# Hepatitis C in Primary Care (Plus PREP)

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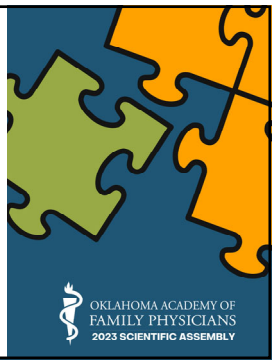
Cherokee Nation




## Objectives

- Be aware of the epidemiology of Hepatitis C in the US
- Understand the steps in evaluating and treating Hepatitis C
- Describe treatment of Hepatitis C
- Describe what PREP is and understand in which patients it is indicated.

## Disclosures and Special Thanks

- No disclosures/Conflict of Interest
- Special thanks to Whitney Essex, APRN and Jorge Mera, MD with Cherokee Nation Infectious Disease Clinic/Hep C Elimination Program
- Special thanks to Janet Rosales, OSU Project ECHO

## Transmission

- **Blood**
  - IVDU is the leading cause in the United States (57%)
    - Snorting
  - Percutaneous injuries
  - Dental
  - Tattooing
  - Blood transfusion (Before 1992)
- **Sexual contact**
  - Rare in heterosexual
  - More frequent in HIV + MSM
- **Mother-to-child**
  - The rate is 4-8%
  - *Increased in IVDU, HIV co-infection, high VL (8-15%).*

Not just needle sharing: Transmission can occur through sharing of any paraphernalia

Syringe, Cooker, Table, Tourniquet, Water

(67% of PWID infected with Hep C)

Health care exposure risk is low: 0.2% risk from sharps injury from patient infected with Hep C.

Household risk low, and risk is from direct exposure to blood (shared razors, toothbrush)

Centers for Disease Control and Prevention. Viral Hepatitis Surveillance—United States, 2016. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2018. Available at:

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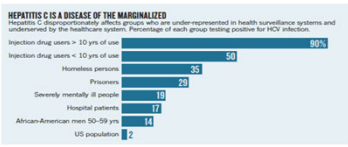
## Social Determinants of Health Role in HCV Epidemic




Edlin, B.R., 2011. Perspective: test and treat this silent killer. Nature 474 (7350),S18–S19.

- 20 to 30% of PWID become infected with within the first 2 years of starting to inject drugs. 50% within 5 years.
- HCV prevalence in US prisons is estimated to be between 12-35%
- Less than 1% of HCV chronic prisoners are being treated

Palmateer N, Hutchinson S, McAllister G et al. Risk of transmission associated with sharing drug injecting paraphernalia: analysis of recent hepatitis C virus (HCV) infection using cross-sectional survey data. J Viral Hepatol 2014 Jan;21(1):25-32

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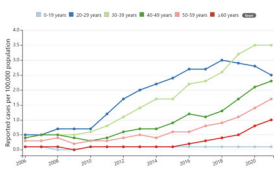
**Rates of reported cases of acute Hepatitis C virus infection, by age group – United States, 2006–2021**




**Number of reported cases of acute Hepatitis C virus infection and estimated infections — United States, 2014–2021**


w.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-c.htm

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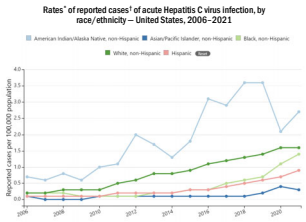
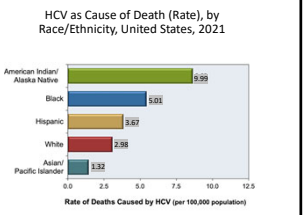
## Hepatitis C (2021)

- The number of reported cases of acute hepatitis C has doubled since 2014 (129% increase), and rate increased 7% from 2020 to 2021.
- Persons aged 20–39 years had the highest incidence of acute hepatitis C (same age group with highest overdose risk).
- Rates of acute hepatitis C are highest among non-Hispanic American Indian/Alaska Native persons.
- 57% of cases with risk information reported injection drug use.
- **Rate of Hepatitis C-Associated Deaths Is Highest in Non-Hispanic American Indian/Alaska Native (AI/AN) and Non-Hispanic Black Persons:** 3.4 times and 1.7 times, respectively, the death rate among non-Hispanic White persons.

