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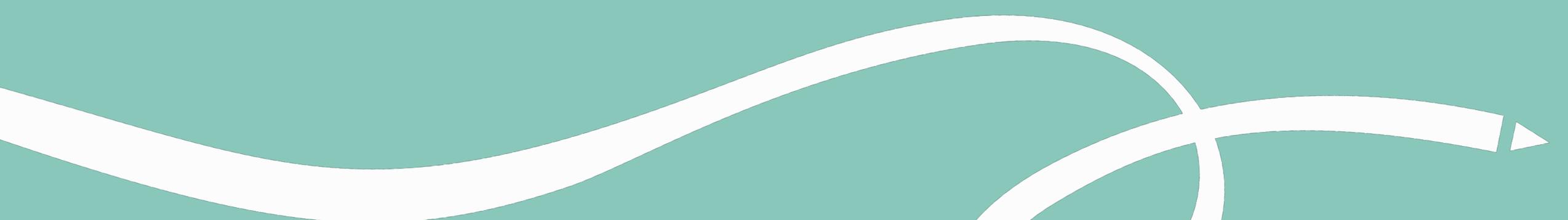


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Texas Collaborative for HIV Education and Prevention (TCHEP) Learning Series

Updates and Recommendations for Primary and Emergency Care Services



Strategies to Support PrEP and Other HIV Prevention Services in Primary Care



Texas Department of State Health Services



Disclosure to Learners

Texas Collaborative for HIV Education & Prevention Learning Activities:

“Strategies to Support PrEP and Other HIV Prevention Services in Primary Care”

July 1, 2021



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- Attend the entire event
- Participate in education activities, and
- Complete the participant evaluation



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Complete and submit the evaluation survey by **July 15th, 2021**.



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- Certified in Public Health
- Social Workers



- 
- For more information on CE credits, please contact Isabel Clark Isabel.Clark@dshs.texas.gov or email us at tcchep@uthct.edu
 - For any other question on TCHEP, including materials from this learning series, please visit: <http://tcchep.org>





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**National Alliance of State and Territorial
AIDS Directors (NASTAD)**



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Strategies to Support and Sustain PrEP and Other HIV Prevention Services in Primary Care

Best Practices in Texas

Financial Disclosures

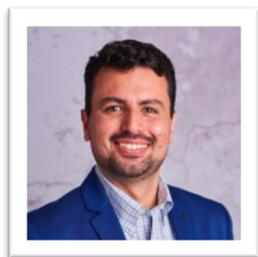
Nicole Elinoff and Edwin Corbin-Gutierrez
have no financial disclosures

NASTAD's PrEP Team



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Manager, Health Systems
Integration

- Telehealth regulations
- Health plan coverage



**Edwin Corbin-
Gutierrez**
Director, Health Systems
Integration

- EHE systems
coordination



Kendrell Taylor
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- Take Me Home



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- PrEP program
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- Regulatory framework



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- TelePrEP learning
collaborative



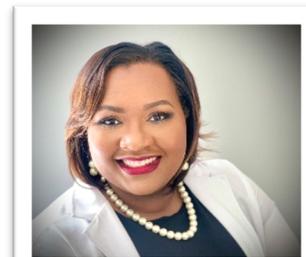
Tim Horn
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- 340B program income
- Generic drug market



Will Lee
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Brittany Sanders
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- 340B

Learning Objectives

- Upon completion of this event, participants should be able to:
 - Discuss resources to address the upcoming changes and reductions to 340B program income to fund PrEP/nPEP programs.
 - Describe effective strategies to fund and sustain PrEP, nPEP, and routine HIV screening services in clinical settings.
 - List patient requirements to qualify for Patient Assistance Programs to access PrEP/nPEP medications at no cost.

Agenda

- ✓ Cost of PrEP Care
- ✓ PrEP Financing Gaps
- ✓ Generic drugs for PrEP on the US market
- ✓ ACA coverage protections for patients through USPSTF
- ✓ Verifying PrEP as a Preventive Service + Coverage Considerations
- ✓ NASTAD's Billing and Coding Guide
- ✓ PrEP access changes on the horizon

Drugs Currently Approved for PrEP

- Tenofovir disoproxil fumarate and emtricitabine (TDF/FTC)
 - Brand name: Truvada by Gilead Sciences
 - Generic TDF/FTC is now available from many different pharmaceutical companies.
- Tenofovir alafenamide fumarate and emtricitabine (TAF/FTC)
 - Brand name: Descovy by Gilead Sciences
 - TAF/FTC was approved with limitations and is indicated only for gay, bisexual, and other men who have sex with men (GBM) as well as transgender women

