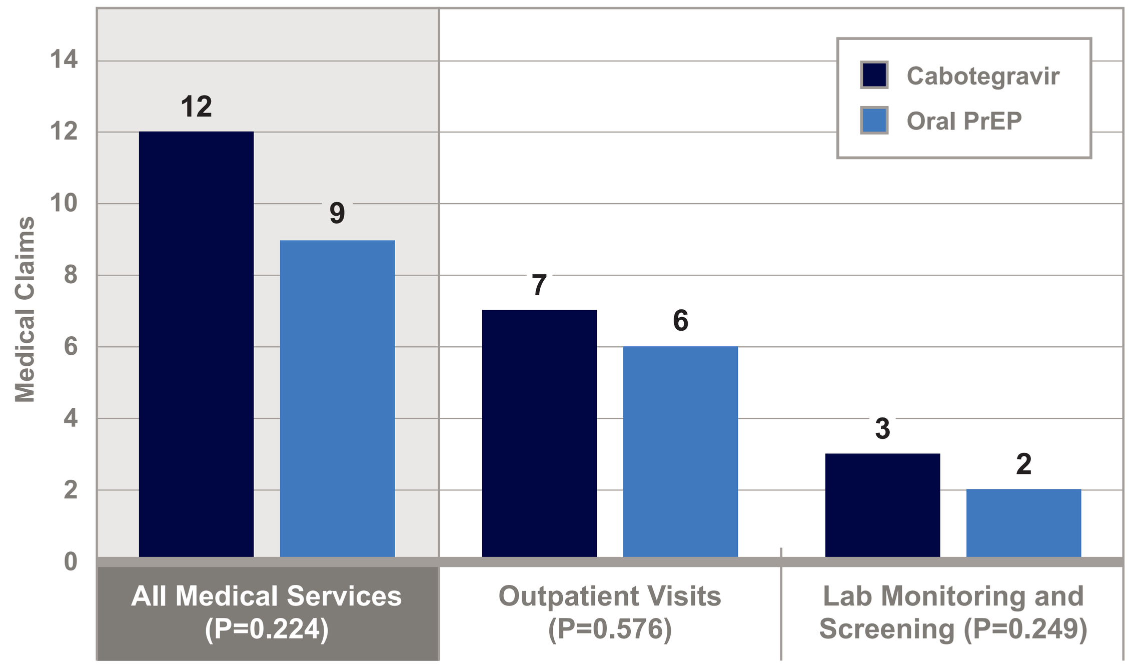
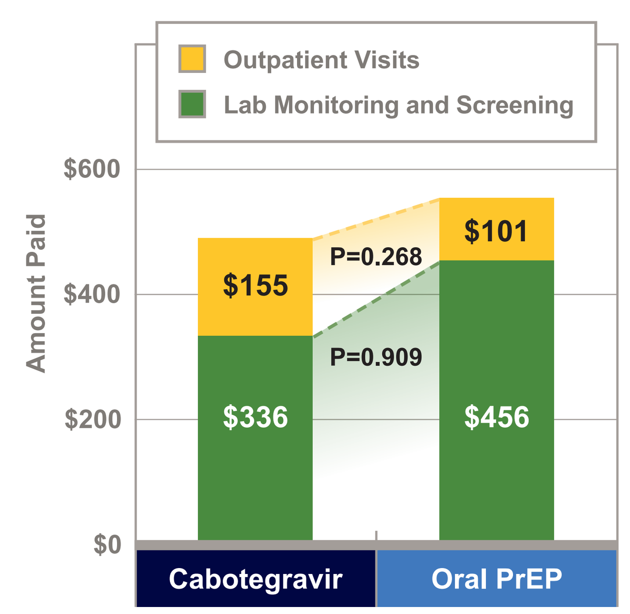
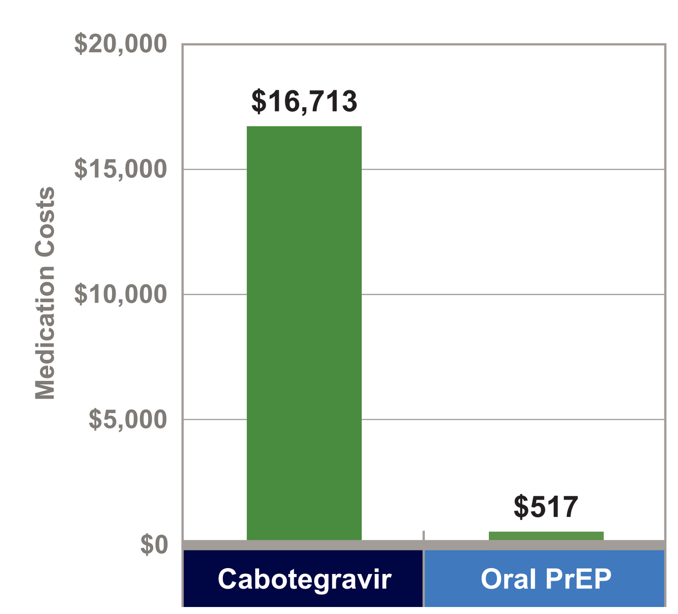