w.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-c.htm

## Racial Disparities in HCV




Disease Control and Prevention (CDC). Viral Hepatitis Statistics and Surveillance—United States, 2021. (August 2023). (

## Who to test?

*Universal Screening:*

- Hepatitis C screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is <0.1%
- Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is <0.1%
- Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks


SOURCES: CDC Recommendations for Hepatitis C Screening, MMWR, April 2020
CDC Viral Trans, April 2020

## Who to test?

- One-time hepatitis C testing regardless of age or setting prevalence among persons with recognized risk factors or exposures:
  - Persons with HIV
  - Persons who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
  - Persons with selected medical conditions, including persons who ever received maintenance hemodialysis and persons with persistently abnormal ALT levels
  - Prior recipients of transfusions or organ transplants, including persons who received clotting factor concentrates produced before 1987, persons who received a transfusion of blood or blood components before July 1992, persons who received an organ transplant before July 1992, and persons who were notified that they received blood from a donor who later tested positive for HCV infection
  - Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
  - Children born to mothers with HCV infection (18 mo-3yr)
- Routine periodic testing for persons with ongoing risk factors, while risk factors persist:
  - Persons who currently inject drugs and share needles, syringes, or other drug preparation equipment (q3-6 mos)
  - Persons with selected medical conditions, including persons who ever received maintenance hemodialysis

➢ Hep C Antibodies present 8-11 weeks after exposure (can range from 2 weeks-6 months)

➢ HCV RNA present 1-2 weeks after exposure

## Acute to Chronic Infection

- Primary infection generally asymptomatic
  - 15–30% of individuals develop symptomatic acute hepatitis illness within 5–12 weeks of exposure lasting 2–12 weeks.[24,25]
  - Around 30% (15–45%) of infected persons spontaneously clear the virus within 6 months of infection without any treatment.
  - The remaining 70% (55–85%) of persons will develop chronic HCV infection.
- Most patients do not have viral clearance and viraemia persists after 6 months, leading to chronic infection. Progression to cirrhosis in 15-30% of those patients within 20 years.

https://www.ncbi.nlm.nih.gov/pmc/ articles/PMC3608418/ World Health Organization, who.int

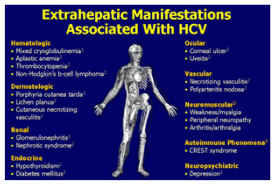
## HCV complications

Why we test and treat

Not just liver disease:

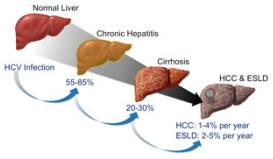
- 40% of people with HCV will develop at least 1 extrahepatic manifestation
- Often not clinically recognized
- Extrahepatic manifestations can occur at any stage of disease
  - Not just in advanced liver disease

Extra-Hepatic Manifestations



## HCV complications

**Why we test and treat:**



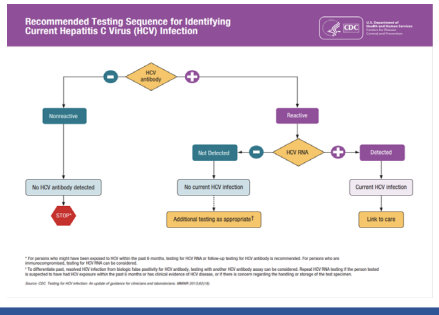

- 70% Reduction of Liver Cancer
- 50% Reduction in All-cause Mortality
- 90% Reduction in Liver Failure

## HCV Complications

**Rates of progression to cirrhosis are increased in the presence of a variety of factors, including:**

- Being male
- Being age >50 years
- Consuming alcohol
- Having nonalcoholic fatty liver disease, hepatitis B, or HIV coinfection
- Receiving immunosuppressive therapy[1,2,3]

- Lok A. NEJM 2012; Ghany M. Hepatol 2009; Van der Meer AJ. JAMA 2012



## Positive screening – Now what?

- **History**
  - History of alcohol use? Current use?
  - History of drug use? IV, intranasal? Current use?
  - First drug use? (timing)
  - Tattoos?
  - Health care exposure?
  - Sexual exposure?
  - Social history – living situation?
- **History**
  - GFR <30?
    Is the patient taking Dilantin, carbamazepine, phenobarbital?
    Is the patient taking antacids (H2 blocker or PPI)? No
    Does the patient have HIV/Aids?
    Is the patient immunosuppressed?
    Previous HCV treatment?
    *If any yes answers above: prompt phone call to specialist*