Cost of PrEP Care

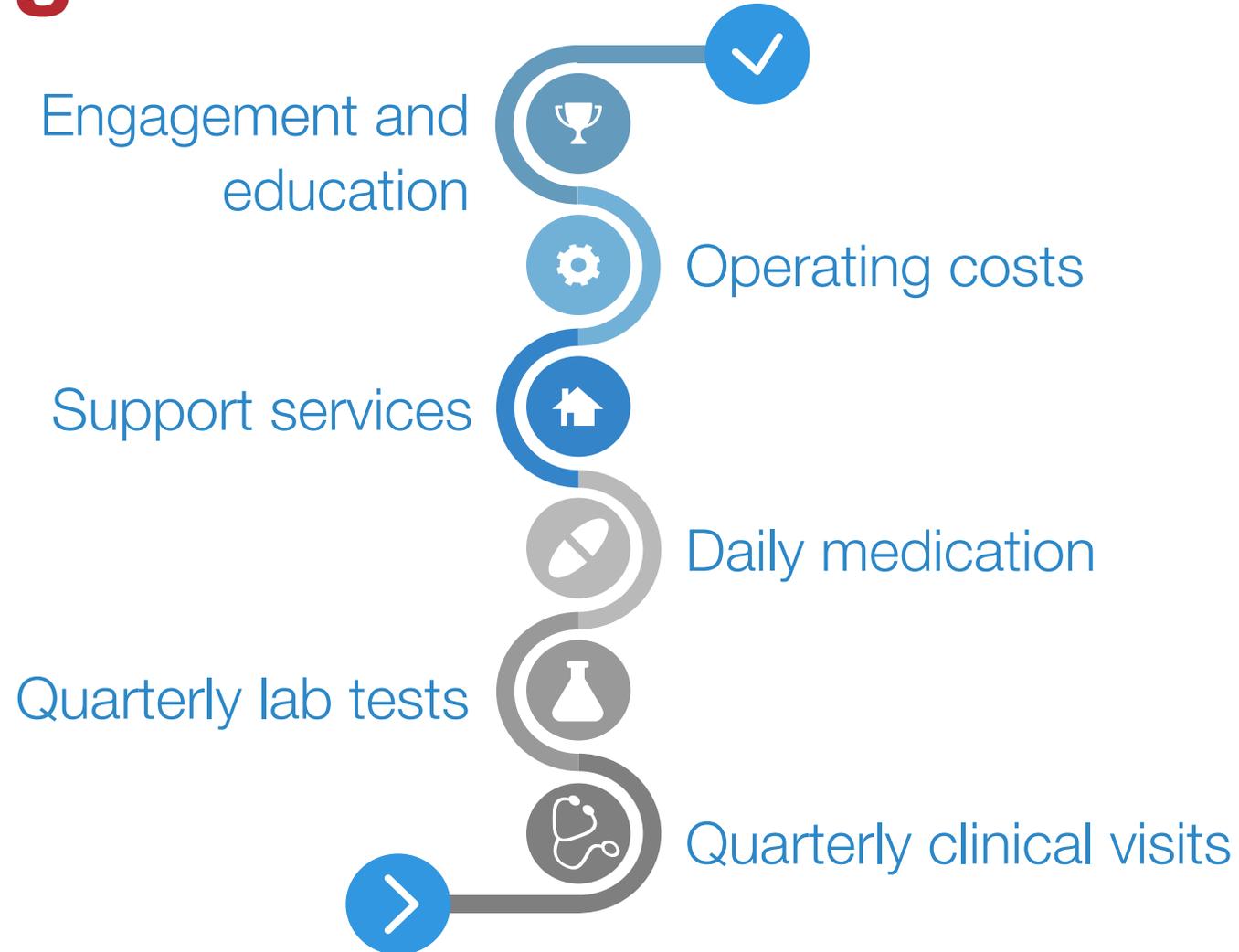
PrEP COMPONENTS	CASH PRICE
Medication	~ \$30- \$1,930 per month
Laboratory tests	~\$502 to \$1,721 per year
Primary care provider visit	~\$73 to \$179 per visit
Support services	Variable



Patients may not seek out PrEP because they are concerned about its cost.

The cost of PrEP may be prohibitive for many patients without insurance coverage and assistance programs

