

Changes in Pre-Exposure Prophylaxis Cost Sharing and HIV-1 Diagnoses Following United States Preventive Services Task Force and Affordable Care Act Coverage Milestones: An Interrupted Time Series Analysis

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Conclusions

- US Preventive Services Task Force (USPSTF) and Affordable Care Act (ACA) policy milestones were incrementally associated with an increased proportion of claims with zero cost-sharing for HIV-1 pre-exposure prophylaxis (PrEP) and PrEP-related ancillary services
 - The largest gains followed implementation of the ACA zero cost-sharing requirement in 2020
 - Further sharp gains for PrEP followed the publication of federal guidance in 2024 prohibiting medical management for PrEP formulations
- These sharp gains in the monthly proportion of zero cost claims coincided with increases in PrEP uptake and decreases in new HIV-1 diagnoses
- Despite these gains, cost-sharing continues to be observed for many PrEP medications and ancillary services, although relatively few PrEP users were included in the ancillary services cohort
- These gaps highlight the need for more consistent implementation and enforcement of ACA coverage requirements

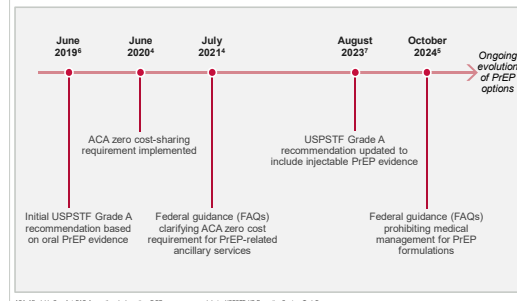
Plain Language Summary

- HIV-1 PrEP is a medicine that helps prevent HIV-1. In 2019, an independent group of US health experts strongly recommended PrEP for individuals who want or need PrEP. Based on this recommendation, the government introduced a requirement in 2020 for health insurance plans to cover PrEP with no out-of-pocket costs (costs that people have to pay themselves)
- Researchers reviewed health insurance records from US adults who used PrEP between 2019 and 2025. They looked at the percentage of claims for PrEP medicines and related care that no out-of-pocket costs before and after five health policy updates
- Over time, more people started using PrEP, and a greater percentage of PrEP claims had no out-of-pocket costs. At the same time, fewer people were diagnosed with HIV-1
- The largest increases in PrEP claims with no out-of-pocket costs happened in 2020, when the requirement for health plans to cover PrEP without these costs took effect, and in 2024, when the US government clarified that health plans must cover recommended PrEP medicines and services without favouring one PrEP option over another
- Despite these changes, some people still had to pay some of the costs of PrEP medicines and related care themselves. Health plans need to more consistently provide PrEP with no out-of-pocket costs, alongside other efforts to reduce financial barriers, so that everyone who could benefit from PrEP can access it

Background

- HIV-1 PrEP is highly effective at preventing HIV-1 acquisition when taken as prescribed; however, financial barriers can limit access to PrEP^{1,2}
- The USPSTF is an independent panel of experts that reviews evidence on clinical preventive services³
- Under the ACA, most US health plans must provide full coverage, without cost sharing, for any service that receives a Grade A or B recommendation from the USPSTF^{4,5}
- The USPSTF issued a Grade A recommendation for PrEP in June 2019 and reaffirmed it in August 2023 after reviewing additional evidence, including evidence for injectable PrEP^{6,7} (Figure 1)
- Despite these policy changes, not everyone who wants or needs PrEP has access to it, and out-of-pocket costs continue to be reported because of inconsistent adoption of ACA/USPSTF coverage for PrEP^{8,9}

Figure 1. USPSTF and ACA Policy Milestones for PrEP



Objective

- To assess changes in the monthly proportion of claims with zero cost-sharing for PrEP medications and ancillary services, the PrEP-to-need Ratio (PnR), and new HIV-1 diagnoses across key USPSTF and ACA policy milestones between 2019 and 2025

Methods

- A retrospective, observational study was conducted using IQVIA de-identified US pharmacy and medical claims data (January 2019–December 2025)
- The study included individuals aged ≥18 years with ≥1 adjudicated prescription for a US Food and Drug Administration (FDA)-approved HIV-1 PrEP medication and excluded individuals diagnosed with or treated for HIV-1 or hepatitis B, or receiving HIV-1 post-exposure prophylaxis
- Assessed outcomes included the monthly proportion of claims for PrEP and ancillary services with zero cost-sharing, PnR, and new HIV-1 diagnoses
 - Ancillary services included testing for HIV-1, hepatitis, and sexually transmitted infections (STI), laboratory monitoring, and counseling
- Interrupted time series models estimated immediate changes in outcome levels and trends following five USPSTF and ACA policy milestones, accounting for secular trends and seasonality

