



New Opportunities: Implementing Long-Acting PrEP in Clinical Practice

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Disclosures

- Unrestricted institutional research grants: Gilead Sciences, Merck Inc, ViiV
- Scientific Advisory Board: Gilead, Merck
- NIH funding to study antiretrovirals for prevention

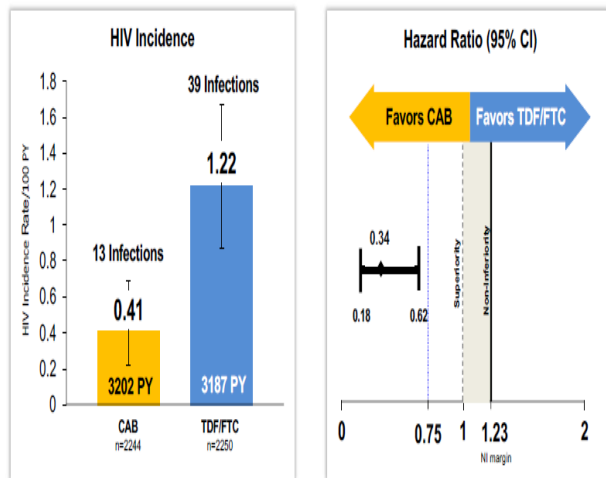
Injectable Cabotegravir: Game Changer?

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HIV Incidence CAB vs. TDF/FTC

52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



CI, confidence interval

HPTN
HIV Prevention
Trials Network



Primary outcome: HIV incidence

40 infections over 3892 person-years
Pooled HIV incidence 1.03 (0.73, 1.4) per 100 person-years

	CAB	TDF/FTC
HIV infections	4	36
Person-years	1,953	1,939
HIV incidence (95% CI)	0.2 (0.06, 0.52)	1.86 (1.3, 2.57)

Wald test z statistic -4.20, efficacy stopping bound (z scale) -3.61

- HPTN 083/084 showed superiority of CAB-LA vs. TDF/FTC control
- CAB-LA was well tolerated despite injection site reactions



Challenges to LA CAB Implementation

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- FDA approved 12/20/21
- Uptake has been slow
- Cost in US: ≈\$26,000/yr.
- Descovy™ \$23,748/yr.
- Generic Truvada \$588/yr.



