



2022
NATIONAL

HIV & HEPATITIS

TECHNICAL ASSISTANCE MEETING



Best Practices for Implementing Long-Acting Injectables and other Provider-Administered Drug Products

How did other ADAPs...

- Determine whether to support long-acting injectable (LAI) white bagging coverage only, buy-and-bill coverage only or both?
- Work with their PBM to set up specialty pharmacy relationship?
- Implement coverage for LAI administration and office visit costs?
- Cover ADAP-funded insurance client cost sharing associated with LAIs?
- Submit claims for rebates?
- Communicate ADAP coverage options and mechanisms to providers and other community members?



Presenters

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Connecticut ADAP's Approach to LAI CAB/RPV

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Overview of CADAP

- The Connecticut AIDS Drug Assistance Program (CADAP) is a rebate option ADAP with a closed formulary
- Serve around 1800 clients per year:
 - 55% uninsured/uninsurable
 - 34% Non-Hispanic Black, 27% Latinx, 25% Non-Hispanic White
 - 66% Male, 33% Female, >1% Transgender
 - Avg Age: 54 y/o
- Pharmacy Benefit Manager is Magellan Rx Management
 - Network of over 700 pharmacies in Connecticut
 - 10 specialty pharmacies outside of Connecticut
- Clinical Advisory Board handles approval of formulary additions
 - 5 MDs, 1 PA, 1 APRN, 4 Pharmacists, 2 CBO Staff, 2 DPH Staff
 - Representation throughout the state



Planning and Preparation

- CAB/RPV FDA approved on January 27, 2021
- Limited distribution from select specialty pharmacies and wholesalers
- Upon FDA approval of CAB/RPV, several healthcare providers inquired when CADAP will cover
- Many considerations prior to adding to formulary
 - Prior Authorization?
 - Buy and Bill?
 - Cover administration fee?
 - What pharmacies are in network?
- Devised 3 steps for successful implementation of CAB/RPV



Step 1: Meet with Manufacturer

- To-Do List:

1. Projected utilization of CAB/RPV?
2. What support was manufacturer offering with ViiV Connect?
3. Procurement options for CAB/RPV?
4. Confirm with providers if information shared was accurate.

- Results:

1. Met with manufacturer. Reviewed the indications for CAB/RPV and the current CADAP population. It was determined only around 5% of clients might qualify or want to switch to CAB/RPV.
2. Reviewed how ViiV Connect works. Identified resources providers could use (field reimbursement managers) as well as potential barriers
3. Identified the specialty pharmacies and wholesalers that could provide CAB/RPV.
4. Met with Pharmacist at CHC to discuss CAB/RPV and verified information relayed to providers was accurate.



Step 2: Meet with PBM

- To-do list:
 1. What specialty pharmacies can distribute CAB/RPV and are in the CADAP network? Are any in Connecticut?
 2. Do any changes need to be made to the prescription dispensing process?
 3. Does CADAP have a mechanism to support Buy-and-Bill?
 4. Paying administration fee at healthcare office?
- Results:
 1. Identified 5 specialty pharmacies in CADAP network that could dispense CAB/RPV. Also confirmed Walgreens Local Specialty Pharmacies could dispense (must still white-bag).
 2. No change needed in prescription filling process. Prior authorization status would be determined by the CADAP Clinical Advisory Board.
 3. No mechanism to support Buy-and-Bill. Would require contracts with individual providers.
 4. Method of paying administration fee developed, but not implemented yet due to contract
 - a) Could still use Outpatient/Ambulatory Ryan White Service Category to cover cost



Step 3: Meet with Providers

- To-Do List:

1. Convene meeting with CADAP Clinical Advisory Board and discuss CAB/RPV formulary addition request.
 1. Prior Authorization?
2. Discuss challenges and strategies for implementing successful CAB/RPV programs.

- Results:

1. Met with Clinical Advisory Board. Unanimously approved adding CAB/RPV to formulary. No prior authorization required due to existing barriers.
2. Providers discussed challenges they had experienced with insurers and shared success stories and other strategies.