## Positive screening – Now what?

- **Additional lab tests**
  - Hepatitis C RNA and genotype
  - Hepatitis Serology (not just hepatitis panel)
    - Hep A Total antibody
    - Hep B surface antibody, Hep B surface antigen, Hep B core antibody
  - HIV serology
  - CBC with differential
  - Comprehensive metabolic panel
  - Urinary drug screen
  - PT/INR
  - Alpha Fetoprotein Tumor Marker (AFP)
  - Fibrotest/Fibrosure
  - Iron profile (Fe, TIBC, Ferritin)
  - 25 OH Vitamin D

## Positive screening – Now what?

- **Fibrosis Staging**
  - APRI
  - FIB-4
  - Fibrosure
  - Fibroscan (imaging)
  - Liver biopsy (invasive, often not needed)
- F0: No fibrosis
- F1: Scattered portal fibrosis
- F2: Diffuse periportal fibrosis
- F3: Bridging fibrosis
- F4: Cirrhosis
  - Compensated
  - Decompensated
    - History or presence of ascites
    - Hx of esophageal bleeding due to esophageal varices
    - Hx or presence of hepatic encephalopathy

## Laboratory Testing

**Genotype**
- Determines treatment in certain cases
- Three main genotypes in the US: GT1, GT2 and GT3

**Hep A serology**
- Order Hep A total antibody or IgG antibody
- If non-reactive, patient needs vaccination

**Hep B serology**
- Immunization and to monitoring reactivation
- Order HBsAg, HBcAb (total or IgG) and HBsAb

**HIV serology**
- Important to treat HIV
- Important to treat HCV (interaction with some HIV medications)

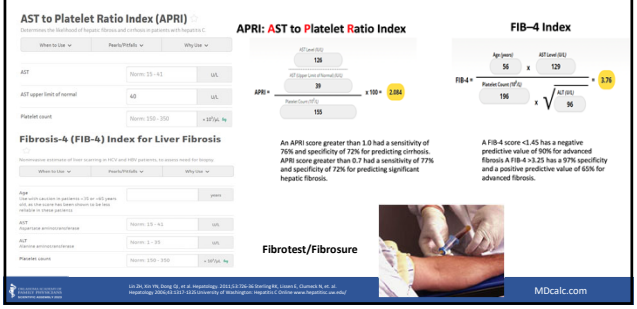
## Laboratory Testing

**CBC**
- Platelets are critical for liver fibrosis staging
- (Earliest marker for cirrhosis is thrombocytopenia)

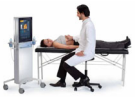
**Comprehensive metabolic panel**
- ALT/AST are important for liver fibrosis staging
- Bilirubin is Important for Child Pugh Score if necessary
- GFR
  - Will determine treatment (if GFR < 30 ml)
  - May point to urgent treatment if it is due to HCV related nephropathy

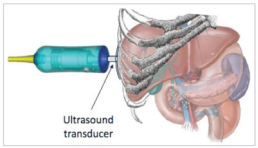
**Urinary Drug Screen**
- Important to address issue and refer to
  - Behavioral health
  - Harm reduction program if available
  - Medication assisted treatment if needed and available

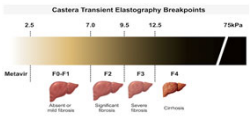
## Non-Invasive Liver Fibrosis Staging in the Office



## Fibroscan





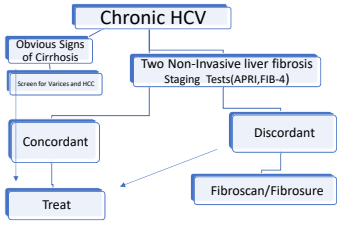




The probe of the Fibroscan device is positioned in an intercostal space near the right lobe of the liver, and a 50-MHz wave is passed into the liver from a small transducer on the end of the probe. The device then measures the velocity of the shear wave (in meters per second) as this wave passes through the liver, and this measurement is converted to a liver stiffness measurement.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3594956/

## Fibrosis Staging

- Treatment may be different for cirrhotic vs non-cirrhotic
- Treatment will be different in compensated vs decompensated cirrhosis
- F3/F4 – need HCC surveillance
- F4 – EGD for varices, hepatic encephalopathy screen, transplant eval




## Reasons to refer

- HIV positive/HIV treatment (especially if renal disease)
- Decompensated cirrhosis
- Kidney disease (GFR<30)
- Anti-convulsant use
- Not treatment-naïve (NS5A-RAS testing)
- Pregnancy (defer treatment)

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## Hepatitis C ECHO

**Tuesdays from 12 – 1 PM/CST via Zoom**

What does the Hepatitis C ECHO offer?