- Cost
- Insurance
- Workflow
- Missed Injections
- Pt. preference



Global CAB LA Roll Out

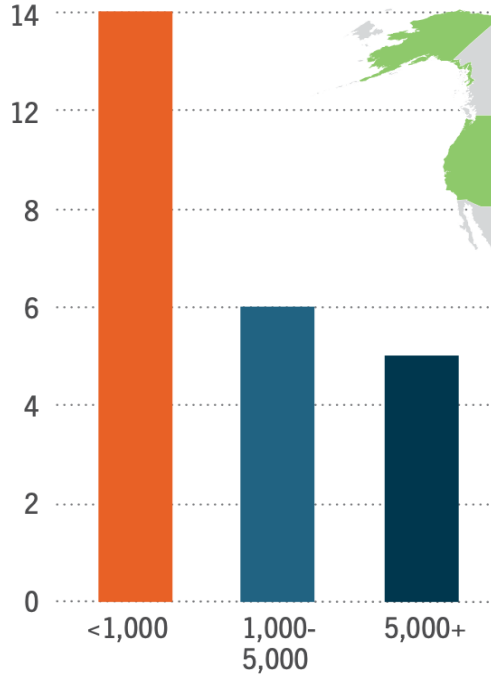
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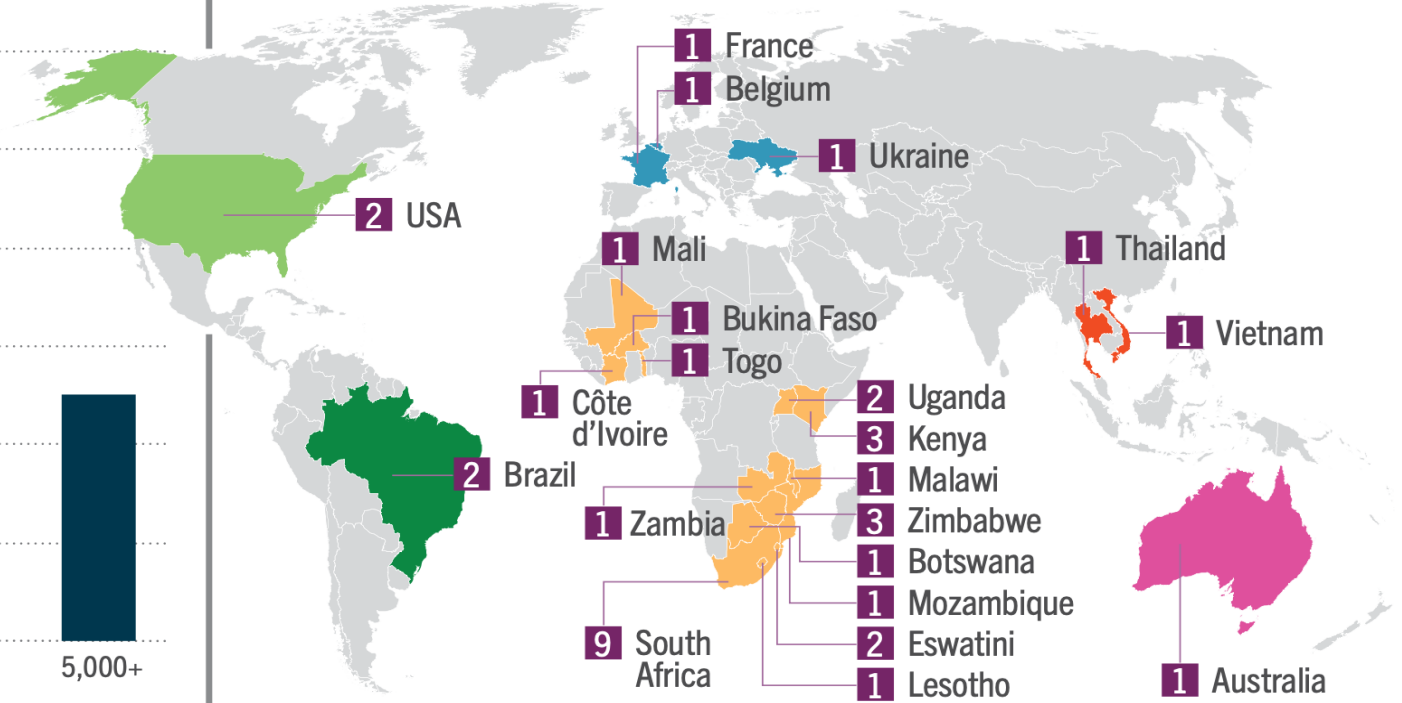
- **Approved:** Australia, Botswana. Malawi, South Africa, USA
- **Recent EMA review**→expect approval soon
- **Pending approval:** Brazil, Kenya, Malaysia, Peru, Philippines, Uganda, Ukraine, Vietnam, Zambia, Zimbabwe
- **To be filed soon:** Argentina, Colombia, Cote d'Ivoire, Mozambique, Nigeria, Rwanda, Tanzania

CAB for PrEP and DVR Implementation Science Studies

Sample size of studies



Only 25 of 29 studies currently have established sample sizes.



Some studies are happening in more than one country, with a total of 29 studies in 22 countries.

Source: AVAC

CAB-LA Implementation Science (IS) Studies Underway or Planned

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(www.prepwatch.org)



- PILLAR (US): 220 cis and transgender MSM, inc. telehealth support
- EBONI (US): 250 Black cisgender women
- Aurora (US): Digital health and behavioral economics
- INNOVATE (US): PWID
- IS studies underway in Kenya, Uganda, Zimbabwe, Lesotho
- Multiple studies underway in South Africa, including Thetha Nami Ngithethe Nave (“Let’s talk) enrolling 26,000 pts. Step wedge design with peer navigation for youth
- IS studies focusing on key pops, mainly MSM/TGW in Brazil, Burkina Faso, Cote d’Ivoire, Mali, Australia, France
- Studies underway to evaluate non-gluteal injection sites
- Studies underway to evaluate mHealth support for TGW, women who inject drugs



What have been the biggest challenges in making CAB LA available to your patients?

**10
experts**

Lack of staff to help navigate patients to appropriate resources

10

Insurance coverage

9

Lack of staff to complete paperwork

6

Lack of staff or time to administer injections*

4

Lack of patient demand

0

*"process takes weeks to complete" "frequent change insurance plans" "staff time also needed to deal with missed injections, etc" frequency of viral loads

Benefit Routes and Method Of Acquisition #ADHERENCE2023



Buy and Bill

- HCP purchases drug from specialty distributor allowing the product to be available on hand.
- Distributor ships the medication to HCP
- The HCP and distributor negotiate price based on volume.
- HCP submits medical benefit claim to insurer who reimburses the HCP
- Pt is charged copay, admin fee if applicable

Specialty Pharmacy: Pharmacy Benefit

- **White bagging:** drug is purchased through specialty pharmacy and shipped to the provider's office for administration
- **Brown bagging:** prescription sent to pharmacy, pt picks up the drug, and brings it to HCP's office
- Specialty pharmacy submits claim to insurer