Results

- CAB/RPV added to CADAP Formulary on April 28, 2021.
- Letter was issued by DPH on May 3, 2021 informing all Ryan White and HIV Providers of the formulary addition as well as procurement procedure.
- Some providers required as needed Technical Assistance implementing their CAB/RPV programs due to administrative challenges.
- As of September 2022, 51 clients on CAB/RPV
 - Majority are ADAP uninsured and use an FQHC (administration fee covered)



Other Considerations

- Cost
 - One month of CAB/RPV is more expensive than oral ART
 - ADAP review and projections indicated marginal increase in expenditures
- Limited Distribution Network
 - Must be dispensed by select pharmacies
 - Connecticut has multiple local specialty pharmacies that are URAC accredited and can order and dispense
- Implementing a mechanism to cover administration fee
 - Some mechanisms already exist (FQHC)
 - May require a network
 - If no network, clients may be charged at time of service



Demographics

- 51 clients* started on CAB/RPV since April 2021
 - 18 clients (35.3%) Hispanic/Latinx
 - 23 clients (45.1%) Non-Hispanic Black
 - 8 clients (15.6%) Non-Hispanic White
 - 2 clients (3.9%) Asian/Pacific Islander/Other
- Insurance Status
 - 40 clients (78.4%) are uninsured
 - 9 clients (17.6%) have private insurance through employer or health exchange
 - 2 clients (3.9%) have Medicare
- Where are clients getting care?
 - 32 clients (62.7%) FQHC
 - 10 clients (19.6%) Ryan White Funded Clinic
 - 9 clients (17.6%) Private Provider

*= ~3% of total CADAP population, 30% increase in usage since June 2022



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California AIDS Drug Assistance Program (ADAP): Cabenuva Implementation

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California Department of Public Health: Office of AIDS

Presenters



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Disclosure

This presentation contains information pertaining to CABENUVA, which is a long-acting injectable complete regimen for the treatment of HIV-1 infection manufactured by ViiV Healthcare. Contents of this presentation solely represent the implementation plan for adding CABENUVA to the California ADAP formulary and the coverage of associated administration fees. The contents of this presentation are not associated with ViiV Healthcare.

Overview of California ADAP Framework

- ADAP Branch – Medication and Insurance Assistance program
 - ADAP
 - Pre-Exposure Prophylaxis Program
 - Pharmacy Benefit Manager (PBM) is Magellan Rx Management
 - Medication Coverage
 - Insurance and Medical Benefits Manager (MBM) is Pool Administrators Incorporated (PAI)
 - Medical Out Pocket Coverage

Planning and Preparation

- FDA approved on January 27, 2021
- Healthcare providers and stakeholders' interest
- Propose plan to MBM and PBM contractors
- Considerations
 - Prior authorization?
 - How will medications be covered?
 - How will ADAP clients access long-acting injectable HIV treatment?
 - How will ADAP ensure administration cost are covered for ADAP clients?
 - How do we ensure equity amongst our clients?

Phase I: Medication Coverage

- Coverage of medication only for all ADAP Clients
- Coverage of administration cost of Cabenuva for clients enrolled in ADAP's insurance assistance program
 - Outpatient services already covered for insurance assistance program clients
- Provide guidance to local Enrollment Workers via Policy Memo

Phase II: Medical Benefit

- Clinical provider network
- Collaborate with medical benefits manager
 - Add services to allowable service list
 - Expand client data transfers
- Coverage of administration cost for all ADAP clients (March 17, 2022)
- Guidance to Enrollment Workers via policy memo

Future Coverage - Phase III: Pharmacy Benefit

- Covering administration cost of Cabenuva for clients when billed as a pharmacy benefit
- Working with PBM to establish a process
 - Envision providers billing PBM for administration services
- Updating contract with PBM to account for additional services

Current Utilization

| SUMMARY STATS BY PAYER SOURCE FOR CABENUVA | | | | | |
|--|--------------------|------------|------------|----------------|-----------------|
| PAYER SOURCE | COSTS | SCRIPS | CLIENTS | COST PER SCRIP | COST PER CLIENT |
| ADAP Only | \$2,404,629 | 512 | 165 | \$4,697 | \$14,574 |
| Medi-Cal | \$0 | 0 | 0 | \$0 | \$0 |
| Priv Ins | \$460,735 | 121 | 39 | \$3,808 | \$11,814 |
| Medicare | \$109,364 | 228 | 77 | \$480 | \$1,420 |
| TOTAL | \$2,974,728 | 861 | 281 | \$3,455 | \$10,586 |
| Oct 2021 to Sep 21, 2022. | | UNDUP | 275 | | |

