



# Bridging the Gap: HIV, Long-Acting Injectables (LAIs) & the Impact on Patient Disparities

Encore Presentation: 2025 Annual Meeting & Expo Highlights

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# Meet The Presenters



**Osaosemwen Aiyevbomwan,  
PHARMD, CSP, AAHIVP, BCMTMS**  
Clinical Pharmacist, CoP Subject  
Matter Expert – Infectious Disease  
Shields Health Solutions



**Kuwan Blake, BS**  
Manager, Communities of  
Practice (CoP)  
Shields Health Solutions



**Asia Suber, MBA**  
Pharmacy Liaison  
CoP Lead-Infectious Disease  
Shields Health Solutions

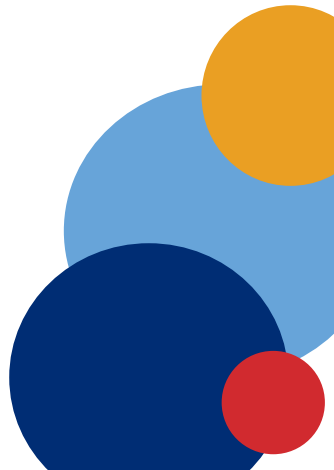
# Speaker Disclosures

We have no relevant financial conflicts of interest in relation to this activity to disclose.

# Learning Objectives

- **Discuss HIV Long-Acting Injectables (LAIs), their prevalence in practice, and how they compare to older regimens**
- **Review the impact of LAIs and the utilization of treatment to eliminate disparities in the HIV patient population**
- **Provide a review of best practices for patient medication access, financial assistance, and additional community resources to provide optimal patient outcomes**

# HIV Background



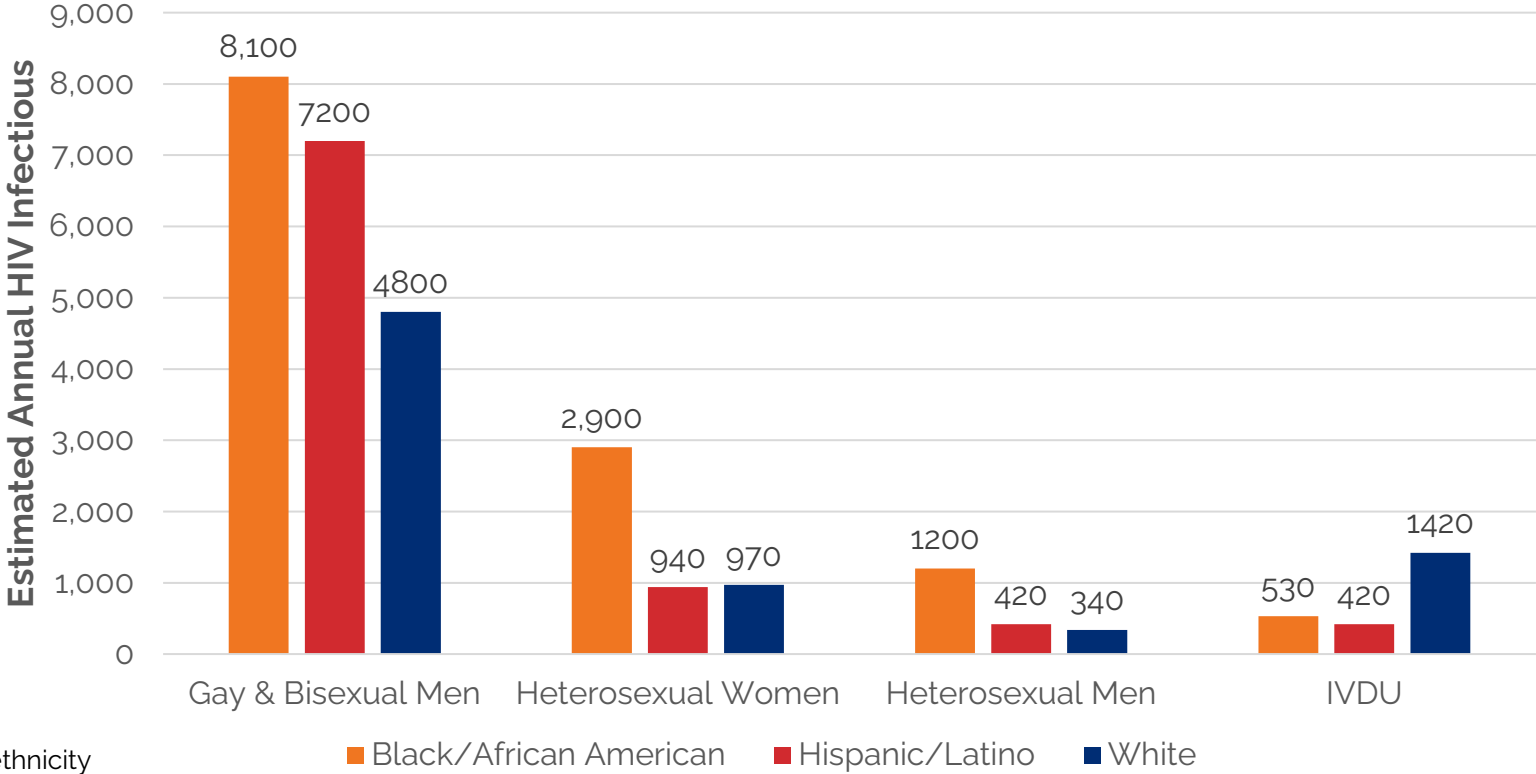
# HIV Epidemic in the U.S.

- ~1.2 million people living with HIV in the U.S.
- Approximately 13 percent are unaware of their positive status
- Disproportionate impact on certain populations, especially racial and ethnic minorities and men who have sex with men
- Highest rates of new diagnoses in the Southern United States

<https://www.cdc.gov/hiv-data/nhss/estimated-hiv-incidence-and-prevalence.html>

# HIV Infections by Race, Sexuality, and Intravenous Drug Use (IVDU)

Estimated New HIV Infections by Race/Ethnicity & Transmission Group, 2021



\* Data unavailable for other race/ethnicity  
Source: Centers for Disease Control & Prevention

