Long-Acting Injectable HIV Treatment Implementation and Coordination

Andrea Weddle, MSW
Executive Director, HIV Medicine Association

Tim Horn, MS
Director, Health Care Access, NASTAD

Marwan Haddad, MD, MPH
Medical Director, Center for Key Populations, Community Health Center Inc.

Kara Lewis, PharmD
Clinical Pharmacist Leader, Community Health Center, Inc.

Mitchell Namias, PharmD
ADAP Coordinator, Connecticut AIDS Drug Assistance Program

2022

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

Disclosures

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

Andrea Weddle, MSW, has no relevant financial interests to disclose.

Tim Horn, MS, has no relevant financial interests to disclose.

Marwan Haddad, MD, MPH, has no relevant financial interests to disclose.

Kara Lewis, PharmD, has no relevant financial interests to disclose.

Mitchell Namias, PharmD, has no relevant financial interests to disclose.

Disclosure will be made when a product is discussed for an unapproved use.

This continuing education activity is managed and accredited by AffinityCE, in collaboration with the Health Resources and Services Administration (HRSA), LRG, and AffinityCE. AffinityCE, LRG and HRSA staff, as well as planners and reviewers, have no relevant financial interests to disclose. AffinityCE adheres to the ACCME's Standards for Integrity and Independence in Accredited Continuing Education. Any individuals in a position to control the content of a CME activity, including faculty, planners, reviewers, or others, are required to disclose all relevant financial relationships with ineligible entities (commercial interests). All relevant conflicts of interest have been mitigated prior to the commencement of the activity.

Commercial support was not provided for this activity.

Learning Objectives

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

At the conclusion of this activity, the participant will be able to:

1. Describe the potential benefits of long-acting antiretrovirals for the treatment of HIV
2. Evaluate key clinical, delivery system, procurement, coverage, and payment considerations associated with implementing provider-administered long-acting antiretrovirals for RWHAP clients
3. Discuss RWHAP program implementation and coordination approaches for providers, patients, and payers

Session Roadmap

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Background and Level Setting
- Clinic Implementation Considerations
- ADAP Implementation Considerations
- Q&A and Discussion

