

# Hepatitis C Screening Guideline

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Last guideline approval: January 2021

**Guidelines** are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

# Major Changes as of January 2021

New	Previous
One-time screening for hepatitis C is recommended for all adults aged 18–79.	One-time screening for hepatitis C was recommended only for adults born between 1945 and 1965 (baby boomers).

# Background

Hepatitis C virus (HCV) is the most common chronic blood-borne infection in the United States. Historically, HCV was most prevalent in the baby boomer generation (persons born between 1945 and 1965), which comprised 75% of the HCV population. In the past decade, the HCV prevalence in young people increased dramatically, concurrent with a steep rise in opioid use. According to the CDC, in 2018 millennials (currently in their 20s and 30s) made up 36.5% of newly reported chronic hepatitis C infections, while baby boomers made up 36.3%, and Generation Xers (currently in their 40s to early 50s) made up 23.1% (Ryerson 2020).

Populations at the highest risk of infection are injection drug users, recipients of clotting factor concentrates before 1987, recipients of blood transfusions before 1992, chronic hemodialysis patients, persons with HIV infection, and children born to HCV-positive mothers.

As people age, life-threatening complications from hepatitis C increase. These complications can be prevented if people who are infected are diagnosed and treated. Of every 100 persons infected with HCV, about 75 to 85 go on to develop a chronic infection; 60 to 70 develop chronic liver disease; 5 to 20 develop cirrhosis over a 20- to 30-year period; and 1 to 5 die from consequences of chronic infection. Progression from initial infection to cirrhosis can take one to two decades and occurs in an indolent fashion.

Antiviral treatment regimens have demonstrated sustained virologic responses as well as reduced treatment-associated harms to patients. Insurance coverage policies have made treatment an option for many HCV-infected patients with little or no liver damage. Staging of liver fibrosis continues to be important for determining the duration of treatment and for informing the need for additional screening for those with advanced fibrosis.

### Screening

### Screening recommendations

Patients aged 18-79 should undergo one-time screening for HCV. Additionally,

- Patients outside this age range may still be eligible for one-time screening based on the risk factors described in Table 1.
- Patients with significant risk of exposure to HCV after a prior screening may be considered for repeat screening (see Table 1 for risk factors).

Consider providing a <u>patient information handout</u> on HCV screening, which is also available as the SmartPhrase **.AVSHEPCSCREENING**.

Table 1. Screening for hepatitis C virus			
Eligible population	Test 1,2	Frequency	
All adults aged 18–79	Hep C screening test with reflex to Hep C RNA quantitative test	One time	
<ul> <li>Patients aged ≤ 17 years or ≥ 80 years with risk factors:         <ul> <li>Current and past injection drug use. This includes patients who injected only once or many years ago.</li> <li>Receipt of clotting-factor concentrates before 1987</li> </ul> </li> <li>Receipt of blood transfusion or solid organ transplant before July 1992</li> <li>Receipt of long-term hemodialysis treatment</li> <li>Known exposure to HCV (e.g., by accidental needle stick). See Infection Control occupational accidental parenteral exposure information on the staff intranet.</li> <li>HIV infection</li> <li>Being born to an HCV antibody–positive mother</li> </ul>	Hep C screening test with reflex to Hep C RNA quantitative test	One time or, if patient has ongoing risks for HCV exposure, screening at appropriate intervals based on clinical judgment	
Previously screened patients of any age who have ongoing risk factors for HCV exposure as described above.	Hep C screening test with reflex to Hep C RNA quantitative test	Repeat screening at appropriate intervals based on clinical judgment	
For immunocompromised patients (e.g., those with HIV or on chemotherapy or dialysis), there is a high rate of false negatives with the Hep C antibody test. Therefore, it is recommended that these patients be screened using only the Hep C RNA quantitative test.  A positive Hep C antibody test followed by a negative Hep C RNA quantitative test indicates that no active infection is present. No follow-up testing is needed. If a patient has no ongoing risk factors, the one-time screening recommendation has been satisfied.			

#### HCV screening is NOT routinely recommended based on the following lower-risk factors:

- Long-term sexual contact with a person infected with HCV
- Multiple sex partners or sexually transmitted infections
- Sharing personal care items, such as razors or toothbrushes that may have come in contact with the blood of an HCV-infected person
- Intranasal cocaine and other non-injecting illegal drug use
- Tattooing or body piercing
- Receipt of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm)

For patients with **limited life expectancy**, the benefits of screening and treatment are smaller and may be outweighed by the potential risks of treatment. In these situations clinical judgment and shared decision-making may be appropriate. Examples of life-limiting clinical conditions include but are not limited to:

- Moderate to severe chronic obstructive pulmonary disease
- Active or severe cardiovascular disease
- Stroke
- Active treatment for a malignancy

# Referrals for Staging and Treatment

Patients who are confirmed to be HCV antibody—positive with positive RNA titers should be referred to a qualified provider for fibrosis staging and treatment decisions. Consider using the SmartPhrase .AVSHEPCNEWDIAGNOSIS in a secure message or letter to the patient.

Depending on location and patient preference, patients may be referred either to Gastroenterology or to a consultative or general internal medicine provider with training in hepatitis C treatment. The KP HealthConnect referral tool has buttons for all the facilities where qualified hepatitis C providers are located, so the referring provider can simply click the closest appropriate location and the referral will go to that location. Patients who are co-infected with HIV, have chronic kidney disease stage 3 or higher, or are suspected to have advanced liver disease should be referred to Gastroenterology; all others can go to a consultative or general internal medicine location. See the Hepatitis C Provider List, linked from the Pharmacy Hepatitis C Medications page on the staff intranet.

