



Hepatitis C Testing Toolkit for Primary Care Providers

*Resources to Support Hepatitis C
Testing in Georgia*

Hepatitis C Testing Toolkit for Primary Care Providers

How to use this file:

This file includes numerous documents related to Hepatitis C testing saved in PDF format. On the left side of this screen you will see several icons. Clicking on the second icon from the top will enable the “bookmark” function. A navigator pane will open on the left side of the document that will show an index of all of the documents in the file. Clicking on the document of interest will take you directly to that document.

This toolkit was developed for primary care providers and contains all of the resources needed to promote hepatitis C testing. By promoting HCV testing in persons at increased risk and one-time screening of adults born between 1945 and 1965, we can detect hepatitis C infection earlier, link patients to care and treatment before developing complications from liver damage and reduce the likelihood of transmission of HCV to others.

- Section 1:** Overview of Hepatitis C Screening Recommendations for Health Care Providers
- Section 2:** U.S. Preventive Task Force Hepatitis C Screening Recommendations and Implications
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Overview of Hepatitis C Testing Recommendations

Background

Hepatitis C is a major health problem in the United States, with an estimated 2.7-3.9 million Americans living with chronic hepatitis C infection and approximately 17,000 new infections each year.² Although the number of new infections has declined over the past two decades, hepatitis C related morbidity and mortality have been steadily rising. The expanded HCV testing recommendations intend to address the following key facts:

- 45-85% of adults with chronic hepatitis C are unaware of their infection and thus do not benefit from available care and treatment.^{3,4}
- Left untreated, chronic hepatitis C can cause significant liver complications, including cirrhosis, cancer and liver failure. It is the leading cause for liver transplants and hepatocellular carcinoma (liver cancer) and is the fastest-rising cause of all cancer-related deaths in the United States.
- HCV infection is typically asymptomatic until substantial liver disease occurs, generally several decades after the onset of infection.
- Americans born between 1945 and 1965 account for 76% of adults living with HCV and 73% of all HCV related deaths.
- Risk-based screening misses up to 2/3 of HCV-infected patients.
- There have been significant advances in HCV testing technology and medical treatment that can benefit persons infected with HCV.
- There is a need to simplify the process of HCV testing to facilitate its incorporation into routine health care.

Hepatitis C is a significant public health problem.

In recent years, the [Institute of Medicine, Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy](#), and the [Centers for Disease Control and Prevention](#) have all put forth recommendations advocating the recognition of hepatitis C as a public health problem requiring public and provider awareness, an integrated prevention and treatment approach, and strong advocacy of one-time testing of all people born between 1945 and 1965 in addition to people with known risk of infection. Primary care providers can play a crucial role in each of these steps.¹

¹ <http://www.nachc.com/hepatitisc.cfm>

² <http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf>

³ <http://annals.org/article.aspx?articleid=1700384>

⁴ <http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf>

Hepatitis C: Who to Test

Most people infected with hepatitis C do not know they are infected. Chronic hepatitis C can lead to serious complications such as cirrhosis, liver cancer, and liver failure. The complications can be prevented through early detection, treatment, and lifestyle/behavioral changes. Serologic testing is the primary means for identifying persons with chronic hepatitis C infection.

Primary care providers play an important role in the national response to the hepatitis C epidemic, serving a population of more than 22 million, of whom approximately 25% were born during 1945-1965. The following outlines hepatitis C testing recommendations put forth by the Centers for Disease Control and Prevention (CDC).

Populations recommended for hepatitis C testing^{5, 6}

- Persons born from 1945 through 1965
- Persons who have ever injected illegal drugs (past or present), including those who injected only once many years ago
- Persons who have used illicit intranasal drugs
- Recipients of clotting factor concentrates made before 1987
- Recipients of blood transfusions or solid organ transplants before July 1992
- Patients who have ever received long-term hemodialysis treatment
- Persons with known exposures to HCV, such as
 - health care workers after needlesticks involving HCV-positive blood
 - recipients of blood or organs from a donor who later tested HCV-positive
- All persons with HIV infection
- Patients with signs or symptoms of liver disease (e.g., abnormal liver enzyme tests)
- Children born to HCV-positive mothers (to avoid detecting maternal antibody, these children should not be tested before age 18 months)

U.S. Preventive Services Task Force (USPTF) Recommends HCV Screening (Grade B)⁶

- One time screening of all adult born between 1945 and 1965, regardless of risk.
- Person of all ages at risk for HCV infection

