



# Viral Hepatitis Tool Kit

2024



**Florida**  
**HEALTH**

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# INTRODUCTION

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This document is intended to be a resource for local county health departments and other medical settings that encounter patients who are infected with the hepatitis B or C virus and need treatment. Information about hepatitis screening, confirmatory testing, and generalized linkage to care is included. A partial list of available treatment services for individual counties may be found at [Hepatitis Resources | Florida Department of Health](#).

This document is not intended to replace clinical research literature or current United States Public Health Service (USPHS) guidelines and may not include the full range of prevention and treatment options for all patients.

## WHAT IS VIRAL HEPATITIS?

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Hepatitis means inflammation of the liver. The liver is a vital organ that processes nutrients, filters the blood, and fights infections. When the liver is inflamed or damaged, its function can be affected. Heavy alcohol use, toxins, some medications, and certain medical conditions can cause an inflammation of the liver, also called hepatitis. However, hepatitis is often caused by a virus. According to the Centers for Disease Control and Prevention (CDC), in the United States, the most common types of viral hepatitis are [Hepatitis A](#), [B](#), and [C](#).



### Hepatitis A (HAV)

- Effective vaccine available
- Outbreaks still occur in the United States; many are foodborne, but recently there are isolated outbreaks among people who are homeless or who inject drugs and men who have sex with men.
- It is often spread in populations that do not have access to sanitary living conditions.
- It is spread when a person ingests fecal matter—even in microscopic amounts—from contact with objects, food, or drinks contaminated by feces or stool from an infected person.

### Hepatitis B (HBV)

- Effective vaccine available
- About 2 in 3 people with hepatitis B do not know they are infected.
- Only 10% of adults and children older than 5 who have hepatitis B go on to have a chronic infection.
- About 50% of people with hepatitis B in the U.S are Asian.
- Is a leading cause of liver cancer.
- Is primarily spread when blood, semen, or certain other body fluids—even in microscopic amounts—from a person infected with the hepatitis B virus enters the body of someone who is not infected.

HBV can also be transmitted from:

- Birth to an infected mother
- Sex with an infected person
- Sharing equipment that has been contaminated with blood from an infected person, such as needles, syringes, and even medical equipment, such as glucose monitors

- Sharing personal items such as toothbrushes or razors
- Poor infection control in health care facilities

## Hepatitis C (HCV)

- No vaccine available
- The leading cause of liver transplants and liver cancer.
- About 50% of people with hepatitis C do not know they are infected.
- Is spread when blood from a person infected with the hepatitis C virus—even in microscopic amounts—enters the body of someone who is not infected.

HCV can also be transmitted from:

- Sharing equipment that has been contaminated with blood from an infected person, such as needles and syringes
- Receiving a blood transfusion or organ transplant before 1992 (when widespread screening virtually eliminated HCV from the blood supply)
- Poor infection control in health care facilities
- Birth to an infected mother (about 6 in 100 infants born to mothers with HCV become infected)

Although infrequent, HCV can also be transmitted by:

- Sex with a person living with HCV (greatest risk-anal sex)
- Unregulated tattooing
- Sharing personal items contaminated with blood such as a razor or toothbrush
- Invasive health care procedures

## CHILDREN AND ADOLESCENTS

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This guideline does not specifically address the special needs of children and adolescents. There is no approved treatment for hepatitis C under the age of 3 years.

Please refer to the American Association for the Study of Liver Diseases, [HCV in Children | HCV Guidance \(hcvguidelines.org\)](https://www.aasld.org/hcv-guidelines) and CDC, [CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children — United States, 2023 | MMWR](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6012a1.htm) for hepatitis testing, management, and treatment recommendations in children and adolescents.

## HEPATITIS TESTING

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### Who Should Be Tested?

#### Hepatitis B

- Screen all adults aged 18 years and older at least once in their lifetime using a triple panel test.
- Screen pregnant women for hepatitis B surface antigen (HBsAg) during each pregnancy regardless of vaccination status and history of testing.

- Expand periodic risk-based testing to include people incarcerated, people with a history of sexually transmitted infections or multiple sex partners, and people with hepatitis C virus infection.
- Test anyone who requests hepatitis B testing regardless of disclosure of risk.