#### Referrals

To make an internal referral for hepatitis C treatment in KP HealthConnect, use this order: **Ref Hepatitis** C Management.

The HealthConnect referral order includes a liver ultrasound elastography (acoustic radiation force impulse [ARFI]) to assess fibrosis. Additional panel tests in the order include:

- Hepatitis C virus genotype (to help determine which medications will be most effective)
- Hepatitis A total
- Hepatitis B surface antigen
- Hepatitis B core
- · Hepatitis B surface antibody
- CBC/PLT/DIFF
- HIV
- · Complete metabolic panel

- Ferritin
- Iron and TIBC
- Protime/INR

Additionally, the HealthConnect referral asks about screening for alcohol use and depression with the AUDIT-C and PHQ-2 questionnaires. Results of these screens should prompt the referring provider to initiate treatment for depression and substance abuse.

The SmartPhrases .AVSHEPCNEWDIAGNOSIS and .AVSHEPCTXFAQ can be included in the After Visit Summary to provide patients with information about their diagnosis and medications, respectively.

### Referrals to external providers

At locations where there is not ready access to an HCV provider (for example, Central Washington), patients should be referred to a contracted specialist in either gastroenterology or infectious disease. The liver ultrasound elastography and the lab panel described above should be ordered **well in advance of the visit to the specialist** to ensure that results are available at the time of the consultation.

#### Treatment and Surveillance Recommendations

The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (ISDA) have updated their published guidance to **recommend HCV treatment for patients at all risk levels.** Where treatment capacity limitations are an issue, the guidance continues to recommend that priority for immediate treatment be given to patients with more advanced disease, as defined by fibrosis stage and other patient characteristics. (AASLD-IDSA 2020)

### Surveillance and treatment by HCV providers and clinical pharmacists

Treatment timing decisions will be made by the patient and HCV provider using shared decision-making.

Patients at all stages who have elected immediate treatment will be followed up at appropriate intervals by an approved HCV provider (gastroenterology or internal medicine), and will have their medication treatment managed by hepatitis C–certified trained clinical pharmacists in the Specialty Medication Program (SMP). (For more information about the SMP, including treatment guide, patient handouts, and lab references, see the Hepatitis C Clinical Pharmacy Program page on the staff intranet.)

### Coverage considerations

**Screening:** Patients meeting eligibility criteria for screening will receive full coverage for the hepatitis C screening antibody and RNA viral load tests under their preventive service benefit. Additional diagnostic tests for purposes of staging will be covered under the usual contract benefit for lab and radiology services.

**Treatment:** Coverage is available for most patients regardless of stage of liver fibrosis (see the Pharmacy Hepatitis C Medications page on the staff intranet), though some patients may have significant cost shares. Because newly infected patients with hepatitis C may spontaneously go into remission with full clearance of their viral load, patients with suspected acute infection should have their hepatitis C RNA titers repeated no later than at 6 months before treatment to ensure that their condition is chronic, not acute, hepatitis C. Patients with questions about their coverage should contact Member Services.

**Patient assistance program:** Patients may be eligible for copay assistance programs. Specialty Pharmacy or a community resource specialist can help determine which options are available. For an estimation of cost-sharing, the Pharmacy Drug Benefit Help Desk on the staff intranet can be helpful.

### **Evidence Summary**

To develop the Hepatitis C Screening Guideline, the guideline team has adapted the following recommendations from externally developed evidence-based guidelines and/or recommendations of organizations that establish community standards:

- 2020 American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD-IDSA). <u>HCV Guidance: Recommendations for Testing, Managing, and Treating</u> Hepatitis C.
- 2020 Centers for Disease Control and Prevention (CDC). <u>CDC Recommendations for Hepatitis C</u> Screening Among Adults – United States.
- 2020 U.S. Preventive Services Task Force (USPSTF). <u>Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement.</u>
- 2020 KP Interregional Hepatitis Workgroup. Chronic Hepatitis C Recommendations for Direct Acting Antiviral Treatment.

#### Reference

Ryerson AB, Schillie S, Barker LK, Kupronis BA, Wester C. *Vital Signs:* Newly Reported Acute and Chronic Hepatitis C Cases — United States, 2009–2018. *MMWR Morb Mortal Wkly Rep.* 2020;69:399–404. DOI: http://dx.doi.org/10.15585/mmwr.mm6914a2

# **Development Process/Team**

### **Development process**

To develop the Hepatitis C Screening Guideline, the guideline team adapted recommendations from externally developed evidence-based guidelines and/or recommendations of organizations that establish community standards. See the Evidence Summary section.

This edition of the guideline was approved for publication by the Guideline Oversight Group in January 2021.

#### Team

The Hepatitis C Screening Guideline development team included representatives from the following specialties: consultative internal medicine, gastroenterology, and pharmacy, and preventive care.

Clinician lead: <u>John Dunn, MD, MPH</u>, Medical Director of Preventive Care Guideline coordinator: <u>Avra Cohen, MN, RN</u>, Clinical Improvement & Prevention

Peter Barkett, MD, Internal Medicine Megan Kavanagh, Patient Engagement Team, Clinical Improvement & Prevention Dan Kent, PharmD, CDE, Pharmacy Administration Channa R Jayasekera, MD, Gastroenterology Ann Stedronsky, Clinical Publications, Clinical Improvement & Prevention Ron Yeh, MD, Gastroenterology