Figure 4. Median Amount Paid Per Member for Medical Services in HIV PrEP Users



Note: Outpatient visits included encounters related to counseling for HIV PrEP, medication administration, and general well patient visits. Lab monitoring claims included kidney function tests and lipid panels. Screening claims included diagnostic tests for HIV, STIs (i.e., syphilis, gonorrhea, chlamydia), and hepatitis B and C.

Figure 5. Median Total Medication Costs Per Member for HIV PrEP Therapy



Note: No paid claims for oral cabotegravir were observed and LAI cabotegravir was primarily reimbursed through the pharmacy benefit.

DISCUSSION

- Due to the presence of outliers and positive skewness in the dataset, the median values were reported instead of the mean for applicable outcomes to provide a more accurate estimate of central tendency.
- The overall median PDC with HIV PrEP therapy was 25% (Table 2), which could be influenced by patterns of use tied to an individual's perceived risk or other access barriers, such as distance to care.
- Proportionally, twice as many cabotegravir users were likely to have a PDC≥0.8 compared to the oral PrEP group (38% vs 19%; Table 2). Although not statistically significant, these results suggest that a longer acting formulation may lead to improved adherence.
- The incidence of HIV seroconversion was low despite poor adherence to PrEP therapy (Table 2), potentially indicating the use of risk-based dosing approaches or other risk management strategies.
- While the median persistence was 6.4 months vs 2.9 months for cabotegravir and oral PrEP, respectively, the majority of members who were persistent on therapy at month three remained persistent at month 12 in both groups (Figure 2).
- Approximately a third of individuals appeared to discontinue HIV PrEP therapy after the first fill (Figure 2). It is unknown if members used a risk-based dosing strategy in the oral PrEP group rather than the recommended daily dosing.
- The overall number of claims for medical services was numerically higher in the cabotegravir group. This may be influenced by the required administration of cabotegravir by a healthcare provider resulting in more frequent outpatient visits and screenings (Figure 3).
- There were no major differences observed between groups in amount paid for medical services (Figure 4). However, cabotegravir use was associated with a higher median total medication cost per member compared to oral PrEP use ($16,713 vs $517; Figure 5).

LIMITATIONS

- Oral PrEP may be prescribed, or taken off-label, as an intermittent or event-driven dose in patients who prefer non-daily dosing, have infrequent sexual intercourse, or are able to anticipate sexual encounters. This may have led to underreported persistence.
- Pharmacy costs may be underreported as medications may have been reimbursed at the 340B acquisition cost.
- All-cause medical claims were identified based on pre-specified Current Procedural Terminology (CPT) codes which may not be exclusive to and inclusive of all healthcare utilization associated with PrEP therapy and monitoring.

CONCLUSIONS

- Long-acting HIV PrEP therapy was associated with numerically higher adherence rates and significantly increased persistence compared to daily oral options in this Medicaid population, which supports use in alignment with CDC recommendations.
- Payers should consider clinical strategies that promote increased uptake of HIV PrEP among individuals who are likely to benefit from its use, as well as outreach programs focused on improving adherence and persistence.

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DISCLOSURES/ACKNOWLEDGMENTS

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