

HIV 2024 Update

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Disclosures

Dr. Spach has no financial disclosures.

NOTE: vaccines do NOT have generic names so trade names are used in the vaccine section to effectively communicate about different vaccines.

Outline

- Antiretroviral Therapy Recommendations
- 2-Drug Antiretroviral Medications
- Immunization Update
- Treatment of HCV in People with HIV
- Recognition of Skin and Oral Lesions



Antiretroviral Therapy Recommendations



Starting Antiretroviral Therapy

- A 31-year-old woman is newly diagnosed with HIV 2 days ago. She was taking TDF-FTC for HIV PrEP (off and on) for the past 18 months. The plan is to start antiretroviral therapy now.
- What antiretroviral regimens would be recommended in this situation?



Initial Antiretroviral Therapy

No Prior Cabotegravir



Order Standard Genotype



Start INSTI-Based Regimen

Prior Cabotegravir



Order Standard and Integrase Genotype

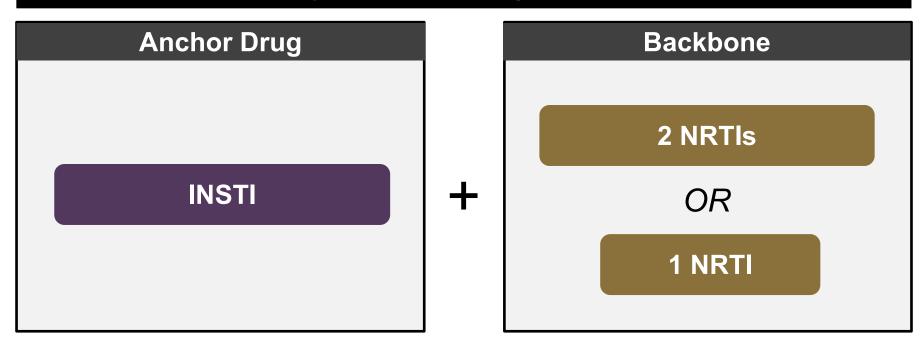


Start PI-Boosted Regimen (pending genotype)
Start INSTI-Based Regimen (after genotype)



HHS Antiretroviral Therapy Guidelines: September 21, 2022 What to Start: Recommended Initial Regimens for Most People with HIV

No Prior Injectable Cabotegravir for HIV PrEP





HHS Antiretroviral Therapy Guidelines: September 21, 2022 What to Start: Recommended Initial Regimens for Most People with HIV

No History of Taking Injectable Cabotegravir for HIV PrEP	
INSTI + 2NRTIs	Abbreviation
Bictegravir-tenofovir alafenamide-emtricitabine	BIC-TAF-FTC
Dolutegravir-abacavir-lamivudine (if HLA-B*5701 negative and no HBV)	DTG-ABC-3TC
Dolutegravir + Tenofovir alafenamide-emtricitabine	DTG + TAF-FTC
Dolutegravir + [Tenofovir DF-emtricitabine or Tenofovir DF-lamivudine]	DTG + [TDF-FTC or TDF-3TC]
INSTI + 1NRTI	Abbreviation
Dolutegravir-lamivudine (except: HIV >500,000 copies/mL, HBV, no genotype)	DTG-3TC



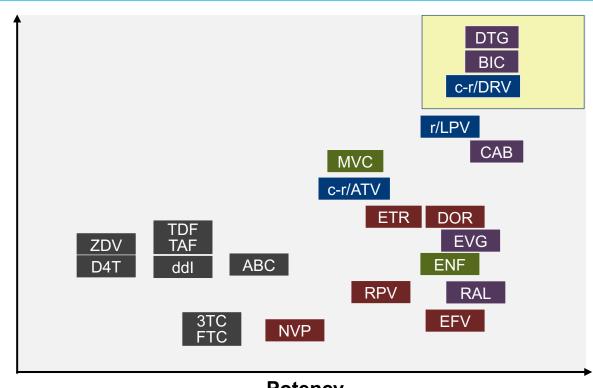
HHS Antiretroviral Therapy Guidelines: September 21, 2022 What to Start: Recommended Initial Regimens for Most People with HIV

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Dolutegravir + [Tenofovir DF-emtricitabine or Tenofovir DF-lamivudine]	DTG + [TDF-FTC or TDF-3TC]
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Potency and Genetic Barrier to Resistance

Barrier to Resistance



Potency



Two-Drug Regimens



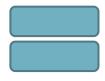
FDA-Approved Antiretroviral 2-Drug Regimens

- Initial Therapy
 - Dolutegravir-lamivudine
- Maintenance Therapy
 - Dolutegravir-lamivudine
 - Dolutegravir-rilpivirine
 - Cabotegravir-rilpivirine (long-acting injectable)