# History of HIV treatment

**1987:** AZT (zidovudine) becomes first FDA-approved HIV medication

**2006:** First single-tablet regimens approved: Atripla (Efavirenz/emtricitabine/tenofovir)

**2021:** Cabenuva (cabotegravir/ rilpivirine) becomes the first complete long-acting injectable regimen

**2022:** Sunlenca (lenacapavir) approved for multidrug-resistant HIV

**1996:** Highly Active Antiretroviral Therapy (HAART) introduced: three-drug combo therapy becomes standard

**2012:** Pre-exposure prophylaxis (PrEP) approved: Truvada (emtricitabine/tenofovir disoproxil fumarate)

**2021:** Apretude (cabotegravir) approved, 1<sup>st</sup> LAI for PrEP

**2025:** Yeztugo (lenacapavir) approved as PrEP, first and only twice-yearly option

# Current HIV Therapy

## HIV Medications by Drug Class

Drug Class	Examples
<b>NRTIs</b> (Nucleoside Reverse Transcriptase Inhibitors)	Tenofovir Disoproxil Fumarate (TDF), Tenofovir Alafenamide (TAF), Emtricitabine (FTC), Lamivudine (3TC), Abacavir (ABC)
<b>NNRTIs</b> (Non-nucleoside Reverse Transcriptase Inhibitors)	Efavirenz (EFV), Doravirine (DOR)
<b>INSTIs</b> (Integrase Strand Transfer Inhibitors)	Bictegravir (BIC), Dolutegravir (DTG), Raltegravir (RAL), Elvitegravir (EVG)
<b>PIs</b> (Protease Inhibitors)	Darunavir (DRV), Atazanavir (ATV)
<b>Capsid Inhibitor</b>	Lenacapavir
<b>Fusion Inhibitor</b>	Enfuvirtide (T-20)
<b>CCR5</b> (C-C Chemokine Receptor Type 5) <b>Antagonist</b>	Maraviroc (MVC)
<b>Attachment Inhibitor</b>	Fostemsavir

# Long-Acting Injectables in HIV

PrEP vs Treatment		
	PrEP	Treatment
<b>Primary Goal</b>	Prevent HIV acquisition	Suppress HIV viral load
<b>FDA-Approved LAIs</b>	Apretude (cabotegravir) Yeztugo (lenacapavir)	Cabenuva (cabotegravir/rilpivirine) Sunlenca (lenacapavir)
<b>Mechanism of Action</b>	Apretude: INSTI Yeztugo: capsid inhibitor	Cabenuva: INSTI + NNRTI Sunlenca: capsid inhibitor
<b>Dosing Interval</b>	Apretude: Q2M (optional oral lead in) Yeztugo: Q6M	Cabenuva: Q1M or Q2M Sunlenca: Q6M (after oral lead-in)
<b>Administration Site</b>	Apretude: IM Yeztugo: SC	Cabenuva: IM Sunlenca: SC
<b>Clinical Trials</b>	HPTN 083/084 (Apretude) PURPOSE-1/2 (Yeztugo)	ATLAS, FLAIR, ATLAS-2M (Cabenuva) CAPELLA (Sunlenca)

# Clinical Trials



# Cabenuva (Cabotegravir/Rilpivirine) Clinical Trials

Trial	Analysis	Outcomes
ATLAS	<p><b>Population:</b> Adults with HIV-1 who were already virally suppressed on oral ART</p> <p><b>Design:</b> Phase 3, randomized, open-label</p> <p><b>Intervention:</b> Cabenuva (monthly injections) vs. continuing oral ART</p>	<ul style="list-style-type: none"> <li>• <b>92.5% in the Cabenuva group had VL &lt;50 vs 95.5% of pts in the oral ART group (95% confidence interval [CI], -6.7 to 0.7)</b></li> <li>• <b>Non-inferior to oral ART (standard therapy)-noninferiority margin, -10 percentage points</b></li> <li>• <b>High patient satisfaction and low rates of virologic failure</b></li> <li>• <b>Sustained efficacy through Week 96 in long-term follow-up</b></li> </ul>
FLAIR	<p><b>Population:</b> Treatment-naïve adults with HIV-1</p> <p><b>Design:</b> Phase 3, randomized</p> <p><b>Intervention:</b> After initial suppression on oral ART, participants were randomized to monthly Cabenuva vs. continuing oral ART</p>	<ul style="list-style-type: none"> <li>• <b>93.6% on Cabenuva maintained viral suppression at Week 48 vs 93.3% of pts on oral ART (95% CI: -2.8% to +3.5%)</b></li> <li>• <b>Comparable efficacy to daily oral ART</b></li> <li>• <b>Participants reported greater satisfaction and less stigma</b></li> </ul>
ATLAS-2M	<p><b>Population:</b> Adults already receiving Cabenuva monthly OR had completed a prior trial (ATLAS/FLAIR)</p> <p><b>Design:</b> Phase 3b, randomized, open-label, multicenter, non-inferiority trial</p> <p><b>Intervention:</b> Cabenuva (monthly injections) vs. Cabenuva (bimonthly injections)</p>	<ul style="list-style-type: none"> <li>• <b>94% (Q2M) vs. 93.5% (Q1M) maintained viral suppression at Week 48 (95% CI: -2.1% to +3.7%)</b></li> <li>• <b>Non-inferior efficacy between the two dosing strategies</b></li> </ul>

Swindells S et al. N Engl J Med. 2020;382(12):1112-1123.  
 Orkin C et al. N Engl J Med. 2020;382(12):1124-1135.  
 Overton ET, et al. Lancet HIV. 2021;8(11):e679-e689.

# Sunlenca (Lenacapavir) Clinical Trial

Trial	Analysis	Outcomes
CAPELLA	<p><b>Population:</b> 72 heavily treatment-experienced adults with MDR HIV</p> <p><b>Design:</b> Phase 2/3, randomized, double-blind (initial phase)</p> <p><b>Intervention:</b> Lenacapavir + failing background regimen vs Placebo + failing background regimen</p>	<ul style="list-style-type: none"><li>• <b>88% in lenacapavir group had viral load reduced by about 3 times (0.5 log<sub>10</sub>) vs. 17% in placebo (95% CI: 34.9%-90%)</b></li><li>• <b>During the maintenance period in cohort 1, 81% of participants had viral load of &lt;50 at week 26 (95% CI, 64 to 92)</b></li><li>• <b>89% of participants had viral load of &lt;200 at week 26 (95% CI, 74 to 97)</b></li></ul>

Kozal M et al. N Engl J Med. 2022;386(18):1793-1803.