Specialty Pharmacy: Medical Benefit

- Drug obtained through a contracted specialty pharmacy e.g. CVS Caremark, Optum, Accredo
- Specialty Pharmacy submits bill to insurance company, drug shipped to office
- Must call every time patient is due and arrange shipment (least favorite)

Patient Savings Programs (ViiV)

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Patient Assistance Program

- Live in one of the 50 states, DC, or Puerto Rico
 - Household income \leq to 500% of the [Federal Poverty Level](#)
 - Not eligible for Medicaid, and either have no rx. coverage or:
 - Have a Medicare Part B, D, or Advantage Plan, spent at least \geq \$600 on out-of-pocket rx. expenses during the current calendar year, or
 - Have a private insurance plan limited to generic-only coverage
- Injection fee not covered**

Patient Savings Program

- Patients with commercial Insurance
- Can receive up to: \$7,850/yr beyond what insurance will cover
- Patients will receive a virtual debit card they can use to pay their bill
- Gets reviewed periodically, and needs new paperwork if insurance changes
- Several states will cover additional gaps with PrEPDAP programs

<https://www.viivconnect.com/providers/financial-support/>

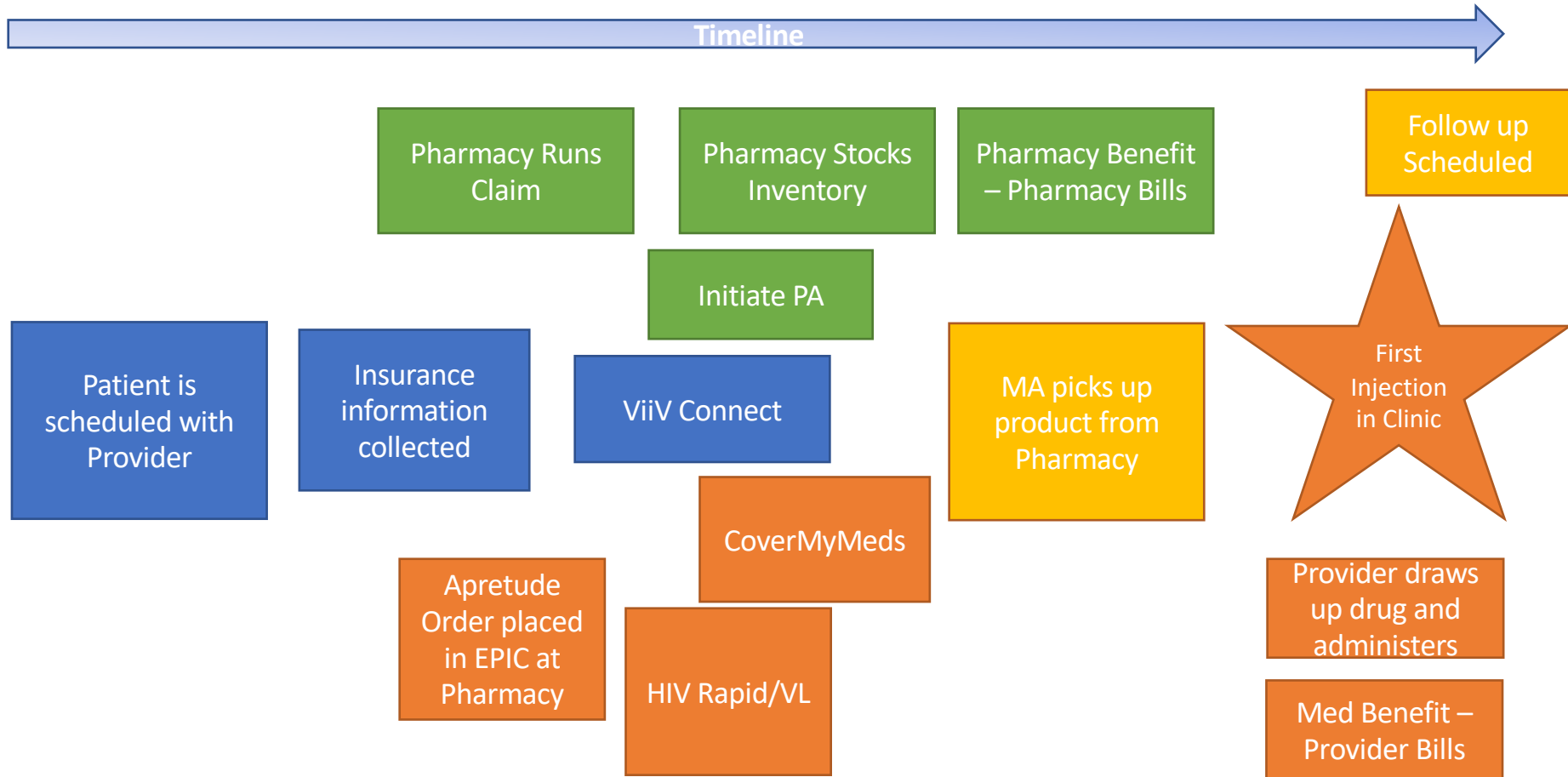
Fenway Experience with CAB LA

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- Transitioned \approx 40 pts from HPTN 083 to routine CAB LA
- Took 3 to 14 days from initiation of insurance process to approval (average 7 days)
- Some insurers did not require PA, while other required lengthy PA process \rightarrow provision of partial coverage, often requiring applying for supplemental coverage from ViiV
- 5-10% of initial requests denied (pt needs to “fail” oral)
- 25% of pts required PrEPDAP or ViiV support
- For each pt, it took 3-5 hours of nurse or coordinator time, plus 2 hours for MD and half hour for pharmacist to get pt their first dose of CAB LA **(It takes a village)**

Cabotegravir-LA for PrEP in Fenway Health



Cabotegravir-LA IM for PrEP in Fenway Health

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a. SmartPhrases

CABHPIFU	# Pre-Exposure Prophylaxis # Use of CAB IM Patient is continuing on CAB IM for PrEP. Side-Effec...
CABHPIINITIAL	# Pre-Exposure Prophylaxis # Use of CAB IM Patient is starting on CAB IM for PrEP. Previous PrE...
CABINSTRUCTIONS	APRETUDE for PrEP You received Apretude (cabotegravir) Intramuscular Injection for PrEP. This...
CABPLAN	Patient is receiving Apretude (CAB) IM for PrEP. Patient denies any known STI/HIV exposures. Cu...

a. Labs to order:

Cr, HIV VL, HIV Ag/Ab, other STI testing (with every visit)

i. Located under database in orders