Dolutegravir-Lamivudine 2-Drug **Initial** Antiretroviral Therapy

Initial 2-Drug Therapy Dolutegravir-Lamivudine



Time

- HIV RNA <500,00 copies/mL
- HBsAg negative
- Results from genotype known



Dolutegravir-Lamivudine 2-Drug **Maintenance** Antiretroviral Therapy

Antiretroviral Therapy Dolutegravir-Lamivudine Maintenance (3-Drug Therapy) (2-Drug Therapy) Time HIV RNA <50 copies/mL on stable regimen No prior virologic failure No resistance to either maintenance drug

HBsAg negative



Dolutegravir-Rilpivirine 2-Drug **Maintenance** Antiretroviral Therapy

Antiretroviral Therapy Dolutegravir-Rilpivirine Maintenance (3-Drug Therapy) (2-Drug Therapy) Time HIV RNA <50 copies/mL for ≥6 months No prior virologic failure No resistance to either maintenance drug

HBsAq negative

Cabotegravir plus Rilpivirine 2-Drug **Maintenance** Antiretroviral Therapy

Antiretroviral Therapy (3-Drug Therapy)

Cabotegravir plus Rilpivirine Maintenance (2-Drug Therapy given every 1-2 months)



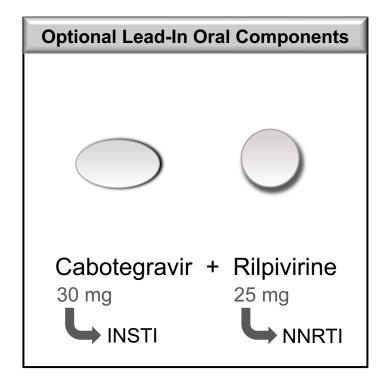


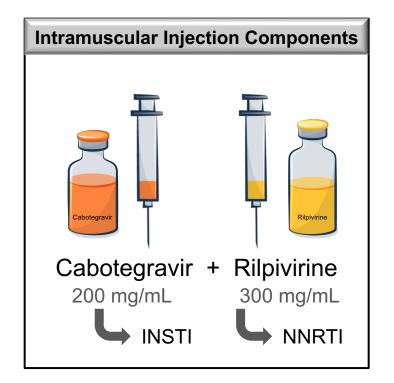
Time

- HIV RNA <50 copies/mL on stable regimen
- No prior virologic failure
- No resistance to either drug
- HBsAg negative



Cabotegravir and Rilpivirine Oral and Injectable Preparations

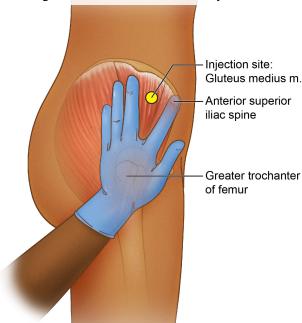






Cabotegravir plus Rilpivirine Long-Acting Injections

Preferred Injection Site (Ventrogluteal)

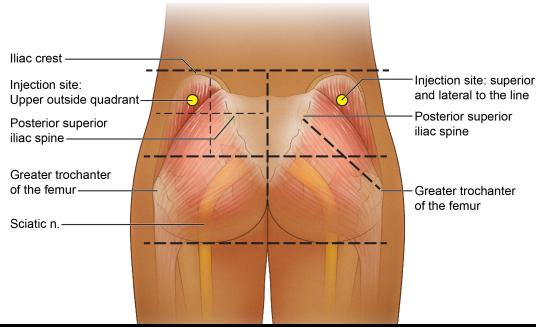


Longer needle (not included in the dosing kit) may be required for people with higher BMI (example: >30 kg/m²)



Cabotegravir plus Rilpivirine Long-Acting Injections

Alternative Injection Site (Dorsogluteal)



Longer needle (not included in the dosing kit) may be required for people with higher BMI (example: >30 kg/m²)



Vaccine Updates



CDC advisers vote to recommend routine use of the mpox vaccine to protect people at high risk of infection

By Brenda Goodman, CNN
② 2 minute read · Updated 4:10 PM EDT, Thu October 26, 2023

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October 26, 2023

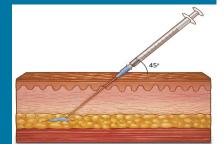




Monkeypox / Smallpox Vaccines in United States

JYNNEOS

Live, Attenuated, **Nonreplicating** Vaccine

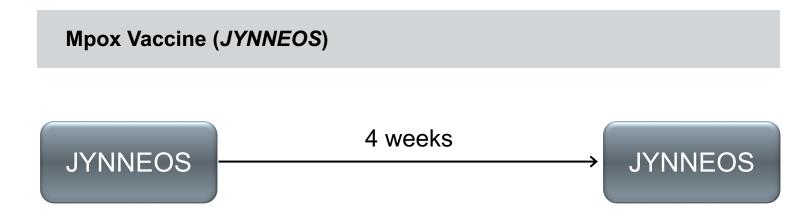


ACAM2000

Live, Attenuated, **Replicating** Vaccine



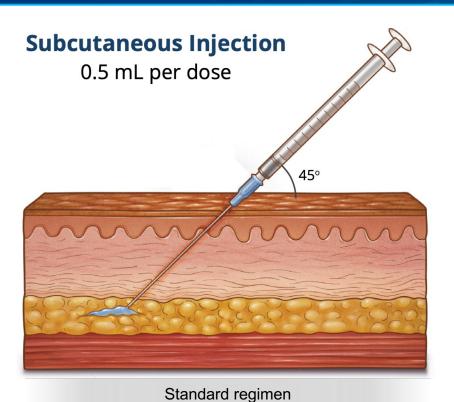
Mpox Vaccine (JYNNEOS)