- Gain expert knowledge in treating Hepatitis C through a virtual learning network focusing on evidence-based practices in prevention, diagnosis, and treatment.
- Our team of specialists, including infectious disease physicians and a clinical pharmacist, provides real-time case reviews and treatment recommendations for Hepatitis C.
- Primary care providers can manage and care for Hepatitis C patients with guidance from the ECHO specialty team, improving access to care for this potentially fatal but curable disease.
- Selected sessions also include brief lectures on the following topics: opioid/HCV syndemic, liver fibrosis staging, motivational interviewing, extrahepatic manifestations, interpreting Hepatitis B serology, HCV in pregnancy, and more!

For more information, you can visit medicine.okstate.edu/echo or scan the QR code.

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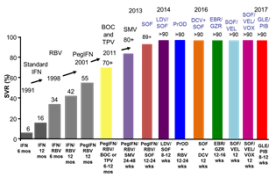
## Treatment

**Most patients can be treated using Simplified Regimens**

### Direct Acting Antivirals

- Epclusa: sofosbuvir-velpatasvir (NS5BI-NS5A1)
- Mavyret: glecaprevir-pibrentasvir (NS3/4API-NS5AI)
- Harvoni: ledipasvir-sofosbuvir (NS5AI-NS5BI)
- Zepatier: elbasvir-grazoprevir (NS5BI-NS3/4AI)
- Vosevi: sofosbuvir-velpatasvir-voxilaprevir (NS5BI-NS5AI-NS3/4AI)

### Evolution of Treatment




## Medication Interactions

- Seizure medications: Dilantin, carbamazepine, phenobarbital
- PPI: Omeprazole (H2 blocker OK)
- Contraception: Ethinyl estradiol (progesterone OK)

Work with pharmacist, use Lexicomp to check interactions

## Prior to Treatment

Labs - within 6 months:
- CBC
- CMP

Labs - Anytime:
- HCV viral load
- HIV Ag/Ab
- Heb BsAg

Before starting therapy:
- Pregnancy testing/contraception discussion
- Vaccinate for Hep A and Hep B if applicable

*Cirrhosis*
- INR
- Genotype necessary

## Treatment

**Who Is Eligible for Simplified Treatment**

Adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment

**Who Is *NOT* Eligible for Simplified Treatment (Without Cirrhosis)**

Patients who have any of the following characteristics:
- Prior hepatitis C treatment
- Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(see HCV guidance for treatment recommendations for these patients)

https://www.hcvguidelines.org/

## Treatment

**Who Is Eligible for Simplified Treatment**

Adults with chronic hepatitis C (any genotype) who have compensated cirrhosis (Child-Pugh A) and have not previously received hepatitis C treatment
Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or any of the following findings from a previously performed test

- Transient elastography indicating cirrho
- Noninvasive serologic tests above prop Fibrosis Test, etc)
- Clinical evidence of cirrhosis (eg, liver n <150,000/mm$^3$, etc)
- Prior liver biopsy showing cirrhosis

**Who Is *NOT* Eligible for Simplified Treatment (With Cirrhosis)**

Patients who have any of the following characteristics:
- Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score ≥7 (ascites, hepatic encephalopathy, total bilirubin >2.0 mg/dL, albumin ≤3.5 g/dL, or INR ≥1.7)
- Prior hepatitis C treatment
- End-stage renal disease (ie, eGFR <30 mL/min/m$^2$) (see Patients with Renal Impairment section)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(see HCV guidance for treatment recommendations for these patients)

https://www.hcvguidelines.org/

## Recommended Regimens

**Patients without Cirrhosis**

- Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks
- Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

**•Patients with cirrhosis**

- **Genotype 1-6**:
  Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks
- **Genotype 1, 2, 4, 5, or 6**
  Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

**NOTE**: Patients with genotype 3 require baseline NSSA resistance-associated substitution (RAS) testing. Those without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir. If Y93H is present, see HCV guidance for treatment recommendations.