## Hepatitis C

The following recommendations for HCV screening augment those issued by CDC in 2012. The recommendations issued by CDC in 1998 remain in effect. CDC recommends:

- Universal HCV screening:
  - HCV screening at least once in a lifetime for all adults aged  $\geq 18$  years, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is  $< 0.1\%$
  - HCV screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is  $< 0.1\%$
- One-time HCV 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
- 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
  - Persons with selected medical conditions, including persons who ever received maintenance hemodialysis
- Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

These guidelines can be found online at: [CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020 | MMWR](#)

## Tests to Diagnose Hepatitis

If you have any risk factors for hepatitis C, the next step is to get tested. Initial testing for HCV consists of three parts. The first is the HCV antibody test, which checks for exposure to the virus. The second is the viral load test, which determines whether you have an active hepatitis C infection or if you were only exposed. If that test is positive, then a genotype test is done to find out what kind of HCV you have.

## HCV Antibody Testing

Diagnosing hepatitis C begins with an antibody test. Antibodies to HCV can be detected in the blood, usually within two or three months after the virus enters the body. If a person is positive for HCV antibodies, he or she has been exposed to the virus in the past. About 15 to 25 percent of people who are initially infected with HCV can clear the virus from their bodies, usually within six months of exposure. The next step is to look for the actual virus in the bloodstream, using a viral load test. If a person has an acute infection, meaning that he or she was recently infected with HCV, antibodies may not have formed yet, so a viral load is necessary to confirm infection.

## HCV Viral Load Testing

A health care provider can request a qualitative HCV RNA test to determine if the virus is in a person's bloodstream. A medical provider can also order a quantitative HCV RNA test to figure out a person's HCV viral load (the amount of HCV in a measurement of blood). Various methods are used to detect HCV RNA, including TMA (transcription-mediated amplification), PCR (polymerase chain reaction), and bDNA (branched DNA). Qualitative viral load testing tends to be more sensitive than quantitative testing. Viral load testing using PCR or TMA is more sensitive than bDNA testing.

HCV viral load testing is used during treatment to determine how well the medications are working. Increases and decreases in HCV RNA do not correlate to disease progression, so the qualitative viral load test is not very useful outside of treatment. HCV viral load results cannot determine if or when someone with hepatitis C will develop cirrhosis or liver failure.

# HEPATITIS TREATMENT

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## Chronic Hepatitis B Treatment

Chronic hepatitis B infection is defined as an infection that lasts longer than six months. There is no medication currently available to cure chronic hepatitis B but there are treatments that will help reduce the risk of liver disease and lower the risk of transmission. Persons with hepatitis B should avoid drinking alcohol, quit smoking, eat a healthy diet, and be aware of medicines and dietary supplements that may harm their liver.

## Chronic Hepatitis C Treatment

There are two main categories of HCV infection: acute and chronic. Chronic HCV infection is a long-term condition, while the acute form is a short-term infection. Acute HCV infection occurs within the first six months of exposure to the hepatitis C virus.

According to CDC, about 75 percent of people with acute HCV will progress to chronic HCV. That means that up to 25 percent of people with acute hepatitis C will recover from it without treatment. Timely treatment is still recommended because of the severe damage chronic hepatitis C can inflict.

There are several medications available to effectively treat chronic hepatitis C, and advancements in these treatments over recent years have been significant. Current therapies typically consist of 8-12 weeks of oral medication, offering the potential for a complete cure in over 95% of patients. These modern treatments not only boast high cure rates but also have minimal side effects, making them a promising option for those looking to eradicate the virus and restore their health. For a complete list of currently approved FDA treatments for hepatitis C, please visit [Medications to Treat HCV - Treatment - Hepatitis C Online](#).

## LINKAGE TO CARE AND NAVIGATION

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For the purpose of this tool kit, linkage to care is defined as actively assisting individuals infected with hepatitis B or C in obtaining medical care and treatment. This process goes beyond a simple phone call; it may involve helping a patient schedule their initial appointment, ensuring they have transportation to get to the appointment, and following up to confirm their adherence to medication and completion of necessary laboratory tests.