PrEP Program Costs



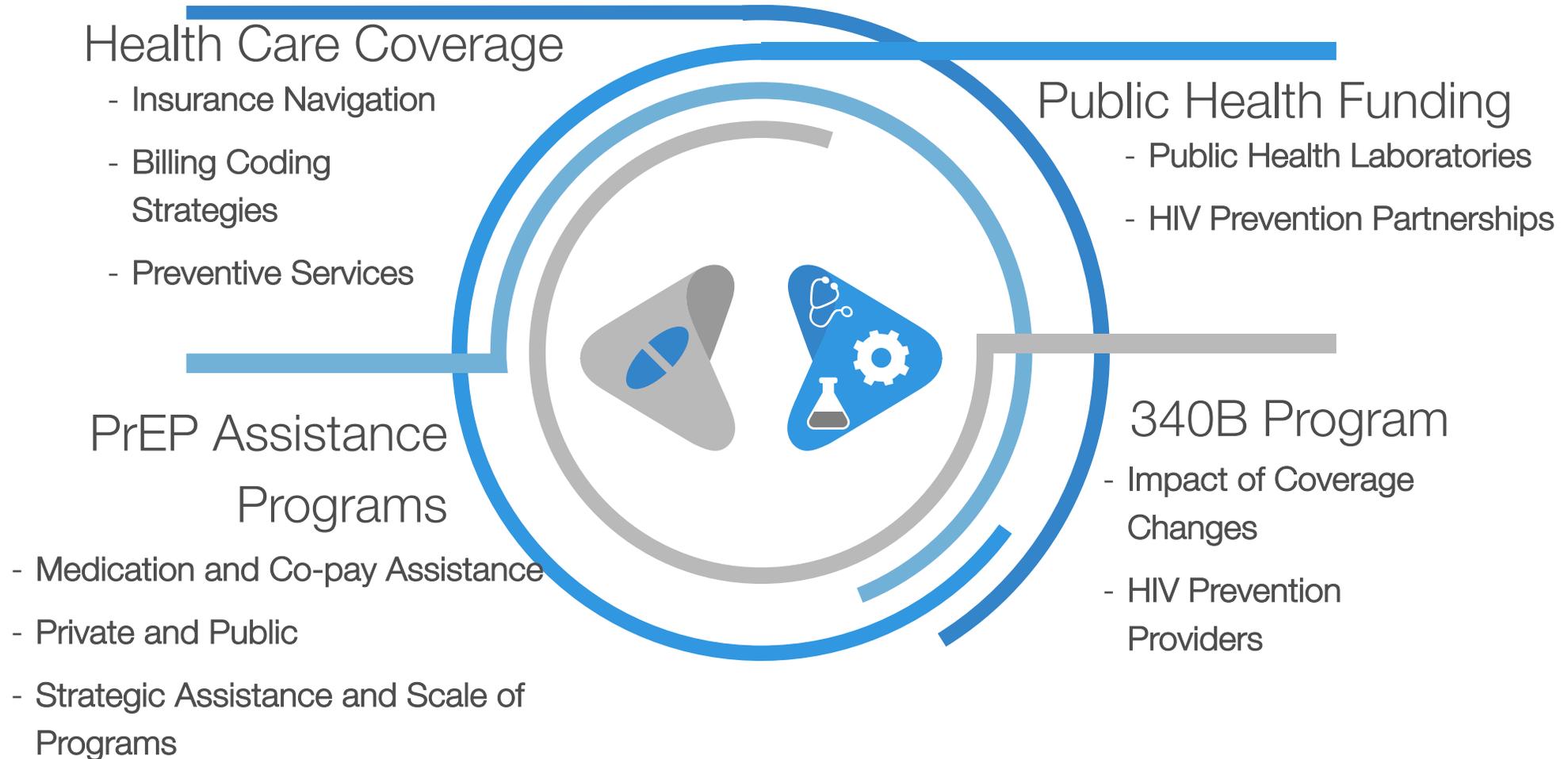
PrEP Financing Gaps

CDC HIV and STD PREVENTION FUNDS	 Cannot be used to purchase the medication for PrEP	 Can be used for public health programs that provide PrEP-related support services
Ryan White HIV/AIDS PROGRAM FUNDS	 Cannot pay for the medication, labs, and clinical visits for PrEP	
 Expertise in HIV care and Ryan White HIV/AIDS Program infrastructure		
 Ending the HIV Epidemic in the U.S: Supplemental CDC EHE funds (PS20-2010) can be used to pay for labs. Supplemental HRSA EHE community health center funds (HRSA-20-091; HRSA-21-092) <ul style="list-style-type: none">• 175 clinics in 57 priority jurisdictions		

Health and Human Resources Administration. (2016) "The Ryan White HIV/AIDS Program and Pre-Exposure Prophylaxis (PrEP) Letter" Reviewed: May 2019: <https://hab.hrsa.gov/program-grants-management/policy-notice-and-program-letters>

US Department of Health and Human Services. (2019) "What is 'Ending the HIV Epidemic: A Plan for America.?' Updated: Sep. 3, 2019: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>