Results

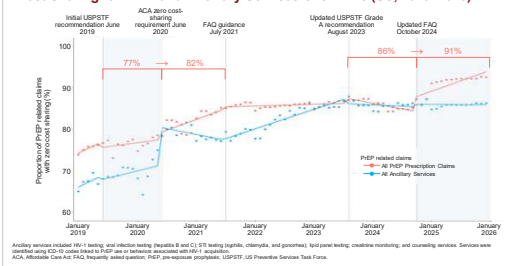
Overview of the Study Population

- The analysis included 853,411 HIV-1-negative individuals who contributed 9,736,043 PrEP prescription claims from 2019 and 2025
- Of these, 106,115 individuals were included in the ancillary service cohort, contributing 966,365 PrEP-related ancillary service claims

Zero Cost-Sharing of PrEP Prescriptions and Ancillary Services

- The proportion of claims with zero cost-sharing increased from June 2019–June 2020 to November 2024–December 2025 from 77% to 91% for PrEP and from 70% to 86% for ancillary services (Figure 2)
- The greatest increases in zero cost-sharing claims for PrEP and ancillary services followed the June 2020 milestone, with an additional sharp increase for PrEP claims following the October 2024 milestone

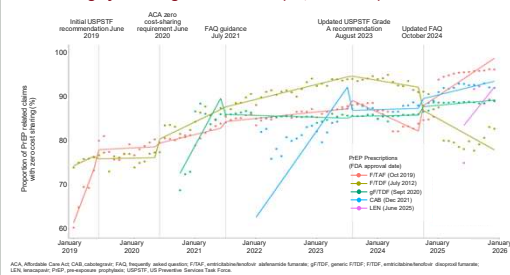
Figure 2. Impact of Successive USPSTF and ACA Coverage Milestones on Cost-Sharing for PrEP and Ancillary Services Over Time (US, 2019–2025)



Cost-Sharing by PrEP Regimen

- The monthly proportion of claims with zero cost-sharing increased for most PrEP regimens (Figure 3)
- Increases following the June 2020 and October 2024 milestones were driven, respectively, by claims for brand emtricitabine/tenofovir disoproxil fumarate (F/TDF) and emtricitabine/tenofovir alafenamide fumarate (F/TAF)
- Following the October 2024 milestone clarifying acceptable pharmacy management techniques, the monthly proportion of claims with zero cost-sharing increased for F/TAF, generic F/TDF, and CAB
- The monthly proportion of zero cost-sharing claims decreased for branded F/TDF, likely due to management techniques that favor generic options
- Lenacapavir was FDA-approved for PrEP after the latest 2024 guidance milestone

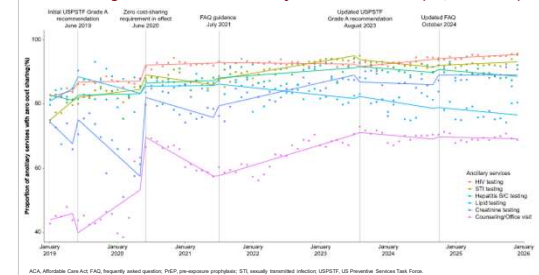
Figure 3. Impact of Successive USPSTF and ACA Coverage Milestones on Cost-Sharing by PrEP Regimen Over Time (US, 2019–2025)



Cost-Sharing by Ancillary Service

- The monthly proportion of zero cost-sharing claims generally increased over time for all PrEP-related ancillary services except lipid panels, which decreased (Figure 4)

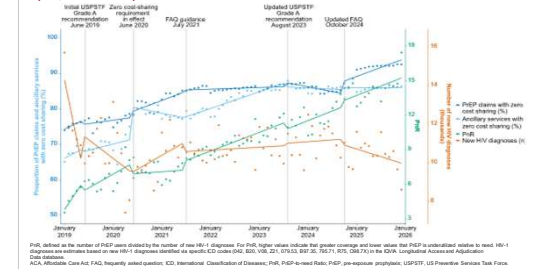
Figure 4. Impact of Successive USPSTF and ACA Coverage Milestones on Cost-Sharing for Different PrEP Ancillary Services Over Time (US, 2019–2025)



PnR and HIV-1 Diagnoses

- PnR increased steadily, indicating more PrEP users relative to new HIV-1 diagnoses among individuals with PrEP indications, while new HIV-1 diagnoses generally declined over time (Figure 5)
- Larger increases in PnR and decreases in HIV-1 diagnoses coincided with the sharp increases in the monthly proportion of PrEP claims with zero cost-sharing following the June 2020 and October 2024 milestones (Figure 5)

Figure 5. Impact of Successive USPSTF and ACA Coverage Milestones on PrEP and Ancillary Services Cost-Sharing, PnR, and New HIV-1 Diagnoses Over Time (US, 2019–2025)



Limitations

- Insurance benefits and ACA/USPSTF coverage eligibility could not be fully determined from claims data
- Claims do not confirm medication use or service completion
- Lenacapavir was introduced late in the study period, limiting evaluation of policy milestone effects
- This observational study cannot establish causal relationships between policy changes, PrEP uptake, and HIV-1 diagnoses

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Disclosures LT, JY, PM, JCC, AH and WZ are all employees and shareholders of Gilead Sciences, Inc.

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