

## Drug Use Evaluation: Pre-exposure Prophylaxis for HIV

### Research Questions:

1. What proportion of fee-for-service (FFS) patients at high risk of HIV transmission receive pre-exposure prophylaxis (PrEP)?

### Conclusions:

- In an evaluation of patients currently enrolled in FFS Medicaid on October 1, 2021, a total of 989 patients were identified who had recent HIV testing or risk factors for HIV transmission in the previous 6 months. The majority of patients (77%) were identified based on a single HIV test. Routine HIV testing is recommended at least once for all adults and more frequently (every 3 to 12 months) in patients with risk factors for transmission.<sup>1,2</sup>
- The following diagnoses were identified in the previous 6 months which may indicate high risk for HIV transmission: 20% of patients (n=193) had a diagnosis from medical claims indicating a sexually transmitted infection (STI), 5% of patients (n=50) had a diagnosis of high-risk sexual behavior, and 10% of patients (n=97) had a diagnosis indicating potential viral exposure.
- Very few of these patients (<1%, n=8) had FFS pharmacy claims for PrEP.

### Recommendations:

- Develop an educational retrospective drug use review (DUR) program to improve provider knowledge of PrEP for patients with a recent STI, diagnosis of high-risk sexual behavior, or potential viral exposure.

### Background

Prophylaxis for HIV is recommended as preventative therapy in patients with recent potential exposure to HIV (post-exposure prophylaxis [PEP]) and in patients at high risk for HIV transmission (pre-exposure prophylaxis [PrEP]). Transmission of HIV primarily occurs through high-risk sexual behavior or exposure to infected blood. Risk of HIV transmission is primarily dependent on risk associated with a specific behavior and likelihood that a sex partner or drug injection partner is living with HIV.<sup>3</sup> For example, HIV transmission is higher with receptive anal intercourse compared to insertive anal intercourse or penile-vaginal intercourse.<sup>3</sup> Similarly, injection drug use associated with needle-sharing has a high risk of HIV transmission. Risk factors which increase the chance of HIV transmission include being in a relationship with a partner living with HIV, inconsistent use of condoms during anal sex or with persons with risk factors for HIV transmission, or a diagnosis of a sexually transmitted infection within the past 6 months.<sup>3</sup>

The US Preventative Services Task Force (USPSTF) currently recommends that therapy with PrEP be considered for the following populations:<sup>3</sup>

1. Persons who inject drugs who have shared use of drug injection equipment
2. Men who have sex with men who are sexually active and have at least one of the risk factors described above
3. Heterosexual and sexually active persons with at least one of the risk factors described above

Recommendations for frequency of HIV testing vary slightly between organizations. The Centers for Disease Control recommends screening at least once in all adults and adolescents (13 to 64 years of age), with at least yearly testing in individuals with high risk of transmission.<sup>1</sup> The USPSTF recommends routine screening for HIV in all patients 15-65 years of age especially in areas with high community prevalence.<sup>2</sup> More frequent testing (every 3 to 6 months) is recommended for individuals at high risk for HIV transmission.<sup>2</sup> In patients being considered for PrEP, HIV testing should be done prior to therapy initiation to rule out an active infection and every 3 months during PrEP treatment.<sup>3</sup>

### Methods:

This analysis evaluated a “snapshot” in time for Medicaid patients with risk factors for HIV transmission. Data was evaluated for members enrolled in Medicaid as of October 1, 2021. Adult or adolescent FFS patients ( $\geq 10$  years of age) were included if they were currently enrolled had either routine HIV testing during the past 6 months (see codes in **Appendix 1**) or had claims indicating potential risk for HIV transmission. Potential risk for HIV transmission was defined based on medical claims within the past 6 months and included the following groups:

- patients with at least 2 claims for HIV testing at least 30 days apart OR
- patients with an STI diagnosis (ICD10 codes: A50x-A64x, O981-O9833, R8581, R8582, R8781x, R8782x) OR
- patients with other high-risk sexual behavior (ICD10 codes: Z725x) OR
- patients with potential viral exposure (ICD10 codes: Z202, Z206, Z7721, Z205)

Details for descriptions of ICD-10 codes are available in **Appendix 1**. Because ICD-10 diagnosis codes categorize substance use disorders based on substance type rather than route of administration, injection drug use was not captured in this analysis as a risk factor for HIV transmission.

