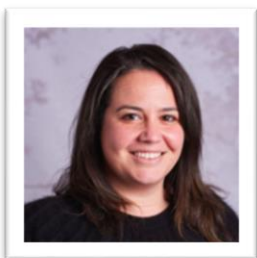


Diversifying PrEP Financing: Strategies to Leverage Funding across the PrEP Care Continuum

March 9, 2022



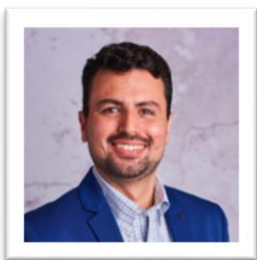
NASTAD's PrEP Team



Dori Molozanov

Senior Manager, Health Systems Integration

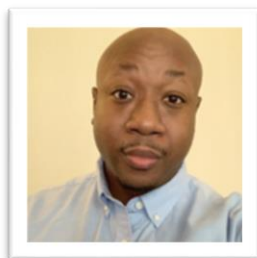
- Telehealth regulations
- Health plan coverage



Edwin Corbin-Gutierrez

Director, Health Systems Integration

- EHE systems coordination



Kendrell Taylor

Manager, Prevention

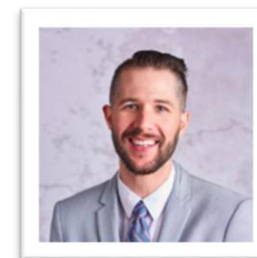
- PrEP implementation
- Take Me Home
- Self-testing



Krupa Mehta

Manager, Prevention

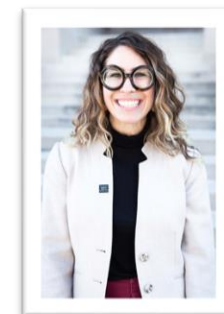
- PrEP program implementation
- TelePrEP learning collaborative



Mike Weir

Senior Manager, Policy & Legislative Affairs

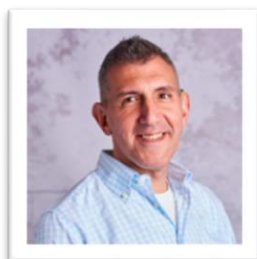
- Federal and state policy
- Regulatory framework



Nicole Elinoff

Manager, Prevention

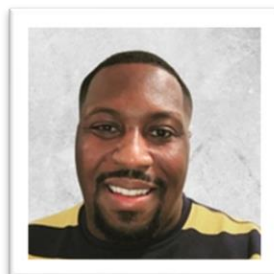
- PrEP implementation
- TelePrEP learning collaborative



Tim Horn

Director, Health Care Access

- 340B program income
- Generic drug market



Will Lee

Manager, Health Systems Integration

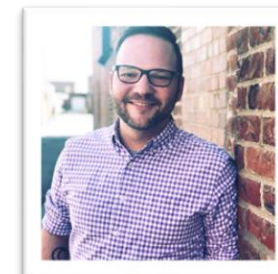
- PrEP policy research



Ralph Moreno

Specialist, Health Systems Integration

- TelePrEP learning collaborative
- 340B



Cody Shafer

Consultant, TelePrEP Access

- TelePrEP learning collaborative



Brittany Sanders

Consultant, TelePrEP Access

- TelePrEP learning collaborative

Agenda

Setting the Stage:

- ✓ 340B Primer
- ✓ PrEP Financing Landscape Changes
- ✓ Current Program Limitations and Opportunities

Service Organization Strategies:

- ✓ Reimbursements
- ✓ Provider types

Federal Funding Overview:

- ✓ Allowable Activities
- ✓ Continuum Crosswalk

Q+A and Discussion

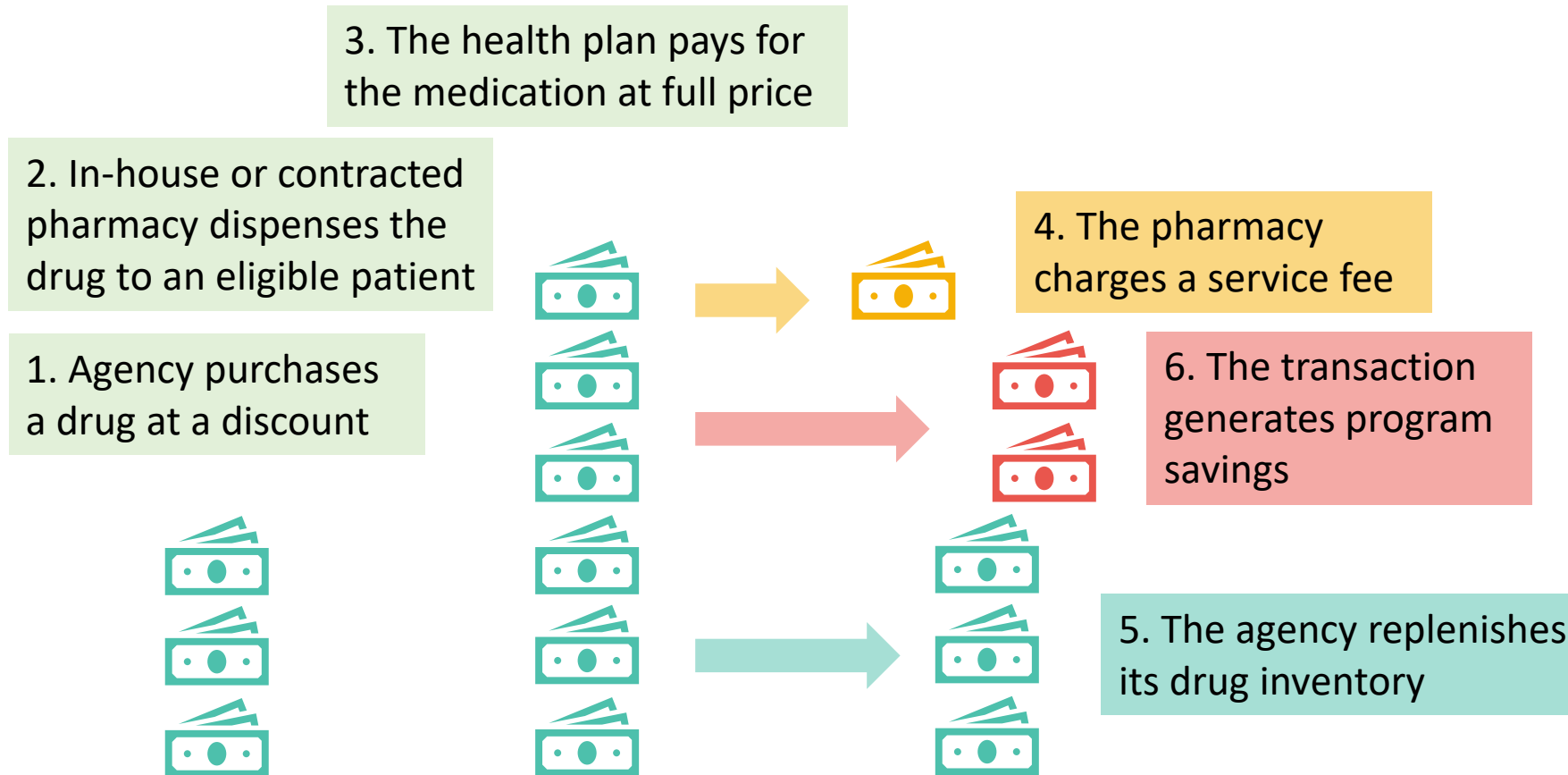


340B Primer

Overview of the 340B Program

- The 340B Drug Pricing Program requires pharmaceutical manufacturers to sell drugs at a discount to eligible safety net clinics and hospitals.
- The savings from the program are intended to “stretch scarce federal resources.”
- The program’s savings help to cover the cost of unreimbursed PrEP-related services.

340B Program Savings



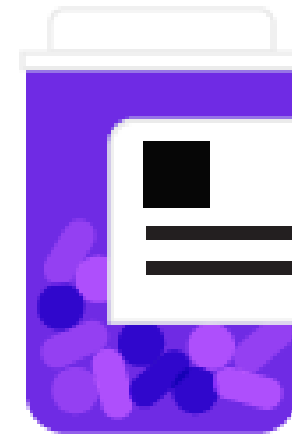
Financing Uncovered Services

- 340B program savings help to cover the cost of unreimbursed services:
 - Clinical visits
 - Lab tests
 - Supportive services, including navigation, case management, and adherence counseling
 - Unreimbursed cost of operation
- Expand PrEP access to uninsured and underinsured patients

PrEP Financing Landscape Changes

PrEP Financing Landscape Changes

- Introduction of Generic TDF/FTC
- Changes to Gilead Sciences Advancing Access Program
- Reduced Voluntary Supplemental Discounts



Generics on the Market

- 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.

