

Real-World Impact of the United States Preventive Services Task Force (USPSTF) Guidelines on HIV-1 Pre-Exposure Prophylaxis Ancillary Service Cost Sharing: Segmented Change Pre- and Post-Milestone USPSTF Timepoints

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Conclusions

- This real-world analysis highlights increased adoption of the United States Preventive Services Task Force (USPSTF) guidelines as related to zero cost sharing for HIV-1 pre-exposure prophylaxis (PrEP) ancillary services between June 2019 and August 2023
- The proportion of zero cost-sharing claims increased for almost all PrEP-related ancillary services, except lipid panels which decreased
 - The proportions of zero cost-sharing claims in August 2023 were highest for sexually transmitted infection (STI) and hepatitis B/C testing, and lowest for lipid panels and counseling/office visits
 - The greatest increase in monthly zero cost sharing from June 2019 to August 2023 was for counseling visits
- However, full implementation of zero cost sharing remains incomplete, with regional and payor-based disparities
 - Individuals in the South had the lowest proportion of zero cost-sharing claims for all ancillary services compared with all other regions
 - Medicaid beneficiaries had a greater proportion of zero cost-sharing claims for all ancillary services versus commercial insurance and Medicare users
- To enhance access and uptake of PrEP, and thereby reduce HIV-1 acquisition and promote public health equity, insurers and regulators must work together to ensure full adherence with USPSTF guidelines across all healthcare plans

Plain Language Summary

- Medications called “PrEP” are used to lower the chances of getting HIV
- In 2019, the USPSTF (a group of experts tasked with helping prevent disease) recommended that healthcare providers should offer PrEP and services linked to PrEP to all people who have a greater chance of getting HIV
 - This is called a “Grade A” recommendation, meaning it is highly recommended
 - Related health services linked to PrEP include testing for HIV, STIs (like syphilis), hepatitis B and C, kidney function, and lipid panels (measurement of fats in the blood), and counseling visits
- Following this Grade A recommendation, the Affordable Care Act (ACA) requires that PrEP and services linked to PrEP are covered by insurance with no out-of-pocket expenses for the user (“zero cost sharing”)
- This study examined how the USPSTF guidelines affected zero cost sharing for PrEP services in the US between 2019 and 2023
- The results showed that the percentage of claims for PrEP services covered by insurance with zero cost sharing increased between 2019 and 2023
 - In August 2023, the highest percentage of claims with zero cost sharing were for STI and hepatitis B and C testing
- However, even with these guidelines in place, some PrEP services still had out-of-pocket expenses for users
- Ongoing efforts are needed in zero cost sharing with PrEP and related health services to stop the spread of HIV

Background

- PrEP is highly effective at preventing HIV-1 acquisition when taken as prescribed; however, financial barriers can limit access to PrEP^{1,2}
- In June 2019, the USPSTF guidelines gave oral PrEP a Grade A recommendation, indicating that PrEP provides a substantial net benefit in reducing the likelihood of HIV-1 acquisition³
 - In August 2023, the Grade A recommendation from the USPSTF was clarified and reaffirmed, this time also including injectable PrEP (cabotegravir)⁴
- Following this guidance, the ACA, which requires commercial insurance plans and Medicaid programs to cover preventative services with a Grade A or B USPSTF recommendation, mandated zero cost sharing for PrEP medications and PrEP-related ancillary healthcare services from June 2020⁵
 - The ACA exempts grandfathered plans from this requirement; in 2019, 22% of employers offering health benefits offered at least one grandfathered health plan, of which 13% of covered workers were enrolled⁶
 - Frequently Asked Questions (FAQ) guidance on the implementation of ACA requirements governing coverage of PrEP services was released in July 2021,⁵ with updated guidance released in October 2024 following the inclusion of cabotegravir in the USPSTF guidelines⁷
- However, the real-world impact of these guidelines in reducing cost-related barriers for ancillary services remains unclear

Objective

- To evaluate the real-world impact of USPSTF guidelines on zero cost-sharing trends for PrEP ancillary services before and after major USPSTF guideline milestones

