

“Hit Me With Your Best Shot” Implementing Injectable Programs for HIV Treatment and Prevention

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Speaker Conflicts

- The speaker has no conflicts of interest to disclose

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Learning Objectives

1. Describe the use of long acting cabotegravir/rilpivirine and lenacapavir for HIV treatment and long acting cabotegravir for HIV prevention
2. Discuss barriers to accessing injectable HIV treatments including medication access, scheduling, and billing
3. Review appropriate steps to implement an injectable agent HIV treatment and prevention program

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Key Abbreviations

- ADAP: Aids Drug Assistance Program
- AIDS: acquired immunodeficiency syndrome
- ART: antiretroviral therapy
- CPK: creatine phosphokinase
- HIV: human immunodeficiency virus
- INSTI: integrase strand inhibitor
- IVDU: intravenous drug use
- NRTI: nucleoside reverse transcriptase inhibitor
- NNRTI: non-nucleoside reverse transcriptase inhibitor
- RNA: ribonucleic acid
- SUBQ: subcutaneous
- VL: viral load

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HIV Basics

- Single stranded RNA Virus
- First case of AIDS identified in US in 1981
- 38.4 million people living with HIV
- 650,000 deaths due to HIV related illness

World Health Organization. WHO Library Cataloguing-in-Publication Date: 2007. ISBN 978 92 4 119562 9.

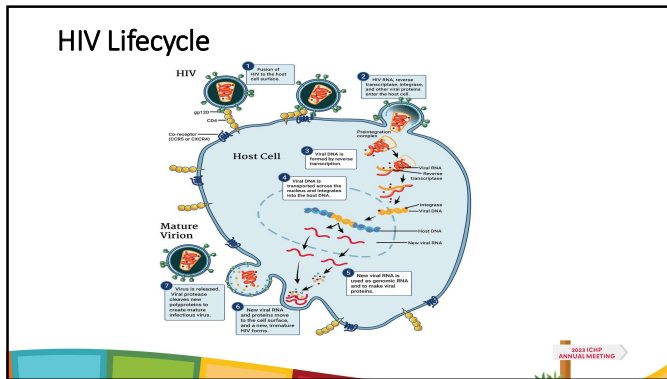
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HIV Basics

- Viral load
 - Measure of replicating virus
 - Goal is undetectable
- CD4 count
 - Measure of immune system health
 - Determining factor for AIDS diagnoses
- AIDS
 - Fatal if left untreated

HIV.gov. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last update 23 Mar 2022.

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HIV Pharmacotherapy

- Regimen with at least 2 highly active medications
- Traditional 2 NRTI backbone + 1 additional agent
- Adherence is key
 - Improved chance of patient being undetectable
 - Significantly decreased rates of transmission
- Only oral options from 1987-2021

HIV.gov. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last update 23 Mar 2023.

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Benefits to Injectable ART

- Improved adherence
 - Physiological barriers
 - Psychosocial
 - Stigma
- More facetime with care team
- Potential decreased cost

HIV.gov. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last update 23 Mar 2023.

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Cabotegravir

- INSTI
- 400mg or 600mg
 - Monthly vs every other month
- Alone for prevention
- With rilpivirine for treatment
- Adverse reactions
 - Injection site reactions
 - Headache
 - Increased CPK

Abetivir [package insert]. Research Triangle Park, NC: VIV. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215499s000b/pdf/212021

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Rilpivirine

- NNRTI
- 600mg or 900mg
 - Monthly vs every other month
- Adverse reactions
 - Injection site reactions
 - Fatigue
 - Increase in depressive symptoms

Etravir [package insert]. Raritan, NJ: Tibotec. https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020222a000b.pdf.5.2011

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Lenacapavir

- Capsid Inhibitor
- 2-day vs 15-day initiation dosing
- Adverse reactions
 - Injection site reactions
 - Increased serum creatinine
 - Hyperglycemia

Suntrenca [package insert]. Foster City, CA: Gilead. https://www.gilead.com/-/media/files/pdf/medicines/hiv/suntrenca_pi.pdf.120202

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Lenacapavir

Treatment time	Lenacapavir dosage	
Initiation dosing	2-day initiation	15-day initiation
Day 1	Oral: 600 mg once and SUBQ: 927 mg once	Oral: 600 mg once
Day 2	Oral: 600 mg once	Oral: 600 mg once
Day 8		Oral: 300 mg once
Day 15		SUBQ: 927 mg once
Maintenance dosing	SUBQ: 927 mg every 6 months (26 weeks) from the date of last injection ± 2 weeks	

Sunlenca (package insert) Foster City, CA: Gilead. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.pdf 12/2022



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Test Your Knowledge #1

Which medication(s) can be used for the prevention of HIV?

- A) Cabotegravir
- B) Cabotegravir + Rilpivirine
- C) Rilpivirine
- D) Lenacapvir

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Test Your Knowledge #2

Which of the following agents has maintenance dosing of every 6 months?

- A. Cabotegravir
- B. Cabotegravir/rilpivirine
- C. Lenacapavir
- D. Lenacapavir/rilpivirine



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Role of the Pharmacy Team

- Choice of agent
- Access
 - Insurance navigation
 - Medical vs pharmacy benefits
 - Copayment assistance
- Education
- Continued coordination/monitoring

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Discussion

- What would be/are roles of pharmacy team?
- What logistical considerations are there?
- What potential barriers exist to implementing programs?