# Apretude (Cabotegravir) Clinical Trials

Trial	Analysis	Outcomes
HPTN 083	<p><b>Population:</b> 4,566 cisgender men and transgender women who have sex with men</p> <p><b>Design:</b> Phase 2b/3, Randomized, double-blind, double-dummy, non-inferiority trial</p> <p><b>Intervention:</b> Apretude (Q2M injections) vs. Truvada</p>	<ul style="list-style-type: none"> <li>• HIV incidence rate (per 100 person-years) of .41 with Apretude vs 1.22 with Truvada (95% CI: 0.18 to 0.62)</li> <li>• Apretude reduced HIV incidence by 66% vs. oral PrEP</li> </ul>
HPTN 084	<p><b>Population:</b> 3,224 cisgender women at risk for HIV</p> <p><b>Design:</b> Phase 3, randomized, double-blind, double-dummy, superiority trial</p> <p><b>Intervention:</b> Apretude (Q2M injections) vs. Truvada</p>	<ul style="list-style-type: none"> <li>• HIV incidence rate (per 100 person-years) of .2 with Apretude vs 1.8 with Truvada (95% CI: 0.05 to 0.24)</li> <li>• Apretude reduced HIV incidence by 89% vs. oral PrEP</li> </ul>

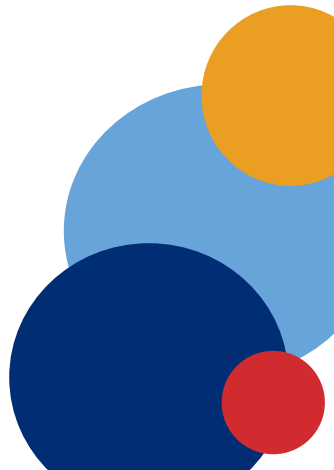
Landovitz RJ et al. N Engl J Med. 2021;385(7):595-608.  
 Delany-Moretlwe S et al. Lancet. 2022;399(10337):1779-1789

# Yeztugo (Lenacapavir) Clinical Trials

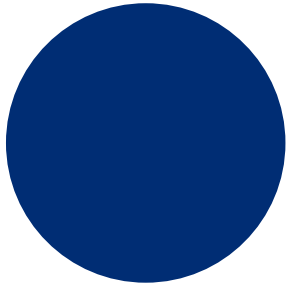
Trial	Analysis	Outcomes
PURPOSE 1	<p><b>Population:</b> 5,340 cisgender adolescent girls and young women (16–25 yrs)</p> <p><b>Design:</b> Phase 3, randomized, double-blind, active-controlled</p> <p><b>Intervention:</b> Lenacapavir 927 mg SC every 6 months (no oral lead-in) vs Oral PrEP</p>	<ul style="list-style-type: none"> <li>• <b>0 infections in the lenacapavir group (95% CI: 0.00 to 0.19) vs HIV incidence rate of ~1.69 per 100 person-years in oral PrEP group (95% (CI) of 0.96 to 2.74)</b></li> </ul>
PURPOSE 2	<p><b>Population:</b> 2,300 cisgender men, transgender women, and nonbinary people who have sex with men</p> <p><b>Design:</b> Phase 3, global, randomized, open-label</p> <p><b>Intervention:</b> Lenacapavir 927 mg SC every 6 months (no oral lead-in) vs Oral PrEP</p>	<ul style="list-style-type: none"> <li>• <b>2 infections in the lenacapavir group (0.10 per 100 person-years; 95% CI: 0.01–0.37) vs 9 infections in oral PrEP group (0.93 per 100 person-years; 95% CI: 0.43–1.77)</b></li> </ul>

Gilead Sciences, Inc. ClinicalTrials.gov identifier: NCT04994509.<https://clinicaltrials.gov/study/NCT04994509>  
 Gilead Sciences, Inc. ClinicalTrials.gov identifier: NCT04925752.<https://clinicaltrials.gov/study/NCT04925752>