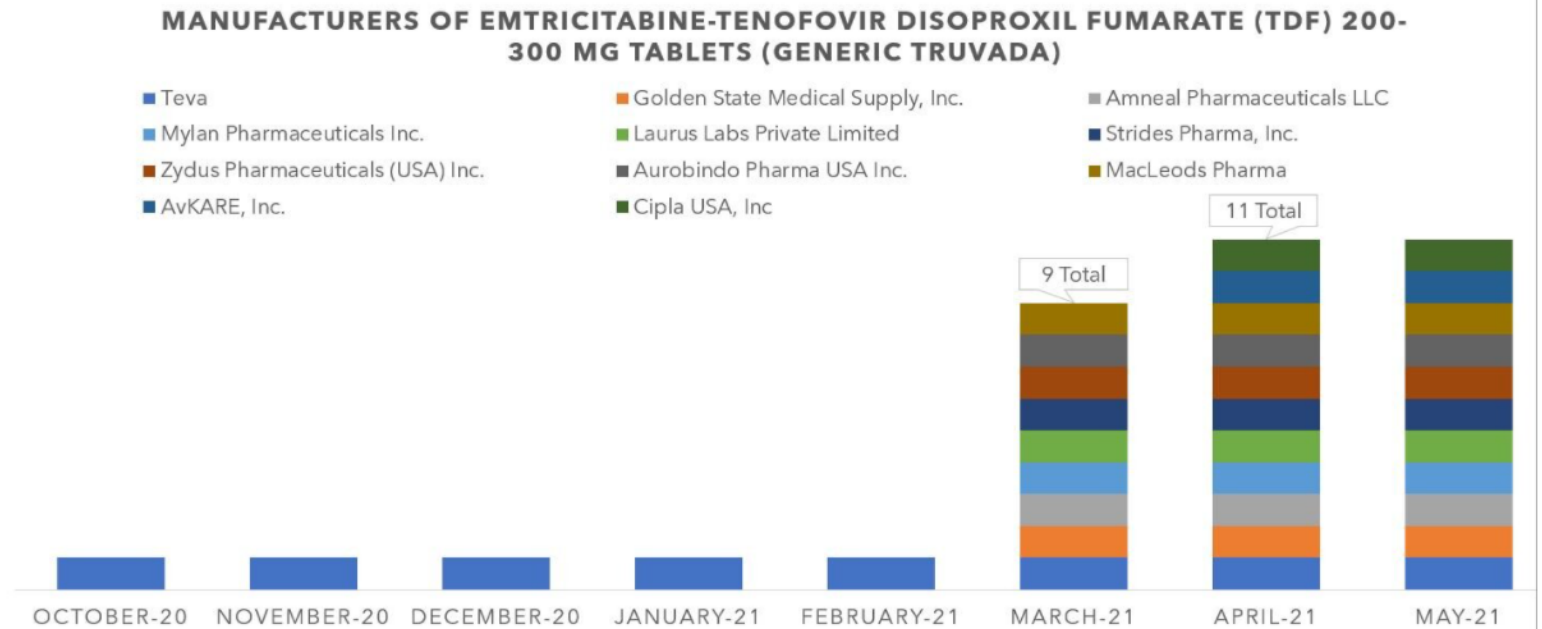


Figure 1
Source: 46brooklyn Research, derived from Elsevier Gold Standard Drug Database (GSDD)

Knowledge Check

Approximately how much do you think generic TDF/FTC costs per month, now that there is robust competition?