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

Background and Level Setting

Tim Horn, MS

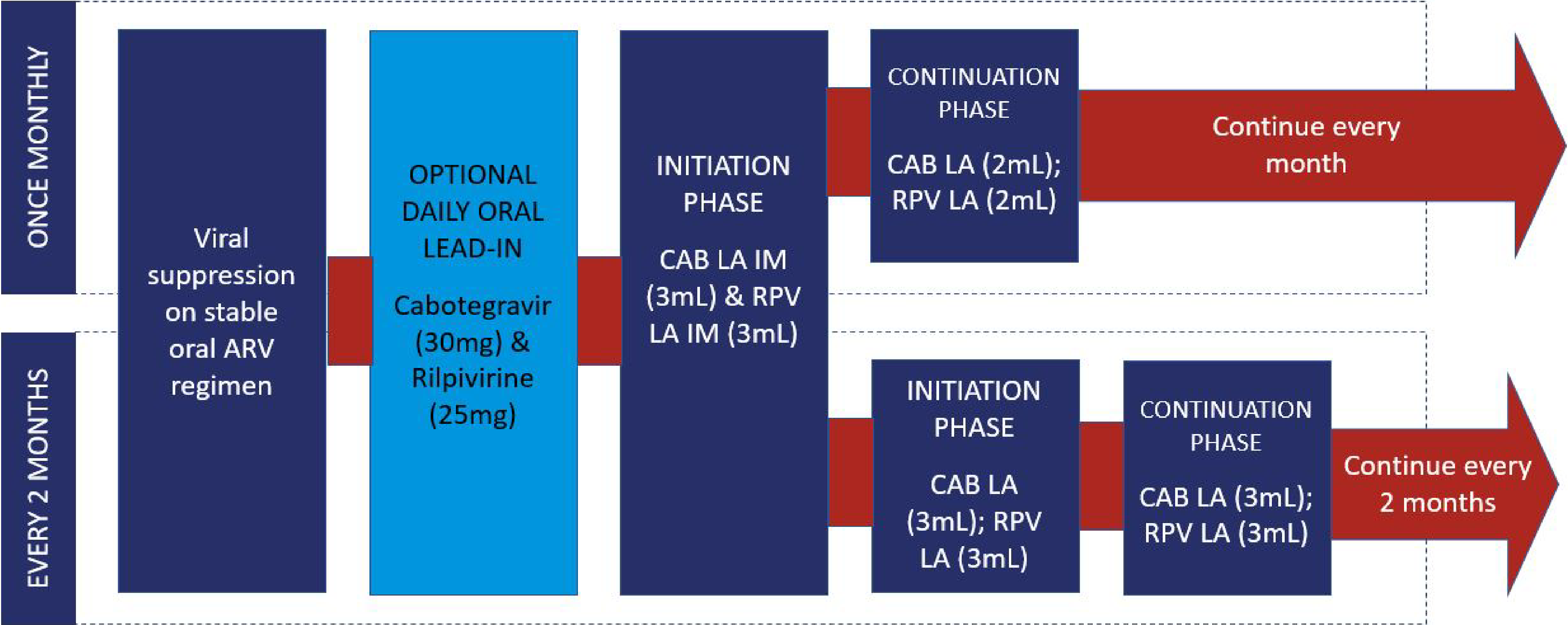
NASTAD
Washington, DC

Potential Advantages of LAIs

- Address suboptimal adherence
- Ameliorate challenges associated with oral medications, including gastrointestinal, neurologic, or psychiatric disease
- Less frequent dosing & avoidance of pill fatigue
- Protection of health privacy
- Avoidance of HIV-related stigma

Several long-acting antiretroviral drug products in development!

Cabotegravir/Rilpivirine LA



Delivery System Issues

- Cold chain and storage required
- Clinic space and resources for more frequent visits
- Workflow for CAB/RPV LA prescribing, insurance, delivery, acceptance, storage, and client reminders/follow up
- Alternative sites of administration may be available
    - Search: https://www.viivconnect.com/injection-site-finder/

Procurement & Purchasing

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- **Buy-and-bill:** Provider or clinic purchases the product from a wholesaler or distributor and bills the primary third-party payer
- **White bagging:** Provider submits prescription to specialty pharmacy; pharmacy processes the claim and ships product to the provider
- **Clear bagging:** A health system's internal specialty pharmacy maintains inventory of drug/biologic; processes claim and delivers product to the provider
- Separate inventories need to be maintained
- CAB/RPV LA available from variety of specialty distributors and pharmacies

Coverage & Cost Sharing

- Many plans covering/expected to cover as medical benefit
- Some plans covering as pharmacy benefit (or as both)
- Coinsurance (e.g., 20% of cost) typical of medical benefit under commercial or Medicare Part B coverage
- Cost sharing assistance via manufacturer copay assistance program; possible assistance via RWHAP Health Insurance Premium and Cost-Sharing Assistance for Low-Income Individuals category or ADAPs

RWHAP & ADAP

- Providers with ADAP clients should check with ADAP to determine formulary coverage and access policies
- Many ADAPs requiring network specialty pharmacy/white bagging
- HIV/AIDS Bureau (HAB) guidance in December 2019 recommending that ADAPs add LA ARV products; allows for coverage of LA ARV administration and office visit costs (full pay and insurance)
  - https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/dcl-rwhap-adap-long-act-arv.pdf
- RW providers may use Outpatient/Ambulatory Health Services category to cover administration and clinic costs

