Hepatitis C Screening Guideline

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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 September 2016

<table>
<thead>
<tr>
<th>New</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment is now recommended for all patients with chronic hepatitis C.</td>
<td>Hepatitis C treatment was prioritized by risk level, as defined by fibrosis stage and other patient characteristics.</td>
</tr>
<tr>
<td>To guide treatment decisions, two lab tests (APRI and FibroSure) and a new imaging test (abdominal ultrasound with acoustic radiation force impulse, or ARFI) have been added to the hepatitis C management referral order in Epic.</td>
<td>For patients with hepatitis C who elect to defer treatment, surveillance was previously done in Primary Care.</td>
</tr>
<tr>
<td>For patients with hepatitis C who elect to defer treatment, surveillance will be done by an HCV provider.</td>
<td>For patients with hepatitis C who elect to defer treatment, surveillance was previously done in Primary Care.</td>
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</tbody>
</table>

Background

Hepatitis C virus (HCV) is the most common chronic blood-borne infection in the United States. More than 75% of patients infected with HCV were born between 1945 and 1965. 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.

With the advent of birth cohort screening among those born between 1945 and 1965, more healthy, asymptomatic patients are being diagnosed with chronic hepatitis C. Newer antiviral treatment regimens have demonstrated sustained virologic responses as well as reduced treatment-associated harms to patients. Recent changes in insurance coverage policy 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

All patients at elevated risk, as described in Table 1, should be screened for the hepatitis C virus.

<table>
<thead>
<tr>
<th>Eligible population</th>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>All adults born during 1945–1965</td>
<td>Hep C screening test with reflex to Hep C RNA quantitative test</td>
<td>One time</td>
</tr>
<tr>
<td>Adults and adolescents of any age with risk factors:</td>
<td>Hep C screening test with reflex to Hep C RNA quantitative test</td>
<td>One time or, if patient has ongoing risks for HCV exposure, screening at appropriate intervals based on clinical judgment</td>
</tr>
<tr>
<td>• Current and past injection drug use. This includes patients who injected only once or many years ago</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Receipt of clotting-factor concentrates before 1987</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Receipt of blood transfusion or solid organ transplant before July 1992</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Receipt of long-term hemodialysis treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Known exposure to HCV (e.g., by accidental needle stick). See Infection Control accidental exposure policy on the staff intranet</td>
<td></td>
<td></td>
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<tr>
<td>• HIV infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Being born to an HCV antibody–positive mother</td>
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</tr>
</tbody>
</table>

1 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.

2 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, additional considerations might include weighing the potential benefits of treatment—given the very slow course of the disease—against the potential harms of treatment should they screen positive for HCV. Life-limiting clinical conditions include:

- Moderate to severe chronic obstructive pulmonary disease
- Active or severe cardiovascular disease
- Stroke
- Active treatment for a malignancy
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 Epic referral tool will have buttons for all the facilities where qualified HCV providers are located, so the referring provider can simply click the closest appropriate location and the referral will go to that CIM/GIM or GI location. A patient who is co-infected with HIV, has chronic kidney disease stage 3 or higher, or is suspected to have advanced liver disease should be referred to GI; all others can go to a consultative or general internal medicine location.

**Referrals**

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

The Epic referral order includes a liver ultrasound (with acoustic radiation force impulse [ARFI]) to assess fibrosis. ARFI is available at Kaiser Foundation Health Plan of Washington’s Bellevue, Capitol Hill and Tacoma Specialty clinics. 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 surface antibody
- CBC/PLT/DIFF
- HIV
- AST
- ALT
- Alkaline phosphatase
- Total bilirubin
- Direct bilirubin
- Albumin
- Ferritin
- Iron and TIBC
- Creatinine with GFR
- Protime/INR
- APRI score

Additionally, the Epic 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 (and ARFI or FibroScan, if available) 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 2016)

**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 in Metavir stages 0 and 1 may elect to defer therapy and undergo surveillance. Reasons to defer therapy could include waiting until drug safety profiles are better established and waiting for drug prices/cost shares to fall, among others. Patients who defer treatment will be followed up annually by an HCV provider. All patients desiring immediate therapy should be treated as soon as possible.

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:** Most 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; however, because certain contracts exclude this coverage, members should contact Customer Service to confirm their coverage. 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 Customer Service.
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:


Guideline Development Process and 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 and References section.

This edition of the guideline was approved for publication by the Guideline Oversight Group in September 2016.

Team
The Hepatitis C Screening Guideline development team included representatives from the following specialties: continuum of care, gastroenterology, medical specialties, and pharmacy.

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Disclosure of conflict of interest
Kaiser Permanente requires that team members participating on a guideline team disclose and resolve all potential conflicts of interest that arise from financial relationships between a guideline team member or guideline team member's spouse or partner and any commercial interests or proprietary entity that provides or produces health care–related products and/or services relevant to the content of the guideline.

Team members listed above have disclosed that their participation on the Hepatitis C Screening Guideline team includes no promotion of any commercial products or services, and that they have no relationships with commercial entities to report.