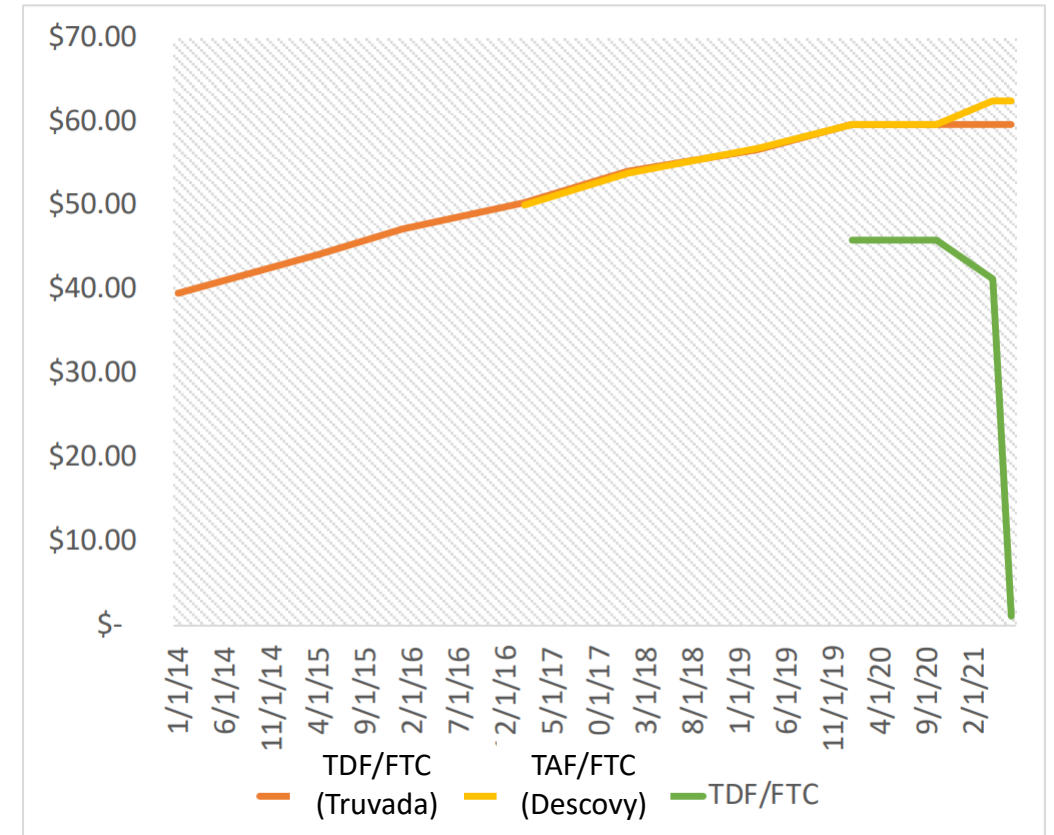
- ☐ \$1455
- ☐ \$500
- ☐ \$100
- ☐ \$25



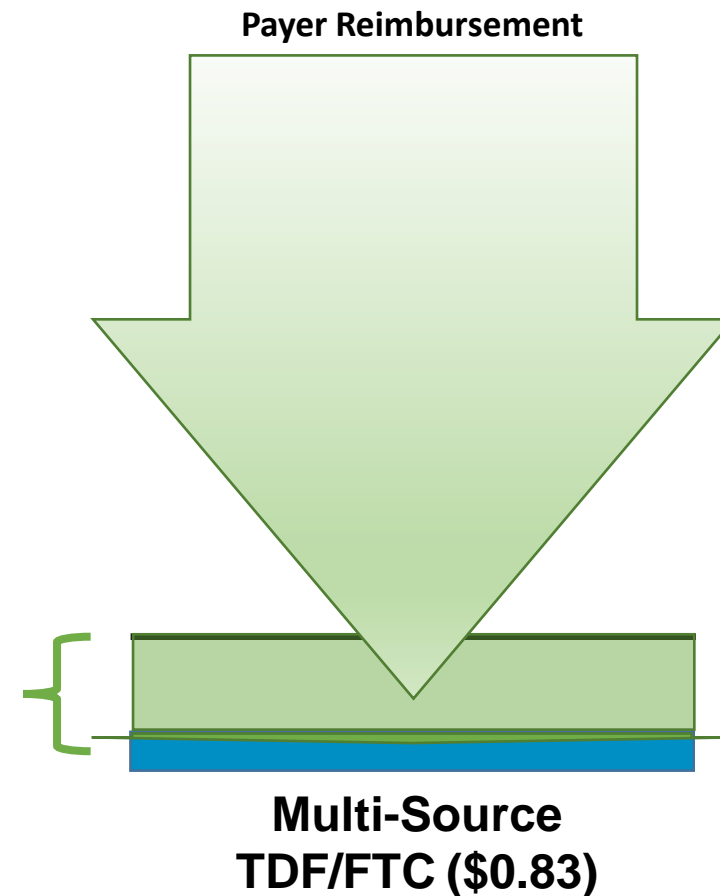