https://www.hcvguidelines.org/

## Treatment: Monitoring

**Non-cirrhosis:**

- No monitoring required
- Tele-visit, or short follow up to evaluate for side effects
- Reminder to notify before taking any OTC medications (esp GERD)
- Monitor for hypoglycemia if on diabetic agents
- Monitor for INR changes if on warfarin
- Monitor for HBV re-activation symptoms if applicable

**Cirrhosis (compensated):**

- Same as non-cirrhotic
- CMP - monitor for liver injury during treatment because hepatic decompensation occurs rarely among patients with cirrhosis receiving HCV antiviral treatment.
- Patients should see a specialist if they develop worsening liver blood tests (eg, bilirubin, AST, ALT, etc); jaundice, ascites, or encephalopathy; or new liver-related symptoms.

## Treatment: Coverage

- Soonercare
  - Mavyret – no prior authorization
  - Others – require recommendation from specialist (ECHO)
- Uninsured
  - Patient assistance programs through manufacturers
- Health Choice:
  - Epclusa, Harvoni, Vosevi – Preferred meds on Advanced Specialty Control medication list – high copay ($100-200) unless deductible met.
- Tricare
  - "Check with MTF pharmacy" "Uniform Formulary medication"
  - Prior Auth required

## Follow-Up

- Sustained Virologic Response
  - *Undetectable HCV RNA 12 weeks post completion of treatment*
  - *Associated with 97-100% chance of being HCV RNA negative at long-term follow up.*
- Non-cirrhotic (F1-F2)
  - No liver related follow up required
  - Risk reduction (test annually or with abnormal LFTs)
  - Avoid excessive alcohol use
- Cirrhosis/Advanced Fibrosis (F3-F4)
  - US/AFP q 6 months
  - Risk reduction (test annually or with abnormal LFTs)
  - Avoid alcohol use

## Prevention/Risk reduction

- Opioid Use Disorder Treatment
  - MAT (buprenorphine-naloxone)
  - Treating opioid dependence lowers risk
  - Prevent transmission
- Syringe Services Programs
  - Sterile needles and syringes
  - State-dependent for legality
  - Increased access to Behavioral health services
  - Decreased infections
  - No increase in crime and/or needles in public places

"The Cherokee Nation was the first tribe in the country to receive a Substance Abuse and Mental Health Services Administration grant specifically to start a harm-reduction program that offers syringe services to reduce drug use and keep tribal citizens healthier by preventing the transmission of blood-borne infections." (Anadisgoi)

- Syringe Exchange
- Fentanyl test strips
- Narcan
- HIV/Hep C Rapid testing
- Recovery Support
- Basic hygiene kits
- Tribal and public

https://www.cdc.gov/ssp/syringe-services-programs-faq.html Anadisgoi.com

## BONUS: PREP

### HIV Prevention Strategies

- Sexual behavior modification
- Condom use
- Test and treat STIs
- HIV treatment as prevention (U=U)
- **PrEP: Pre-Exposure Prophylaxis**
- PEP: Post-Exposure Prophylaxis
- Offer sterile, personalized injection drug use equipment for people who inject drugs

## What is PrEP?

- **Pre-exposure prophylaxis** (or PrEP) is when people at very high risk for HIV take antiretroviral medication to lower their chances of HIV infection
  - Helps prevent an HIV-negative person from getting HIV from a sexual or injection-drug-using partner who is HIV positive
- Medication
  - Tenofovir and emtricitabine combo pill (Truvada®) or (Descovy®) taken daily

  OR
  - Cabotegravir extended-release injectable suspension (Apretude®) taken intramuscularly as two initiation injections administered one month apart, and then every two months thereafter
- Doesn't prevent other STIs. Doesn't replace other HIV prevention strategies.