Methods

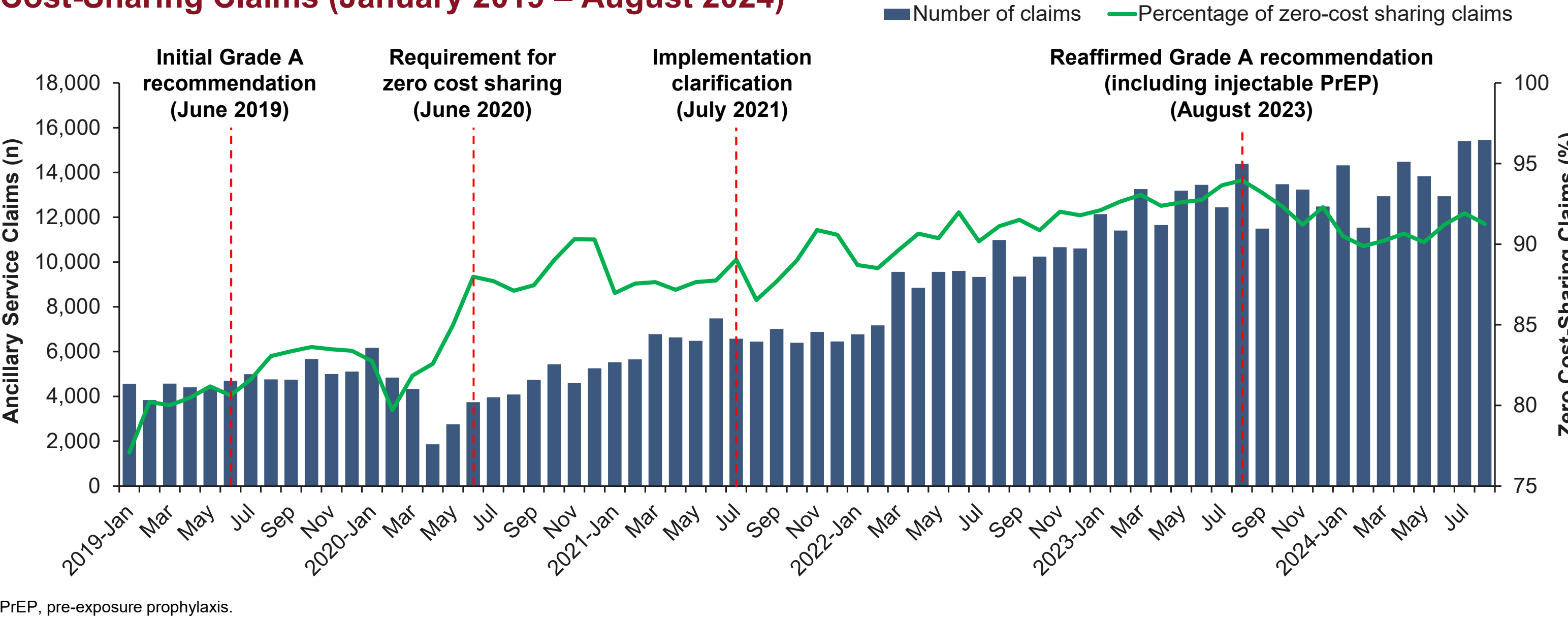
- Individuals with at least one PrEP prescription and claim for a PrEP-related ancillary service between January 2019 and August 2024 were identified from the IQVIA Longitudinal Access and Adjudication Dataset
 - PrEP ancillary services included HIV-1 testing, STI testing (syphilis, chlamydia, gonorrhea), hepatitis B/C testing, creatinine testing, lipid panels, and counseling/office visits
- USPSTF guideline adherence was assessed as the percentage of zero cost-sharing claims among PrEP ancillary services in the US between January 2019 and August 2024
- The monthly number of ancillary service claims was described and segmented regression in a time-series analysis was used to compare the percentage of zero cost-sharing claims at pre- and post-milestone USPSTF guideline timepoints:
 - Initial USPSTF Grade A recommendation for oral PrEP (June 2019)³
 - Zero cost-sharing coverage requirement per ACA guidance (June 2020)⁵
 - Implementation clarification on USPSTF and ACA guidelines (July 2021)⁵
 - This FAQ document provides clear and specific information to stakeholders for the purpose of assisting in the implementation of policies relating to preventative services⁵
 - Reaffirmed USPSTF Grade A recommendation, which includes injectable PrEP (August 2023)⁴

