Drug Pricing in the Age of Generics

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Faculty and Planning Committee Disclosures
Please consult your program book or Conference App.

Off-Label Disclosure

• There will be no off-label/investigational uses discussed in this presentation.

Learning Objectives
Upon completion of this presentation, learners should be better able to:

• Describe the fundamentals of HIV drug pricing and its net impact on key public and private payer systems in the United States
• Evaluate the potential cost savings associated with prescribing generic antiretroviral regimen components
• Articulate recent and emerging public and private policies that may impact antiretroviral pricing and access
• Discuss the potential strengths and challenges of cost containment associated with generic TDF/FTC for PrEP
ARS QUESTION

- ARV treatment constitutes what percentage of lifetime HIV care costs?
  - 10%
  - 15%
  - 60%
  - 70%


Getting to 90-90-90 (73% VL Suppression)

Discounting adjustment (estimated):
- Commercial and Medicare — None
- Medicaid (24%), Full-Pay ADAP (16%), VA (4%) — 40%
- Does not include non-ADAP 340B purchases or voluntary rebates to ADAPs


ARS QUESTION

- ARVs rank No. ___ in Medicaid prescription drug spending:
  - 1
  - 2
  - 4
  - 6
ARS QUESTION

- Generic drugs are approved and available for use as first-line therapy, consistent with the HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV
  - Yes
  - No
  - Not sure

Generic Options (2019)

• Generic Drugs
  • abacavir, abacavir/lamivudine, atazanavir, didanosine, fosamprenavir, lamivudine, nevirapine, ritonavir, stavudine, tenofovir disoproxil fumarate

• Branded “Quasi-Generic” Drugs
  • Mylan: EFV [600 mg]/TDF/3TC, EFV [400 mg]/TDF/3TC, TDF/3TC
  • Celltrion: TDF/3TC (not yet commercially available)

• Pending Generics
  • 2021: TDF/FTC
  • 2025/2026: darunavir, raltegravir

HHS Guidelines Preferred Regimens

- BIC/TAF/FTC
- DTG/ABC/3TC
- DTG/TXF/XTC
- RTG/TXF/XTC

<table>
<thead>
<tr>
<th>Regimen</th>
<th>NADAC1</th>
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<tbody>
<tr>
<td>BIC/TAF/FTC</td>
<td>$2,856</td>
</tr>
<tr>
<td>DTG/ABC/3TC</td>
<td>$2,797</td>
</tr>
<tr>
<td>DTG + TDF/3TC</td>
<td>$2,694</td>
</tr>
<tr>
<td>DTG + ABC/3TC</td>
<td>$1,778</td>
</tr>
<tr>
<td>DTG + TDF + 3TC</td>
<td>$1,798</td>
</tr>
<tr>
<td>RTG + TDF + 3TC</td>
<td>$1,680</td>
</tr>
</tbody>
</table>

TXF = tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide fumarate (TAF)
XTC = lamivudine or emtricitabine


Italics denote generic/quasi-generic availability
Generics

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

Average Manufacturer Price (AMP)

Unit rebate: 23.1% / 13% of AMP or AMP – Best Price plus CPI penalties

Best Price

Private sector prices

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)

Generics

Federal Upper Limit
State Maximum Allowable Cost
Commercial Payer MAC

Rebates to PBMs
Copay assistance
Other price concessions

340B Price
Medicaid Price

Supplemental rebates and discounts negotiated (including ADAPs)

Medicaid Price

340B Price

Supplemental rebates and discounts negotiated (including ADAPs)

Best Price

Unit rebate: 23.1% / 13% of AMP or AMP – Best Price plus CPI penalties

Generics

Federal Upper Limit
State Maximum Allowable Cost
Commercial Payer MAC

Rebates to PBMs
Copay assistance
Other price concessions

Private sector prices

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)

 мероприятие

COMMERCIAL PAYERS
EFV/TDF/FTC Formulary Changes in 2019

- Dropped from all United Healthcare commercial formularies (Medicaid and Medicare plans unaffected)
- Dropped by Express Scripts National Preferred Formulary (NPF)
- Dropped by some BC/BS plans in some states (possibly driven by NPF changes)
- Likely driven by lower-cost comparable STR: EFV/TDF/3TC

UHC: My ScriptRewards $0 Cost-Sharing & Incentive Option

- Coformulated TDF/3TC plus either dolutegravir or raltegravir
  - Consistent with HHS Guidelines
- Will not be subject to deductible or copayment/coinsurance charges
- May be eligible to receive up to two $250 debit cards annually to offset other medical expenses (limited use to certain merchant codes and healthcare-related SKUs)
- Limited to small and large group plans (no individual, ACA Marketplace/QHP, Medicare, or Medicaid plans)
UHC: Pharmacy Soft Rejects

• Originally applied to all new prescriptions for BIC/TAF/FTC, EVG/COBI/TAF/FTC, EVG/COBI/TDF/FTC
• Now applied after 90 days/on fourth fill
• Optum (UHC PBM) will reject claim and pharmacy will instruct patient to call My ScriptRewards program
• Opt-out: Immediate override and Rx filled
• Opt-in: New Rx required from provider

UHC My ScriptRewards: Results (as of 3/1/19)

<p>| | |</p>
<table>
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<tr>
<th></th>
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<tbody>
<tr>
<td>Signups</td>
<td>95</td>
</tr>
<tr>
<td>MSR Regimens Filled</td>
<td>40</td>
</tr>
<tr>
<td>Eligible</td>
<td>38</td>
</tr>
<tr>
<td>Ineligible</td>
<td>17</td>
</tr>
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</table>
Notice of Benefit and Payment Parameters – 2020