Clinic Implementation Considerations

Marwan Haddad, MD, MPH
Kara Lewis, PharmD

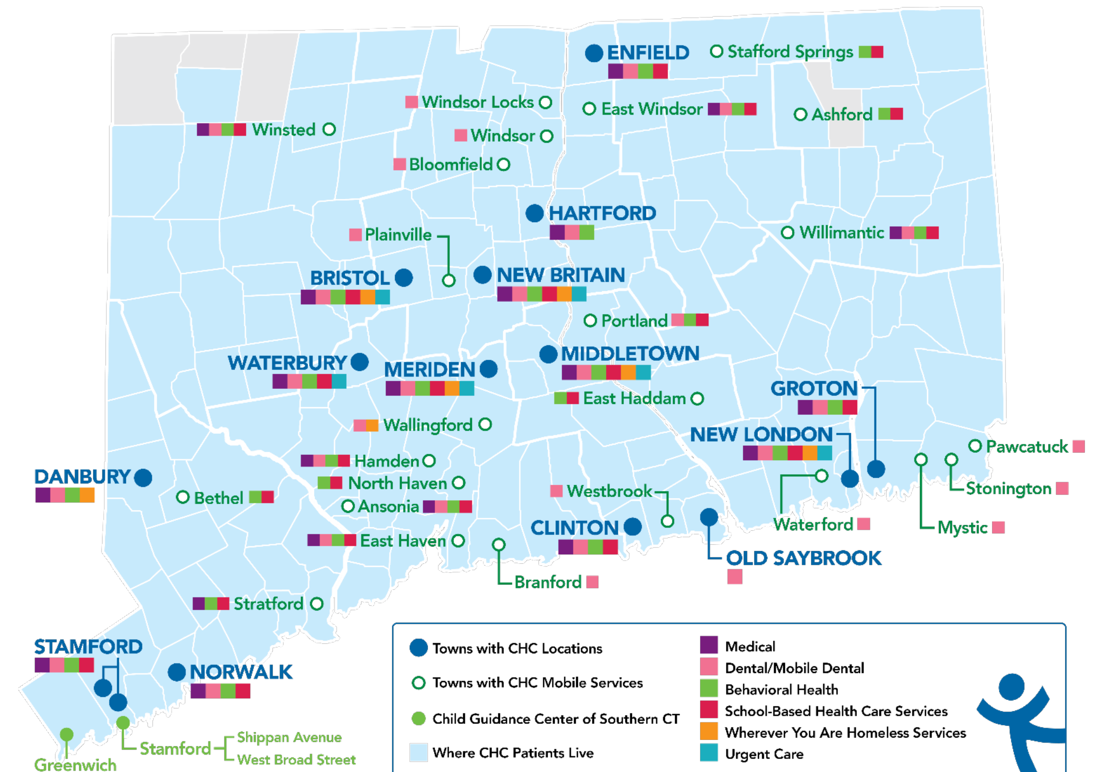
Community Health Clinic, Inc. (CHC, Inc.)
Middletown, CT

Community Health Center, Inc.

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Founding year: 1972
- Primary care hubs: 15; 204 practice locations
- Staff: 1,140
- Active Patients: 150,000

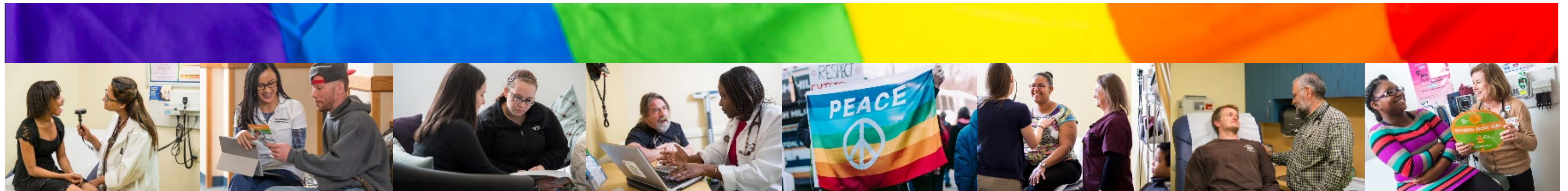
Locations & Service Sites in Connecticut



Center for Key Populations

The Center for Key Populations is the first center of its kind that focuses on key groups who experience health disparities secondary to stigma and discrimination and who belong to communities that have suffered many barriers to healthcare.

The Center brings together healthcare, training, research, and advocacy for:
People who use drugs, the LGB and Transgender populations, the homeless and those experiencing housing instability, the recently incarcerated, and sex workers.



HIV Primary Care | HIV Testing and Prevention including PrEP and PEP | Oasis Community Drop-In Center | Viral Hepatitis Screening and Treatment | Substance Use Health Program including Medication for Opioid Use Disorder | LGB and Transgender Health Care | Sexually Transmitted Infections | Health Care for the Homeless | Migrant Farmers Health Program

Clinical Decision Making

- **Eligibility for Long Acting Injectable (LAI) ARV**
  - Individuals 12 years+ at least 35 kg
  - On stable oral ARV regimen
  - HIV RNA virally suppressed
  - No history of treatment failure
  - No known or suspected resistance to rilpivirine or cabotegravir

Clinical Decision Making 2

- Assessment of LAI candidates
  - Struggling with oral medication
    - Pill fatigue
    - Pill sizes
    - Swallowing difficulty
  - Would prefer injectable regimen
  - Experiencing side effects with oral meds, e.g. GI
  - Able to adhere to visits every 1-2 months for injections
    - Costs associated with visits
    - Transportation
    - Child care
    - Work
  - Coverage of LAI ARV