Vaccination with JYNNEOS is considered safe for people with HIV

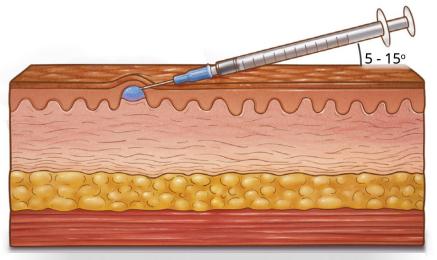


Mpox Vaccine (JYNNEOS) Delivery



Intradermal Injection

0.1 mL per dose



Alternative regimen for persons Age ≥18 Years



Pneumococcal Immunization





Pneumococcal Vaccines

Polysaccharide Vaccine



PPSV23 (Pneumovax 23)

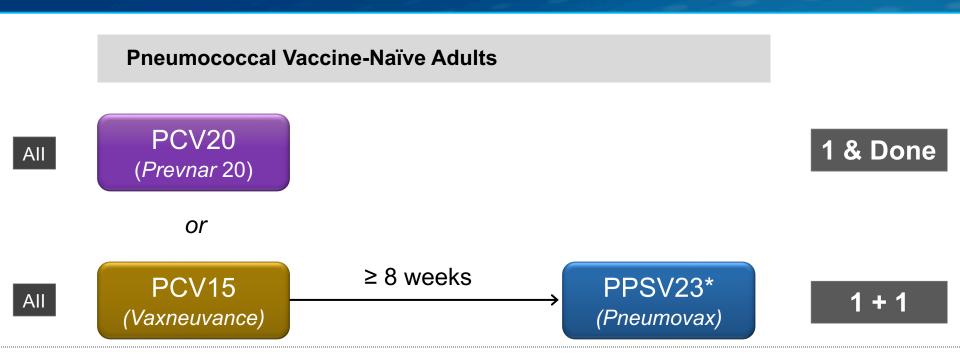
Conjugate Vaccines



PCV13 (*Prevnar-*13) PCV15 (*Vaxneuvance*) PCV20 (*Prevnar-*20)



Adult Opportunistic Infections Guidelines Pneumococcal Immunization in Adults with HIV



*PPSV23 can be given if CD4 count <200 cells/mm³ (**CIII**), but preferably defer until CD4 count >200 cells/mm³ while on ART (**BIII**)

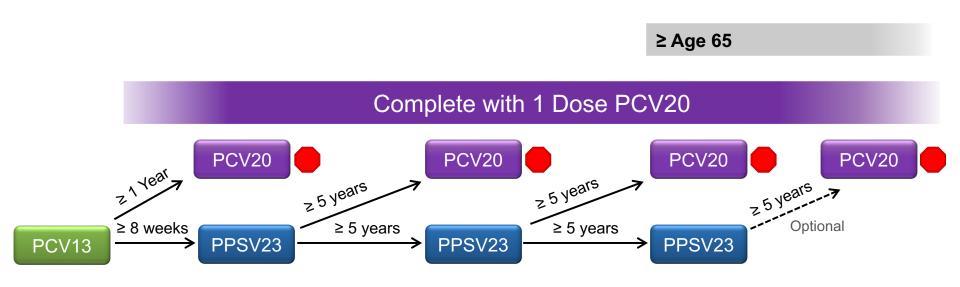


What do you do if a person with HIV has already started the Pneumococcal Series?



Adult Opportunistic Infections Guidelines Pneumococcal Immunization in Adults with HIV

Prior Receipt of PCV13 without Completing Vaccine Schedule



Adult Opportunistic Infections Guidelines Pneumococcal Immunization in Adults with HIV

Prior Receipt of PCV13 without Completing Vaccine Schedule

≥ Age 65



Source: HHS. Opportunistic Infections Guidelines. September 7, 2023.

Meningococcal Vaccines





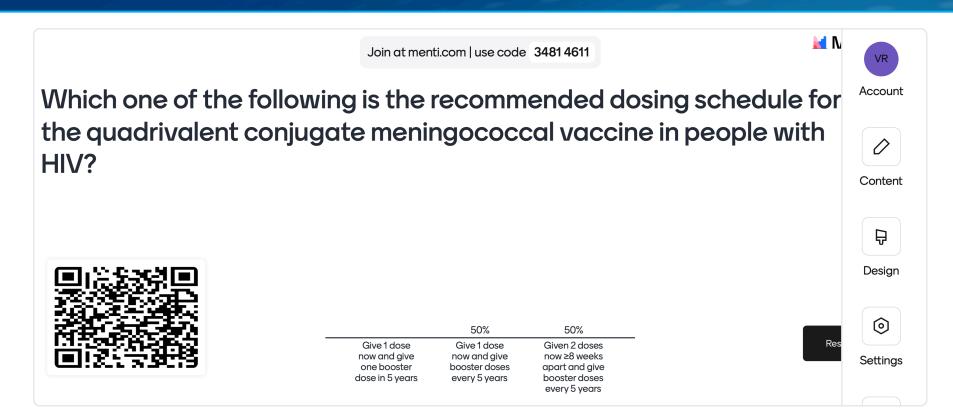
Quadrivalent Meningococcal Vaccine Dosing Schedule