Results

Individuals With Zero Cost-Sharing Claims for All Ancillary Services

- In total, 64,866 individuals with 563,096 PrEP ancillary services in the US were included in the analysis
- The number of claims and percentage of zero cost-sharing claims increased over time, from 4695 (81%) in June 2019 to 14,382 (94%) in August 2023 (**Figure 1**)
 - As of August 2024, the number of claims and percentage of zero cost-sharing claims was 15,453 (91%)

Figure 1. Total Number of PrEP Ancillary Service Claims and Monthly Percentage of Zero Cost-Sharing Claims (January 2019 – August 2024)

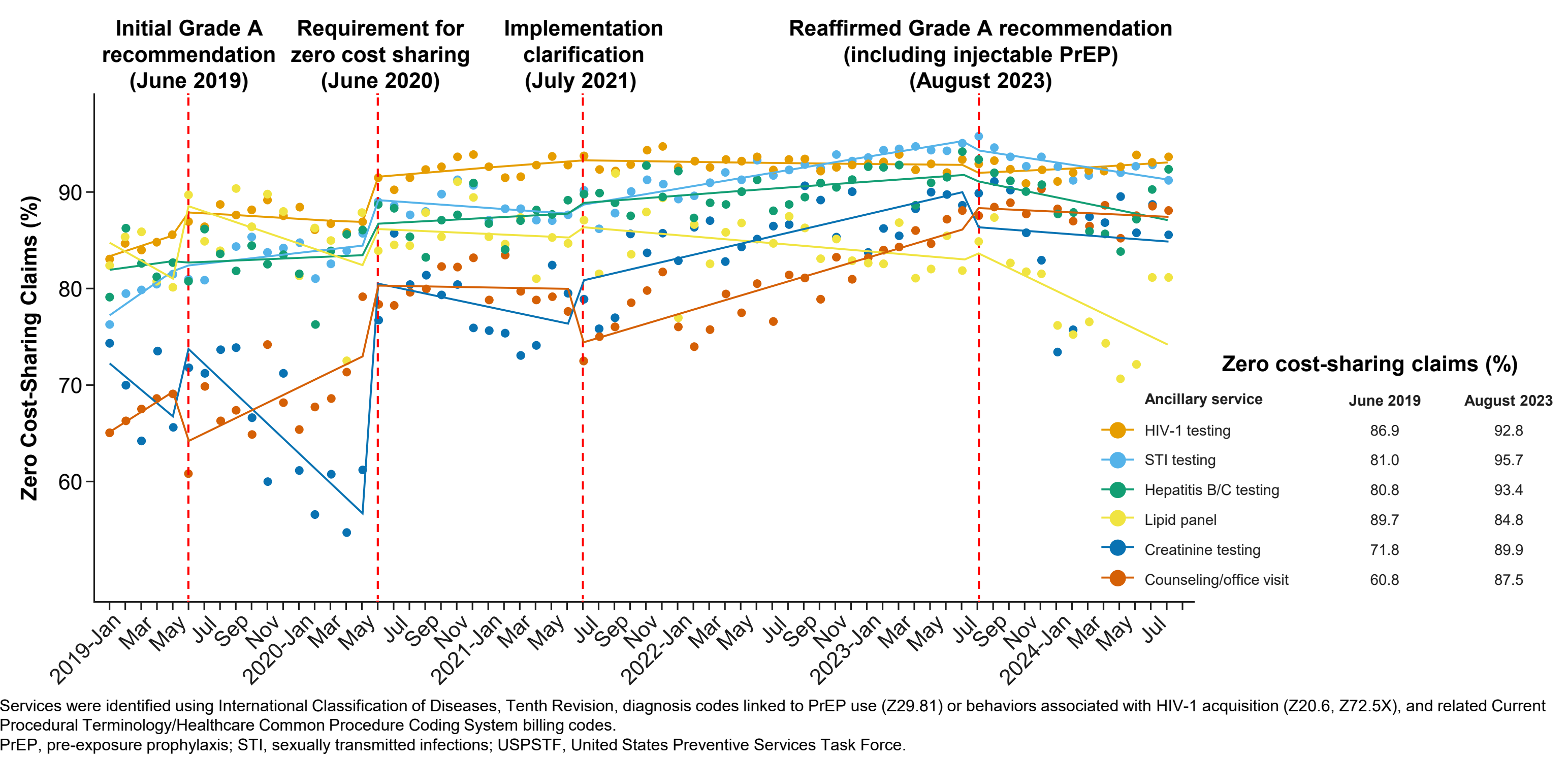


PrEP, pre-exposure prophylaxis.