Financing Strategies



Generics on the Market

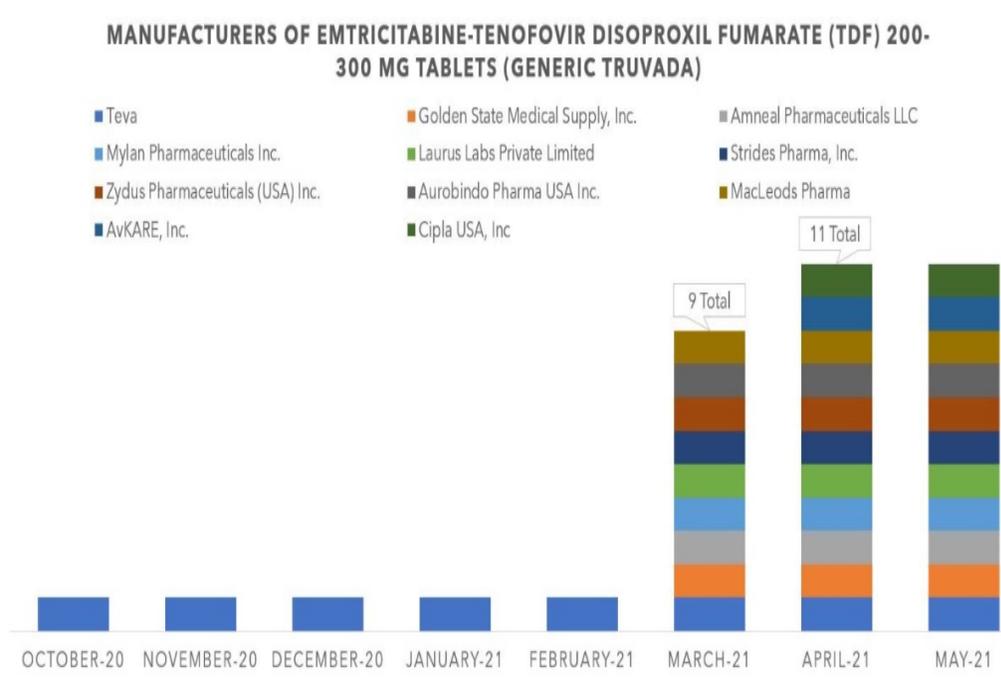


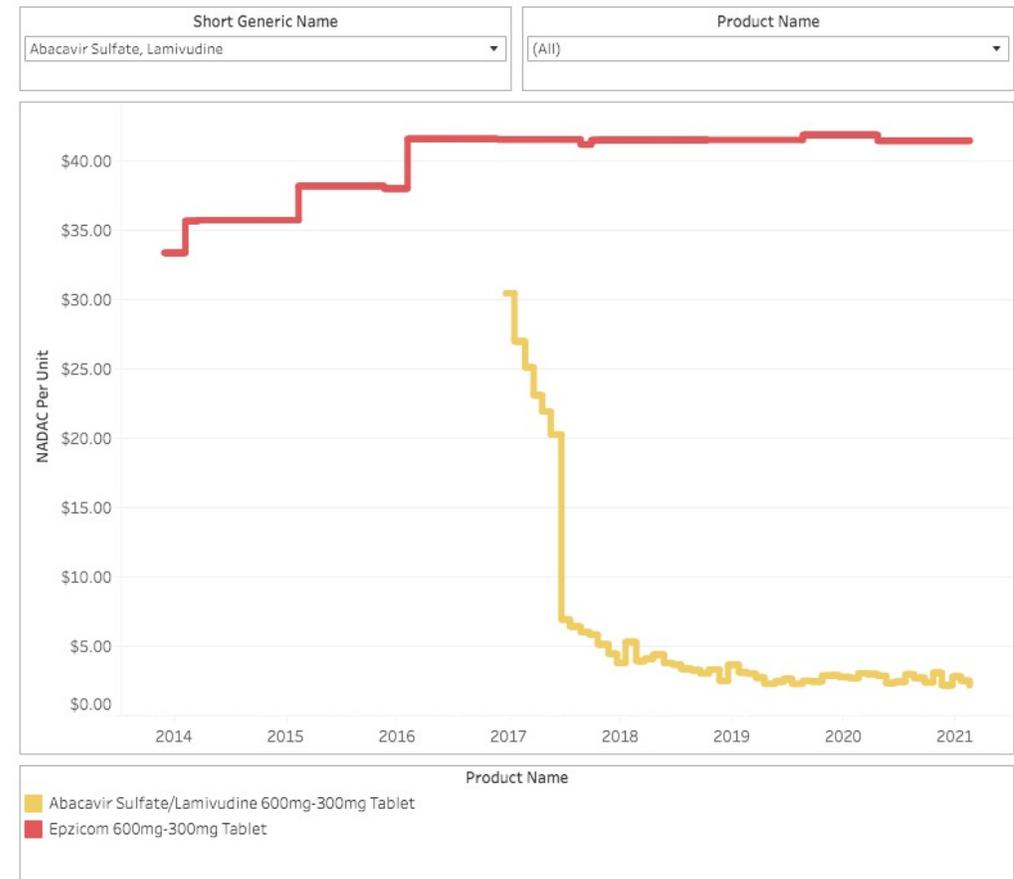
Figure 1
Source: 46brooklyn Research, derived from Elsevier Gold Standard Drug Database (GSDD)

- Generics have been on the market since, October 2, 2020, when Teva Pharmaceuticals USA began selling generic TDF/FTC in the US.
- **On April 1, 2021, additional generics came onto the market**
- All have AB bioequivalence
 - AB bioequivalence indicates that pharmacies can switch patients from the brand-name drug to the generic therapeutic equivalent.

Competition and Pricing

- Manage costs to support sustainability, expansion, and affordability through our public and private payer systems.
- New public health coverage: new community programs, new school-based health clinics, prisons/jails
- Ensure individuals who are underinsured or struggle with high cost-sharing have access to PrEP.