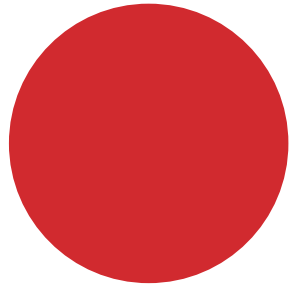
# Overcoming Disparities in HIV Care



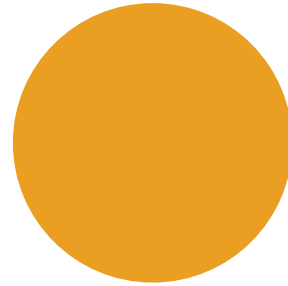
# Disparities in HIV Care



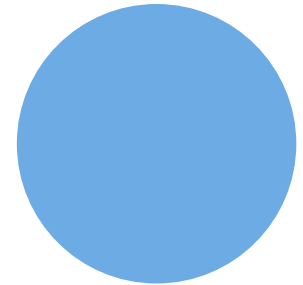
**Adherence**



**Stigma**



**Geographic**

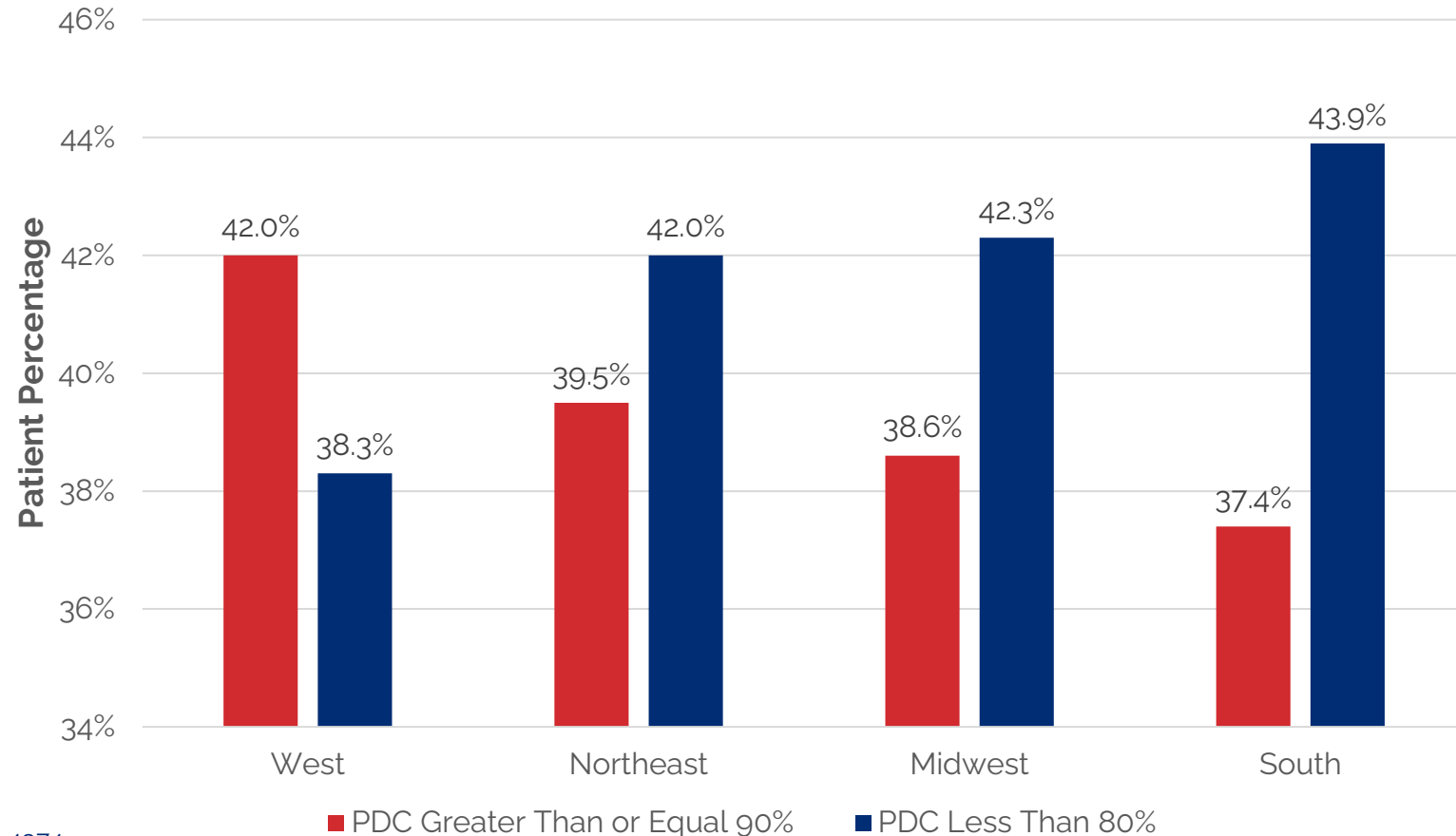


**Racial/Ethnic**

# Adherence

# ART Adherence by U.S. Region

ART Adherence by U.S. Region (July 2017-Sept 2018)



**PDC=Proportion of Days Covered**

McComsey GA, et al. Adv Ther. 2021;38(9):4961-4974.

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# Bridging the Adherence Gap with LAIs

- Eliminates the need for daily medication, reducing missed doses linked to pill fatigue, stigma, and unstable living situations
- Injection visits every 4–8 weeks double as adherence check-ins, improving retention and engagement

# Bridging the Adherence Gap with LAIs

LAIs Adherence Studies		
Study	Analysis	Outcomes
BEYOND	<p><b>Design:</b> Ongoing 2-year, multicenter, prospective, observational real-world study</p> <p><b>Population:</b> 308 virally suppressed adults living with HIV across 27 HIV treatment centers in the U.S.</p> <p><b>Inclusion Criteria:</b> Virologically suppressed individuals initiating Cabenuva</p>	<ul style="list-style-type: none"> <li>• <b>97% of participants maintained HIV RNA &lt;50 copies</b></li> <li>• <b>91% of injections given within 7 days of target date</b></li> <li>• <b>3% missed doses</b></li> <li>• <b>98% preferred Cabenuva over daily oral ART</b></li> </ul>
LATITUDE	<p><b>Design:</b> Ongoing randomized, open-label, two-arm study</p> <p><b>Population:</b> 434 adults with HIV who had suboptimal adherence to oral ART</p> <p><b>Arms:</b> Cabenuva (Q1M or Q2M) vs daily oral ART</p> <p><b>Primary Endpoint:</b> HIV-1 RNA &lt;200 copies/mL at 52 weeks</p>	<ul style="list-style-type: none"> <li>• <b>84% Cabenuva vs 74% daily oral ART (HIV-1 RNA &lt;200 copies/mL (Week 52))</b></li> <li>• <b>75% Cabenuva vs 63% daily oral ART (HIV-1 RNA &lt;50 copies/mL)</b></li> </ul>

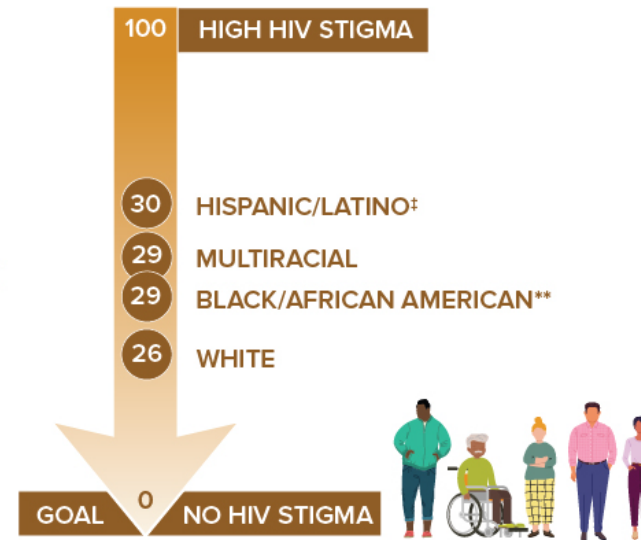
Dandachi D et al. Open Forum Infect Dis. 2025;12(5):ofaf220. Published 2025 Apr 19.  
 Landovitz RJ, et al. Presented at: IAS 2023 – 12th IAS Conference on HIV Science; July 23–26, 2023

# Stigma

# Stigma Disparities

Median HIV stigma score among people with diagnosed HIV in the US by race and ethnicity, 2020\*†

People with HIV experience stigma. The median HIV stigma score among all people with HIV was 28.



Median HIV stigma scores are presented based on a ten-item scale ranging from 0 (no stigma) to 100 (high stigma) that measures personalized stigma during the past 12 months, current disclosure concerns, current negative self-image, and current perceived public attitudes about people with HIV.

\* Among people with HIV aged 18 and older.

† Data not available for Asian, American Indian/Alaska Native, and Native Hawaiian and other Pacific Islander people.

‡ Hispanic/Latino people can be of any race.

\*\* *Black* refers to people having origins in any of the Black racial groups of Africa. *African American* is a term often used for people of African descent with ancestry in North America.

Source: CDC. Behavioral and clinical characteristics of persons with diagnosed HIV infection—Medical Monitoring Project, United States 2020 cycle (June 2020–May 2021). *HIV Surveillance Special Report 2022*;29.

# Bridging the Stigma Gap with LAIs

- Eliminates the daily reminder and visible cues, making it easier for patients to keep their HIV status private
- Helps reframe HIV care as routine health maintenance rather than constant treatment
- BEYOND study
  - 83% of participants reported never “feeling stigmatized by HIV-1 treatment” at month 12 vs 42 % of participants at baseline

# Geographic

# Geographic Disparities

- In 2023, among 39,201 new HIV diagnoses in the U.S.:
  - 51% occurred among individuals residing in the South region
  - 21% in the West
  - 13% each in the Northeast and Midwest
- Urban areas tend to have higher HIV prevalence but often better access to care and preventative services
- Rural areas, especially in the South, face barriers like fewer HIV specialty providers and limited transportation

Centers for Disease Control and Prevention. HIV Diagnoses, Deaths, and Prevalence. Centers for Disease Control and Prevention. Published April 29, 2025. Accessed August 13, 2025 <https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html>.