TABLE 1

**Preexposure Prophylaxis for the Prevention of HIV Infection: Clinical Summary of the USPSTF Recommendation**

| | |
|---|---|
| **Population** | Persons at high risk of HIV acquisition |
| **Recommendation** | Offer PrEP<br>Grade: A |
| **Risk assessment** | Persons at risk of HIV infection include men who have sex with men, persons at risk via heterosexual contact, and persons who inject drugs. Within these groups, certain risk factors or behaviors (outlined below) can place persons at high risk of HIV infection.<br>Men who have sex with men, are sexually active, and have 1 of the following characteristics:<br>• A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)<br>• Inconsistent use of condoms during receptive or insertive anal sex<br>• A sexually transmitted infection with syphilis, gonorrhea, or chlamydia within the past 6 months<br>Heterosexually active women and men who have 1 of the following characteristics:<br>• A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)<br>• Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or a man who has sex with men and women)<br>• A sexually transmitted infection with syphilis or gonorrhea within the past 6 months<br>Persons who inject drugs and have 1 of the following characteristics:<br>• Shared use of drug injection equipment<br>• Risk of sexual acquisition of HIV (see above)<br>Persons who engage in transactional sex, persons who are trafficked for sex work, men who have sex with men and women, and transgender women and men who are sexually active can be at high risk of HIV infection and should be considered for PrEP based on the criteria outlined above. |
| **Preventive medication** | Once-daily oral treatment with combined tenofovir disoproxil fumarate and emtricitabine (Emtriva) is the only formulation of PrEP currently approved by the U.S. Food and Drug Administration for use in the United States in persons at risk of sexual acquisition of HIV infection. |
| **Other relevant USPSTF recommendations** | The USPSTF has issued recommendations on behavioral counseling to reduce risk of sexually transmitted infections and on screening for HIV infection. |

**Note:** For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, go to https://www.uspreventiveservicestaskforce.org/.

PrEP = preexposure prophylaxis; USPSTF = U.S. Preventive Services Task Force.

## Efficacy

- When taking oral PrEP daily or consistently (*at least 4 times per week*) the risk of acquiring HIV is reduced by:
  - about 99% among MSM (men who have sex with men)
  - an estimated 74 – 84% among PWID

## Safety

- Overall, well tolerated: headache, nausea, vomiting, abdominal pain, and weight loss may occur infrequently
- Small potential harms: kidney and GI effects. (Require GFR>60; Fanconi)

## Prescribing PrEP

- Baseline
  - HIV
  - STI
  - Kidney function
  - HBV Serology
  - Lipid Panel
- 6 mo follow up
  - eGFR/CrCl
  - STI screening
- 12 mo follow up
  - CrCl
  - Lipid
  - HIV/STI (as above)

- 3 mo follow up
  - Repeat HIV testing
  - Assess for signs or symptoms of acute HIV infection
  - Provide RX for no more than 90 days (until the next HIV test)
  - Assess medication adherence and risk-reduction behaviors
  - Conduct STI testing if symptoms of infection
  - Conduct STI screening for asymptomatic MSM at high risk for syphilis, gonorrhea, or chlamydia
- How Do I Prescribe PrEP? | Prevention | Clinicians | HIV | CDC
- With Cab – CrCl, Lipid, Hep B – not required

## Medication

- Daily oral PrEP with F/TDF (Truvada) is recommended to prevent HIV among all people at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF (Descovy) is recommended to prevent HIV among people at risk through sex, ***excluding people at risk through receptive vaginal sex***. F/TAF has not yet been studied for HIV prevention for people assigned female at birth who could get HIV through receptive vaginal sex.
- Injectable PrEP with CAB is recommended to prevent HIV among all people at risk through sex. CAB is given as an intramuscular injection. CAB for PrEP is started by administering the first injection followed by a second injection 1 month after the first. CAB injections are given every 2 months thereafter.
  - All require weight of 35 kg/77lb

## Cabotegravir

- Increased efficacy over orals
  - Trials stopped early due to efficacy ( compared with emtricitabine/tenofovir in two studies)
  - Reduced risk in cisgender men/transgender women by 69% (NNT = 273)
  - Reduced risk in cisgender women by 90% (NNT = 482)
- Cabotegravir costs approximately $4,000 per injection. In comparison, a 30-day supply of emtricitabine/tenofovir disoproxil (Truvada) costs about $2,000 for brand and $30 for generic.[5]

## Prescribing:

- Insurance coverage: “preferred” on Soonercare list; Advanced Specialty on Health Choice; covered by Tricare
- Generics available and priced at <$1/pill
- If no coverage: readysetprep.hiv.gov
- For prescribers: iassist.com
- HIV ECHO

Primary Care will be crucial in fighting the hepatitis C epidemic: decreasing the incidence, morbidity, and mortality through prevention and treatment. We can also play a pivotal role in fighting opioid epidemic and preventing HIV. I hope you will consider adding any of these methods to your practice.

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Questions?