Zero Cost-Sharing Claims for Six PrEP Ancillary Services

- Across USPSTF milestones, the highest percentages of zero cost-sharing claims were for HIV-1 testing (87%, June 2019; 93%, August 2023), STI testing (81%, June 2019; 96%, August 2023), and hepatitis B/C testing (81%, June 2019; 93%, August 2023) (**Figure 2**)
 - Greatest increases in monthly zero cost sharing between June 2019 and August 2023 were for creatinine testing (18%-point increase from June 2019 to August 2023) and counseling visits (27%-point increase) (**Figure 2**)
- The impact of the initial USPSTF Grade A recommendation on the percentage of zero cost-sharing claims appeared to be more marked for HIV-1 and STI testing (change in slope of -0.63 and -0.96 , respectively [June 2019–June 2020]) compared with other services (range: -0.25 to 0.35) (**Figure 2**)
 - The impact of the reaffirmed Grade A recommendations on the percentage of zero cost-sharing claims was generally consistent across STI testing, hepatitis B/C testing, lipid panel, creatinine testing, and counseling/office visits (change in slope: -0.53 , -0.46 , -0.64 , -0.50 , and -0.57 , respectively [August 2023–August 2024]), but smaller for HIV-1 testing (change in slope: 0.11)
- Complete adherence (100% zero cost sharing) was not observed, although monthly zero cost-sharing claims increased over time for all services except lipid panels, which decreased

Figure 2. Interrupted Time Series Analysis with Segmented Regression for Six PrEP Ancillary Services by USPSTF Guideline Milestones (January 2019 – August 2024)