• Encouraging use of generic drugs
  – Allow for mid-year formulary changes (dropping brand-name for generic)
  – Allow brand-name to be excluded from essential health benefits (EHB) if generic is available
  – Plans not required to count brand-name copay cards toward annual cap on cost sharing (only if generic is available)

• Introduces therapeutic substitutions (comments only)
  – Possible example: breaking up single-tablet regimens

• Introduces referencing pricing for newer, higher-cost drugs
  – Possible example: patient pays spread difference
Medicare Basics

- ~25% of PLWHIV in care are covered by Medicare\(^1\)
- >50% of PLWHIV expected to be covered by Medicare in next 2 decades\(^1\)
- Single largest federal source of HIV care and treatment funding (50% of all federal funding; $10 billion in 2016)\(^1\)
- Antiretrovirals are one of six Medicare Part D protected classes
- Part D Plan/PBM rebating minimal/non-existent\(^2\)

Protected Classes Proposed Rule

- **Goal:** Force brand-name discounting and/or preference for generic drug products
  - Expanded use of step therapy and prior authorization (including in the ARV class)
  - Exclusion of a drug that is a new formulation of an existing drug or biologic without a unique route of administration
  - Exclusion of a drug if the price of the drug increased beyond a certain threshold
- **Problem:** Population-level cost containment when generics are limited and individualized therapy requires access to brand-name products
340B DRUG PRICING PROGRAM & ADAPS

340B: Multiple Challenges

• Created in 1992 requiring manufacturers provide discounted outpatient drugs to certain health care entities
  – Goal: to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”
• Considerable growth: 20,000 entities in 2013 (38% hospitals) to 38,000 in 2017 (56% hospitals)¹
• Federal grantees (e.g., Ryan White, ADAPs, family planning, STI clinics) must reinvest and document spending²
• Hospitals (and affiliates) comprise 80% 340B sales, with limited standards and transparency for revenue spending²

340B: Multiple Challenges

• 340B reduces manufacturer revenues by 1.9% (all sales)\(^1\)
• Federal/state reform efforts: increase standards and transparency (particularly for hospitals), reduce discount size, reduce payments to 340B entities, limit 340B eligibility definitions, regulate contract pharmacies and PBMs, scale back 340B billing of Medicaid MCOs
• Organic shifts also impact 340B
  – Newer drugs with less discounting
  – Generics with minimal discounting


AIDS Drug Assistance Programs

• Pipeline dynamics
  – Long-acting injectables (IV, IM) associated with medical costs, copay issues
• Payers-of-last-resort: on the hook if insurance plans do not cover high-cost treatments?
• If/when generics become standard-of-care, cost-effectiveness supporting insurance purchasing may shift
PRE-EXPOSURE PROPHYLAXIS (PREP)

PrEP use has been increasing every year.

Estimated 1.1 million U.S. residents considered to be at high risk for HIV and could benefit from PrEP\(^1\)

110,000 to 205,000 estimated U.S. PrEP users in 2017 (172,500 best estimate)\(^2\)

Average persistence: 14.5 months (insured) and 7.6 months (Medicaid)\(^3\)

PrEP Access and Utilization Requires...

- Knowledge of HIV vulnerability/risk
- Knowledge of PrEP and its availability
- Culturally competent care and providers willing to prescribe PrEP
- *Must be affordable*

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### PrEP-based Primary Prevention is Expensive

<table>
<thead>
<tr>
<th>Description</th>
<th>Average Annual Cost</th>
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</thead>
<tbody>
<tr>
<td>Number of Clinic Visits¹</td>
<td>4.9</td>
</tr>
<tr>
<td>Number of Lab Tests¹</td>
<td>26.1</td>
</tr>
<tr>
<td>Visit Payments¹</td>
<td>$925</td>
</tr>
<tr>
<td>Lab Payments (Negotiated)¹</td>
<td>$291</td>
</tr>
<tr>
<td>Lab Payments (Non-Negotiated)¹</td>
<td>$3,955</td>
</tr>
<tr>
<td>TDF/FTC (Undiscounted @ $1,700/month)</td>
<td>~$20,400</td>
</tr>
<tr>
<td>TDF/FTC (Discounted 340B @ ~75%/month)</td>
<td>~$5,100</td>
</tr>
<tr>
<td>TOTAL Per Patient Per Year (Approximate)</td>
<td>$6,317 – $24,355</td>
</tr>
</tbody>
</table>

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• Will require coverage, **without cost sharing**, under group and individual health plans and Medicaid
• Plans must adopt in the plan year that begins at least one year following final USPSTF recommendation
• Potential for utilization management – preference for generics
• Potential for onerous (and stigmatizing) risk assessments by payers
• Includes HIV, hep, and STI testing at initiation and Q3M; provider appointments – all should be covered without cost sharing
The Big Questions

- Assuming many people living with/vulnerable to HIV may be able to use lower-cost TDF-inclusive regimens, how should this be factored in to clinical decision making and guide payer cost-containment measures?
- Do ARV prescription costs need to be contained and, if so, can this be done without restrictive market forces to drive competition?
- Can any cost savings be reinvested in HIV care/prevention?
- Is the 340B Drug Pricing Program a sustainable solution for our critical medical and social support programs?

THANK YOU!

thorn@NASTAD.org
ACTHIV 2019: A State-of-the-Science Conference for Frontline Health Professionals