 Which one of the following is the recommended dosing schedule for the quadrivalent conjugate meningococcal vaccine in people with HIV?

- 1. Give 1 dose now and give one booster dose in 5 years
- 2. Give 1 dose now and give booster doses every 5 years
- 3. Given 2 doses now ≥8 weeks apart and give booster doses every 5 years

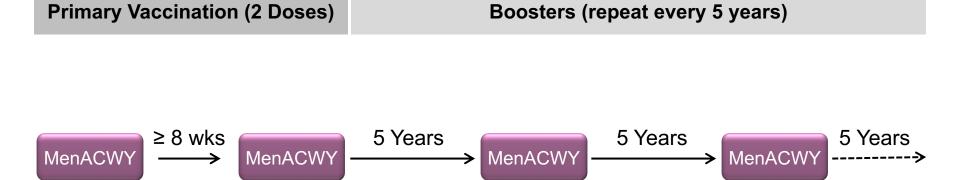


Quadrivalent Meningococcal Vaccine Dosing Schedule





Quadrivalent Meningococcal Conjugate (MenACWY) Vaccine in Adults



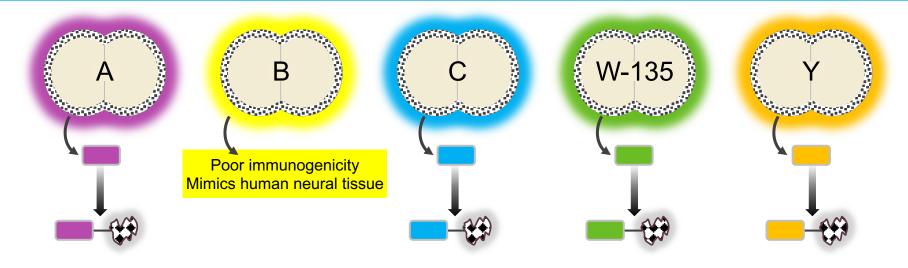


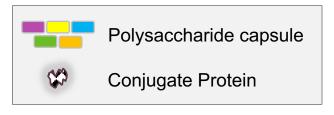
Meningococcal Vaccines

- Meningococcal Conjugate Quadrivalent Vaccines
 - MenACWY-CRM (Menveo)
 - MenACWY-TT (MenQuadfi)
 - MenACWY-D (Menatra) [Discontinued]
- Meningococcal B Vaccines
 - MenB-4C (Bexero)
 - MenB-FHbp (*Trumemba*)
- Meningococcal Pentavalent Vaccine
 - MenABCWY (Penbraya)



Conjugate Quadrivalent Meningococcal Vaccines

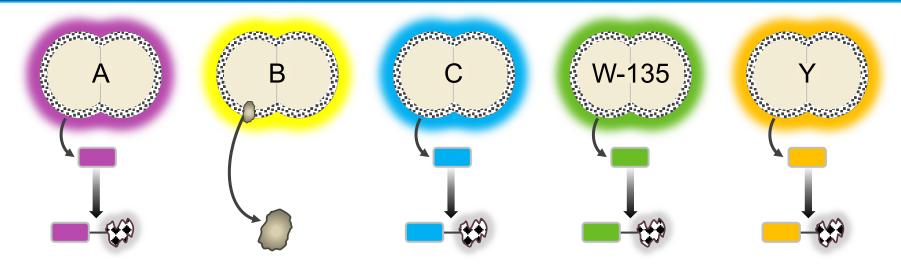








Pentavalent Meningococcal Vaccine (Penbraya)



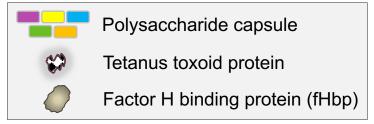
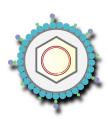






Illustration: David H. Spach, MD

Hepatitis B Vaccines



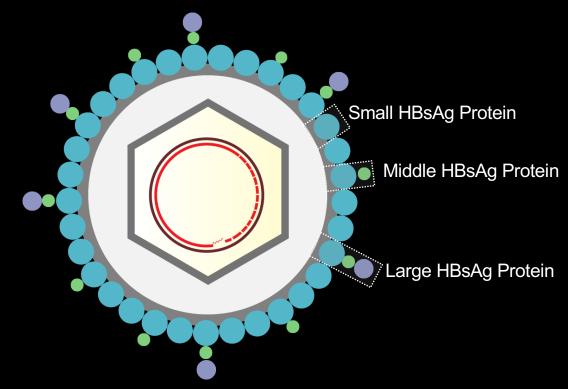


Hepatitis B Virus Surface Antigen Proteins

preS1 protein

preS2 protein

S protein





Recombinant Hepatitis B Vaccine

Old (Single Antigen) Aluminum Adjuvant HbsAq Aluminum Adjuvant rHBsAg (Recombivax) rHBsAg (Engerix-B)

