Long-Acting Antiretrovirals: Considerations for ADAPs and RWHAP Part B programs

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Director, Medication Access and Pricing

NASTAD
# Long-Acting Injectables on the Horizon

<table>
<thead>
<tr>
<th>Drug</th>
<th>MOA</th>
<th>Administration</th>
<th>Potential Dosing Frequency</th>
<th>Ongoing Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAB + RPV (Cabenuva)</td>
<td>INSTI + NNRTI</td>
<td>IM injection</td>
<td>Once a month or once every 2 months</td>
<td>NDA/Phase III</td>
</tr>
<tr>
<td>MK-8591 (Islatravir)</td>
<td>NRTTI</td>
<td>Oral</td>
<td>Once a week</td>
<td>Phase 2b</td>
</tr>
<tr>
<td>GS-6207</td>
<td>Capsid inhibitor</td>
<td>SC injection</td>
<td>Once every 3 months</td>
<td>Phase 1</td>
</tr>
<tr>
<td>PRO-140 (leronlimab)</td>
<td>CCR5 antagonist</td>
<td>SC injection</td>
<td>Once a week</td>
<td>Phase 2/3</td>
</tr>
<tr>
<td>Aluvirtide</td>
<td>Fusion inhibitor</td>
<td>IV; potential for SC</td>
<td>Once a week</td>
<td>Phase 2/3 (China)</td>
</tr>
<tr>
<td>TAF</td>
<td>NRTI</td>
<td>Subdermal implant</td>
<td>Once every 6 or 12 months</td>
<td>Pre-clinical</td>
</tr>
</tbody>
</table>
FDA approval anticipated on or before December 29, 2019; launch in January 2020 – possibly earlier

Phase III ATLAS, FLAIR maintenance therapy trials demonstrated non-inferiority with all-oral regimens

Initial indication will involve two IM injections every four weeks; ATLAS-2M trial evaluating two IM injections every eight weeks
Cabenuva Dosing Considerations

- **Initial therapy:** Standard ART regimen to achieve/maintain virologic suppression
- **Oral lead-in dosing:** 30 mg cabotegravir plus 25 mg rilpivirine once daily for four weeks
  - Limited distribution system anticipated
- **IM loading dose:** Two 3 mL IM injections (600 mg cabotegravir plus 900 mg rilpivirine) administered once
- **IM maintenance dosing:** Two 2 mL IM injections (400 mg cabotegravir plus 600 mg rilpivirine) administered four weeks after the IM loading dose and every four weeks thereafter (+/− 1 week)
- Provider administered gluteus medius injections; z-tracking technique
- Standard oral regimen to cover Cabenuva injection delays
Cabenuva will primarily be available from several specialty pharmacies (SP) and specialty distributors (SD) with experience in handling, dispensing, and shipping provider-administered drugs and biologics.

Specialty distributors are often divisions of the “Big Three” full-line wholesalers:

- Product ordering via AmerisourceBergen, McKesson, and Cardinal Health anticipated.

Product ordering via specialty pharmacy in ADAP’s PBM network also feasible; contracting may be required.

Cold-chain transport and storage.
Does your ADAP have procurement and/or payment mechanisms in place with any specialty distributors or pharmacies for any drugs or biologics requiring provider administration to full-pay prescription program ADAP clients?

26 ADAPs Responding

<table>
<thead>
<tr>
<th>Yes</th>
<th>23%</th>
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<tbody>
<tr>
<td>No</td>
<td>77%</td>
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</tbody>
</table>
HRSA HAB: Anticipated Guidance

- HRSA HAB finalizing letter to ADAPs; mirrors language to be included in forthcoming ADAP Manual
  - The cost of administering an antiretroviral medication on the RWHAP ADAP formulary, including the cost of an office visit exclusively for medication administration, is an allowable cost under the ADAP service category
  - For clients with health care coverage, ADAPs can cover the client’s cost-sharing related to that visit
Buy-and-bill: Provider purchases drug/biologic product and bills primary payer

White bagging: Specialty pharmacy adjudicates claim and ships product to provider for administration

Brown bagging: Specialty pharmacy adjudicates claim; product acquired by patient and taken to provider for administration

ADAP can establish preference for product procurement and payment types for full-pay prescription program clients
Full-Pay Prescription Program Clients

- **Buy-and-bill**
  - Provider maintains stock of Cabenuva purchased at list price from SD; submits bundled claim (product + administration) to Part B or ADAP; paid by ADAP and/or Part B; ADAP submits rebate claim to manufacturer
  - Establishing reimbursement rates (e.g., Average Sales Price + 6%), contracting with providers may apply
Full-Pay Prescription Program Clients

