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
- 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

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

- Cost
- Insurance
- Workflow
- Missed Injections
- Pt. preference
Global CAB LA Roll Out

• **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

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Number of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1,000</td>
<td>14</td>
</tr>
<tr>
<td>1,000-5,000</td>
<td>2</td>
</tr>
<tr>
<td>5,000+</td>
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</tbody>
</table>

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 (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?

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Experts</th>
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<tbody>
<tr>
<td>Lack of staff to help navigate patients to appropriate resources</td>
<td>10</td>
</tr>
<tr>
<td>Insurance coverage</td>
<td>9</td>
</tr>
<tr>
<td>Lack of staff to complete paperwork</td>
<td>6</td>
</tr>
<tr>
<td>Lack of staff or time to administer injections*</td>
<td>4</td>
</tr>
<tr>
<td>Lack of patient demand</td>
<td>0</td>
</tr>
</tbody>
</table>

*“process takes weeks to complete” “frequent change insurance plans” “staff time also needed to deal with missed injections, etc” frequency of viral loads
<table>
<thead>
<tr>
<th>Benefit Routes and Method Of Acquisition</th>
<th>#ADHERENCE2023</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Buy and Bill</strong></td>
<td></td>
</tr>
<tr>
<td>• HCP purchases drug from specialty distributor allowing the product to be available on hand.</td>
<td></td>
</tr>
<tr>
<td>• Distributor ships the medication to HCP</td>
<td></td>
</tr>
<tr>
<td>• The HCP and distributor negotiate price based on volume.</td>
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<tr>
<td>• HCP submits medical benefit claim to insurer who reimburses the HCP</td>
<td></td>
</tr>
<tr>
<td>• Pt is charged copay, admin fee if applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Specialty Pharmacy: Pharmacy Benefit</strong></td>
<td></td>
</tr>
<tr>
<td>• <strong>White bagging</strong>: drug is purchased through specialty pharmacy and shipped to the provider’s office for administration</td>
<td></td>
</tr>
<tr>
<td>• <strong>Brown bagging</strong>: prescription sent to pharmacy, pt picks up the drug, and brings it to HCP’s office</td>
<td></td>
</tr>
<tr>
<td>• Specialty pharmacy submits claim to insurer</td>
<td></td>
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<tr>
<td><strong>Specialty Pharmacy: Medical Benefit</strong></td>
<td></td>
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<tr>
<td>• Drug obtained through a contracted specialty pharmacy e.g. CVS Caremark, Optum, Accredo</td>
<td></td>
</tr>
<tr>
<td>• Specialty Pharmacy submits bill to insurance company, drug shipped to office</td>
<td></td>
</tr>
<tr>
<td>• Must call every time patient is due and arrange shipment (least favorite)</td>
<td></td>
</tr>
</tbody>
</table>
**Patient Assistance Program**

- Live in one of the 50 states, DC, or Puerto Rico
- Household income ≤ 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 $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**

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**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/for-providers/financial-support/](https://www.viivconnect.com/for-providers/financial-support/)
Fenway Experience with CAB LA

• Transitioned ≈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 → 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

Timeline

- Patient is scheduled with Provider
- Insurance information collected
- Apretude Order placed in EPIC at Pharmacy
- Pharmacy Runs Claim
- Pharmacy Stocks Inventory
- Pharmacy Benefit – Pharmacy Bills
- ViiV Connect
- Initiate PA
- MA picks up product from Pharmacy
- CoverMyMeds
- HIV Rapid/VL
- Provider draws up drug and administers
- Med Benefit – Provider Bills
- Follow up Scheduled
- First Injection in Clinic

HIV Rapid/VL

Timeline:

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- First Injection in Clinic
Cabotegravir-LA IM for PrEP in Fenway Health

- **SmartPhrases**
  - CABHPIFU # Pre-Exposure Prophylaxis # Use of CAB IM Patient is continuing on CAB IM for PrEP. Side-Ef…
  - CABPIINITIAL # Pre-Exposure Prophylaxis # Use of CAB IM Patient is starting on CAB IM for PrEP. Previous PrE…
  - CABIINSTRUCTIONS APRETUDE for PrEP You received Apretude (cabotegravir) Intramuscular Injection for PrEP. Th…
  - CABPLAN Patient is receiving Apretude (CAB) IM for PrEP. Patient denies any known STI/HIV exposures. Cu…

- **Labs to order:**
  - Cr, HIV VL, HIV Ag/Ab, other STI testing (with every visit)
<table>
<thead>
<tr>
<th>Activity</th>
<th>Score</th>
</tr>
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<tbody>
<tr>
<td>Work with private or public insurers to facilitate access</td>
<td>5</td>
</tr>
<tr>
<td>Create dedicated injection clinic</td>
<td>5</td>
</tr>
<tr>
<td>Hire or deploy case managers to work on access</td>
<td>5</td>
</tr>
<tr>
<td>Hire or deploy peer navigators to work on access</td>
<td>3</td>
</tr>
<tr>
<td>Deploy pharmacist to work on access</td>
<td>2</td>
</tr>
<tr>
<td>Social media campaign; Staff meetings</td>
<td>2</td>
</tr>
<tr>
<td>Work with Legislature to decrease barriers</td>
<td>1</td>
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</tbody>
</table>
Oral PrEP users: 100-≈6000
CAB LA users: 18-125

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

- 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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