Navigating the pathway to care can vary significantly based on a person's financial situation, their ability to keep appointments, and their adherence to prescribed treatments, as well as the resources available within their community. Effective linkage to care requires a comprehensive approach that addresses these diverse factors, providing tailored support to ensure individuals receive the care they need. Understanding payor sources is crucial for facilitating access to hepatitis B and C care. Different insurance options and financial assistance programs can significantly impact a patient's ability to receive timely treatment. This section will explore various payor sources, including private insurance, Medicaid, Medicare, and patient assistance programs, to help individuals navigate their options and secure the necessary resources for their healthcare needs. Payors include:

- Private insurance
- Medicaid
- Veteran's Administration
- Federally Qualified Health Centers (FQHCs)/Community Health Centers
- Ryan White Care Act/AIDS Drug Assistance Program (ADAP)

### **Private Insurance**

In the current insurance marketplace, there are a wide variety of plans that individuals can buy, the "silver, gold, and platinum" plans that offer less coverage and a higher deductible in exchange for lower monthly premiums. Even though people do have coverage, their request for coverage for treatment of hepatitis C medications is sometimes denied or the copays and deductibles are out of reach for their client. It is often recommended that a client reapply or appeal a decision if their request for coverage is denied. In this instance, it would be inherent on the case manager or linkage specialist to assist the client in locating a specialty clinic that would accept the coverage available or utilize a free or low-cost clinic.

### **Medicaid**

As of March 2023, Florida Medicaid does not require prior authorization for preferred direct acting antivirals (DAA) and does cover the treatment for the hepatitis C virus with fewer restrictions. However, there are stipulations regarding retreatment, which include:

- Member adherence to previous therapy as evidenced by pharmacy claims
- Submission of hepatitis B surface antigen screening to verify no reactivation
- Evidence of failure to achieve a sustained virologic response (SVR) or lack of efficacy during retreatment
- Evidence of adverse event that required therapy discontinuation
- Patient is receiving substance or alcohol abuse counseling services or seeing an addiction specialist as an adjunct to HCV treatment and it is documented in the medical records

To find more information about Florida Medicaid's requirements for coverage of hepatitis C treatment, please refer to: [Hepatitis C Agents Criteria 03.13.2023.pdf \(myflorida.com\)](#).

### **Veteran's Administration**

The Veteran's Administration (VA) has treated more patients for HCV than any large health care system in the US. A veteran that can document an honorable discharge from any branch of the military is eligible for hepatitis C treatment, even if they do not qualify for routine medical care from the VA. The VA has treated more than 123,000 patients and cured more than 105,000 veterans with HCV. As of 2020, fewer than 22,000 veterans in the VA remain to be treated.<sup>1</sup> The VA has worked to eliminate as many barriers to treatment as possible and has a 95% rate of cure for the patients they have treated. For more information, please refer to: [Viral Hepatitis and Liver Disease Home \(va.gov\)](#) or go to your nearest VA clinic.

### **Federally Qualified Health Centers (FQHCs)/Community Health Centers**

A FQHC is a community-based organization that provides comprehensive primary care and preventative care including health, oral, and mental health/substance abuse services to persons of all ages, regardless of their ability to pay or health insurance status. Thus, they are a critical component of the health care safety net. The government also designates a category of health centers as FQHC Look-Alikes. FQHC Look-Alikes receive cost-based reimbursement for their Medicaid services, but do not receive malpractice coverage under the Federal Tort Claims Act (FTCA) or a cash grant.

The availability of hepatitis services at FQHCs varies across the state. Some offer testing only and some offer a full array of services, including screening and confirmatory testing, laboratory tests and treatment. For persons infected with the hepatitis C virus, please check with the FQHC in your county to find out if they provide treatment.

### **AIDS Drug Assistance Program (ADAP)**

ADAP is administered through the Florida Department of Health and is a statewide, prescription medication program for low-income people living with HIV. ADAP offices can be found in each county at the local county health department. This program, funded through the Ryan White Care Act, provides medications to uninsured or underinsured individuals living with HIV. Services are provided through the distribution of medication directly to eligible clients or by purchase of health insurance that includes coverage for HIV/AIDS medications.

Eligibility for ADAP includes:

- HIV positive
- In need of HIV/AIDS prescriptions
- Income at 400% or less of the [Federal Poverty Level \(FPL\)](#)
- Uninsured or do not have adequate prescription coverage
- Not confined to a hospital, nursing home, hospice, or correctional facility

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<sup>1</sup> Belperio, P., Korshak, L., & Moy, E. (2020). *HEPATITIS C TREATMENT IN MINORITY VETERANS*. Veterans Health Administration Department of Veterans Affairs Office of Health Equity.  
[https://www.va.gov/HEALTHYEQUITY/docs/HCV\\_and\\_Minority\\_Veterans\\_Information\\_Brief\\_FINAL.pdf](https://www.va.gov/HEALTHYEQUITY/docs/HCV_and_Minority_Veterans_Information_Brief_FINAL.pdf)



For persons who are ADAP clients and have a diagnosis of chronic hepatitis C, their hepatitis treatment is covered by the ADAP. The same physician that prescribes HIV medication can oversee the hepatitis C treatment.

