PrEP is Comprehensive

Laboratory Services  ❑  Scheduling  ❑  Follow Up Monitoring  ❑  TelePrEP  ❑  Office Visits  ❑  PrEP Navigation  ❑  Social Work  ❑  Case Management  ❑  Billing  ❑  Referral Services  ❑  Housing Support  ❑  Mental Health Counselling  ❑  Outreach  ❑  Education  ❑  Awareness Campaigns  ❑  Adherence Education and Counselling  ❑  PrEPDAP programs
PrEP is Comprehensive

The 340B Drug Pricing Program helps Ryan White HIV/AIDS Programs, including ADAPs, to achieve both cost containment and revenue “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

—H. R. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session
Laboratory Services º Scheduling º Follow Up Monitoring º TelePrEP º Office Visits º PrEP Navigation º Social Work º Case Management º Billing º Referral Services º Housing Support º Mental Health Counselling º Outreach º Education º Awareness Campaigns º Adherence Education and Counselling º PrEPDAP programs
U.S. Drug Pricing: It’s Complicated

- **Average Wholesale Price (AWP)**
- **Wholesale Acquisition Cost (WAC)**

### Average Manufacturer Price (AMP)
- Best Price
- Unit rebate: 23.1% / 13% of AMP or AMP – Best Price plus CPI penalties

- **340B Price**
- **Medicaid Price**

### Generics
- Federal Upper Limit
- State Maximum Allowable Cost
- Commercial Payer MAC

### Private sector prices
- Rebates to PBMs
- Copay assistance
- Other price concessions

### Nonfederal Average Manufacturer Price (Non-FAMP)
- Negotiation on most-favored commercial customer price
- 76% of non-FAMP minus additional discounts

### Federal Supply Schedule (FSS) Price

### Federal Ceiling Price

### Federal Ceiling; “Big 4” Price

### Supplemental discounts negotiated (VA and DoD)
34B Discount and Program Income Basics

- Insurance Payment
  - WAC Price
- 340B Ceiling Price
- 340B Entities
- Discount from Manufacturer
- Program Income
340B: Covered Entities

Health Centers
- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Hospitals
- Children’s Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

Ryan White HIV/AIDS Program Grantees

Specialized Clinics
- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- STD Clinics and 318 Grantees
- Tuberculosis Clinics
340B Program Income Over Time

LAUNCH: $100.00
YEAR 4: $140.00
YEAR 8: $175.00

PROGRAM INCOME
Insurance Payment
URA 23.1%
CPI Penalty

Insurance Payment
URA 23.1%
CPI Penalty

Insurance Payment
URA 23.1%
CPI Penalty

PROGRAM INCOME

Insurance Payment

PROGRAM INCOME

Insurance Payment

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Insurance Payment

PROGRAM INCOME

Insurance Payment

PROGRAM INCOME

Insurance Payment

PROGRAM INCOME

Insurance Payment
Challenges to 340B Program Income

- Any legislation or regulations that lowers list prices and prices in private market
- Legislation or regulations that alter 340B Drug Pricing Program, including entity and patient definitions
- Legislation or regulations allowing payers to reimburse 340B discounted drugs at lower rates
- Competition that lowers prices
- Patent cliffs and commercialization of generic drug products
TDF/FTC ($58)

TAF/FTC ($58)

TDF/3TC ($33.50)

TDF/FTC ($52)

TDF/FTC ($3.50)
<table>
<thead>
<tr>
<th></th>
<th>Medicare &amp; Commercial Plans</th>
<th>Medicare &amp; Commercial Plans</th>
<th>Medicare &amp; Commercial Plans</th>
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<tbody>
<tr>
<td><strong>TDF/FTC</strong></td>
<td>![TDF/FTC ($58)]</td>
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<td><strong>TAF/FTC</strong></td>
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<tr>
<td><strong>TDF/FTC</strong> (single source)</td>
<td>![TDF/FTC ($52)]</td>
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<tr>
<td><strong>TDF/FTC</strong> (multi-source)</td>
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<thead>
<tr>
<th></th>
<th>List/WAC</th>
<th>TAF/FTC</th>
<th>TDF/3TC</th>
<th>TDF/FTC (single source)</th>
<th>TDF/FTC (multi-source)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>List/WAC</strong></td>
<td>$1,757</td>
<td>$1,757</td>
<td>$1,005</td>
<td>$1,580</td>
<td>$105</td>
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<tr>
<td><strong>340B Price</strong></td>
<td>$415</td>
<td>$415</td>
<td>$772</td>
<td>$1,374</td>
<td>$91</td>
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<tr>
<td><strong>340B Program Income</strong></td>
<td>$1,347</td>
<td>$1,347</td>
<td>$238</td>
<td>$211</td>
<td>$19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>TDF/FTC ($58)</th>
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<th>TDF/3TC ($33.50)</th>
<th>TDF/FTC ($52)</th>
<th>TDF/FTC ($3.50)</th>
</tr>
</thead>
</table>
ACA mandates that private insurance plans and Medicaid expansion programs cover preventive services with a USPSTF A or B rating at no cost.

