

Long-Acting Injectable HIV Treatment Implementation and Coordination

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ON HIV CARE & TREATMENT

Disclosures

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.

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Learning Objectives

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

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

Background and Level Setting

Tim Horn, MS

NASTAD

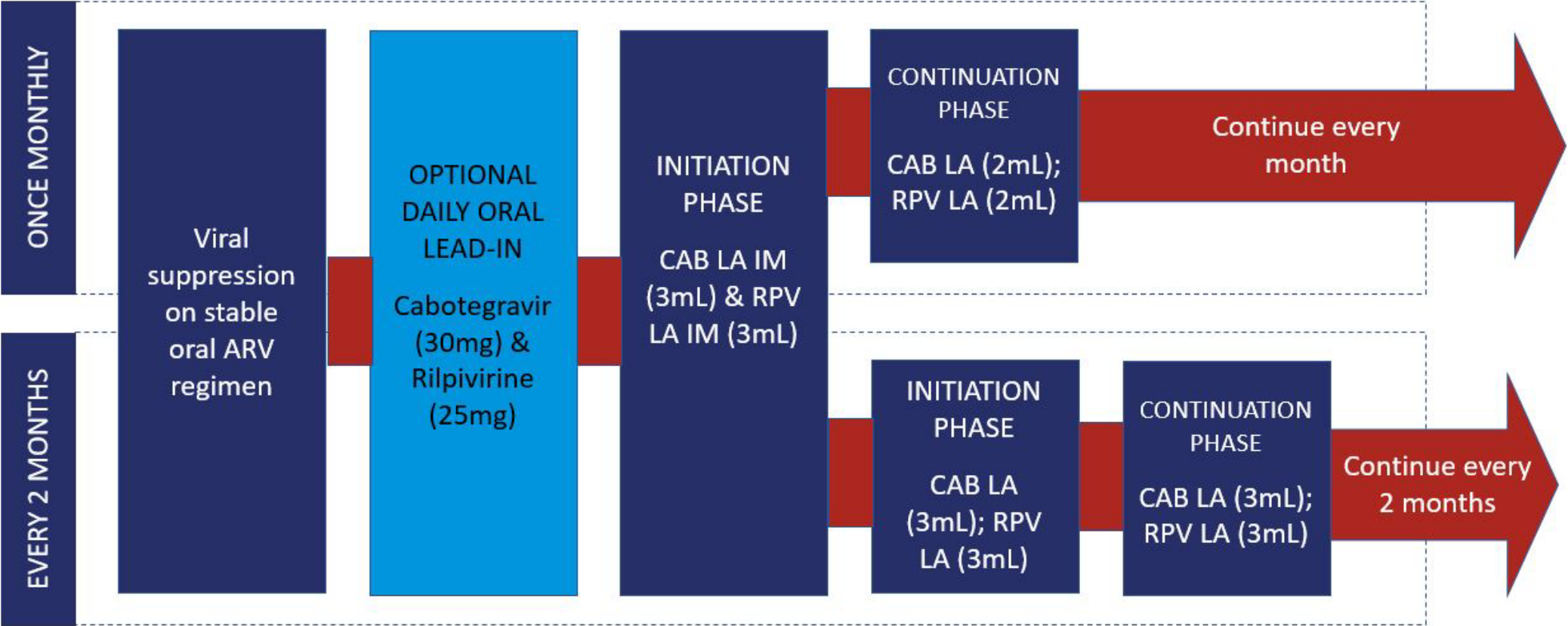
Washington, DC

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

- **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

- 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

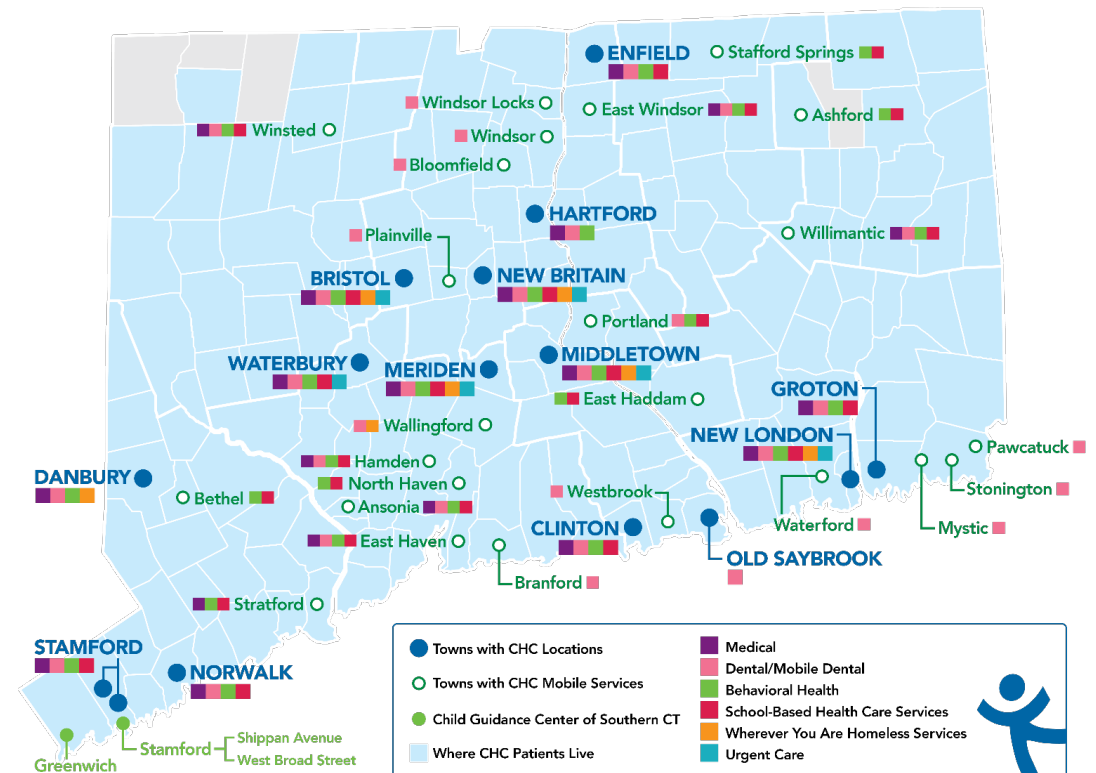
Clinic Implementation Considerations

Marwan Haddad, MD, MPH
Kara Lewis, PharmD

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

Locations & Service Sites in Connecticut

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



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

- **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

- 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

- 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 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

- 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.

- 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

- 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

- 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.

The screenshot shows the internal website for Community Health Center, Inc. The top navigation bar includes 'DEPARTMENTS', 'POLICIES & PROCEDURES', and 'CHC DATA'. The main content area is titled 'Community Health Center > Pharmacy' and features a search bar labeled 'Find a file'. A sidebar on the left lists various services, with 'Apretude/Cabenuva' highlighted and a red arrow pointing to it. The main content area displays a list of documents under the heading 'All Documents'. The list includes: '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)', and 'Cabenuva Injection Instructions (written directions)'. A red box highlights the 'Cabenuva' section of the document list.

HIVMA and NASTAD Resources

www.hivma.org

NASTAD hivma
 The National AIDS Treatment Advocacy Center

Long-Acting Antiretroviral Treatment: Considerations for Health Care Providers
 Version: June 2022

VIV Healthcare's Cabenuva™ (cabotegravir and rilpivirine extended-release injectable suspension) was approved by the U.S. Food and Drug Administration on January 21, 2022. Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents (2 years of age or older who weigh at least 35 kg) to replace the current antiretroviral regimen in those who are virologically suppressed on a stable ART regimen, with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva is delivered via monthly or every-other-month injections that generally need to be administered in a clinical setting. This novel maintenance therapy option may help to improve adherence and reduce stigma for some patients but requires pharmacy and/or clinical delivery system and administrative adjustments for clinics and providers.¹