### Uninsured/Underinsured

There are an ever-changing number of entities that assist or provide hepatitis C treatment for persons who have no/inadequate insurance coverage. The pharmaceutical companies have patient assistance programs to provide the medications for free, but do not provide funding for the laboratory costs or physician's fees. There is a patchwork of free clinics around the state, some of which provide hepatitis C treatment: <https://www.freeclinics.com/sta/florida>. There are also some local county health departments and FQHCs that treat hepatitis C and that number is expanding regularly.

To locate free or low-cost hepatitis C treatment, please consult this map and the accompanying county listing with contact information found under Hepatitis Treatment Options [Hepatitis Resources | Florida Department of Health](#). If you are aware of additional options for free/low-cost hepatitis C treatment, please send that information to zzzz Feedback, HSD\_Hepatitis [HSD.Hepatitis@flhealth.gov](mailto:HSD.Hepatitis@flhealth.gov).

### Co-pay and Patient Assistance Programs

Co-pay programs assist people with private insurance, reducing the co-payments or coinsurance costs required to obtain hepatitis C drugs at the pharmacy. Many of these programs are not available for those enrolled in Medicare, Medicaid, or another government-based prescription plan. Patient assistance programs offer free hepatitis C drugs to low-income individuals who are uninsured or underinsured, and who do not qualify for insurance programs such as Medicaid or Medicare.

If you are ineligible for co-pay or patient assistance funds because you have Medicare, Medicaid, or another government-based prescription plan, and cannot afford your prescription(s), ask the pharmaceutical company to refer you to a patient advocacy organization. Some are listed below:

#### Patient Assistance Programs

<b>AbbVie Inc.</b>
Drugs covered: Mavyret (glecaprevir + pibrentasvir)
Contact Information: For Mavyret 877-628-9738 or <a href="#">Patient Assistance   AbbVie</a>
Program Details: Offers co-pay assistance and free drug programs for those meeting eligibility requirements.
<b>Gilead Sciences</b>
Drugs covered: Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Contact Information: 855-7MY-PATH (855-769-7284) or <a href="http://www.mysupportpath.com">www.mysupportpath.com</a>
Program Details: Offers co-pay assistance and free drug programs for those meeting eligibility requirements.

### Merck

Drugs covered: Zepatier (elbasvir/grazoprevir)

Contact Information: 866-251-6013 or [Merck Patient Assistance Programs to Help Those in Need - Official Site \(merckhelps.com\)](#)

Program Details: Offers co-pay assistance and free drug programs for those meeting eligibility requirements.

## Other Patient Advocacy Programs

In addition to pharmaceutical patient assistance and co-pay programs, patient advocacy programs may help you find affordable medication and navigate other issues relating to access to care.

### HealthWell Foundation

Contact Information: 800-675-8416 or [Hepatitis C Fund for Prescriptions - HealthWell Foundation](#)

Program Details: The HealthWell Foundation provides financial assistance to eligible individuals to cover coinsurance, co-payments, health care premiums and deductibles for certain medications and therapies.

### Help-4-Hep

Contact Information: 877-HELP4HEP (877-435-7443) or [www.help4hep.org](http://www.help4hep.org)

Program Details: Help-4-Hep is a nonprofit, peer-to-peer helpline where counselors work with patients to meet the challenges of hepatitis C. Help-4-Hep provides information and resources about finding financial help to pay for low-cost testing or finding a free or low-cost clinic, or financial help with payment for treatments. They may also help find doctors and support groups. Services are provided free of charge.

### Partnership for Prescription Assistance (PPA)

Contact Information: 888-477-2669 or [Participating Patient Assistance Programs | Partnership for Prescription Assistance \(helpingpatients.org\)](#)

Program Details: The Partnership for Prescription Assistance helps qualifying patients without prescription drug coverage get the medicines they need by matching them with the right assistance programs.