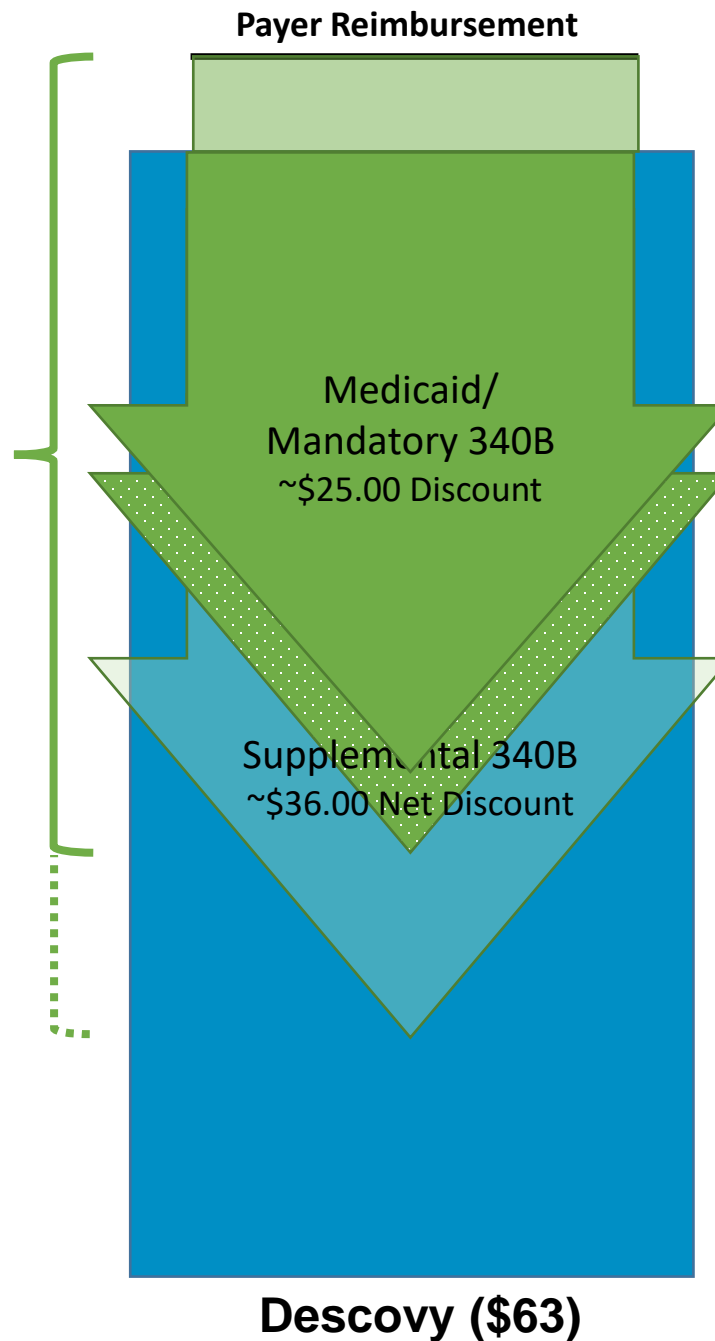
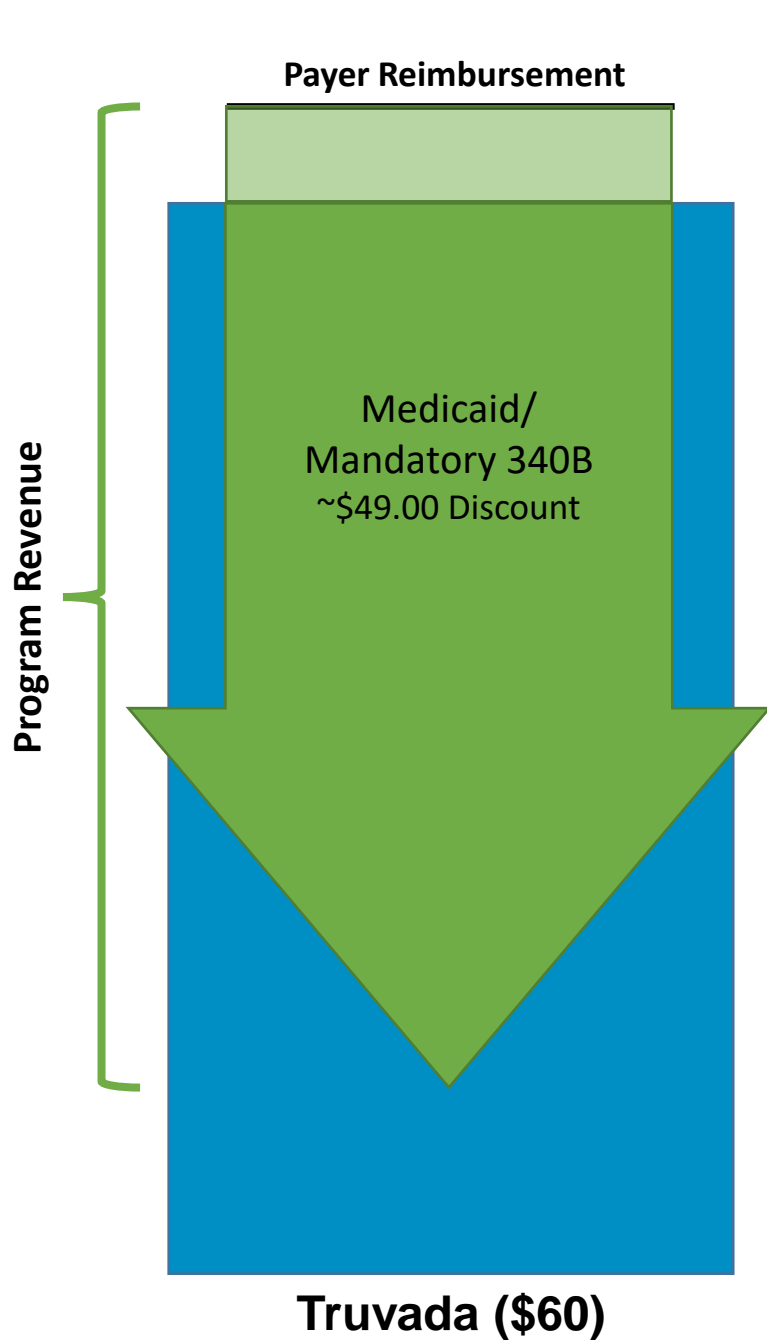
Generic Competition is Here