| CLIENTS BY MONTH BY PAYER SOURCE FOR CABENUVA | | | | | |
|---|------------|----------|-------------------|-----------|------------|
| REPORT MONTH | ADAP ONLY | MEDI-CAL | PRIVATE INSURANCE | MEDICARE | TOTAL |
| Oct 21 | 3 | 0 | 1 | 0 | 4 |
| Nov 21 | 16 | 0 | 3 | 4 | 23 |
| Dec 21 | 23 | 0 | 4 | 7 | 34 |
| Jan 22 | 26 | 0 | 8 | 20 | 54 |
| Feb 22 | 31 | 0 | 14 | 31 | 76 |
| Mar 22 | 51 | 0 | 13 | 24 | 88 |
| Apr 22 | 54 | 0 | 15 | 22 | 91 |
| May 22 | 48 | 0 | 8 | 25 | 81 |
| Jun 22 | 61 | 0 | 17 | 22 | 100 |
| Jul 22 | 54 | 0 | 9 | 22 | 85 |
| Aug 22 | 74 | 0 | 16 | 29 | 119 |
| Sep 22 | 55 | 0 | 11 | 14 | 80 |
| TOTAL | 165 | 0 | 39 | 77 | 281 |
| Data thru Sep 21, 2022. | | | | UNDUP | 275 |

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BEST PRACTICES FOR IMPLEMENTING LONG-ACTING INJECTABLES AND OTHER PROVIDER-ADMINISTERED DRUG PRODUCTS