The drug combinations currently FDA approved for PrEP include combination emtricitabine/tenofovir disoproxil fumarate and emtricitabine/tenofovir alafenamide. Paid FFS pharmacy claims for PrEP were identified in the previous 120 days based on drug codes (HSNs 026515 and 043241). Patients were excluded if they had any pharmacy claims for active HIV drug treatment (excluding PrEP HSNs) within that time. Patients were excluded if they had Medicare coverage, limited Medicaid drug benefits (benefit plans CWM, MND, BMM, BMD, MED), had other insurance (TPL), or were enrolled in a CCO during the prior 6 months as pharmacy claims data may be inaccurate or incomplete for these populations.

### Results:

Overall, 989 patients were included in the analysis. Most patients were over 18 years of age and identified as female upon enrollment with Medicaid. However, historically data has been collected patients based on sex assigned at birth rather than gender and does not regularly include non-binary gender options. The majority of patients (77%) were identified based on a single HIV test in the past 6 months (**Table 1**). HIV testing itself is not a definitive indication for PrEP, and current guidelines recommend routine testing for all adults and adolescents. However, a significant proportion of patients had other diagnoses which may indicate high risk for HIV transmission. For example, 20% (n=193) of patients had a diagnosis from medical claims indicating a sexually transmitted infection in the previous 6 months, 5% (n=50) of patients had a diagnosis of high-risk sexual behavior, and 10% (n=97) of patients had a diagnosis indicating potential viral exposure. Diagnoses are not mutually exclusive, and patients with multiple diagnoses may be included in more than one category. However, only a small proportion of patients (~10%) were included in the analysis based on more than one diagnosis. Very few patients had multiple subsequent HIV tests. Multiple HIV tests over a short timeframe may indicate frequent testing in a patient at high risk for transmission or a provider performing repeated tests due to suspicion of an active HIV infection. Only 8 patients (<1%) were identified who had claims for PrEP in the previous 120 days (**Table 2**).

Of note, very few white patients were identified, and more than half of patients with HIV testing or risk factors for HIV transmission were American Indian or Alaskan Natives (53%). About 24% of patients included in this analysis identified as other non-white racial groups. This group includes, but not limited to, patients identifying as Black, Hispanic, Asian, and Pacific Islander.

**Table 1. Patients with recent HIV testing or potential risk factors for HIV transmission AND without claims for PrEP**

	Patients	
	N=	%
<b>Patients with HIV testing</b>	754	76.9%
<b>Risk factor category (patients may be counted more than once)</b>		
Patients with $\geq 2$ HIV tests at least 30 days apart	11	1.1%
STI diagnosis in the past 6 months	193	19.7%
Patients with other high risk sexual behavior in the past 6 months	50	5.1%
Potential viral exposure in the past 6 months	97	9.9%
<b>Number of diagnoses used to identify patients for inclusion (grouped by any HIV testing, STI, or other high-risk diagnoses)</b>		
1	876	89.3%
2	97	9.9%
3	8	0.8%
<b>Demographics</b>		
<b>Race</b>		
White	17	1.7%
American Indian/Alaskan Native	525	53.5%
Unknown	204	20.8%
Other	235	24.0%
<b>Female</b>	812	82.8%
<b>Average Age in years (min-max)</b>		
10-18	46	4.7%
19-64	935	95.3%
$\geq 65^*$	0	0.0%

\* Patients enrolled in Medicare were excluded from this analysis as Medicaid is not the primary payer in this population and claims data is likely incomplete

**Table 2. Patients with recent HIV testing or potential risk factors for HIV transmission**

	Patients	%
<b>Current FFS patients with HIV testing or risk factors for HIV transmission</b>	989	
Patients with PrEP claims in the past 120 days	8	0.8%
Patients without PrEP claims in the past 120 days	981	99.2%