- Plans must adopt in the plan year that begins at least one year following the final USPSTF recommendation (for PrEP that means January 2021 for most plans and Medicaid).

**USPSTF Draft Grade A Recommendation**

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons at high risk of HIV acquisition</td>
<td>The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.</td>
<td>A</td>
</tr>
</tbody>
</table>
Implementation Considerations

Access to the medication

• Competition in the PrEP medication space; individuals need access to clinically recommended regimen, but may not be appropriate to push for open formulary
• Potential for UM to be used in discriminatory ways (e.g. prior authorization to determine risk should be prohibited)

Access to PrEP services beyond medication

• Lab tests and clinical visit costs at initiation and every three months should be covered without cost sharing, but are not explicitly included in USPSTF recommendation
Advocates have asked CMS/CCIIO and CMS/CMCS to issue guidance to private insurance plans and state Medicaid agencies about appropriate implementation.

Advocates are asking state insurance regulators to issue bulletins and guidance to plans (e.g., NY Department of Insurance Bulletin on non-discriminatory practices for PrEP coverage).

Provider and consumer education is critical to ensure that USPSTF and CDC guidelines are being followed and to ensure consumers know about new cost-sharing protections.
PrEP Donation

- Gilead has committed to provide the PrEP medication for up to 200,000 people a year for up to 11 years
- Commitment to donate Truvada and Descovy
- Gilead bears the cost for the medication itself. Specifically, Gilead must reimburse pharmacies for (or back fill) PrEP medication that the pharmacies distribute to eligible patients
Gilead has been awarded a $6 million six-month contract to provide Truvada to 4,250 uninsured patients

- Optional six-month extension for a total of 10,000 people in Year 1 of program
- During the six-month period, HHS will hold a full and open competition to select a longer-term contractor or contractors.

HHS will cover the cost of verifying eligibility, enrollment, building a network of participating pharmacies, dispensing medication to uninsured patients, etc.

HHS has announced webinar on November 15th to provide more information about the program, which is expected to launch in the next month.
PrEP Donation Program

- To qualify, patients must:
  - Lack health insurance coverage for outpatient prescription drugs
  - Have a valid “on-label” prescription
  - Have appropriate testing showing that the patient is HIV-negative
  - Patients who are currently enrolled or have been enrolled in the last 12 months in the Gilead Medication Assistance Program CANNOT enroll in the HHS program

- Any provider with a qualified patient can access the program
- Eligible patients can enroll in the program and receive donated medication through the mail or at a pharmacy
- Nationwide rollout with initial focus on Phase 1 ETE jurisdictions
- HHS awarded a contract to Brunet-Garcia to develop an education and awareness campaign to maximize the impact of the PrEP donation program. The awareness campaign will focus its efforts on Phase 1 EtHE jurisdictions.
Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms

<table>
<thead>
<tr>
<th>Drug Access</th>
<th>PrEP Clinical Visits &amp; Lab Costs</th>
<th>Counseling and Linkage</th>
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</thead>
<tbody>
<tr>
<td><strong>Uninsured</strong></td>
<td></td>
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<tr>
<td>Manufacturer Patient Assistance Program</td>
<td>PrEP DAPs (state funded)</td>
<td>PrEP DAPs (state funded)</td>
</tr>
<tr>
<td>HHS/Gilead Donation Program</td>
<td>CDC prevention funds to pay for HIV/STD testing</td>
<td>CDC prevention grants and 340B savings</td>
</tr>
<tr>
<td>PrEP Drug Assistance Programs or “PrEP DAPs” (state funded)</td>
<td>CHCs; Family Planning Clinics; STD Clinics using 340B savings</td>
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</tr>
<tr>
<td>CHCs; Family Planning Clinics; STD Clinics using 340B savings</td>
<td>?? CDC EtHE NOFO flexibility??</td>
<td></td>
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<tr>
<td><strong>Insured</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covered by payers; co-pay assistance through manufacturer assistance program</td>
<td>Largely covered, but with patient co-pays; some state programs cover co-pays with state funds</td>
<td>Not well covered by public or private insurance</td>
</tr>
</tbody>
</table>
Summary

- Generic TDF/FTC poses new opportunities to contain individual and health care system costs of a critical biomedical prevention tool
- Generic competition poses important challenges to many PrEP program financing models dependent on 340B Program Income
- Implementation of USPSTF recommendation must balance maximized access with cost-conscious formulary design
- TAF/FTC must be available with the same cost-sharing protections for individuals for whom it is indicated based on clinical judgment and grounded in clinical guidelines
THANK YOU!

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