Clinical Decision Making 3

- Challenges
  - Identification
    - Active outreach and education vs. as patients are seen
  - Capacity of staff and clinic and how fast to roll out and scale up
  - Oral lead-in
    - Advantage:
      - Trial of meds for tolerance prior to long acting injection
    - Disadvantage:
      - Difference in side effects between oral vs. injection
      - Difficulty taking with large meal or stopping treatment for acid reflux
  - Incomplete information
    - ARV history
    - HIV resistance information
  - Oral meds no longer an option, not virally suppressed, but LAI is only choice
  - Handling disappointment if LAI not an option

Workflow

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Start small, identify pain points before rolling out to entire organization
- Identify members of clinical team involved in process
  - Provider, nurse, pharmacist, medical assistant, care coordinator, front desk staff
- Identify collaborative pharmacy partner (limited distribution drug)
- Be aware some insurances may have specific specialty pharmacy requirements, and some can bill medical benefit
- Develop/provide protocols, trainings, forms and make accessible in same place for reference (see example on CHC Resource slide)

Workflow 2

- Trainings
  - How to administer injections
- Steps and roles
  - Who and how to identify patients
  - Who and when to determine eligibility
  - Who can educate on LAI option
  - How to prescribe, e.g. where to send script
  - Who works on procuring coverage for the medication
  - Who will give appointments for injections and how will those appointments be made
  - Who will call/send reminders for appointments
  - Who coordinates with pharmacy re delivery of medication
  - Who accepts medication when it arrives, where is it stored
  - What happens if patient misses appointment, who reaches out, troubleshoots
  - Who administers the injections; is there cross coverage set up

ADAP Implementation Considerations

Mitchell Namias, PharmD

Connecticut AIDS Drug Assistance Program (CADAP)
Hartford, CT

Overview of CADAP

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- 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

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- CAB/RPV LA FDA approved on January 27, 2021
- Limited distribution from select specialty pharmacies and wholesalers
- Upon FDA approval of CAB/RPV LA, 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 LA

Step 1: Meet with Manufacturer

- To-Do List:
  1. Projected utilization of CAB/RPV LA?
  2. What support was manufacturer offering with ViiV Connect?
  3. Procurement options for CAB/RPV LA?
  4. Confirm with providers if information shared was accurate.
- Results:
  1. Met with manufacturer. Reviewed the indications for CAB/RPV LA and the current CADAP population. It was determined only around 5% of clients might qualify or want to switch to CAB/RPV LA.
  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 LA.
  4. Met with Pharmacist at CHC to discuss CAB/RPV LA and verified information relayed to providers was accurate.

Step 2: Meet with PBM

- To-do list:
  1. What specialty pharmacies can distribute CAB/RPV LA 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 LA. 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

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- To-Do List:
  1. Convene meeting with CADAP Clinical Advisory Board and discuss CAB/RPV LA formulary addition request.
     1. Prior Authorization?
  2. Discuss challenges and strategies for implementing successful CAB/RPV LA programs.
- Results:
  1. Met with Clinical Advisory Board. Unanimously approved adding CAB/RPV LA 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

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- CAB/RPV LA 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 LA programs due to administrative challenges.
- As of June 2022, 36 clients on CAB/RPV LA
    - Majority are ADAP uninsured and use an FQHC (administration fee covered)

Other Considerations

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Cost
  - One month of CAB/RPV LA 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

CHC, Inc. Resources

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Cabenuva Injection Video: https://www.youtube.com/watch/mXEXdC8SDMM
- Connect w/ ViiV Reimbursement Specialist/MSL: https://cabenuvahcp.com/speak-to-a-resource
- Example of CHC internal site: each page has links to external website for most up-to-date info.

Community Health Center, Inc.

DEPARTMENTS POLICIES & PROCEDURES CHC DATA

Pharmacy Home
Apretude/Cabenuva
CT Medicaid/Husky Links
Continuous Glucose Monitoring (CGM)
Parachute Health DME
340B Program Med List
By Drug Name
By Condition
By Drug Class

Community Health Center > Pharmacy

All Documents Find a file

Name
Apretude (how to start, where to send script, scheduling appts)
Apretude Info Links (injection video, dosing guide, copay assistance)
Apretude Injection Instructions (written directions)
Cabenuva (how to start, where to send script, scheduling appts)
Cabenuva Info Links (injection video, dosing guide, copay assistance)
Cabenuva Injection Instructions (written directions)

HIVMA and NASTAD Resources

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

www.hivma.org

www.nastad.org

How to Claim CE Credit

NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- If you would like to receive continuing education credit for this activity, please visit:

ryanwhite.cds.pesgce.com