# Bridging the Geographic Gap with LAIs

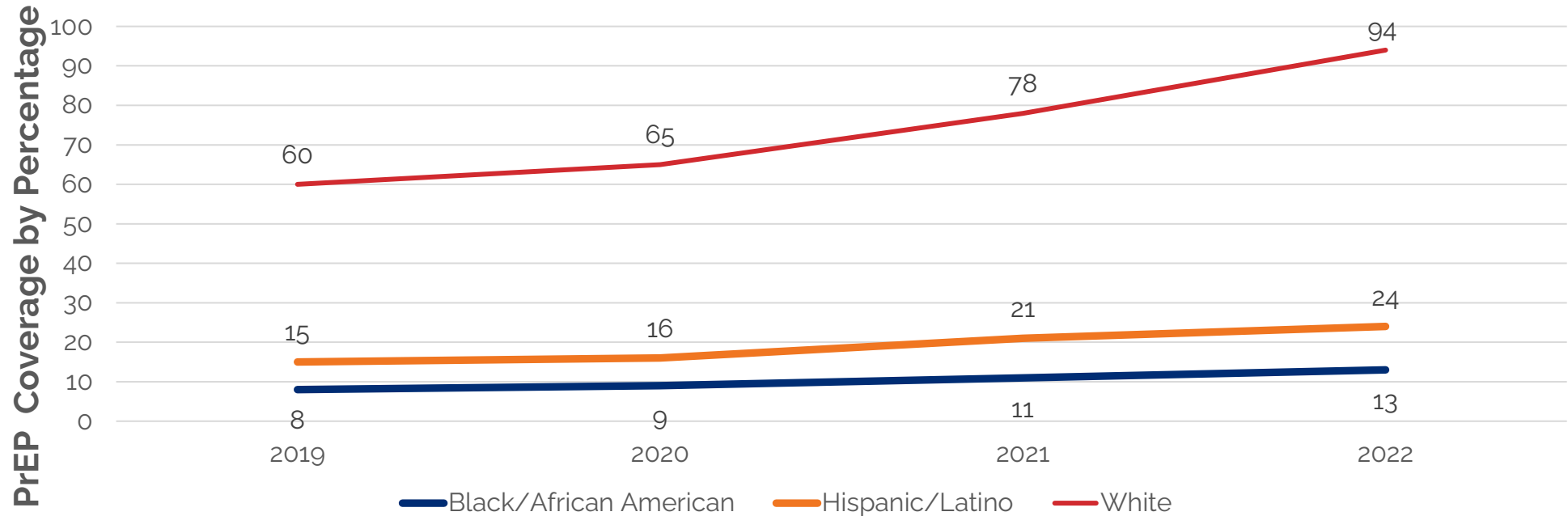
- LAIs have shown favorable adherence outcomes when compared to oral ARTs, regardless of region
- Long-acting injectables can be delivered through clinics and mobile health services, making care more accessible for rural or underserved communities with few healthcare providers

Dandachi D et al. *Open Forum Infect Dis.* 2025;12(5):ofaf220. Published 2025 Apr 19.  
Landovitz RJ, et al. Presented at: IAS 2023 – 12th IAS Conference on HIV Science; July 23–26, 2023

# Racial/Ethnic

# Racial and Ethnic Disparities in PrEP

## Trends In Prescriptions Among People Who Could Benefit, By Race/Ethnicity, 2019-2022\*

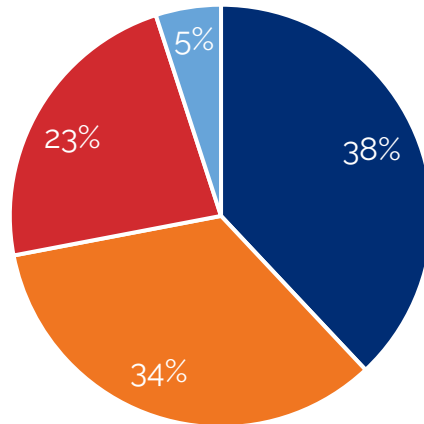


\*Data are preliminary. The data on PrEP prescriptions by race and ethnicity are limited, and findings are estimated.

Source: Centers for Disease Control & Prevention

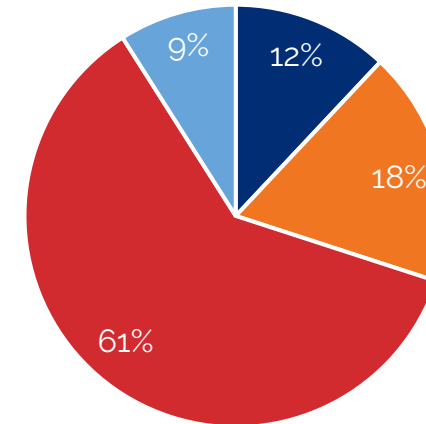
# Racial and Ethnic Disparities in HIV Population

Percentage of new HIV diagnosis, by race (N=39201)



■ Black/African American ■ Hispanic/Latinx  
■ White ■ Other

Percentage of US population, by race (N=333,287,557)



■ Black/African American ■ Hispanic/Latinx  
■ White ■ Other

Centers for Disease Control and Prevention. Fast Facts: HIV in the US by Race and Ethnicity. CDC. Updated 2024. Accessed August 12, 2025. <https://www.cdc.gov/hiv/data-research/facts-stats/race-ethnicity.html>

# Bridging the Ethnic/Racial Gap With LAIs

- HIV Care Retention (2+ visits per year)
  - 38% among Black people vs 49% for both Hispanic/Latinx people and White people (2011-2013)
  - BEYOND study showed by 24 months, 69% of LAI patients were retained and continued with care
- LAIs showed lower HIV infection rates compared to oral PrEP in HPTN 083/084, especially relevant when considering study participants were majority Black people

Dasgupta S, et al. MMWR Morb Mortal Wkly Rep. 2016;65(4):77-82.

Dandachi D et al. Open Forum Infect Dis. 2025;12(5):ofaf220.

Landovitz RJ et al. N Engl J Med. 2021;385(7):595-608.

Delany-Moretlwe S et al. Lancet. 2022;399(10337):1779-1789

# Overcoming Disparities with LAIs



## Adherence

LAI's eliminate the need for daily pills, reducing forgetfulness and pill fatigue.



## Stigma

LAI's are discreet with no pill bottles and no risk of accidental disclosure at home/work.



## Geographic

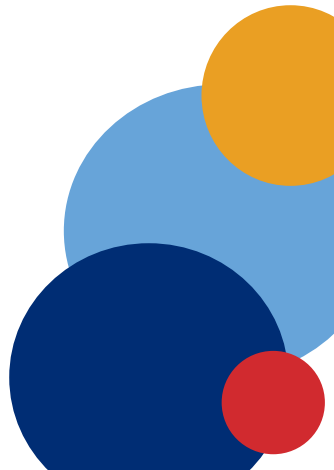
Injections can be given in Federally Qualified Health Centers (FQHC), mobile clinics, or community settings - not just specialty centers.