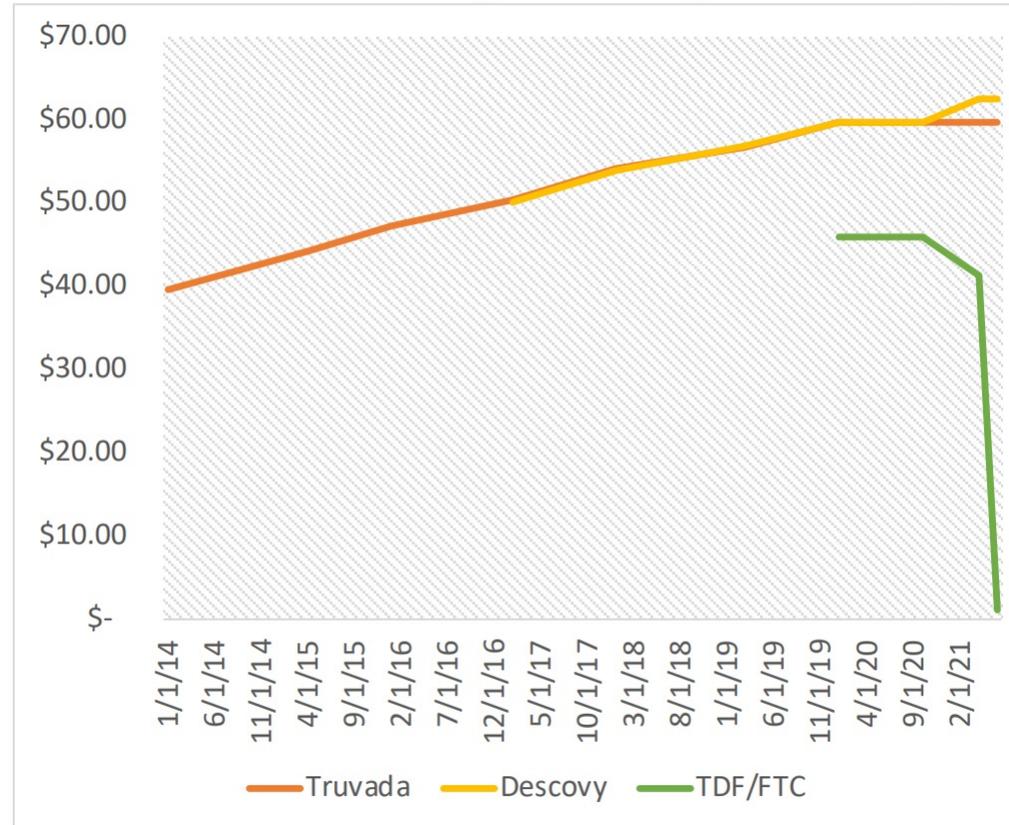
Competition and Drug Prices



Generic Competition is Here

- Robust competition started at the end of Teva's exclusivity agreement, April 1, 2021.
- National Average Drug Acquisition Cost (NADAC) prices TDF/FTC at about \$1 per pill.

NADAC* Pricing Trends (Per Tablet)



National Average Drug Acquisition Cost (data.medicaid.org)

Availability of Copay Assistance

Generic TDF/FTC	Truvada and Descovy
Copay assistance is not available for generic TDF/FTC	Gilead Sciences has not announced any changes to its Advancing Access Copay Relief for Truvada or Descovy program at this time.

Advancing Access Patient Assistance Program

- Changes are on the horizon for Gilead's Advancing Access Patient Assistance Program
- Advancing Access will continue its retail pharmacy model as an option for securing Gilead HIV drug products via the Patient Support Program
- Beginning January 1, 2022, Gilead will no longer reimburse pharmacies dispensing HIV medications under Advancing Access at usual and customary rates
- NASTAD is developing tools to help jurisdictions navigate these upcoming changes.

Ready, Set, PrEP

- The *Ready, Set, PrEP* program makes PrEP medication available at no cost for PrEP candidates who don't have drug coverage.

Qualifying criteria:

- Lack prescription drug coverage
- Be tested for HIV with a negative result
- Have a prescription for PrEP



Enroll at www.getyourprep.com



PrEP is a Preventive Service: USPSTF + Coding Considerations



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Routine HIV Screening

- HIV testing is the point of entry for PrEP
- Testing is Opt-Out
 - Texas does not require a separate written consent for HIV testing (see Texas Health and Safety Code Sections 81.105 and 81.106)
- Language matters. An example of opt-out language: “We will include an HIV test in your blood work today. Do you have any questions?”
- Test Texas HIV Coalition Resources

Recommendation Summary

Population	Recommendation	Grade
Pregnant persons	The USPSTF recommends that clinicians screen for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.	A
Adolescents and adults aged 15 to 65 years	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened. See the Clinical Considerations section for more information about assessment of risk, screening intervals, and rescreening in pregnancy.	A

Non-occupational Post-Exposure Prophylaxis (nPEP)

- PEP is an entry way to PrEP
- Recommended since 2005
- Must be accessed within 72 hours of exposure
 - 28-day antiretroviral regimen
- Paying for PEP
 - Patient Assistance Programs
 - Must follow specific instructions
 - Billing Codes for PEP
 - Assistance for survivors of sexual assault
- AIDS Education and Training Center nPEP Implementation Tool Kit
- Texas Program Operating Procedures and Standards (POPS) for nPEP

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP^{a,b}

Age group	Preferred/alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	Preferred	A 3-drug regimen consisting of tenofovir DF 300 mg and fixed dose combination emtricitabine 200 mg (Truvada [®]) once daily with raltegravir 400 mg twice daily or dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg and fixed dose combination emtricitabine 200 mg (Truvada [®]) once daily with darunavir 800 mg (as 2, 400-mg tablets) once daily and ritonavir [®] 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤ 59 mL/min)	Preferred	A 3-drug regimen consisting of zidovudine and lamivudine, with both doses adjusted to degree of renal function with raltegravir 400 mg twice daily or dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine and lamivudine, with both doses adjusted to degree of renal function with darunavir 800 mg (as 2, 400-mg tablets) once daily and ritonavir [®] 100 mg once daily

CDC PEP Clinical Guidelines, 2016

PrEP is an Essential Health Benefit

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition	A

- Starting in January 2021 (and earlier for some employer and student health plans), most private insurance plans must provide \$0 cost-sharing for at least one PrEP product, so most patients should not need copay assistance programs.