Newer (Single Antigen)

CpG1018 Adjuvant



HBsAg-CpG1018 (Heplisav-B)

New (Triple Antigen)

Aluminum Adjuvant



3-AgHB (*PreHevbrio*)



Hepatitis B Vaccine: Question

For initial hepatitis B immunization in persons with HIV, which one
of the following hepatitis B vaccines has the highest (most
preferred) rating in the 2023 Opportunistic Infections Guidelines?

- 1. Three doses of "standard-dose" *Engerix-B* vaccine
- 2. Two doses of "standard-dose" Heplisav B vaccine
- 3. Four doses of "double-dose" Recombivax-B vaccine



Hepatitis B Vaccine Question

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For initial hep B immunization in PWH which one of the following hep B vaccines has the highest rating in the 2023 Opp Infections Guidelines?



Three doses of "standarddose" Engerix-B vaccine

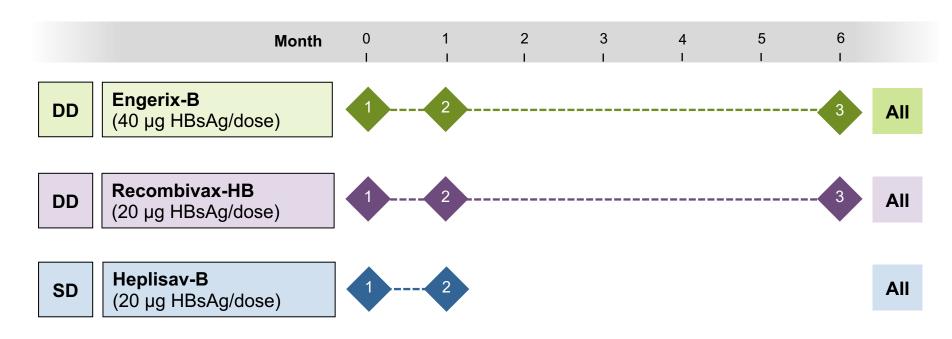
Two doses of "standarddose" Heplisav B vaccine Four doses of "doubledose" Recombivax-B vaccine







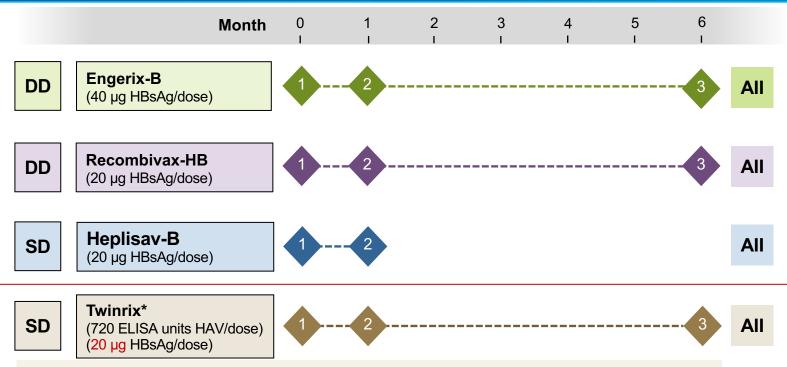
Adult Opportunistic Infections Guidelines Hepatitis B Immunization In Persons with HIV



SD = standard dose; **DD** = double dose



Adult Opportunistic Infections Guidelines Hepatitis B Immunization In Persons with HIV



*Combined hepatitis A and B vaccine, with same components used in Havrix (HAV vaccine) and Engerix-B (Hepatitis B vaccine)

SD = standard dose; **DD** = double dose



Why is HBsAg-CpG1018 (*Heplisav-B*) now a recommended vaccine for people with HIV?



Heplisav-B Vaccine in HBV Vaccine-naive People With HIV ACTG 5379 (BEe-HIVe): Study Design

Entry Criteria Arm A and B

- Person with HIV age 18-70 years
- On ART & HIV-1 RNA <1,000 copies/mL*
- CD4 >100 cells/mm³ (median 625)
- Negative HBsAg, anti-HBs, and anti-HBc
- Not pregnant

Arm A (Vaccine Non-Responders)

- Serum Hep B sAb <10 mIU/mL
- HBV vaccination (>168 days prior)
- Arm B (Vaccine Naïve)
 - Hep B sAb negative (<45 days)

*96% with HIV RNA <60 copies/mL

Arm A: HBV Vaccine Non-RespondersHepB (CpG)2 doses: 0, 4 weeksHepB (CpG)3 doses: 0, 4, and 24 weeksHepB (Eng-B)3 doses: 0, 4, and 24 weeks