**Discussion and Limitations:**

- This analysis evaluates a single point in time and captures only a snapshot of patients who were enrolled in Medicaid during October 2021. Populations and enrollment may change over time.
- This analysis likely does not capture all patients who may be at risk for HIV transmission. Patients with potential risk for HIV transmission were identified based on diagnoses on medical claims. In particular, patients with injection drug use were not captured in this analysis as ICD-10 diagnosis codes do not differentiate between routes of administration for patients with substance use disorder. Additionally, because there is often a delay in billing for medical claims, diagnoses which were included in the analysis are likely incomplete.
- Billed diagnoses may not accurately reflect actual diagnoses in the patient’s chart. For example, providers may submit medical claims with diagnoses of STI or HIV when they are just performing screening tests for these infections.
- Because this analysis only evaluates claims data, many of the clinical considerations and risk-benefit evaluation surrounding use for PrEP are not captured. For example, it is unclear whether providers are already discussing use of PrEP or other risk mitigation strategies (such as routine condom use) with their patients. Similarly, it is unknown how many patients may have already been offered use of PrEP and declined based on their individual situation.
- The specific ICD-10 codes used in this analysis to identify HIV testing and at-risk groups may influence demographics for included patients. For example, 83% of patients identified as female, and there are multiple ICD-10 codes associated with STIs during pregnancy which may inadvertently result in inclusion of more female patients. Similarly, HIV testing is frequently performed as part of routine screening during a pregnancy, which may have resulted in inclusion of more female patients in this analysis.
- A large proportion of American Indian/Alaskan Native patients were identified in this analysis. This data is likely influenced in part by method of enrollment with Medicaid for American Indian/Alaskan Native patients. Unlike most other patient groups, American Indian/Alaskan Native patients are not automatically assigned to a Coordinated Care Organization upon enrollment with Medicaid, resulting in a larger proportion of these patients in FFS Medicaid.
- It is unclear why so few white patients were included in this analysis. HIV testing is recommended at least once in all adults, and FFS Medicaid typically includes a large proportion of patients who identify as white. Multiple factors may contribute to this discrepancy. For example, the diagnoses included in this analysis are often stigmatized which could result in variability in access to testing or billing for diagnoses depending on the patient, provider, or setting. Additionally, multiple programs within the state offer free HIV and STI testing which may be utilized more by some groups than others.

## References:

1. Center for Disease Control and Prevention. HIV Testing. Updated June 9, 2020. Accessed November 1, 2021. <https://www.cdc.gov/hiv/testing/index.html>
2. Owens DK, Davidson KW, Krist AH, et al. Screening for HIV Infection: US Preventive Services Task Force Recommendation Statement. *Jama*. 2019;321(23):2326-2336.
3. Owens DK, Davidson KW, Krist AH, et al. Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement. *Jama*. 2019;321(22):2203-2213.

## Appendix 1: Drug coding

**Table A1. PrEP Drug regimens**

HSN	Route	Generic
043241	PO	emtricitabine/tenofovir alafenam
026515	PO	emtricitabine/tenofovir (TDF)

**Table A2. Diagnosis codes descriptions used to identify high risk for HIV transmission**

<u>ICD-10 code</u>	<u>Generic description</u>	<u>Category</u>
A50	Congenital syphilis	STI
A51	Early syphilis	STI
A52	Late syphilis	STI
A53	Other and unspecified syphilis	STI
A54	Gonococcal infection	STI
A55	Chlamydial lymphogranuloma (venereum)	STI
A56	Other sexually transmitted chlamydial diseases	STI
A57	Chancroid	STI
A58	Granuloma inguinale	STI
A59	Trichomoniasis	STI
A60	Anogenital herpesviral [herpes simplex] infections	STI
A63	Oth predominantly sexually transmitted diseases, NEC	STI
A64	Unspecified sexually transmitted disease	STI
O981	Syphilis compl preg/chldbrth	STI
O9811	Syphilis complicating pregnancy	STI
O98111	Syphilis complicating pregnancy, first trimester	STI

O98112	Syphilis complicating pregnancy, second trimester	STI
O98113	Syphilis complicating pregnancy, third trimester	STI
O98119	Syphilis complicating pregnancy, unspecified trimester	STI
O9812	Syphilis complicating childbirth	STI
O9813	Syphilis complicating the puerperium	STI
O982	Gonorrhea compl preg/chldbrth	STI
O9821	Gonorrhea complicating pregnancy	STI
O98211	Gonorrhea complicating pregnancy, first trimester	STI
O98212	Gonorrhea complicating pregnancy, second trimester	STI
O98213	Gonorrhea complicating pregnancy, third trimester	STI
O98219	Gonorrhea complicating pregnancy, unspecified trimester	STI
O9822	Gonorrhea complicating childbirth	STI
O9823	Gonorrhea complicating the puerperium	STI
O983	Oth infections w sexl mode of transmiss compl preg/chldbrth	STI
O9831	Oth infections w sexl mode of transmiss comp pregnancy	STI
O98311	Oth infect w sexl mode of transmiss comp preg, first tri	STI
O98312	Oth infect w sexl mode of transmiss comp preg, second tri	STI
O98313	Oth infect w sexl mode of transmiss comp preg, third tri	STI
O98319	Oth infect w sexl mode of transmiss comp preg, unsp tri	STI
O9832	Oth infections w sexl mode of transmiss comp childbirth	STI
O9833	Oth infections w sexl mode of transmiss comp the puerperium	STI
R8581	Anal high risk human papillomavirus (HPV) DNA test positive	STI
R8582	Anal low risk human papillomavirus (HPV) DNA test positive	STI
R8781	High risk HPV DNA test positive from female genital organs	STI
R87810	Cervical high risk HPV DNA test positive	STI
R87811	Vaginal high risk HPV DNA test positive	STI
R8782	Low risk HPV DNA test positive from female genital organs	STI
R87820	Cervical low risk HPV DNA test positive	STI
R87821	Vaginal low risk HPV DNA test positive	STI
Z725	High risk sexual behavior	High risk sexual behavior
Z7251	High risk heterosexual behavior	High risk sexual behavior
Z7252	High risk homosexual behavior	High risk sexual behavior
Z7253	High risk bisexual behavior	High risk sexual behavior
Z202	Contact w and exposure to infect w a sexl mode of transmiss	Potential viral exposure