## Racial/Ethnic

Trials and studies show higher retention rates on LAIs as well as superiority of LAIs vs oral PrEP

# Real World Observations

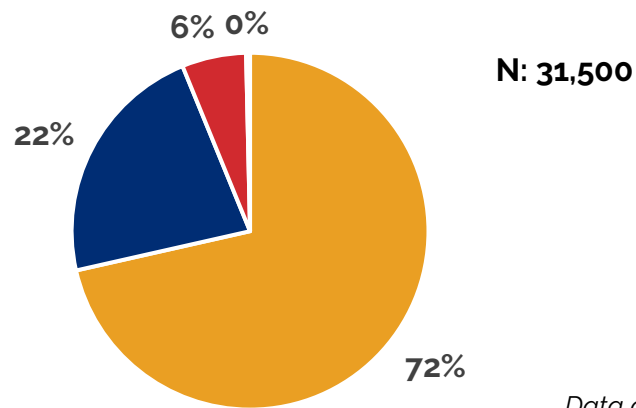


# Distribution of Patients on Various HIV Therapies

## Northeast Region

- Primarily, Urban Structure
- Clinics are closer in proximity
- High Population Density
- States Incorporated in Data: CT, MA, NY, NJ, RI

Percentage of Prescriptions Written in Northeast Region (2023-2024)

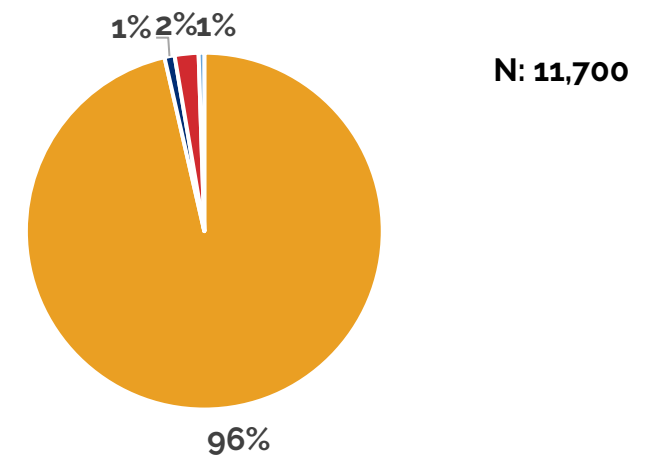


■ Biktarvy ■ Truvada ■ Cabenuva ■ Sunlenca

## South Region

- Primarily Rural Structure
- Clinics are further in proximity
- Low Population Density
- States Incorporated in Data: FL, DE, MD, GA, LA, MS, SC, & TX

Percentage of Prescriptions Written in South Region (2023-2024)



■ Biktarvy ■ Truvada ■ Cabenuva ■ Sunlenca

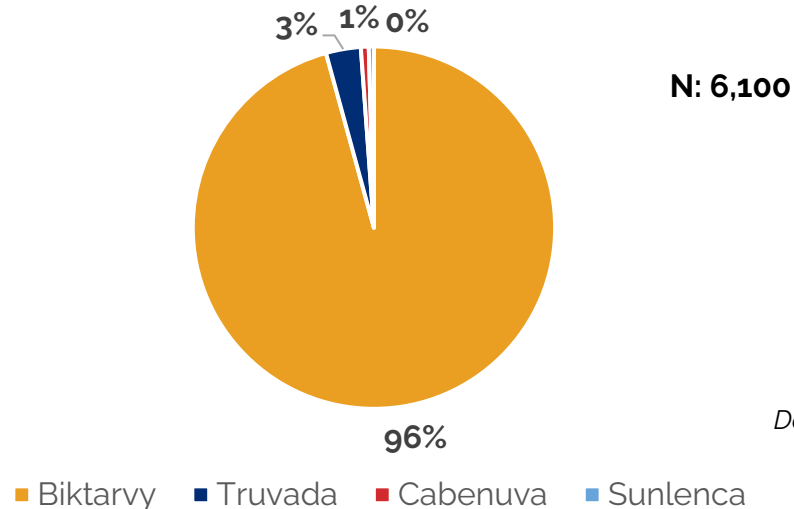
Data derived from internal analytics and reporting tools at Shields Health Solutions.

# Distribution of Patients on Various HIV Therapies

## Mid-West Region

- Primarily Rural Structure
- Clinics are furthest in proximity
- Low Population Density
- States Incorporated in Data:  
IA, MI, SD

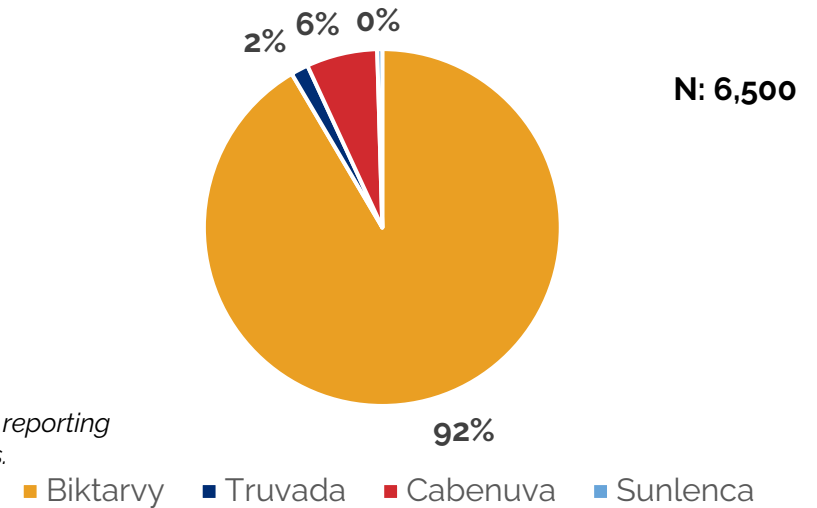
Percentage of Prescriptions Written in  
Midwest Region (2023-2024)



## West Region

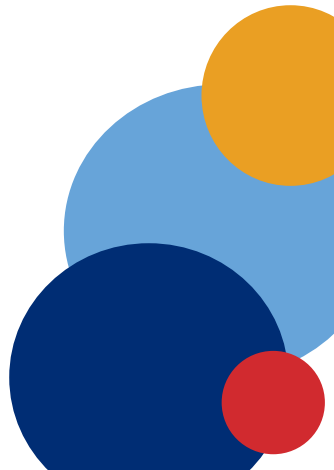
- Primarily Urban Structure
- Clinics are closer in proximity
- High Population Density in Urban Areas
- States Incorporated in Data:  
AZ, MT, CA, CO, NV, OR, & WA

Percentage of Prescriptions Written in  
West Region (2023-2024)



Data derived from internal analytics and reporting  
tools at Shields Health Solutions.