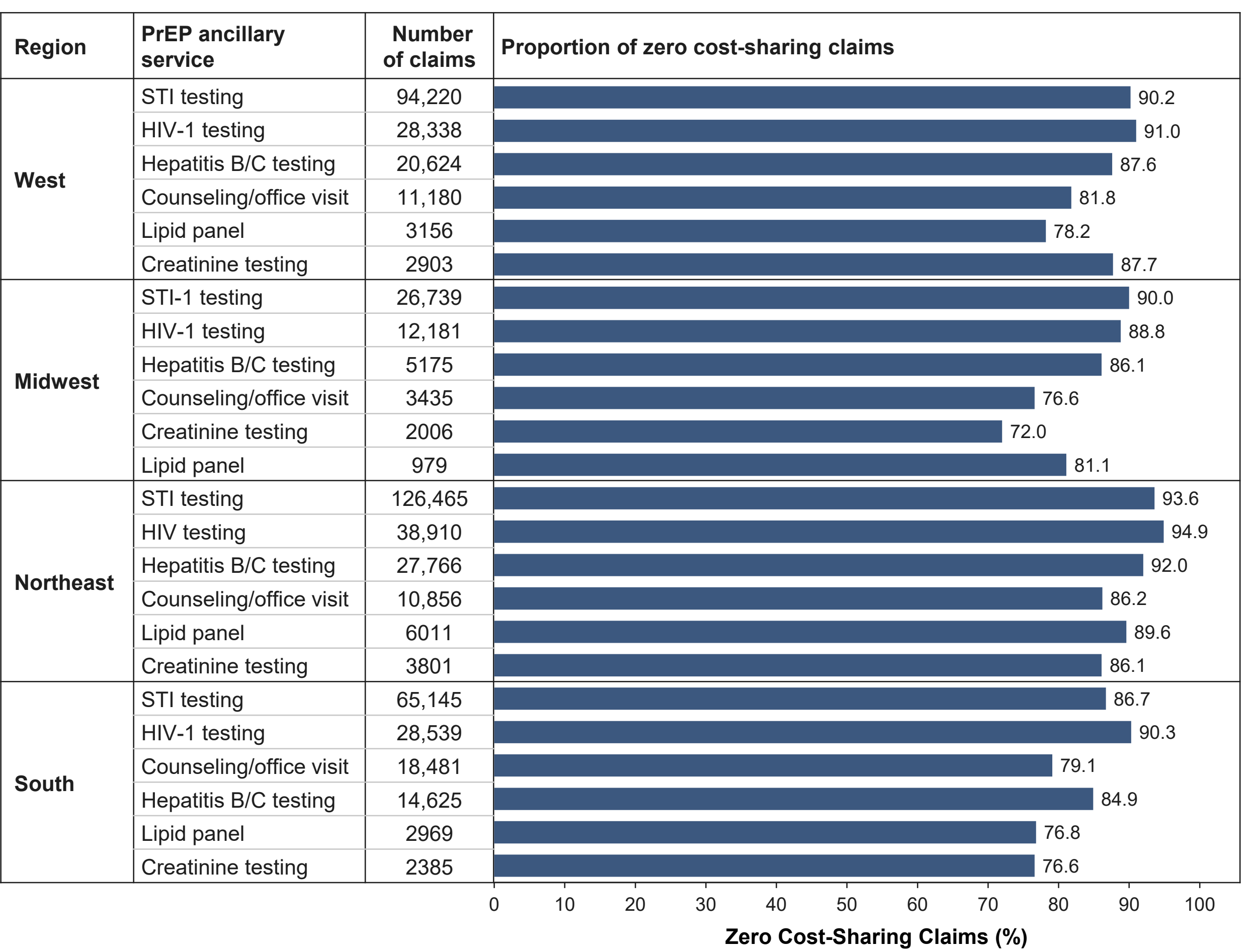


Services were identified using International Classification of Diseases, Tenth Revision, diagnosis codes linked to PrEP use (Z29.81) or behaviors associated with HIV-1 acquisition (Z20.6, Z22.5X), and related Current Procedural Terminology/Healthcare Common Procedure Coding System billing codes. PrEP, pre-exposure prophylaxis; STI, sexually transmitted infections; USPSTF, United States Preventive Services Task Force.

Differences in Zero Cost-Sharing Claims by Region and Payor Type

- Overall, individuals in the Northeast had 93% zero cost sharing for all services versus 86% for Southern states, 88% for Midwestern states, and 89% for Western states
 - Proportions of zero cost-sharing claims for HIV-1, STI, and hepatitis B/C testing were generally consistent across regions, with proportions ranging from 85% to 95% (**Figure 3**)
 - Proportions of zero cost-sharing claims were generally lower and more varied between regions for creatinine testing (72–88%), lipid panels (77–90%), and counseling/office visits (77–86%) (**Figure 3**)

