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**Viral Hepatitis**

**Tool Kit**

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**INTRODUCTION**

**FOREWORD**

*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* <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/hepatitis-resources.htm> *.*

*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?**

[Recommend on Facebook](https://www.cdc.gov/hepatitis/abc/index.htm) Tweet **Compartir**



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 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(https://www.cdc.gov/hepatitis/hav/index.htm)](https://www.cdc.gov/hepatitis/hav/index.htm), [hepatitis B(https://www.cdc.gov/hepatitis/hbv/index.htm)](https://www.cdc.gov/hepatitis/hbv/index.htm), and [hepatitis C(https://www.cdc.gov/hepatitis/hcv/index.htm)](https://www.cdc.gov/hepatitis/hcv/index.htm).

**Hepatitis A**

* 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
* Hepatitis A 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**

* 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. The majority of people will get well and have lifelong immunity.
* About 50% of people with hepatitis B in the U.S are Asian
* Hepatitis B is a leading cause of liver cancer
* Hepatitis B 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.
The hepatitis B virus 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 has resulted in outbreaks in health care facilities

**Hepatitis C**

* About 50% of people with hepatitis C do not know they are infected
* 3 in 4 people with hepatitis C were born from 1945-1965
* Hepatitis C is a leading cause of liver transplants and liver cancer
* Hepatitis C 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.

The hepatitis C virus (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 has resulted in outbreaks in health care facilities
* Birth to an infected mother (only 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 MSM
* Unregulated tattooing
* Sharing personal items contaminated with blood such as razor or toothbrush
* Invasive health care procedures

**CHILDREN AND ADOLESCENTS**

This guideline does not specifically address the special needs of children and adolescents. Please refer to the American Association for the Study of Liver Diseases, HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C and their information regarding children. <https://www.hcvguidelines.org/unique-populations/children>

**HEPATITIS TESTING**

**Who Should Be Tested?**

The decision to test an individual for hepatitis should be based on their risk.

* persons who have ever injected drugs
* persons who have had a long-term HCV positive partner
* persons who have exchanged sex for money, food or other goods.
* persons who received clotting factor concentrates before 1987
* persons who received a blood transfusion or organ transplant prior to 1992
* persons who were ever on long-term hemodialysis
* persons who were born to a HCV positive mother
* persons who were told they have elevated liver enzymes
* persons born from 1945 through 1965 (“Baby Boomers”)
* Jail or prison inmates or ex-offenders
* persons who acknowledge intranasal drug use (snorting/sniffing)
* persons undergoing drug rehabilitation treatment at substance abuse treatment facilities
* persons with known occupational exposure to HCV
* recipient of an unregulated tattoo
* persons living with HIV

**Tests to Diagnose Hepatitis**

If you have any risk factors for hepatitis C, then the next step is to test for it. Initial testing for HCV has three parts. The first test, the HCV antibody test, sees if you have been exposed to the virus. The second test is the viral load test, and it detects whether you were merely exposed or if you actually have hep C. 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 are 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.

**HCV Genotypic Testing:** Genotype refers to the genetic structure or makeup of living organisms. The hepatitis C virus has eight different genotypes, which are numbered in the order of their discovery. (The identification of genotype 8 was announced at the 2017 Liver Meeting.) Each of these genotypes has subtypes, which were lettered in the order that they were discovered. It is important to find out which hepatitis C genotype you have, because it determines the best treatment for you. HCV genotype also helps to predict the likelihood of curing HCV, but improved medications with high cure rates have made this less useful.

Worldwide, HCV genotype 1 is most common, accounting for 46 percent of cases. In the United States, 75 percent of all HCV infections are genotype 1; genotypes 2, 3 and 4 are less common in the United States, and other genotypes are rare. Genotype 7 was discovered in 2013 and there is only one known case. Two genotype 8 cases were identified in India. It is possible to be infected with more than one HCV genotype; this most likely occurs among injection drug users, and people who received contaminated blood products before 1987 (when viral inactivation started), or a blood transfusion before July 1992 (when effective screening procedures were instituted).