# **Barriers to LAIs and Patient Access**



# LAI Utilization in Practice

- **Cabenuva** (cabotegravir/rilpivirine-treatment)
  - At least 15,000 US patients (~ 836,000 pts on HIV treatment)
  
- **Apretude** (cabotegravir-PrEP)
  - ~19,000 U.S. patients (~382,000 PREP users)

GSK. Real-World Use of Cabenuva. July 25, 2025. Accessed August 15, 2025. <https://medinfo.gsk.com/>  
ViiV Healthcare. APRETUDE HCP Website. Published 2025. Accessed August 15, 2025. <https://apretudehcp.com/>

# Barriers to LAI Uptake

- **Insurance and Prior Authorization (PA) Requirements**
- **Clinic Infrastructure and Workflow Challenges**
- **Patient Access and Transportation Issues**
- **Provider Awareness and Hesitancy**

# Prior Authorization Criteria for LAIs (Treatment)

## Initial Criteria (cabotegravir/rilpivirine)

- Positive HIV Diagnosis
- Suppressed HIV viral load (<50 copies/ml)
- Prescribed by an HIV or Infectious Disease Specialist
- Sometimes require documentation or oral lead-in antiretroviral medication therapy

## Continuation Criteria (cabotegravir/rilpivirine)

- Continued viral suppression
- Routine HIV testing
- No evidence of treatment failure, resistance, or non-adherence

# Prior Authorization Criteria for LAIs (PrEP)

## Initial Criteria (*Cabotegravir*)

- Confirmed negative HIV-1 test prior to initiation
- Ongoing HIV testing required with each injection
- Must follow FDA-approved dosing guidelines

## Continuation Criteria (*Cabotegravir*)

- Patient must have previously received *Cabotegravir*
- HIV-1 status must remain negative
- Continued HIV testing required with each injection
- Dosing must remain consistent with FDA labeling

# Strategies to Overcome Barriers to Uptake

- **Insurance and Prior Authorization (PA) Requirements**
  - Advocate for policy changes to eliminate unnecessary PAs, especially in Medicaid
  - Streamline internal workflows with pre-populated PA templates and dedicated access staff
- **Clinic Infrastructure and Workflow Challenges**
  - Apply for Ryan White, HRSA, or state infrastructure grants to support staffing, refrigeration, and injection tracking
  - Implement standing orders and standard injection protocols to reduce provider burden
  - Train medical assistants or nurses to administer injections and manage follow-ups

# LAI U.S. Data

U.S. LAI Data Distribution (2023-2024)			
	Cabenuva	Biktarvy	Truvada
Patients Prescribed	2,875	49,399	7,513
Average Prior Authorization Approval rate %	92%	96%	86%
Average Copay	\$8.65	\$9.12	\$8.35
Proportion of Days Covered	87.2%	94.8%	92.5%

*Data derived from internal analytics and reporting tools at Shields Health Solutions.*

# Strategies to Overcome Barriers to Uptake

- **Provider Awareness and Hesitancy**
  - Offer continuing education (CE) and decision-support tools on LAI eligibility, dosing, and bridging strategies
  - Integrate electronic medical record prompts to flag eligible patients
- **Patient Access and Transportation Issues**
  - Partner with rideshare programs (e.g., Uber Health, Medicaid NEMT) for clinic visits
  - Offer mobile clinics or community injection sites (e.g., FQHCs, outreach vans)
  - Provide case management support to help patients coordinate schedules and reminders.

# Financial Assistance Availability

## Manufacturer Support

- **Cabenuva & Apretude:** ViiV Patient Savings Program for Out-of-Pocket Cost (Commercial Patients), ViiV Patient Assistance Program (uninsured or underinsured patients)
- **Sunlenca & Yeztugo:** Gilead Copay Savings Program (commercial Patients), Gilead Patient Assistance Program (uninsured or underinsured patients)

## Social Services

- **Ryan White Foundation:** Federal program that provides numerous services, including Co-pay assistance
- **HealthWell Foundation:** support co-pays, insurance premiums, & out-of-pocket expenses

# Summary

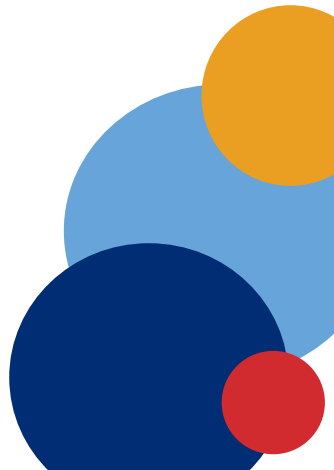
LAI is the newest form of HIV medications and can help bridge the gap, reducing the disparities we see in HIV care across the U.S. and the world. While there are still barriers still to overcome, there are applicable solutions that could help release these medications to the broader affected population and help bring us closer to ending this epidemic.

# Supplemental Resources

HRSA Ryan White HIV/AIDS Program

<https://ryanwhite.hrsa.gov/>

# Post-Test Questions



# Post-Test Questions

**1. Which of the following best describes a key benefit of long-acting injectable (LAI) ART?**

- A. Requires fewer clinical visits
- B. Improves adherence and reduces stigma
- C. Eliminates the need for all follow-up
- D. Replaces all HIV prevention options

# Post-Test Questions

**2. What was the primary finding of the ATLAS trial comparing long-acting injectable ART (Cabenuva) to daily oral ART in virologically suppressed adults?**

- A. Long-acting injectable ART was inferior to oral ART in maintaining viral suppression
- B. Long-acting injectable ART was associated with higher rates of resistance development
- C. Long-acting injectable ART was non-inferior to oral ART in maintaining viral suppression
- D. Long-acting injectable ART was only effective in treatment-naïve individuals

# Post-Test Questions

**3. Which LAI has been approved as the first twice-yearly injectable for HIV PrEP?**

- A. Cabenuva
- B. Apretude
- C. Sunlenca
- D. Yeztugo

# Post-Test Questions

4. **True or False:** Uninsured patients can receive assistance in covering the cost of Long-Acting Injectable (LAI) HIV therapies.

# Post-Test Questions

**5. Which of the following best describes a key finding from the LATITUDE trial evaluating long-acting injectable ART in people with adherence challenges?**

- A. Long-acting injectable ART showed no difference in viral suppression compared to daily oral ART.
- B. Participants receiving LAI ART had a higher rate of virologic failure than those on oral ART.
- C. Long-acting injectable ART resulted in significantly higher rates of viral suppression than daily oral ART at 52 weeks.
- D. The study only included participants with perfect prior adherence to ART.