- White bagging
  - Rebate model:
    - Provider orders refill from wholesaler or SD; ADAP invoiced and pays list price of drug; paid product shipped to provider; provider submits separate medical/administration claim to ADAP or Part B; ADAP submits full rebate claim to manufacturer
Full-Pay Prescription Program Clients

- **White bagging (cont’d)**
  - Direct purchase models:
    - Provider orders refill from ADAP; ADAP orders from wholesaler or SD, pays ACTF-negotiated net price of drug; product shipped to provider; provider submits separate medical/administration claim to ADAP or Part B
    - Provider orders refill from wholesaler or SD; product shipped by SD to provider; SD stock replenished via ship-to/bill-to mechanism; provider submits separate medical/administration claim to ADAP or Part B
Full-Pay Prescription Program Clients

- **Brown Bagging** – *not recommended for Cabenuva*
  - Traditionally, specialty pharmacy fills prescription and adjudicates claim; product acquired by patient and taken to provider for administration
  - Not feasible for cold-chain products
  - Some ADAP require clients to pick up drugs from ADAP pharmacy, even provider administered products
    - Policy revisions may be necessary to allow for white bagging or buy-and-bill for Cabenuva
Does your jurisdiction’s ADAP/Part B accept buy-and-bill claims submitted by providers for full-pay prescription program ADAP clients requiring a drug or biological product on the ADAP’s formulary?

26 ADAPs responding
How does your ADAP/Part B process (buy-and-bill) claims?

- When/if this is the only mechanism to obtain the medication (i.e. can not be filled/purchased directly by our contracted pharmacy), the claims are paid via HIPCSA funds by our Medical Benefits Manager (MBM). No rebate is pursued
- Providers submit monthly invoices for reimbursement
- Billed through Outpatient Ambulatory provider contract
- Manual claims submission to PBM for reimbursement
4. Does your ADAP/Part B accept white-bag claims submitted by specialty pharmacies or distributors for drug or biological products shipped to providers for administering to full-pay prescription program ADAP clients?

26 ADAPs responding
How does your ADAP/Part B process (white-bagged) claims?

- While we have not done it yet, our current PBM mechanism would allow ADAP to cover white-bag claims provided that the dispensing specialty pharmacy is in, or could be added to, our pharmacy network.
- The specialty pharmacy bills our PBM. We do have some vaccines that we allow to not go through our PBM, the provider bills with CPT code for the Rx.
- In the same way as any pharmacy claim. Pharmacy would submit invoice through PBM and PBM would bill ADAP.
How does your ADAP/Part B process (white-bagged) claims?

- This process is only used for Trogarzo. Our contracted 340B pharmacy orders Trogarzo from one of the preferred distributors, requests shipment to the provider, and pays the [lowest] price directly to the preferred distributor using special line item funds in the contract. The invoice (including the contracted dispensing fee to our contracted pharmacy) is subsequently submitted to RWHAP Part B Finance for processing and adjudication and the special line item funds are replenished via our monthly Contractor Expenditure Report (CER) process.
ADAP-Funded Insurance Clients

- **Medical Benefit**
  - Providers purchase Cabenuva and bill payer for drug, administration, and any other associated office visit costs; mixed cost sharing

- **Pharmacy Benefit**
  - Prescription submitted to pharmacy and pharmacy ships drug to provider’s office (white bagging)
  - Pharmacy bills for drug cost and charges drug cost sharing
  - Provider bills for administration and other associated office visit costs and charges medical cost sharing
ADAP-Funded Insurance Clients

- Medicaid
  - Separate physician-administered drug list
    - Cost sharing: Nominal copay

- Medicare
  - Provider-administered drug/buy-and-bill: Medicare Part B
    - Cost sharing: Up to 20% of Medicare allowable cost (Average Sales Price + 6%); possibility of separate 20% cost sharing on administration/office visit charge
  - May be Part D pharmacy benefit/white bagging (e.g., MA-PD plans)
    - Cost sharing: copayment or coinsurance on drug product; separate cost sharing for administration/office visit
ADAP-Funded Insurance Clients

- **Commercial Insurance**
  - Cabenuva may be medical benefit or pharmacy benefit; may not appear on drug formulary if medical benefit
  - Medical benefit/buy-and-bill
    - Cost sharing: One or two cost-sharing payments may be required. Example: Only one if administered by nurse; two if administered by doctor or as part of an evaluation and management (E/M) visit
  - Pharmacy benefit/white bagging
    - Cost sharing: Two cost-sharing payments generally required. Example: One to specialty pharmacy, one to provider for office visit/administration
  - **ADAPs & Part Bs will need to establish mechanism to pay cost sharing at provider level.** Example: Provider invoicing
Does your ADAP/Part B provide cost-sharing support on buy-and-bill claims submitted by providers for any drugs or biologics administered to ADAP-funded insurance program clients?