- 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 \$0.83 per pill (Feb 2022)
- Price declines have reduced 340B cost-savings.
- Low-cost generics create opportunities for innovative community and public health programming

NADAC* Pricing Trends (Per Tablet)



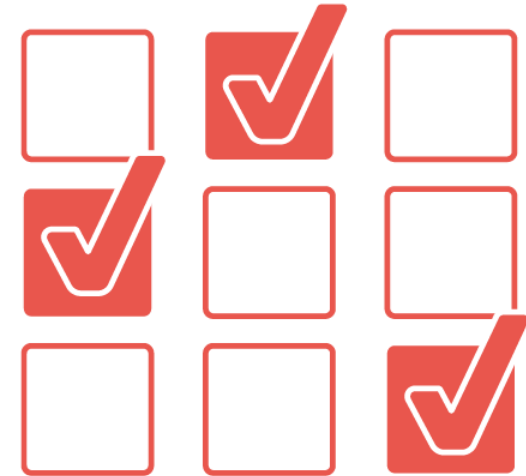
National Average Drug Acquisition Cost (data.medicaid.org)



Knowledge Check

Does drug company policy influence 340B savings? For instance, a company determining how a medication can be filled.

- ☐ Yes
- ☐ No
- ☐ Unsure



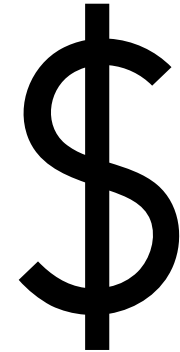
Changes to Gilead Sciences Advancing Access Program

- Advancing Access will continue its retail pharmacy model as an option for securing Gilead HIV drug products via the Patient Support Program
- Gilead will no longer reimburse pharmacies dispensing HIV medications under Advancing Access at usual and customary rates
- Will reimburse pharmacies dispensing drug products for both HIV prevention and treatment under Advancing Access at the acquisition cost (net of 340B discounts and chargebacks) plus a dispensing fee (\$2.75) and an administration fee (\$80.00)
- Greater impact on states without Medicaid expansion

NASTAD is starting to hear more about the impact this change is having on programs.

Reduced Voluntary Supplemental Discounts

- Sole discretion of the manufacturer.
- Gilead Sciences reduced its voluntary supplemental discounts for Descovy® in 2021 after extending them for several years.
- The significant increase in the price of Descovy® led to decreasing 340B revenue generation on prescription fills subject to insurance payments



Current Program Limitations and Opportunities

Opportunities

- United States Preventive Services Task Force (USPSTF) Grade A recommendation of PrEP
- Continuation of the Gilead Advancing Access[®] program.
- The Ready, Set, PrEP Program
- U.S approval and commercialization of Apretude, cabotegravir extended-release injectable suspension.