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Medication Access

- Payer
 - Covered through medical or pharmacy benefits
 - Confirm ability to work with institution
- Insurance restrictions
 - Prior authorization
 - Appeal
- Affordability
 - Copayment card
 - Manufacturer/foundation assistance

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Test Your Knowledge #3

Which of the following is a barrier to the implementation of an injectable ART program?

- A. State practice is located in
- B. Credentials of attending physician
- C. Insurance restrictions of patient
- D. Affiliation with a medical university

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Scheduling

- Patients can choose frequency
 - Every 30 days vs every 60 days
- Ensure follow up appointments made
 - Appropriate timing
 - Initiation vs continuation
- Collaborate with nursing and administrative team

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Education

- Setting expectations
 - What will happen at appointment
 - Time frame
 - Patient responsibility
- Side effects
- Emphasizing importance of adherence

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Billing

- Medical
 - “Buy and bill”
 - Medical copayment savings program
- Pharmacy
 - Obtain through specialty pharmacy
 - Copayment card
- Other
 - ADAP
 - Manufacturer

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Implementation of Injectable ART Program

- Need to answer the following questions
 - Who?
 - When?
 - Where?
 - How?

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Implementation of Injectable ART Program- Who

- Confirm patient medically eligible
 - Virally suppressed
 - Resistance
 - Allergies
 - Co-morbid conditions
- Obtain consent
 - Signed consent form

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Consent Form Example

cabotegravir/raltegravir Treatment Plan

Name: _____

Medication Regimen:


- cabotegravir/raltegravir intramuscular injection in buttock (2 separate injections)

Required follow-up:

- Before leaving your injection visit you will be required to make a follow-up appointment for your next injection in 1 month.
- If appointment is canceled new appointment must be scheduled within 7 days from originally scheduled injection visit.
- If you are unable to reschedule within 7 days from associated appointment you will be removed from enrollment in cabotegravir/raltegravir treatment plan.
- If you miss an appointment ("no show") you will be removed from enrollment in cabotegravir/raltegravir treatment plan.
- Monthly phone calls with medical team to discuss adherence, side effect management, and follow-up.

I, _____ will comply with the treatment plan outlined for me in receiving cabotegravir/raltegravir. I have been informed that I must follow the plans and follow-up as required. I am aware that if at any point I do not follow the above plan I will be transitioned to my previous therapy and will not be eligible for re-enrollment in the cabotegravir/raltegravir treatment plan for 1 year. If at any point in time I am concerned with the ability to follow the above plan I will contact my physician to determine next steps.


X _____



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Implementation of Injectable ART Program- When


- Specific dates vs open scheduling
- Ensure patient understands commitment
- How often will patients be followed



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Implementation of Injectable ART Program- Where


- What location of health system will provide injections
 - ED
 - Urgent care
 - Infectious disease clinic
 - Infusion center



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Implementation of Injectable ART Program- How


- How will team be consulted?
- How will patients be followed?
- How will patients be cleared for insurance payment?
- How to cover if gaps in therapy?



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Stepwise Approach

- Create workflow that best fits needs
- Defined algorithm
 - Can share amongst health system
 - Provides guideline for covering employee




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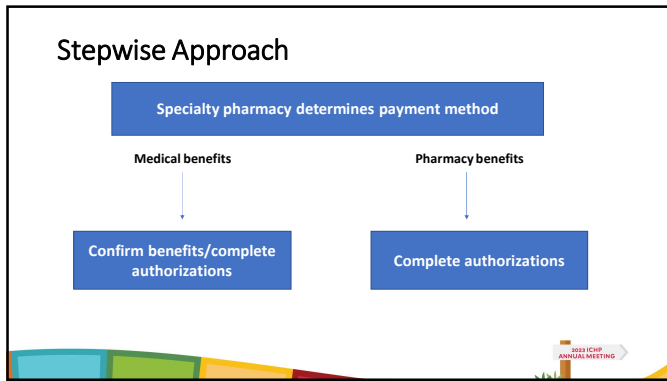
Stepwise Approach

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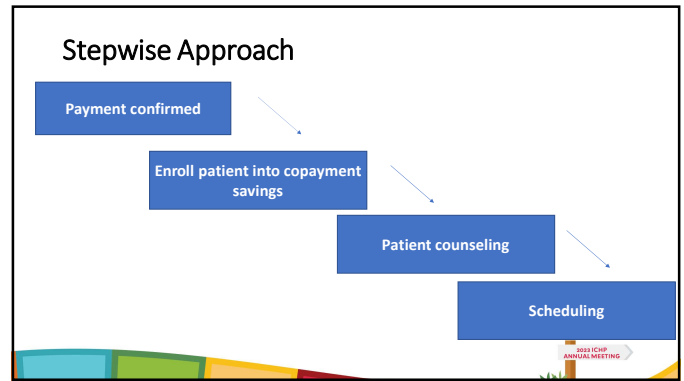
    graph TD
      A[Identify patient] --> B[Evaluate clinical appropriateness]
      B --> C[Send prescription to designated pharmacy]
    
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Test Your Knowledge #4

After identifying a patient what is the next step in the stepwise approach to implementation of an injectable ART program?

- Confirm patient is medically eligible to receive drug
- Confirm patient has insurance coverage
- Send prescription to designated pharmacy
- Complete insurance authorizations

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Continued Follow Up

- Designated point person
 - Monitor future appointments
 - Resource for patients/providers
- Policy updates as needed
- Metrics to measure efficiency

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Discussion

- How would members of your team be incorporated?
- Does your institution have an affiliated specialty pharmacy?
- What facets could present the biggest barriers?

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