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# Thank You

Via email: [oaiyevbomwan@shieldsrx.com](mailto:oaiyevbomwan@shieldsrx.com)

Via LinkedIn: <https://www.linkedin.com/in/osaosemwen-aiyevbomwan-pharmd-rph/>

Via email: [kblake@shieldsrx.com](mailto:kblake@shieldsrx.com)

Via LinkedIn: <https://www.linkedin.com/in/kuwan-blake-aa494b228/>

Via email: [asuber@shieldsrx.com](mailto:asuber@shieldsrx.com)

Via LinkedIn: <https://www.linkedin.com/in/asia-suber-698366135/>

Encore Presentation: 2025 Annual Meeting & Expo Highlights

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Contact: [info@naspnet.org](mailto:info@naspnet.org)



**Presentation Title: Bridging the Gap: HIV, Long-Acting Injectables (LAI) & the Impact on Patient Disparities**

**Presenter Name: Osaosemwen Aiyebomwan, Kuwan Blake, Asia Suber**

**Learning Objectives:**

- Discuss HIV Long Acting Injections, their prevalence in practice, and how they compare to older regimens
- Review the impact of Long Acting Injections and the utilization of treatment to eliminate disparities in the HIV patient population
- Provide and review of best practices for patient medication access, financial assistance, and additional community resources to provide optimal patient outcomes

<b>Test Question</b>	<b>Corresponding Learning objective</b>	<b>Corresponding text or slide number with answer</b>	<b>Rationale for correct/incorrect answers</b>
<p>1. Which of the following best describes a key benefit of long-acting injectable (LAI) ART?</p> <p>A. Requires fewer clinical visits</p> <p>B. Improves adherence and reduces stigma</p> <p>C. Eliminates need for all follow-up</p> <p>D. Replaces all HIV prevention options</p>	<p>Review the impact of Long-Acting Injections and the utilization of treatment to eliminate disparities in the HIV patient population.</p>	<p>Slide 32</p>	<p>Correct answer-B</p> <p>Rationale: LATITUDE Trial showed adherence improvement vs daily oral ART.</p> <p>Incorrect Answer:</p> <p>A. Requires fewer clinical visits Incorrect. LAI ART typically requires more structured clinical visits, often monthly or every 2 months for injections, compared to oral ART refills.</p> <p>C. Eliminates need for all follow-up Incorrect. Ongoing lab monitoring, injection scheduling, and follow-up visits are essential with LAI use. Follow-up is a key part of safety and adherence.</p> <p>D. Replaces all HIV prevention options Incorrect. LAI ART is used for treatment, not prevention. While some LAIs (e.g., Apretude,</p>

			Yeztugo) are approved for PrEP, they do not replace all options such as oral PrEP or condoms.
<p>2. What was the primary finding of the ATLAS trial comparing long-acting injectable ART (Cabenuva) to daily oral ART in virologically suppressed adults?</p> <p>A. Long-acting injectable ART was inferior to oral ART in maintaining viral suppression</p> <p>B. Long-acting injectable ART was associated with higher rates of resistance development</p> <p>C. Long-acting injectable ART was non-inferior to oral ART in maintaining viral suppression</p> <p>D. Long-acting injectable ART was only effective in treatment-naïve individuals</p>	Discuss HIV Long-Acting Injections (LAI), their prevalence in practice, and how they compare to older regimens	Slide 18	<p>Correct Answer: C. Long-acting injectable ART was non-inferior to oral ART in maintaining viral suppression</p> <p>Incorrect Answers: A. Incorrect because the ATLAS trial specifically demonstrated non-inferiority, not inferiority. B. Incorrect because The ATLAS trial found very low rates of virologic failure and resistance in both groups. D. Incorrect because the ATLAS trial enrolled treatment-experienced individuals who were already virologically suppressed on oral ART.</p>
<p>3. Which LAI has been approved as the first twice-yearly injectable for HIV PrEP?</p> <p>A. Cabenuva (cabotegravir/rilpivirine)</p> <p>B. Apretude (cabotegravir)</p> <p>C. Sunlenca (lenacapavir)</p> <p>D. Yeztugo (lenacapavir)</p>	Discuss HIV Long-Acting Injections (LAI), their prevalence in practice, and how they compare to older regimens	Slide 11	<p>Correct Answer: D</p> <p>Yeztugo (lenacapavir) was FDA-approved in 2025 as the first and only twice-yearly injectable for HIV PrEP.</p> <p>Incorrect Answers: A. Cabenuva Incorrect. Cabenuva is a long-acting injectable used for HIV treatment, not prevention. It contains cabotegravir + rilpivirine and is dosed monthly or every 2 months.</p>

			<p>B. Apretude Incorrect. Apretude is a PrEP LAI but requires injection every 2 months, not twice yearly. It also has an optional oral lead-in phase.</p> <p>C. Sunlenca Incorrect. Sunlenca (lenacapavir) is approved for treatment of multidrug-resistant HIV, not for PrEP. However, it shares the same active drug as Yeztugo.</p>
<p>4. True or False: Uninsured patients can receive assistance in covering the cost of Long-Acting Injectable (LAI) HIV therapies.</p>	<p>Provide a review of best practices for patient medication access, financial assistance, and additional community resources to provide optimal patient outcomes</p>	<p>Slide 36</p>	<p>Correct Answer: True</p> <p>Uninsured patients can access manufacturer-sponsored Patient Assistance Programs (PAPs) that provide free or low-cost access to medications like:</p> <p>Cabenuva and Apretude through ViiVConnect</p> <p>Sunlenca (and Yeztugo, once available) through Gilead's Advancing Access program</p>
<p>5. Which of the following best describes a key finding from the LATITUDE trial evaluating long-acting injectable ART in people with adherence challenges?</p> <p>A. Long-acting injectable ART showed no difference in viral suppression compared to daily oral ART.</p> <p>B. Participants receiving LAI ART had a higher rate of virologic failure than those on oral ART.</p>	<p>Review the impact of Long-Acting Injections and the utilization of treatment to eliminate disparities in the HIV patient population.</p>	<p>Slide 32</p>	<p>Correct Answer: C Rationale: primary results of the LATITUDE trial, a Phase 3, randomized, open-label study comparing long-acting injectable Cabotegravir + Rilpivirine (LAI ART) to daily oral ART in people living with HIV who had suboptimal adherence.</p> <p>Incorrect Answers A. The LATITUDE trial did show a significant difference in favor of LAI ART.</p>

<p>C. Long-acting injectable ART resulted in significantly higher rates of viral suppression than daily oral ART at 52 weeks.</p> <p>D. The study only included participants with perfect prior adherence to ART.</p>			<p>B. The opposite is true — virologic failure was lower in the LAI group.</p> <p>D. LATITUDE specifically targeted people with poor or inconsistent adherence to daily oral ART.</p>
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