Limitations

- Funding ancillary services, such as:
 - HIV Testing;
 - HCV Testing;
 - HBV Testing and Immunization;
 - Syphilis Testing;
 - Chlamydia and Gonorrhea Testing;
 - Pregnancy Testing;
 - Serum Creatinine Screening; and
 - Provider Consultations/Office Visits.

Service Organization Strategies

Provider Types

When assessing strategies to constrain costs, organizations may consider provider type when building or scaling programs.

- Utilizing non-MD provider types may provide opportunities to reduce organizational costs of care management and extend the life of available resources.
- In some jurisdictions, Registered Nurses and/or Pharmacists may be able to prescribe and manage PrEP under collaborative practice agreements.

Provider Type	National Median Salary 2020 ¹²
Physician	\$208,000.00
Physician Assistant	\$115,390.00
Nurse Practitioner	\$117,670.00
Registered Nurse	\$75,330.00
Clinical Pharmacist	\$128,710.00

Knowledge Check

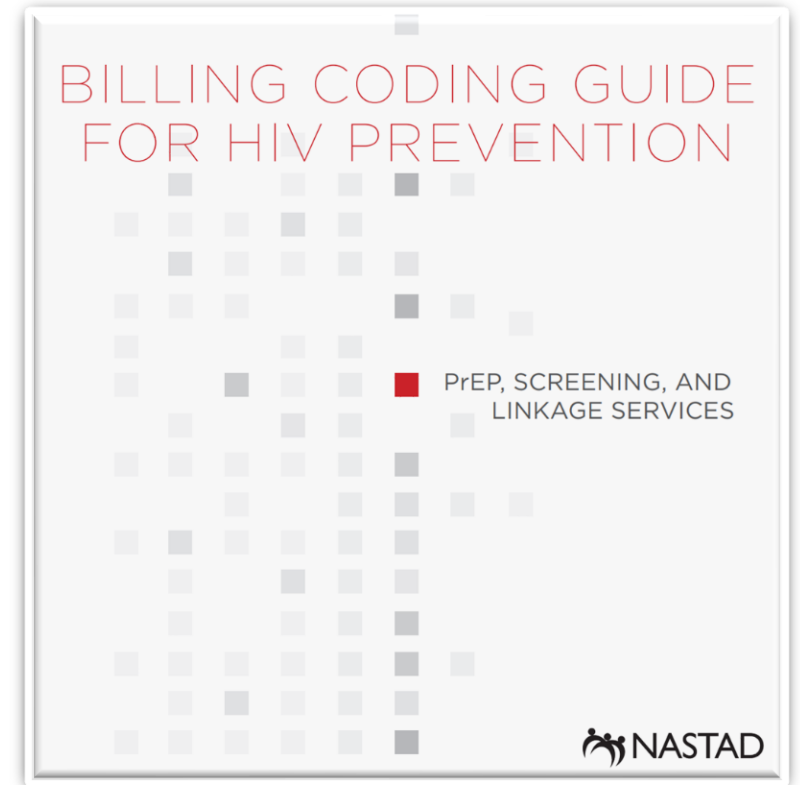
Under the USPSTF Grade A recommendation, what PrEP services must be covered without cost-sharing?

- ☐ PrEP Medication
- ☐ Routine PrEP Labs
- ☐ Clinical Visit
- ☐ Adherence Counseling
- ☐ All of the above
- ☐ None



Appropriate Billing and Coding

- Organizations that provide PrEP care can and should seek reimbursement for services through payors when individuals have health insurance.
- Using appropriate codes is an essential strategy in ensuring appropriate coverage.
- NASTAD Billing and Coding Guide for HIV Prevention
- NCSD STD Technical Assistance Center Billing Toolkit
- Illinois Public Health Association Billing Manual for HIV Testing and Related Services



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

Federal Grants Overview

Federal Programs & the PrEP Continuum

Cascade Step

- Priority populations
- HIV counseling / testing
- PrEP Awareness
- PrEP Linkage
- PrEP Start
- PrEP Initiation
- PrEP Persistence

Federal Programs

- HRSA / Ryan White Part B
- HRSA – EHE Primary Care
- CDC – High Impact Prevention CBO
- CDC – HIV Prevention & Surveillance
- CDC – STD Prevention
- CDC – Hepatitis C
- CDC – EHE

Grants overview:

- ❑ PS18-1802: CDC Integrated HIV Surveillance and Prevention
- ❑ PS19-1901: CDC STD Prevention and Control
- ❑ PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic
- ❑ PS21-2102: Comprehensive High-Impact HIV Prevention Programs for Community-Based Organizations
- ❑ PS21-2103: CDC Integrated Viral Hepatitis Surveillance and Prevention
- ❑ HRSA-21-091; HRSA-21-092; HRSA-22-104: Ending the HIV Epidemic-Primary Care HIV Prevention (PCHP) Funding
- ❑ HRSA Ryan White HIV/AIDS Program