Z205	Contact with and (suspected) exposure to viral hepatitis	Potential viral exposure
Z206	Contact w and (suspected) exposure to human immunodef virus	Potential viral exposure
Z7721	Contact w and exposure to potentially hazardous body fluids	Potential viral exposure

**Table A3. Codes for HIV testing**

<u>Procedure Code</u>	<u>Description</u>
G0432	Infectious Agent Antibody Detection By Enzyme Immunoassay (Eia) Technique, Hiv-1 And/Or Hiv-2, Scree
G0433	Infectious Agent Antibody Detection By Enzyme-Linked Immunosorbent Assay (Elisa) Technique, Hiv-1 An
87901	Analysis Test By Nucleic Acid For Hiv-1 Virus
87906	Analysis Test By Nucleic Acid For Hiv-1 Virus, Other Region
86314	Hiv (Htlv-iii) Antibody Detection; Confi
86312	Hiv (Htlv-iii) Antibody Detection; Immun
G0298	Hiv Antigen/Antibody, Combination Assay, Screening
G0475	Hiv Antigen/Antibody, Combination Assay, Screening
0575F	Hiv Rna Control Plan Of Care, Documented (Hiv)
3502F	Hiv Rna Viral Load Below Limits Of Quantification (Hiv)
3503F	Hiv Rna Viral Load Not Below Limits Of Quantification (Hiv)
87806	Detection Test By Immunoassay For Hiv-1
86311	Hiv, Antigen
87390	Detection Test By Immunoassay Technique For Hiv-1
87389	Detection Test By Immunoassay Technique For Hiv-1 And Hiv-2
S3645	Hiv-1 Antibody Testing Of Oral Mucosal Transudate
87534	Detection Test By Nucleic Acid For Hiv-1 Virus, Direct Probe Technique
87535	Detection Test By Nucleic Acid For Hiv-1 Virus, Amplified Probe Technique
87536	Detection Test By Nucleic Acid For Hiv-1 Virus, Quantification
G0100	Hiv-1, Viral Load, Quantitative
86703	Analysis For Antibody To Hiv-1 And Hiv-2 Virus
86701	Analysis For Antibody To Hiv -1 Virus
87391	Detection Test By Immunoassay Technique For Hiv-2
86702	Analysis For Antibody To Hiv-2 Virus
87537	Detection Test By Nucleic Acid For Hiv-2 Virus, Direct Probe Technique
87538	Detection Test By Nucleic Acid For Hiv-2 Virus, Amplified Probe Technique
87539	Detection Test By Nucleic Acid For Hiv-2 Virus, Quantification
86689	Confirmation Test For Antibody To Human T-Cell Lymphotropic Virus (Htlv) Or Hiv

86687	Analysis For Antibody To Human T-Cell Lymphotropic Virus, Type 1 (Htlv-1)
86688	Analysis For Antibody To Human T-Cell Lymphotropic Virus, Type 2 (Htlv-2)
PUB02	Omap: Public Health Hiv Screening & Confirmation Testing
G0435	Infectious Agent Antibody Detection By Rapid Antibody Test, Hiv-1 And/Or Hiv-2, Screening
87904	Analysis Test By Nucleic Acid For Hiv-1 Virus, Each Additional Drug Tested
87903	Analysis Test By Nucleic Acid For Hiv-1 Virus, First Through 10 Drugs Tested