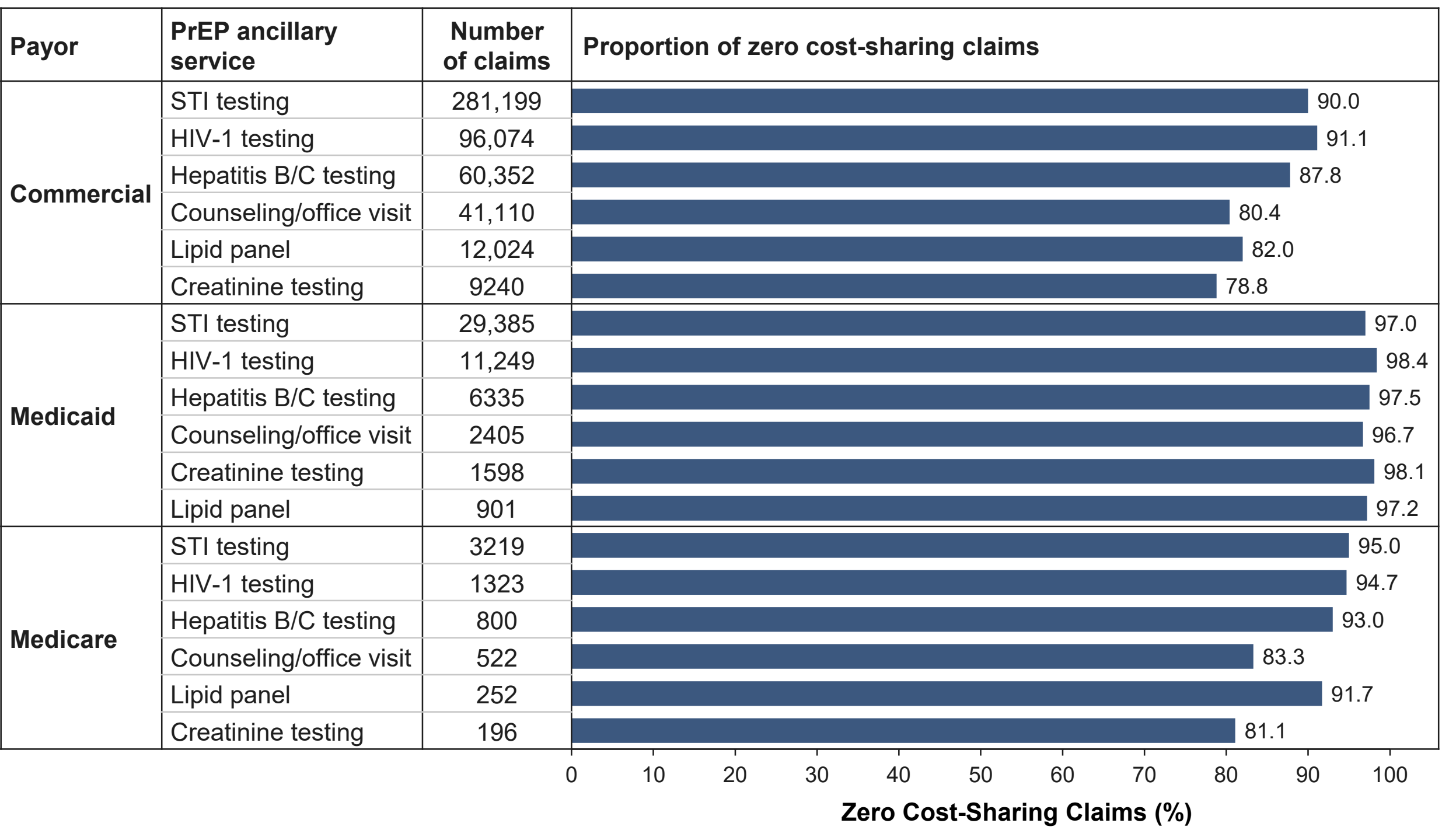
Figure 3. Proportion of Zero Cost-Sharing Claims for PrEP Ancillary Services by Region



Claims between January 2019 and August 2024. In total, 6221 claims were excluded as region was not known. Services were identified using International Classification of Diseases, Tenth Revision, diagnosis codes linked to PrEP use (Z29.81) or behaviors associated with HIV-1 acquisition (Z20.6, Z22.5X), and related Current Procedural Terminology/Healthcare Common Procedure Coding System billing codes. PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

- Overall, Medicaid beneficiaries had 97% zero cost sharing for all services versus 89% for commercial insurance users and 93% for Medicare users
 - Proportions of zero cost-sharing claims for each service were highest for Medicaid beneficiaries (97–98%) compared with commercial insurance (79–91%) and Medicare (81–95%) users (**Figure 4**)
 - For commercial insurance and Medicare users, the proportions of zero cost-sharing claims were lowest for creatinine testing (79% and 81%, respectively) and counseling/office visits (80% and 83%, respectively) (**Figure 4**)

Figure 4. Proportion of Zero Cost-Sharing Claims for PrEP Ancillary Services by Payor Type



Claims between January 2019 and August 2024. In total, 4526 claims were excluded as payor type was not known. Services were identified using International Classification of Diseases, Tenth Revision, diagnosis codes linked to PrEP use (Z29.81) or behaviors associated with HIV-1 acquisition (Z20.6, Z22.5X), and related Current Procedural Terminology/Healthcare Common Procedure Coding System billing codes. PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

Limitations

- The analysis was limited to claims with valid copay information and services billed through insurance
- Lipid panels and creatinine testing were less frequently conducted compared with HIV-1 testing, and possibly an artifact of how common they are as part of general annual physical exams
- Individuals may have unknown healthcare insurance benefits that determine coverage under the ACA-USPSTF guidance
- There may be drivers of observed differences in zero cost-sharing trends across payer types and regions that need to be explored in future work

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Conflicts of Interest: Li Tao, Juan Yang, Alice Hsiao, JeanPierre Coaquira Castro, Chris Nguyen, Joshua Gruber, and Woodie Zachry are all employees and shareholders of Gilead Sciences, Inc.