This document highlights clinical considerations based on the FDA label and delivery system, as well as staffing and administrative issues for clinics and clinicians to consider in providing patient access to this novel treatment modality. Please refer to the FDA approved product package insert and the Department of Health and Human Services' [Guidance for the Use of Antiretroviral Agents in Adults and Adolescents \(Long-Acting\)](#) for additional clinical guidance.²

QUICK LINKS:

- [CLINICAL CONSIDERATIONS](#)
- [DELIVERY SYSTEM ISSUES](#)
- [PROCUREMENT AND PURCHASING](#)
- [HEALTH CARE COVERAGE](#)
- [RYAN WHITE HIV/AIDS PROGRAM ASSISTANCE](#)
- [COST SHARING AND PATIENT ASSISTANCE FOR THE UNINSURED](#)
- [DRUG COST INFORMATION](#)

CLINICAL CONSIDERATIONS:

Prior to Initiation:

- Prior to prescribing, providers should complete a thorough history of prior ART treatment regimens containing integrase strand transfer inhibitors or non-nucleoside reverse transcriptase inhibitors or prior use of Apretude (cabotegravir) for HIV pre-exposure prophylaxis to rule out any potential drug-resistance issues.³

www.nastad.org

NASTAD

Cabenuva (cabotegravir & rilpivirine extended-release injections)
 Considerations for AIDS Drug Assistance Programs
 March 2022

VIV Healthcare's Cabenuva™ (cabotegravir and rilpivirine extended-release injectable suspension) was approved by the U.S. Food and Drug Administration on January 21, 2022. Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen, with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

This novel antiretroviral therapy option may help to alleviate pill fatigue, maintain long-term adherence, reduce stigma associated with taking oral medications, and improve quality of life for some people living with HIV. Access for Ryan White HIV/AIDS Program Part B (RWAP Part B) AIDS Drug Assistance Program (ADAP) clients may, however, require program policy and procedural adjustments associated with the procurement and payment of provider-administered drugs.

GENERAL CONSIDERATIONS

Clinical Considerations

- Prior to initiating Cabenuva as maintenance therapy, patients will need to be virologically suppressed on a stable oral regimen, with no known or suspected resistance to either cabotegravir (an integrase strand transfer inhibitor) or rilpivirine (a non-nucleoside reverse transcriptase inhibitor).
- **Oral lead-in dosing** with Vocabria (30 mg cabotegravir) and Edurant (25 mg rilpivirine) used for one month to assess the tolerability of cabotegravir and rilpivirine is now **optional**. Thirty-day supplies of Vocabria and Edurant will be provided by VIV Healthcare through a non-commercial dispensing pharmacy without cost to the patient, provider, or payer (including ADAP); see Page 4 for additional details. Vocabria will not be available from community/retail pharmacies.
- **Cabenuva initiation dosing** requires two 3 mL, 600 mg cabotegravir plus 900 mg rilpivirine, administered at separate gluteal injection sites during the same visit.
- **Cabenuva continuation dosing** involves either of the following:
 - Two 3 mL, gluteal IM injections (600 mg cabotegravir plus 900 mg rilpivirine) administered **every 3 months**; or
 - Two 2 mL, gluteal IM injections (600 mg cabotegravir plus 600 mg rilpivirine) administered **every 6 months**.

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