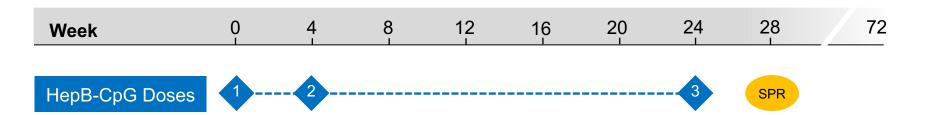
Arm B: HBV Vaccine Naive

HepB (CpG)

3 doses: 0, 4, and 24 weeks



Heplisav-B Vaccine in HBV Vaccine-naive People With HIV ACTG 5379 (BEe-HIVe): Study Design



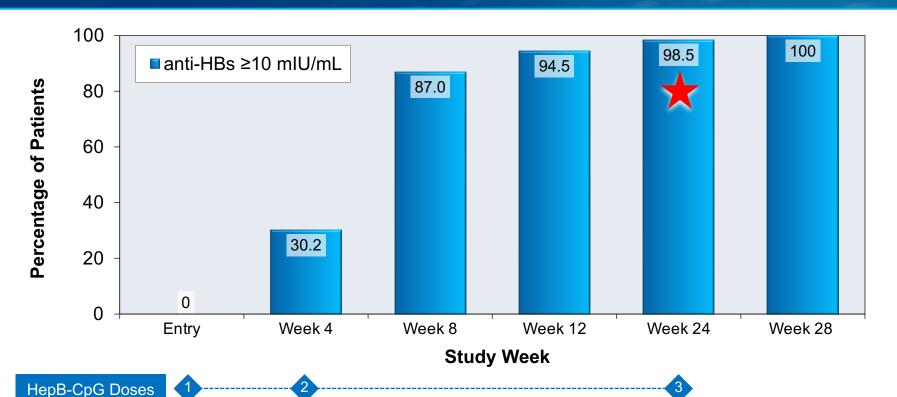
Delay in vaccination administration up to 4 weeks permitted

68 of 74 PWH* in Arm B completed 3 doses of HepB-CpG vaccine and had an HBsAb measurement

SPR = seroprotective response



Heplisav-B Vaccine in HBV Vaccine-naive People With HIV ACTG 5379 (BEe-HIVe): Seroprotection Response by Study Week

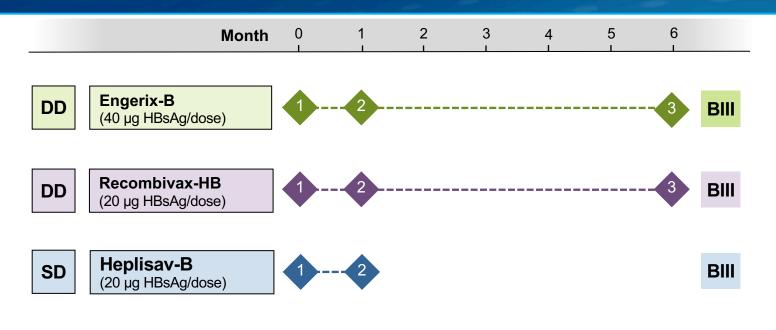




What do you do if a person with HIV does not respond to a HBV vaccine series with *Recombivax* or *Engerix B*?



Adult Opportunistic Infections Guidelines Recommendations for Hepatitis B Vaccine Non-Responders In Persons with HIV*



SD = standard dose; **DD** = double dose

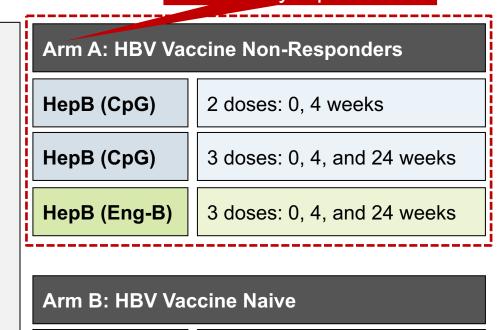
*If CD4 count <200 cells/mm³ at first vaccine series, some experts would delay revaccination until CD4 count ≥200 cells/mm³



Heplisav-B Vaccine in HBV Vaccine-naive People With HIV ACTG 5379 (BEe-HIVe): Study Design Data not yet published

- Entry Criteria Arm A and B
 - Person with HIV age 18-70 years
 - On ART & HIV-1 RNA <1,000 copies/mL*
 - CD4 >100 cells/mm³ (median 625)
 - Negative HBsAg, anti-HBs, and anti-HBc
 - Not pregnant
- Arm A (Vaccine Non-Responders)
 - Serum Hep B sAb <10 mIU/mL
 - HBV vaccination (>168 days prior)
- Arm B (Vaccine Naïve)
 - Hep B sAb negative (<45 days)

*96% with HIV RNA <60 copies/mL



HepB (CpG)