26 ADAPs responding
Buy-and-bill: How does ADAP/Part B differentiate cost sharing for the drug or biological product from cost sharing related to administration of the medication and/or provider visit services?

- Through CPT code
- When/if this is the only mechanism to obtain the medication, the medical claim(s) are paid via HIPCSA funds by our Medical Benefits Manager (MBM). In turn, the prescription copay is paid by our PBM (Ramsell) directly to the provider (via a manual request/payment process) as this in turn allows us to generate a rebate for partial pay
Does your ADAP/Part B provide cost-sharing support on product administration and/or office visit claims submitted by providers for drugs or biologics subject to white bagging for ADAP-funded insurance program clients?

26 ADAPs responding

2019 ADAP Questionnaire

PERCENT

Yes 31%

No 69%
2019 ADAP Questionnaire

- White bagging: How does ADAP/Part B cover administration/office visit cost sharing?
  - Part B program can cover these in the same way other eligible CSA is handled. It would not be counted as ADAP unless we separate the expenditures after-the-fact and reassign the expenditures to ADAP.
  - Through monthly invoices submitted by providers using RWHAPB. ADAP also allows any local health department to purchase and administer vaccines for clients using ADAP.
### Long-Acting Injectables

#### 1 Possible Delivery Model

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Prior Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dual Enrollment Required for:</td>
<td>• Injectables or Infusion Medication (example: Trogarzo) are on Prior Approval:</td>
</tr>
<tr>
<td>• Illinois ADAP (Medication Assistance) and Premium Assistance (if insured)</td>
<td>• Medical Provider provides location for infusion / injectable</td>
</tr>
<tr>
<td>• Illinois Part B Medical Care</td>
<td>• Illinois PBM will dispense to location provided on Prior Approval Form</td>
</tr>
</tbody>
</table>

Source: IL ADAP/RWHAP Part B; courtesy Jeff Maras
### Long-Acting Injectables

#### 1 Possible Delivery Model

<table>
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<tr>
<th>Medical Service</th>
<th>Payment</th>
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<tbody>
<tr>
<td>• Case Manager within the Illinois jurisdictional location will make referral to medical provider where the injectable medication will be administered.</td>
<td>• Medical Facility or Client (out-of-pocket cost documentation) will submit payment for office visit/service to case management site.</td>
</tr>
<tr>
<td>• Medical Transportation will be provided if needed to attend medical appointment for the injection.</td>
<td>• Part B Case Manager will submit a payment request for negotiated cost for the medical service (if uninsured); or payment request for OOP cost submitted by insurance company.</td>
</tr>
<tr>
<td>• Client will arrive to medical appointment for the administration of the medication by an appropriate provider.</td>
<td>• ADAP will cover the cost of the medication dispensed by PBM.</td>
</tr>
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</table>

Source: IL ADAP/RWHAP Part B; courtesy Jeff Maras
Long-Acting Injectables
1 Possible Delivery Model

- If HRSA provides a PCN that allows ADAP’s to cover the cost of medical administration of a medication; then the Illinois ADAP will absorb the cost for medical visit/service along with the cost of medication.

- Illinois will design an enhancement within its data system that will allow Case Managers to submit medical service payment request that will report to ADAP for payment through the Program’s Medical Benefit Coordinator.

- As ADAP’s begin to develop capacity, more streamlined administration and payment systems will be explored.

Source: IL ADAP/RWHAP Part B; courtesy Jeff Maras
ADAP Formulary Considerations

- Provider/client demand
- Cost
  - Price-neutrality with existing products
  - Higher ADAP price allowance for value added
  - Lower ADAP price (sub-neutrality) to compensate for provider and administration fees
- Other payer considerations
  - Unclear how other payers will respond
  - ADAPs as payer-of-last-resort: Is your ADAP responsible for full-pay costs for ADAP-funded insurance clients if primary payer is slow/unwilling to cover?
  - Potential challenges determining which commercial payers are covering (depending on medical benefit vs. drug benefit categorizations)