PS18:1802 CDC Integrated HIV Surveillance and Prevention

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
			HIV Testing + additional required initiation and monitoring labs for uninsured and underinsured.	Limited, when occurring in conjunction with other essential support services.		Incentives, transportation or communication assistance, counseling

● Limited ● Allowable ● Unallowable

*Retention and adherence support services are those services that empower individuals to remain engaged in care and overcome obstacles to medication adherence. These are often an extension of initial navigation services and clinical care. Support types may include incentives, transportation assistance, and ongoing medication management counseling, among other strategies.

- May be used to support required initiation and monitoring labs for uninsured or underinsured persons.
- May support prescriber time when occurring in conjunction with other essential support services.
- Incentives, transportation support, and communication assistance are now allowable ancillary costs to support retention/adherence.

PS19-1901: CDC STD Prevention and Control

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
			STI Testing (limited to a percentage of the total award)			

● Limited ● Allowable ● Unallowable

- May be used to support STI testing – limited to a capped percentage of the total award (10%).

PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
			<i>HIV Testing + additional required initiation and monitoring labs for uninsured and underinsured.</i>	<i>Limited, when occurring in conjunction with other essential support services.</i>		<i>Incentives, transportation or communication assistance, counseling</i>
● Limited	● Allowable	● Allowable			● Unallowable	

- May be used to support required initiation and monitoring labs for uninsured or underinsured persons.
- May support prescriber time when occurring in conjunction with other essential support services.
- Incentives, transportation support, and communication assistance are now allowable ancillary costs to support retention/adherence.

PS21-2102: Comprehensive High-Impact HIV Prevention Programs for Community-Based Organizations

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
						May use funds to navigate clients to existing essential support services
● Limited	● Allowable	● Unallowable				

- May use funds to support navigation of clients to existing essential support services.

PS21-2103: CDC Integrated Viral Hepatitis Surveillance and Prevention

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
		Patient or Peer Navigation	Hepatitis B&C Testing			

● Limited ● Allowable ● Unallowable

- May be used to support patient or peer navigation activities.
- May be used to support Hepatitis B and C testing.

HRSA-21-091; HRSA-21-092; HRSA-22-104: Ending the HIV Epidemic-Primary Care HIV Prevention (PCHP) Funding

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
					Funds may be used after all other sources are exhausted	Communication assistance, provider counseling

● Limited ● Allowable ● Unallowable

- May be used to support medication costs, without limits, after all available patient assistance options have been exhausted.
- Communication assistance and provider counseling are allowable to support retention and adherence efforts.

HRSA Ryan White HIV/AIDS Program

Marketing & Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
Specific to status awareness		Navigation to HIV services based on status	HIV Testing Only			
Limited	Allowable			Unallowable	Unallowable	Unallowable

- Marketing efforts are allowable to increase status awareness and entry into a status neutral systems of care.
- May be used to support navigation to HIV prevention and care services based on status.
- May be used to support HIV testing as the point of entry into care systems - but cannot be used for other laboratory tests.
- Must supplement and not supplant existing funding sources.

Federal Grants PrEP Continuum Crosswalk

Funding Opportunity	Marketing and Awareness	HIV Testing & PrEP Evaluation	Navigation Services	Lab Studies	Prescribing	Medication	Retention / Adherence Support*
PS18-1802				HIV Testing + additional required initiation and monitoring labs for uninsured and underinsured.	Limited, when occurring in conjunction with other essential support services.		Incentives, transportation or communication assistance, counseling
PS19-1901				STI Testing (limited to a percentage of the total award)			
PS20-2010				HIV Testing + additional required initiation and monitoring labs for uninsured and underinsured.	Limited, when occurring in conjunction with other essential support services.		Incentives, transportation or communication assistance, counseling
PS21-2102							May use funds to navigate clients to existing essential support services
PS21-2103			Patient or Peer Navigation	Hepatitis B&C Testing			
HRSA-21-091/092 & 22-104						Funds may be used after all other sources are exhausted	Communication assistance, provider counseling
HRSA-Ryan White Part B	Specific to status awareness		Navigation to HIV services based on status	HIV Testing Only			

● Limited

● Allowable

● Unallowable



Contact Information

Contact Information:

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