APRETUDE

Browse Preference List Facility List Database

Panels (No results found) Search panels by user

Medications

Name	Dose	Fr...	Formulary	Copay	Cover...	Drug...	Formula...
APRETUDE 600 MG/3ML IM SUER			Not...		Prior...	Brand...	Not...

Procedures (No results found)

ii. Complete necessary fields

Cabotegravir ER (Apretude) 600 MG/3ML Suspension Extended Release

Product: APRETUDE 600 MG/3ML IM SUER

Sig Method: Specify Dose, Route, Frequency Taper/Ramp Combination Dosage

Dose: 1 mL

Route: Intramuscular

Frequency: 1

Duration: 30 days 2 months 1 year

Starting: 2/16/2023 Ending: First fill:

Dispense: 1 mL Refill: 0 1 2 3 11

Total Supply: Unable to calculate

Dispense As Written

Renewal Provider: Do not send renewal requests to me

Cabotegravir ER (Apretude) 600 MG/3ML Suspension Extended Release

Product: APRETUDE 600 MG/3ML IM SUER

Sig Method: Specify Dose, Route, Frequency Taper/Ramp Combination Dosage

Dose: 3 mL

Route: Intramuscular

Frequency: Once

Duration: Starting: 2/16/2023 First fill:

Dispense: 3 mL Refill: 7 0 1 2 3 11

Total Supply: Unable to calculate

Dispense As Written

Renewal Provider: Do not send renewal requests to me

Has your clinic done any of the following?

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Work with private or public insurers to facilitate access	5
Create dedicated injection clinic	5
Hire or deploy case managers to work on access	5
Hire or deploy peer navigators to work on access	3
Deploy pharmacist to work on access	2
Social media campaign; Staff meetings	2
Work with Legislature to decrease barriers	1

- Oral PrEP users: 100-~6000
- CAB LA users: 18-125

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Do you anticipate major transition to CAB LA?

- Anticipate transition, but will be slow
- Process too cumbersome
- Demand is there, requires a large team
- Currently, >100 on the waiting list
- “In these times of financial insecurity among FQHCs, I worry how sustainable our current model will be.”
- Cabneuva experience was helpful in several clinics
- Some created dedicated clinics for injectable ART and gender affirming hormone rx.



Conclusions

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- Despite definitive demonstration of efficacy, CAB LA roll out has not been smooth
- Operational challenges have included funder and health system challenges
- Innovative models, ranging from dedicated injection clinics to community delivery, are being evaluated
- The diffusion of innovation is taking time, but the expansion of PrEP choices offers another tool to address the HIV epidemic

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