PrEP Coverage Changes

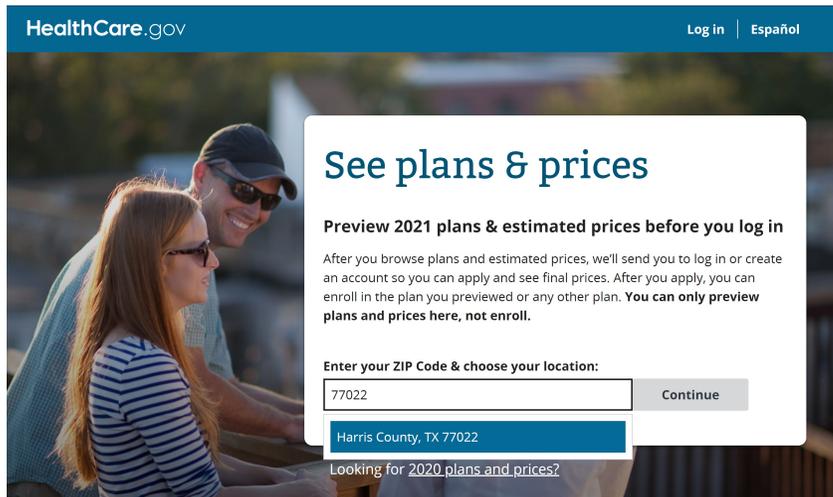
- As generics enter the TDF/FTC market, commercial insurers will have an additional incentive to use generic TDF/FTC to contain their costs.
- Many are expected to use prior authorization requirements (PA) to control the use of high-cost medications and services.
 - PAs are never recommended—burdensome on providers and patients
 - PA implementation should not be a barrier to needed care
 - Clinically sound
 - Adherent to federal guidelines
 - Does not restrict access to clinically indicated regimens
 - Is not discriminatory or stigmatizing

Verifying Preventive Service Coverage

1 Go to healthcare.gov/see-plans and enter your zip code

2 After finding a health plan, select “[list of covered drugs](#)” under “plan documents”

3 Search “[Truvada](#)” or “[emtricitabine-tenofovir disoproxil fumarate](#)” (or Descovy if indicated)



Plan documents

[PDF Summary of Benefits](#)

[PDF Plan brochure](#)

[PDF Provider directory](#)

[PDF List of covered drugs](#)



Drug Name Search

Enter a drug name to begin
[emtricitabine-tenofovir disoproxil fumarate](#)

Verifying Preventive Service Coverage

4 The drug should be listed as “**Health Care Reform**” or “**ACA Preventive.**” There is no uniform format to list preventive drugs and the **preventive drug** tier number varies by insurance carrier.

Some plans mark the drug as ACA, without changing the drug tier used

TRUVADA TABLET 100-150 MG ORAL	2	
TRUVADA TABLET 133-200 MG ORAL	2	
TRUVADA TABLET 167-250 MG ORAL	2	
TRUVADA TABLET 200-300 MG ORAL	2	ACA NCDL, limitations may apply

- (\$0) emtricitabine-tenofovir df oral tablet 200-300 mg
- T2 Truvada Oral Tablet 100-150 MG
- T2 Truvada Oral Tablet 133-200 MG
- T2 Truvada Oral Tablet 167-250 MG
- (\$0) Truvada Oral Tablet 200-300 MG

TRUVADA 200-300 MG TAB
emtricitabine-tenofovir disoproxil fumarate

4

S
HCR Health Care Reform
PR Preventive Medication

ACA Preventive (ACA): Medicines marked in the ACA column are under the Affordable Care Act coverage of preventive services. These products have limited or \$0 member cost-sharing (copay or co-insurance), when meeting the conditions as outlined under the regulation. These are also indicated with an "A" in the drug tier column. To see what contraceptive products may be covered, visit www.bcbsil.com/PDF/rx/contraceptive-list-il.pdf

Drug Name	Drug Tier	Prior Authorization	Step Therapy	Dispensing Limits	ACA	Limited Distribution
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 100-150 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 133-200 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 167-250 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 200-300 mg	3			•	•	

Verifying Preventive Service Coverage

The drug should be listed as “**Health Care Reform**” or “**ACA Preventive.**” There is no uniform format to list preventive drugs and the **preventive drug** tier number varies by insurance carrier.

Some plans place preventive drugs as the lowest drug tier

- Tier 0 - No copayment for those drugs that are used for prevention and are mandated by the Affordable Care Act. Select oral contraceptives, vitamin D, folic acid for women of child bearing age, over-the-counter (OTC) aspirin, and smoking cessation products may be covered under this tier. Certain age or gender limits apply.
- - Tier 1: Preventative drugs with no member cost share under the Affordable Care Act
 - Tier 2: Generic Drugs
 - Tier 3: Preferred Brand Drugs
 - Tier 4: Non-Preferred Brand Drugs
 - Tier 5: Specialty Drugs

Others use the highest drug tier

- • **Tier 7 – (Zero Cost Share Preventive Drug)**-The Patient Protection and Affordable Care Act of 2010 allows members to receive some preventive, evidence-based items and services at no cost to the member with certain stipulations.

Plans may also list preventive services on a **separate list**

→ Human Immunodeficiency Virus (HIV) prevention Medication for preexposure prevention of HIV in those at an increased risk.	
Truvada 200 mg/300 mg tablet	\$0 copay if utilizing for HIV prevention

Preventive Service Coverage Considerations

- The following are considerations when verifying PrEP as a preventive service:

Services	A PrEP service such as office visit, laboratory test, or adherence counseling intervention must be covered without cost-sharing if it is integral to PrEP delivery and if PrEP is its primary purpose.
Treatment	Health plans are required to cover at least one approved PrEP drug.
Frequency	Coverage frequency must follow PrEP clinical guideline recommendations.
Providers	The provider must be in-network with the health plan.
Health Plans	All non-grandfathered commercial health plans must cover these PrEP services without cost-sharing.
Deadline	By July 1, 2021, all health plans must cover PrEP.

