Drug Pricing and Generics: Impact on Ryan White HIV/AIDS Programs

Tim Horn, MS
Director, Medication Access and Pricing
National Alliance of State & Territorial AIDS Directors
Washington, DC

Financial Relationships With Commercial Entities

Mr Horn has no relevant financial affiliations to disclose. (Updated 11/11/19)

Learning Objectives

After attending this presentation, learners will be able to:
• Describe the 340B Drug Pricing Program and its role in achieving cost containment and program income for Ryan White HIV/AIDS Programs
• Describe the challenges associated with high antiretroviral drug pricing
• Assess the impact of generic drugs on program cost containment and 304B program income
**RWHAP Core Medical and Support Services**

AIDS Drug Assistance Program Treatments + AIDS Pharmaceutical Assistance +
Early Intervention Services (EIS) + Health Insurance Premium and Cost Sharing
Assistance for Low-Income Individuals + Home and Community-Based Health
Services + Home Health Care + Hospice Services + Medical Nutrition Therapy +
Medical Case Management, including Treatment Adherence Services + Oral
Health Care + Outpatient Ambulatory Health Services + Substance Abuse
Outpatient Care + Child Care Services + Emergency Financial Assistance + Food
Bank/Home Delivered Meals + Health Education/Risk Reduction + Housing +
Linguistic Services + Medical Transportation + Non-Medical Case Management
Services + Outreach Services + Professional Services + Psychosocial Support
Services + Referral for Health Care and Support Services + Rehabilitation
Services + Respite Care + Residential Substance Abuse Services

---

**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
Over the past 10 years, list prices of DHHS Guidelines “preferred” single-tablet regimens have increased by how much?

A. 10% to 50%
B. 50% to 100%
C. 100% to 150%
D. 150% to 200%
E. More than 200%
Payer and Access Considerations

- Total undiscounted spending on ARVs in 2018: $22.8 billion\(^1\)
- HIV among the top five therapeutic classes in non-discounted spending in 2018, after medications for diabetes, autoimmune diseases, cancer and respiratory diseases\(^2\)
- ARVs are No. 1 Medicaid outpatient drug expenditure (No. 5 and 4 for commercial and ACA plans, respectively)\(^2\)
- Public and private payers: increasing formulary restrictions, utilization management (e.g., prior auth)
- Out-of-pocket spending is an issue; copay assistance programs in crosshairs

---

1. IQVIA. Medicine Use and Spending in the U.S. 2018 April.
**Multi-Source “Generic” Drugs**
- abacavir, abacavir/lamivudine, atazanavir, didanosine, fosamprenavir, lamivudine, nevirapine, ritonavir, stavudine, tenofovir disoproxil fumarate

**Multi-Source “Quasi-Generic Brand” Drugs**
- Mylan: EFV/TDF/3TC, EFV(400)/TDF/3TC, TDF/3TC
- Celltrion: TDF/3TC

**Pending Generics**
- September 2020: TDF/FTC
- Mid-2020s: darunavir, raltegravir

---

**ARS QUESTION 2**

Can generic drugs be used in DHHS Guidelines-recommended regimens?

A. No

B. Only “Initial Regimens in Certain Clinical Situations”

C. Both “Initial Regimens for Most People With HIV” and “Initial Regimens in Certain Clinical Situations”

---

**Generics in the HHS Guidelines**

- Recommended for Regimens for Most People With HIV
- Recommended for Regimens in Certain Clinical Situations
- Pending Generics

---

New Orleans, LA, December 4-7, 2019, Ryan White HIV/AIDS Program CLINICAL CONFERENCE
U.S. Drug Pricing: It’s Complicated

- Average Wholesale Price (AWP)
- Wholesale Acquisition Cost (WAC)
- Average Manufacturer Price (AMP)
- Federal Ceiling Price
- Federal Ceiling; “Big 4” Price
- Private sector prices
- Rebates to PBMs
- Copay assistance
- Other price concessions
- Supplemental discounts negotiated (including ADAPs)
- Medicaid Price
- 340B Price
- Unit rebate: 23.1% / 13% of AMP or AMP – Best Price plus CPI penalties
- Federal Upper Limit
- State Maximum Allowable Cost
- Commercial Payer MAC
- 24% of non-FAMP plus additional discounts

340B and the Ryan White HIV/AIDS Program

- The 340B Drug Pricing Program was developed to allow manufacturers to continue offering discounted drugs to safety net entities, following the introduction of the Medicaid Drug Rebate Program
- Medicaid required manufacturers to calculate average and best prices for the Medicaid program, and any discounts to safety net entities would reduce Medicaid reimbursement
- The 340B Program was established to allow manufacturers to exclude these discounts from their Medicaid calculations

340B Background
Manufacturers and 340B

- Why do manufacturers participate in 340B (and Medicaid)?
  - Manufacturers are not required to participate – they choose to participate and offer discounts
  - Participation is the only way to receive Medicare Part B and Medicaid reimbursement

340B and RWHAP

- RWHAP grantees are essential public health care programs and therefore eligible for 340B Drug Pricing Program
- RWHAPs also subject to extensive restrictions on how 340B can be used: program-eligible PLWHIV, "additive" use consistent with grant terms
- HRSA Policy Clarification Notice (PCN) 15-03
- Most RWHAP programs – or their contract pharmacies – access up-front discounts
- ADAPs, under RWHAP Part B, may choose up-front discounts and/or rebates paid by manufacturer
- ADAP Crisis Task Force negotiates supplemental discounts/rebates with manufacturers – agreements with all ARV manufacturers on behalf of all ADAPs

340B Discount and Program Income Basics

- 340B entities subject to a minimum discount of 23.1% off the Average Manufacturer Price; "Best Price" adjustment also possible
- When manufacturer takes a price increase that exceeds the Consumer Price Index for All Urban Costumers (CPI-U), an additional rebate – or "inflation penalty" – is added to base discount
- Achieves prescription drug cost containment
- Revenue, or "program income," is generated when clinics are able to purchase the drug at a discounted rate but are reimbursed by third-party payers at a higher usual and customary rate
340B Discount and Program Income Basics

- DISCOUNT or REBATE FROM MANUFACTURER
- PROGRAM INCOME
- DISCOUNT FROM MANUFACTURER
- PROGRAM INCOME
- PROGRAM INCOME

340B Program Income Over Time

- LAUNCH: $100.00
- YEAR 5: $140.00
- YEAR 10: $175.00

Challenges to 340B Program Income

- Any legislation or regulations that directly or indirectly lower "AMP" or "Best Price"
- Legislation or regulations that alter 340B Drug Pricing Program, including entity and patient definitions
- Legislation, regulations, or policies allowing payers to reimburse 340B discounted drugs at lower rates
- Competition that lowers list prices, AMP, or Best Price
- Patent cliffs and commercialization of generic drug products
A Word About PrEP

- Generic TDF/FTC
- USPSTF
- TAF/FTC LA-CAB

Payer Cost Containment

340B Savings

Summary

- The era of cost containment and generic competition has arrived; clinician knowledge/engagement increasingly important
  - Payers asking the same critical questions of data as clinicians: TAF vs. TDF, STRs vs. MTRs, added value of LA ARVs
- 340B has been a lifeline to US HIV programs, including RWHAP clinics and AIDS Drug Assistance Programs (ADAPs)
- ARV market (e.g., generics) and policy dynamics may impact 340B as savings source
- The big question: How do we make lower drug prices work to the advantage of people with, or at risk for, HIV?

THANK YOU!
thorn@NASTAD.org
Question-and-Answer Period