3 doses: 0, 4, and 24 weeks

Zoster Vaccine

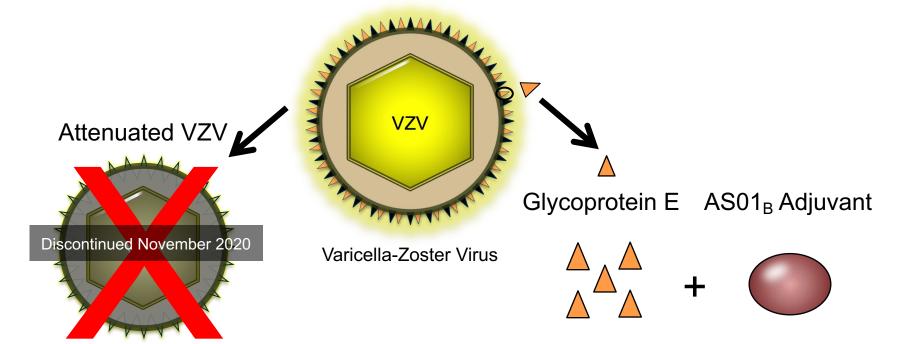




Zoster Vaccines

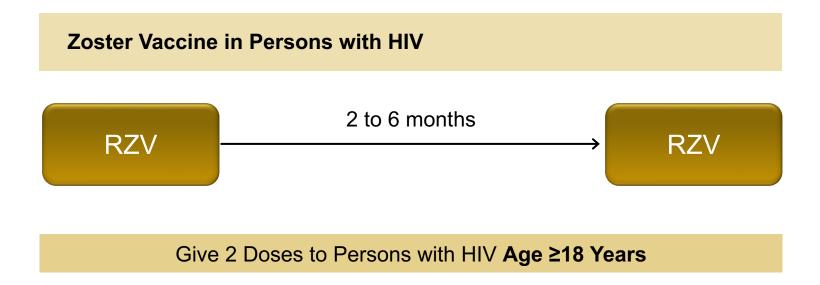
Zoster Vaccine Live (ZVL): Zostavax

Recombinant Zoster Vaccine (RZV): Shingrix



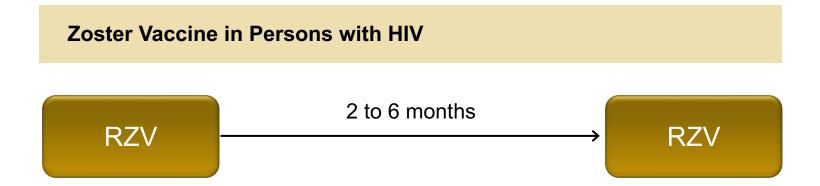


HHS Opportunistic Infections Guidelines Recombinant Zoster Vaccine (RZV) in Persons with HIV





HHS Opportunistic Infections Guidelines Recombinant Zoster Vaccine (RZV) in Persons with HIV



Give 2 Doses to Persons with HIV Age ≥18 Years

Give Regardless of:

- Past episode of zoster
- Prior receipt of ZVL (Zostavax)
- CD4 cell count

Avoid if:

· Acute episode of zoster



Treatment of Hepatitis C with HIV Coinfection



A 41-Year-Old with HIV and HCV Coinfection

- A 41-year-old cisgender man who has sex with men has HIV and has been taking dolutegravir plus TAF-FTC for 2 years and he consistently has suppressed HIV RNA levels and most recent a CD4 count of 562 cells/mm³.
- Testing for HCV at a regular clinic visit shows a new positive HCV antibody test and a positive quantitative HCV RNA 920,000 IU/mL. He had a negative HCV antibody test 2 years prior.
- Additional Labs
 - -HBsAg (negative); HBsAb (positive)
 - -CBC normal; INR normal; PLT normal; AST and ALT slightly elevated

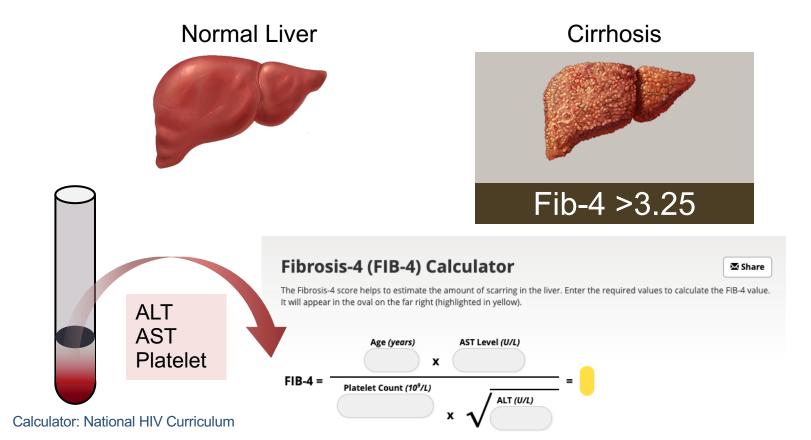


A 41-Year-Old with HIV and HCV Coinfection

- You are planning to treat the HCV as soon as possible.
- What should you do next?