Gordana Cokrljic

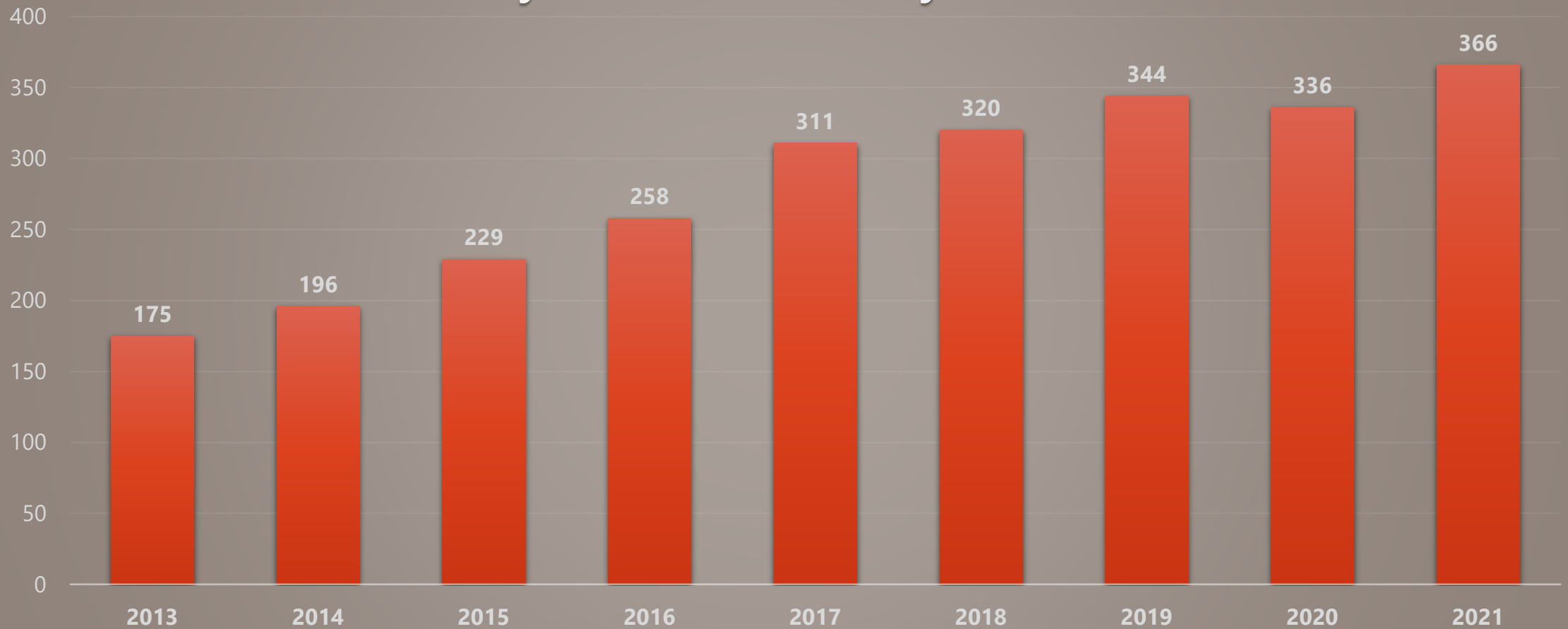
ND Ryan White Program Coordinator

October 12, 2022 National HIV & Hepatitis Technical Assistance Meeting

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RW CLIENT DEMOGRAPHICS

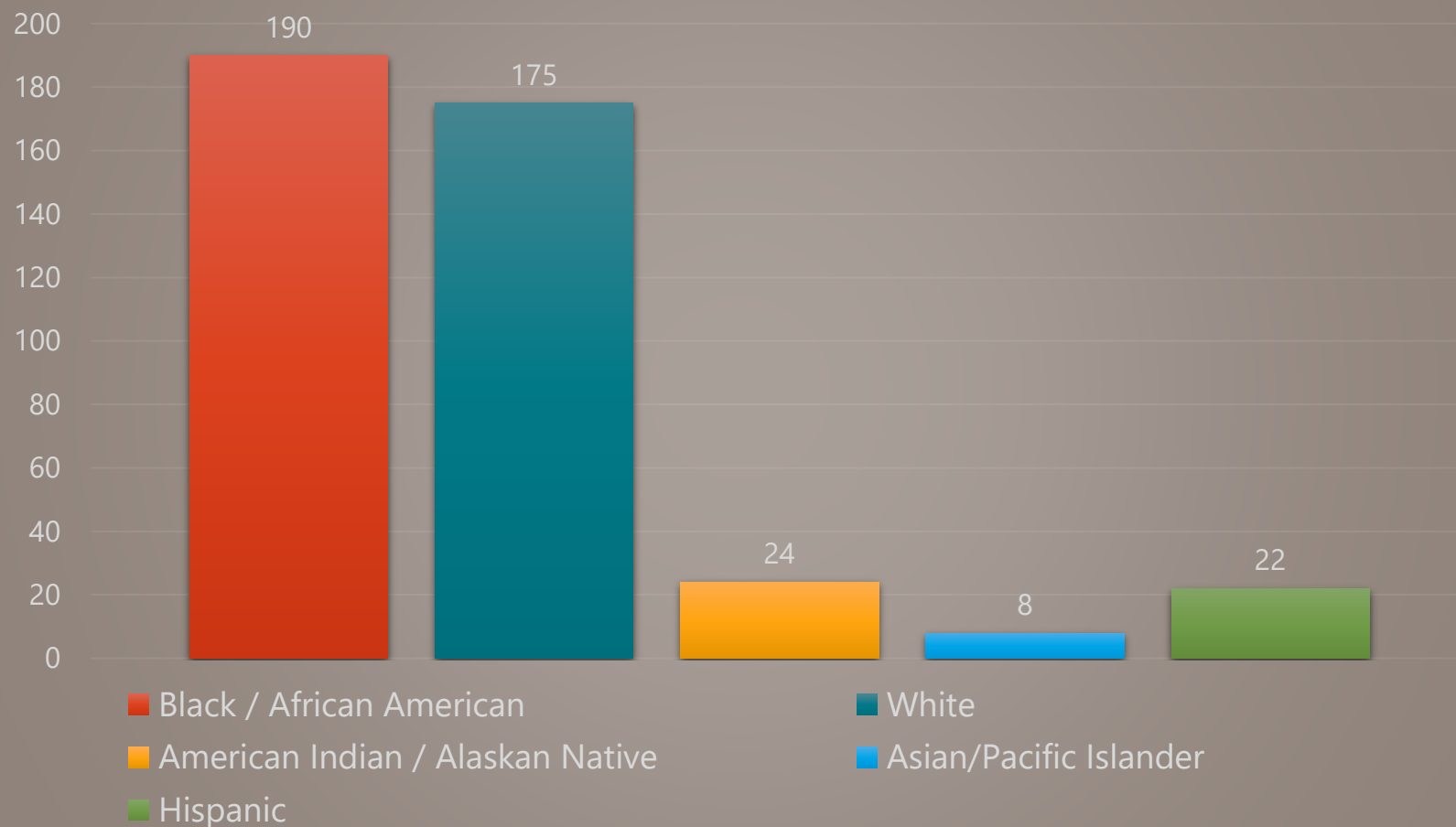
Enrolled Ryan White Clients by Calendar Year



Source: NDDoH Division of Sexually Transmitted and Bloodborne Diseases

RW CLIENT DEMOGRAPHICS, 2021

2021 Ryan White Clients by Race



Source: NDDoH Division of Sexually Transmitted and Bloodborne Diseases

Race: 190 (52%) are Black/African American, 175 (48%) are White, and 24 (7%) are American Indian.

Country of Birth: 181 (49%) are born in US; 133 (36%) are born outside of US, and 49 (13%) are unknown.