### Patient Advocate Foundation's Hepatitis C CareLine

Contact Information: 800-532-5274 or [www.hepatitisc.pafcareline.org](http://www.hepatitisc.pafcareline.org)

Program Details: Patient Advocate Foundation's Hepatitis C CareLine is a hotline for patients and providers that aids patients who have been diagnosed with hepatitis C and are seeking education and access to care.

### Patient Access Network Foundation (PAN)

Contact Information: 866-316-PANF (866-316-7263) or [www.panfoundation.org](http://www.panfoundation.org)

Program Details: The Patient Access Network Foundation offers help to people with chronic or life-threatening illnesses for whom cost limits access to medical treatments.

## THE LINK BETWEEN HEPATITIS AND SUBSTANCE USE

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Drug and alcohol use places people at higher risk for contracting viral hepatitis. Engaging in risky sexual behavior that often accompanies drug use increases the risk of contracting HBV and HCV. People who inject drugs (PWID) are at high risk for contracting HBV and HCV from shared needles and other drug preparation equipment, which exposes them to bodily fluids from other infected people. Because drug use can affect judgment, people who inject drugs may find themselves engaging in unsafe behaviors, which can elevate their risk of contracting viral hepatitis. One study reported that each person who injects drugs infected with HCV is likely to infect about 20 others, and that this rapid transmission of the disease occurs within the first 3 years of initial infection<sup>2</sup>. Drug and alcohol use can also directly damage the liver, increasing risk for chronic liver disease and cancer among those infected with hepatitis. This underscores that early detection and treatment of hepatitis infections in PWID and other drug users is paramount to protecting both the health of the person and that of the community.

The integration of hepatitis testing into substance abuse treatment programs is incomplete. Even though the proportion of treatment programs that offer hepatitis testing options to their clients has increased in recent years, missed opportunities for testing remain. Substance abuse treatment programs increasingly refer their clients to off-site facilities for HCV testing – a practice associated with significant reductions in the use of recommended services.

It is recommended that substance abuse treatment centers offer in-house hepatitis testing or ensure their clients have access to testing at another entity. For those persons who are infected with HCV, treatment center staff should be able to refer their clients to options for hepatitis C care and treatment.

## HEPATITIS IN CORRECTIONAL SETTINGS

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### Jails

In Florida, jails are funded and staffed by county governments and run by the sheriff's office. People are housed in jails for being accused of a crime or are waiting for a trial whether they are innocent or guilty. The length of time that people are held in jails can be up to one year or longer. Jails typically have a more transient population, with individuals often only staying a day or two. Jails sometimes offer educational, substance abuse, and vocational (work) programs, but each county jail is autonomous and decisions about services offered to inmates are made by the local sheriff's office.

Jails do not routinely screen for hepatitis and seldom, if ever, offer treatment. Some allow community-based organizations or the local health department to come in and test and provide referrals to local agencies.

### Prisons

People who are convicted of a felony and generally sentenced for a year or more are sent to a prison. State and federal governments operate prisons or contract with the private prison industry. A

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<sup>2</sup> National Institute on Drug Abuse. (2020, August 3). *Viral Hepatitis*. National Institute on Drug Abuse. <https://nida.nih.gov/research-topics/viral-hepatitis>

person who is convicted of a crime and who is incarcerated in a prison is a felon. Prisons can have a minimum, medium, and maximum security. There are also halfway houses, work-related programs, and community restitution programs. The average length of time of incarceration in Florida prisons has risen in recent years and is now three and a half years.

Medical care for all inmates in state prison is the exclusive responsibility of the Florida Department of Corrections (FDOC). Using CDC's estimate of 17.6% of prison inmates being infected with HCV, there are currently more than 16,000 inmates in state prison infected with hepatitis C. Historically, FDOC did not treat inmates for hepatitis C and there was a class action lawsuit filed on behalf of prisoners in Florida. The judgment for the case, *Hoffer v. Jones, et al*<sup>3</sup>, was decided in November 2017 in favor of the inmates. FDOC has begun treating inmates infected with the hepatitis C virus, prioritizing the sickest individuals.

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<sup>3</sup> *Hoffer v. Jones*, 290 F. Supp. 3d 1292 (N.D. Fla. 2017)

## REFERENCES

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Some materials and guidance contained in this document have been modified or adapted from the following resources:

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