**HEPATITIS TREATMENT**

**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 watch out for medicines and dietary supplements that may hurt their livers.

**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 the 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. For this reason, and because treatment for HCV can be expensive, doctors typically don’t treat acute HCV. They’ll often monitor an acute infection to see if it progresses to the chronic form. If the chronic form does develop, treatment can be introduced at that time.

There are several medications available to treat chronic hepatitis C. Hepatitis C treatments have gotten much better in recent years. Current treatments usually involve just 8-12 weeks of oral therapy (pills) and cure over 90% of people with few side effects. For a complete list of currently approved FDA treatments for hepatitis C, please visit <http://www.hepatitisc.uw.edu/page/treatment/drugs>.

**LINKAGE TO CARE**

For the purposes of this toolkit, linkage to care is defined as actively assisting persons infected with the hepatitis B or C virus to obtain medical care and treatment. This is more than a phone call and may involve helping a patient schedule their first appointment, ensuring they have the means to arrive at the appointment, checking in with the patient to confirm they are adherent to the medication and complete the needed laboratory tests. Linkage to care is a different process depending on a person’s ability to pay, follow through with appointment times and medication adherence and the resources available in their community. Payor sources may include:

* + Private insurance
	+ Medicaid
	+ Veteran’s Administration
	+ Federally Qualified Health Centers/Community Health Centers
	+ Ryan White Care Act/AIDS Drug Assistance Program
	+ Uninsured

**Private Insurance**

In the current insurance marketplace, there are a wide variety of coverages 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 are sometimes denied or the co-pays and deductibles are out of reach for their client. It is often recommended that a client re-apply 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**

Florida Medicaid requires previous authorization and does cover the treatment for the hepatitis C virus with some stipulations. They include:

* The medication must be prescribed by or in consultation with a hematologist, gastroenterologist, infectious disease specialist or transplant physician AND
* Patient has no history of the requested medication (no claims history or reference in medical records to previous trial and failure of requested medication). Decisions regarding coverage for retreatment is made on a case-by-case basis.
* Submission of hepatitis B surface antigen screening to verify no reactivation.
* One of the following:
	+ Patient has abstained from the use of illicit drugs and alcohol for a minimum of one month as evidenced by negative urine or blood confirmation test collected within the past 30 days, prior to initiation of therapy (results must be submitted with request); or
	+ 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: <http://ahca.myflorida.com/medicaid/Prescribed_Drug/drug_criteria_pdf/Hepatitis_C_Agents_Criteria.pdf> .

**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. Through June 2018, the VA has treated 110,220 patients and an average of 323 Veterans are started on treatment every week. They have worked to eliminate as many barriers to treatment as possible and have a 95% rate of cure for the patients they have treated. For more information please refer to: <https://www.hepatitis.va.gov/patient/index.asp> or go to your nearest VA clinic.

 **Federally Qualified Health Centers (FQHC)/Community Health Centers**

FQHC is a community-based organization that provides comprehensive [primary care](https://en.wikipedia.org/wiki/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-a-likes." FQHC Look-a-likes 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**

The AIDS Drug Assistance Program (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 and;
* In need of HIV/AIDS prescriptions;
* Income at 400% or less of the [Federal Poverty Level](http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/_documents/2017-federal-poverty-guidelines.pdf);
* Uninsured or do not have adequate prescription coverage;
* Not confined to a hospital, nursing home, hospice, or correctional facility.

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 will 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 do provide hepatitis C treatment. <https://www.freeclinics.com/sta/florida> There are 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 (click web layout view). <http://www.floridahealth.gov/diseases-and-conditions/hepatitis/hepatitis-resources.html> 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 .