Modifier 33

33 - Preventive Service	Used when a service is provided that is a service that carries an “ A ” or “ B ” rating from the USPSTF (and is thus required to be provided without patient cost sharing)	
Recommendation	Population	Grade
HIV screening	All adolescents and adults Pregnant women	A A
Chlamydia and gonorrhea screening	Adults aged 18 or older	B
Hepatitis B screening	Pregnant women Persons at high risk for infection	A B
Hepatitis C screening	Persons at high risk for infection and adults born between 1945 and 1965	B
Syphilis screening	Persons at increased risk for infection All pregnant women	A A
STI behavioral counseling	All sexually active adolescents and adults at increased risk for STIs	B

ICD-10 Coding

COMMON DIAGNOSIS CODES

ICD-10 code	Description	Use for
Z01.812	Encounter for pre-procedural laboratory examination	Use for blood or urine tests prior to treatment.
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission	STI screening
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]	HIV screening
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	HIV, STI screening
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]	HIV screening
Z51.81	Encounter for therapeutic drug level monitoring	PrEP monitoring
Z72.51	High risk heterosexual behavior	HIV, STI screening
Z72.52	High risk homosexual behavior	HIV, STI screening
Z72.53	High risk bisexual behavior	HIV, STI screening

Labs for PrEP Initiation Coding

Code	Description
86689	HTLV or HIV antibody, confirmatory test (eg, Western Blot)
	Antibody
86701	HIV-1
86702	HIV-2
86703	HIV-1 and HIV-2, single result (For HIV-1 antigen(s) with HIV-1 and HIV-2 antibodies, single result, use 87389) (When HIV immunoassay [HIV testing 86701-86703 or 87389] is performed using a kit or transportable instrument that wholly or in part consists of a single use, disposable analytical chamber, the service may be identified by adding modifier 92 to the usual code)
	Infectious agent detection by nucleic acid (DNA or RNA)
87534	HIV-1, direct probe technique
87535	HIV-1, amplified probe technique, includes reverse transcription when performed
87536	HIV-1, quantification, includes reverse transcription when performed
87357	HIV-2, direct probe technique
87538	HIV-2, amplified probe technique, includes reverse transcription when performed
87539	HIV-2, quantification, includes reverse transcription when performed

Common Billing Errors That May Trigger a Denial...

- Missing / incorrect demographic information
- Missing / incorrect diagnosis code(s)
- Frequency limits established by the payer for the service
- Modifier 33 was not appended to the CPT® or HCPCS code and was needed to tell the payer the service was preventive.



NASTAD's Billing Coding Guide

PrEP initiation and follow-up clinical visits

- Medical office visits for PrEP initiation
- Shared medical visits

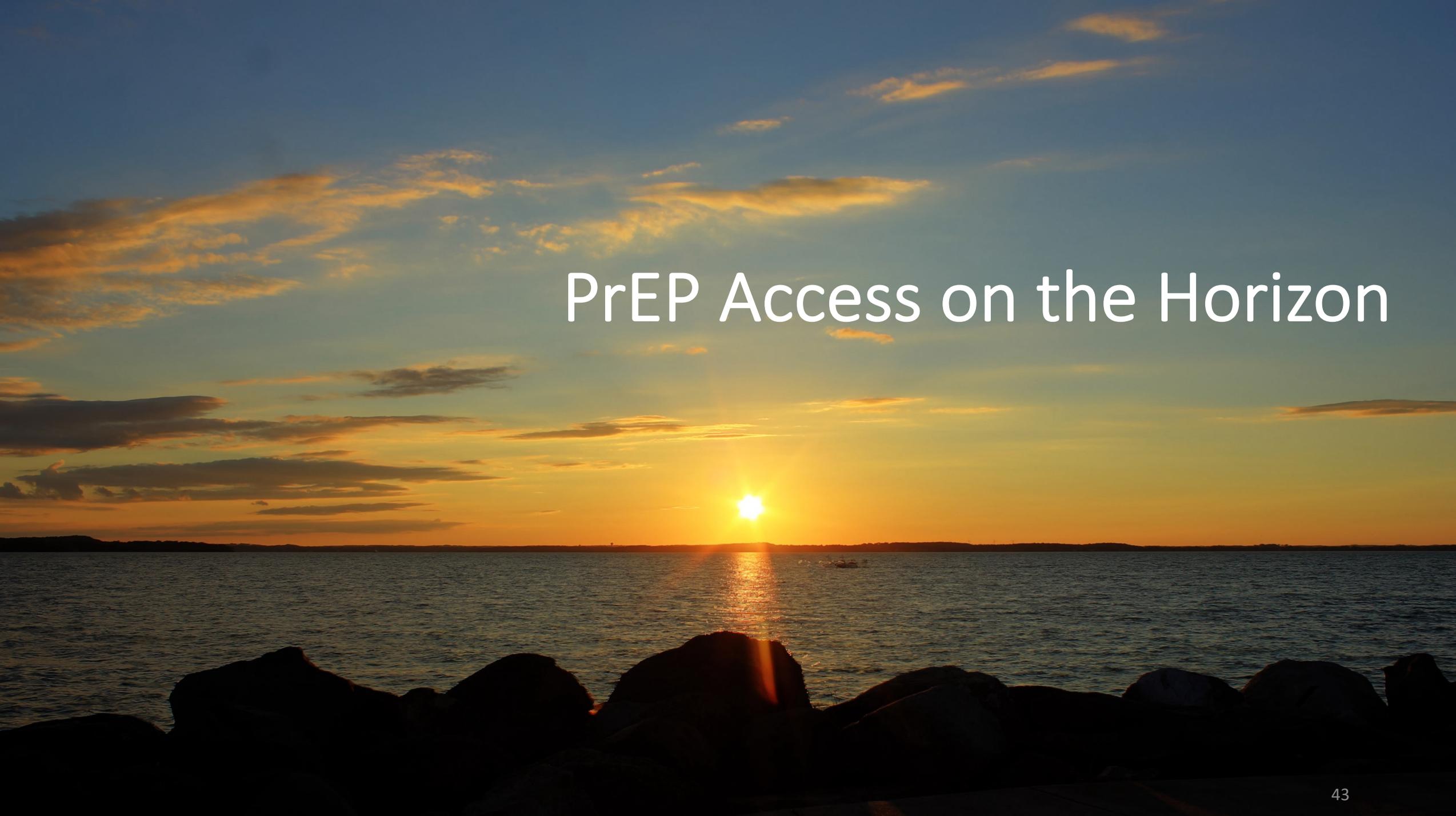
Lab tests for PrEP initiation:

- HIV screening
- HIV screening in a non-primary care setting
- Screening for other STIs: syphilis, gonorrhea, hepatitis B, and chlamydia

Adherence, linkage, and counseling services for PrEP:

- PrEP adherence counseling by a physician, advance practice nurse, physician assistant
- High intensity behavioral counseling to prevent STIs
- Chronic care management services
- Care coordination, linkage, and adherence services by community health workers and other non-licensed peer providers in non-traditional healthcare settings
- Targeted case management

PrEP Access on the Horizon

A scenic photograph of a sunset over a large body of water. The sun is a bright, glowing orb on the horizon, casting a shimmering path of light across the water's surface. The sky is a mix of deep blue and warm orange, with scattered, thin clouds. In the foreground, the dark silhouettes of large, rounded rocks are visible, framing the bottom of the scene.

On the Horizon: Long-Acting Cabotegravir

- **HPTN 083:**
 - Studied safety and effectiveness among gay men and other men who have sex with men and transgender women.
- **HPTN 084:**
 - Sister study to HPTN 083, showing efficacy among cisgender women.
- **Both studies shared data findings in 2020.**



Long-acting injectable PrEP is a prevention strategy under investigation that involves receiving an injection every two months of the antiretroviral cabotegravir.

On the Horizon: Long-Acting Cabotegravir

Knowns

- Received Break-Through Therapy designation by the FDA – November 2020
- New Drug Application filed May 2021
- Considered more effective than daily pill regimens
- Can assist with PrEP adherence
- Does not require cold chain storage
- Administered by a clinician
- Included in CDC's draft 2021 PrEP Clinical Practice Guidelines

Unknowns

- Cost
- Health plan coverage

Now is the time to start thinking about the implementation of long-acting injectables for PrEP .

2021 PrEP Clinical Practice Guidelines

What's new to the guidelines:

- A recommendation to inform all sexually active adults and adolescents about PrEP
- Routine lab changes
- Language that is more gender affirming
- Information for F/TAF (Descovy)
- Information on Cabotegravir
- Procedures for off-label “2-1-1”
- Utilizes flow charts and simplifies determining indication for PrEP
 - Flow charts do not include a “don’t prescribe PrEP” option.

The CDC’s PrEP Clinical Practice Guidelines are being updated for 2021!

Plan Review Timeline:

Public Comment Webinars: May 24 + 25, 2021
Webinar Recordings: Released June 15
The CDC writing team will prepare responses to comments by June 30

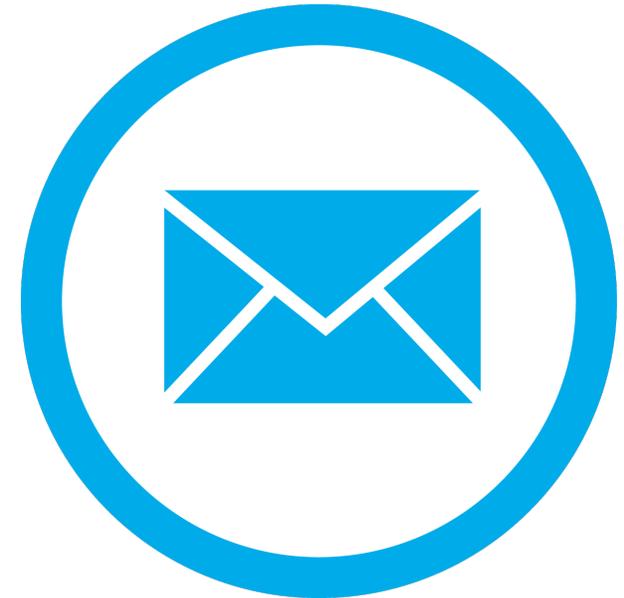
Resources

- [NASTAD's Billing and Coding Guide](#)
- [Billing Manual for HIV Testing and Related Services](#)
- [PrEP Generics Entering the US. Market: Frequently Asked Questions \(FAQs\)](#)
- [Verifying PrEP is Covered as a Preventive Service](#)
- [Ready, Set, PrEP](#)
- [Pharmaceutical Company Patient Assistance Programs and Cost-Sharing Assistance Programs for Pre-Exposure Prophylaxis \(PrEP\) and Post-Exposure Prophylaxis \(PEP\)](#)
- [Routine Universal Screening for HIV Intervention](#)

Contact Information

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That's all, folks!

Any Questions?



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Thank you!