- **Income:**
- 35% are below poverty level
- 27% are between 101 and 200% FPL



ND ADAP OVERVIEW

Utilization:

- In 2021, 366 clients were enrolled in RWPB, 259 (71%) clients utilized ADAP

Health Coverage:

- 22% of clients enrolled in 2021 were uninsured at some point in the year
- 5-15% of clients at any time are uninsured
- ND has expanded Medicaid

OVERVIEW OF ND ADAP

- The North Dakota AIDS Drug Assistance Program (ADAP)
 - Rebate based
 - Open formulary with certain categories excluded since 2019
- ND receives Part B only
- ND's Medicaid Managed Information System (MMIS) serves as PBM for ND ADAP
- Network of 171 retail pharmacies throughout ND
- Outpatient medical care is provided by private infectious disease providers and reimbursed through case management agencies.



ADAP EXPENDITURES, 2021

- ADAP covers cost of medications at full cost for the uninsured and premiums & drug copays for insured clients.
- Clients must enroll in eligible insurance as cost/uninsured client is double than for insured clients.

| Type of Assistance | No. of Clients | Percent | Cost | Percent | Cost/Client |
|--------------------|----------------|---------|-----------------------|---------|-------------------|
| Medication | 79 | 31 | \$559,587.87 | 44 | \$7,083.39 |
| Insurance | 231 | 89 | \$718,369.27 | 56 | \$3,109.82 |
| Copays | 223 | | \$541,687.97 | | \$2,429.09 |
| Premiums | 82 | | \$176,681.30 | | \$2,154.65 |
| Total | 259 | | \$1,277,957.14 | | |

ADDITION OF CABENUVA TO ND ADAP FORMULARY

- FDA Approval January 27, 2021 – added to ND Medicaid's formulary and ND ADAP formulary as medical benefit.
- Memo sent to all infectious disease providers, RW case managers, and pharmacies April 2021.
- In communication with ViiV representative on how providers can obtain oral lead-in and Cabenuva.



ADDITION OF CABENUVA TO ND ADAP FORMULARY

- Questions we had:
 - Can we sustain the cost for all interested clients?
 - How will rebate submission work?
 - What if the client is not adherent and is there a potential for waste if client no-shows?
- Reimbursement:
 - Cover insured clients only (exceptions considered on a case-by-case basis)
 - Medical visit and administration fee – RW Part B Outpatient/Ambulatory Medical Care
 - Cabenuva copay – ADAP funds
- Rebate:
 - Track separately and generate a separate rebate invoice outside of DRAMS (Drug Rebate Analysis & Management System)

ADDITION OF CABENUVA TO ND ADAP FORMULARY

- Quarterly call with Infectious Disease providers in ND
 - Some utilization
 - Insurance covering the cost and utilizing ViiV assistance program
 - Some patients continue to have persistent detectable low viral load, especially those with high BMI (over 35)
- September 2, 2022 – Cabenuva reimbursed as pharmacy benefit through MMIS
 - Memo sent to providers, case managers , and pharmacies
 - All clients informed via letter

No utilization to date yet through ND ADAP.
ND Medicaid has had 6 units billed in 1Q22.





Thank you!

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NASTAD Online Resources



Cabenuva Considerations for AIDS Drug Assistance Programs

Last Updated: Mar 29, 2022

This brief is designed to assist AIDS Drug Assistance Programs (ADAPs) through the development of policies and procedures associated with the procurement and payment of provider-administered antiretrovirals, including cabotegravir and rilpivirine extended-release injections.

↓ **CABENUVA CONSIDERATIONS FOR AIDS DRUG ASSISTANCE PROGRAMS**

[Cabenuva Considerations for AIDS Drug Assistance Programs](#)

nastad.org/resources/adap-provider-administered-long-acting-injectable



| Resources Health Care Access Long-Acting ARV Treatments | | |
|---|---------|--------------|
| Name | Size | Type |
| CA Cabenuva ADAP Medical Services 2022.pdf .pdf | 168.5KB | PDF document |
| CA Cabenuva Phase II Implementation Plan 2022.pdf | 253.5KB | PDF document |
| Florida DOH Barriers to LAIs .pdf | 124.8KB | PDF document |
| NH ADAP Cabenuva Policy Letter 2021 | 207.5KB | PDF document |
| NH ADAP Work Flow 2021.pdf | 170.7KB | PDF document |
| VA Cabenuva Specific Policy 2021.pdf | 672.2KB | PDF document |
| VA LA ARV General Policy 2021.pdf | 538.3KB | PDF document |

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Questions and Discussion