**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 other government-based prescription plan.

Patient assistance programs (PAPs) offer free hepatitis C drugs to lower-income people 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**

| **AbbVie Inc.** |
| --- |
| **Drugs covered:** Mavyret (glecaprevir + pibrentasvir), Technivie (ombitasvir/paritaprevir/ritonavir), Viekira (ombitasvir/paritaprevir/ritonavir; dasabuvir), Moderiba (ribavirin) |
| **Contact Information:** For Mavyret 877-628-9738 or [www.mavyret.com](http://www.mavyret.com/). For Technivie and Viekira 844-277-6233 or [www.rxabbvie.com](https://www.rxabbvie.com/). For Moderiba 844-663-3742 or [www.abbvie.com/patients/patient-assistance.html](https://www.abbvie.com/patients/patient-assistance.html) |
| **Program Details:** Offers co-pay assistance and free drug programs for those meeting eligibility requirements. |

| **Bristol-Myers Squibb (BMS)** |
| --- |
| **Drugs covered:** Daklinza (daclatasvir) |
| **Contact Information:** 844-44CONNECT (844-442-6663) or [www.bms.com/patient-and-caregivers/get-help-paying-for-your-medicines.html](https://www.bms.com/patient-and-caregivers/get-help-paying-for-your-medicines.html) |
| **Program Details:** Offers co-pay assistance and free drug programs for those meeting eligibility requirements. |

| **Genentech/Roche** |
| --- |
| **Drugs covered:** Pegasys (peginterferon alfa-2a) and Copegus (ribavirin) |
| **Contact Information:** 888-941-3331 or [www.genentech-access.com/pegasys/patients](http://www.genentech-access.com/pegasys/patients) |
| **Program Details:** Offers co-pay assistance and free drug programs for those meeting eligibility requirements. |

| **Gilead Sciences** |
| --- |
| **Drugs covered:** Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Vosevi (sofosbuvir/velpatasvir/voxilaprevir) |
| **Contact Information:** 855-7MY-PATH (855-769-7284) or [www.MySupportPath.com](http://www.mysupportpath.com/) |
| **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 [www.merckaccessprogram-zepatier.com/hcc](https://www.merckaccessprogram-zepatier.com/hcc/) |
| **Program Details:** Offers co-pay assistance and free drug programs for those meeting eligibility requirements. |

| **Kadmon Pharmaceuticals** |
| --- |
| **Drugs covered:** Ribasphere (ribavirin) |
| **Contact Information:** 877-377-7862 or [www.ribapak.com/index.html](https://www.pparx.org/prescription_assistance_programs/kadmon_patient_assistance_program) |
| **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 [www.healthwellfoundation.org/hepatitis-c](http://www.healthwellfoundation.org/hepatitis-c) |
| **Program Details:** The HealthWell Foundation provides financial assistance to eligible individuals to cover coinsurance, copayments, 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 [www.pparx.org](http://www.pparx.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://hepatitisc.pafcareline.org/) |
| **Program Details:** Patient Advocate Foundation’s Hepatitis C CareLine is a hotline for patients and providers that provides assistance to 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 ABUSE**

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, less frequently, 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 often impairs judgement, PWID repeatedly engage in these unsafe behaviors, which can increase 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.[4](https://www.drugabuse.gov/related-topics/viral-hepatitis-very-real-consequence-substance-use#References) 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 the 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**

**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 who 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 automatous 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 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 the 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 judgement for the case, Hoffer v. Jones, et al., 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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| ACKNOWLEDGMENTS  |

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

* Centers for Disease Control and Prevention (CDC) – Hepatitis C Questions and Answers for the Public <https://www.cdc.gov/hepatitis/hcv/cfaq.htm>
* CDC – Testing Recommendations for Hepatitis C Virus Infection <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>
* CDC - Preventing New Infections, <http://www.cdc.gov/hiv/guidelines/preventing.html>
* Florida/Caribbean AIDS Education and Training Center
* American Association of Professional Coders (AAPC), <https://www.aapc.com>
* Substance Abuse Treatment Prevention and Policy, Hepatitis C testing in substance use disorder treatment: the role of program managers in adoption of testing services, Jeminma A. Frimpong and Thomas D’Aunno, April 2016
* Agency for Healthcare Administration, Medicaid Policy: Hepatitis C Direct Acting Antivirals.
* Infectious Diseases Society of America, HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C