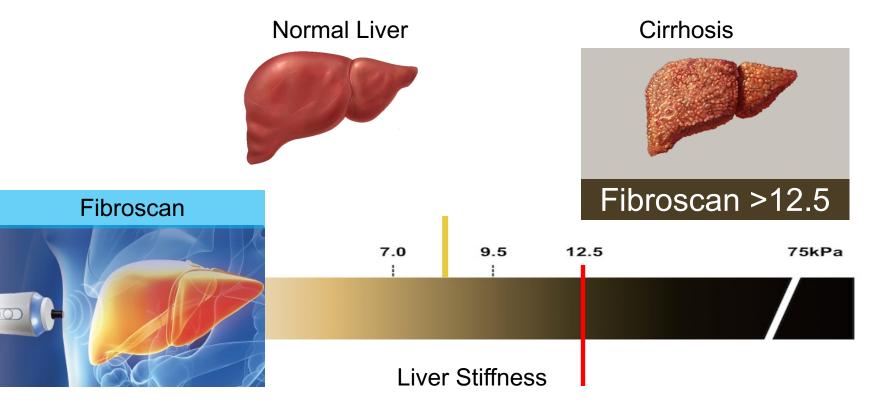


FIB-4: Laboratory Assessment for Cirrhosis





Fibroscan (Liver Stiffness) Assessment for Cirrhosis





A 41-Year-Old with HIV and HCV Coinfection

The Fib-4 and Fibroscan show no evidence of cirrhosis.
 Can this man with HIV get the HCV "Simplified Treatment"?

- 1. Yes
- 2. No



A 41-Year-Old with HIV and HCV Coinfection

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The Fib-4 and Fibroscan show no evidence of cirrhosis. Can this man with HIV get the HCV "Simplified Treatment"?



No



HHS Opportunistic Infections Guidelines HCV Simplified Treatment: EXCLUSIONS for People with HIV

- Prior HCV treatment (reinfection after prior cure OK)
- Decompensated cirrhosis
- On Tenofovir DF with eGFR ≤60 mL/min
- On an ART that includes efavirenz, etravirine, or boosted PI
- Untreated chronic HBV infection
- Pregnancy



AASLD/IDSA Simplified HCV Treatment (without Cirrhosis)

Glecaprevir-Pibrentasvir (*Mavyret*)

Sofosbuvir-Velpatasvir (*Epclusa*)



3 pills once daily x 8 weeks (with food)



1 pill once daily x 12 weeks (+/- food)



AASLD/IDSA Simplified HCV Treatment (with Cirrhosis)

Glecaprevir-Pibrentasvir (*Mavyret*)



3 pills once daily x 8 weeks (with food)

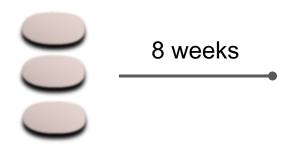
Sofosbuvir-Velpatasvir (*Epclusa*)

ORDER HCV Genotype



AASLD/IDSA Simplified HCV Treatment (with Cirrhosis)

Glecaprevir-Pibrentasvir (*Mavyret*)



3 pills once daily x 8 weeks (with food)

Sofosbuvir-Velpatasvir (*Epclusa*)

HCV GT 1, 2, 4, 5, 6

12 weeks

1 pill once daily x 12 weeks (+/- food)

HCV GT3

Guided by resistance testing



Recognition of Clinical Manifestations of HIV



- CD4 cell count = 36 cells/mm³
- Not on ART
- "Burn on face"

Diagnosis?





- CD4 cell count = 56
- Lesions present >3 months
- Just newly diagnosed with HIV
- Not on ART yet

Diagnosis?





- CD4 count <20
- In hospice care
- Lesions developed over 10-14 days
- Would want to place a gown on before examining this man

Diagnosis? Treatment?





- CD4 cell count >700
- Suppressed HIV RNA
- Urgent visit for spider bite
- Temp 38.0°, WBC elevated

Diagnosis?





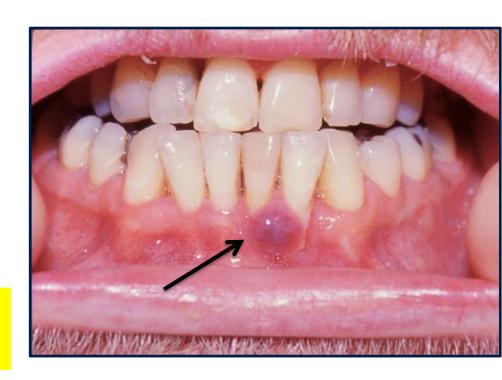






- New lesion on gums
- CD4 count 282 cells/mm³
- Pathogen for this disorder also causes multicentric Castleman's Disease

Diagnosis?





- CD4 cell count = 126 86 cells/mm³
- Mouth burns when eating spicy food or drinking orange juice

Diagnosis?





- CD4 cell count = 86 cells/mm³
- What is the preferred treatment based on OI guidelines

Preferred Treatment?







Questions