The final USPSTF recommendations statement; evidence reports on screening, mother-to-infant transmission, and treatment; and the comparative effectiveness reports on screening and treatment can be viewed at:

<http://www.uspreventiveservicestaskforce.org/uspstf/uspshcpc.htm>

⁵ Centers for Disease Control and Prevention, Division of Viral Hepatitis
<http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#c1>

⁶USPTF Hepatitis C Screening Recommendations
<http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.pdf>



**SCREENING FOR HEPATITIS C VIRUS INFECTION IN ADULTS
CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

Population	Persons at high risk for infection and adults born between 1945 and 1965
Recommendation	Screen for hepatitis C virus (HCV) infection. Grade: B

Risk Assessment	The most important risk factor for HCV infection is past or current injection drug use. Additional risk factors include receiving a blood transfusion before 1992, long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures. Adults born between 1945 and 1965 are more likely to be diagnosed with HCV infection, either because they received a blood transfusion before the introduction of screening in 1992 or because they have a history of other risk factors for exposure decades earlier.
Screening Tools	HCV antibody testing followed by confirmatory polymerase chain reaction testing accurately identifies patients with chronic HCV infection. Various noninvasive tests with good diagnostic accuracy are possible alternatives to liver biopsy for diagnosing fibrosis or cirrhosis.
Screening Interval	Persons with continued risk for HCV infection (such as injection drug users) should be screened periodically. Evidence on how often screening should occur in these persons is lacking. Adults born between 1945 and 1965 and persons who are at risk because of potential exposure before universal blood screening need only be screened once.
Treatment	Refer to http://hcvguidelines.org/ for the most up-to-date treatment recommendations.
Balance of Benefits and Harms	On the basis of the accuracy of HCV antibody testing and the availability of effective interventions for persons with HCV infection, the USPSTF concludes that there is a moderate net benefit to screening in populations at high risk for infection. The USPSTF concludes that there is also a moderate net benefit to 1-time screening in all adults in the United States born between 1945 and 1965.
Other Relevant USPTF Recommendations	The USPSTF has made recommendations on screening for hepatitis B virus infection in adolescents, adults, and pregnant women. These recommendations are available at http://www.uspreventiveservicestaskforce.org/ .

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statements, and supporting documents, please go to <http://www.uspreventiveservicestaskforce.org/>

USPTF and Implications of the Testing Recommendations

What is the US Preventive Services Taskforce?

The U.S. Preventive Services Task Force (USPSTF) is an independent panel of clinical experts established by Congress to evaluate and make recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms. USPSTF recommendations only address services offered in the primary care setting or services referred by a primary care clinician.

The USPSTF grades recommendations based on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF assessment does not consider service provision costs. The table below summarizes the USPSTF grades and their implication for clinical practice.

A grade of 'A' indicates that the evidence suggests with a high degree of certainty that the recommendation is of substantial net benefit and USPSTF recommends providing the services. A grade of 'B' indicates that the evidence suggests with a high degree of certainty that the

USPSTF MISSION

To improve health by making evidence-based recommendations about clinical preventive services such as :

- Screenings
- Counseling services
- Preventive medicine

USPSTF Grades Definitions & Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	Recommended	Offer/provide the service.
B	Recommended	Offer/provide the service.
C	Recommended depending on patient situation	Offer/provide the service for selected patients depending on individual circumstances.
D	Not recommended	Discourage the use of the service.
I	There is not enough evidence to make a recommendation	Review the clinical considerations of the service in the USPSTF statement. If the service is offered, patients should understand about the balance of benefit and harm.

recommendation is of moderate net benefit or with a moderate degree of certainty that the recommendation is of moderate to substantial net benefit. The USPSTF recommends providing 'B' grade services. A grade of 'C' indicates that the evidence suggests with moderate certainty that the net benefit is small; therefore the USPSTF recommends selectively offering the service to individual patients based on professional judgment and

patient preferences. A grade of 'D' indicates that the evidence suggests with a moderate or high degree of certainty that the service has no net benefit or that the harms outweigh the benefits

and the USPSTF recommends against the service. A grade of ‘I’ indicates that the evidence is insufficient to assess the balance of benefits and harms. Evidence may be lacking, of poor quality or conflicting. If the services are offered, it is important that the patient understand the uncertainty about the balance of benefits and harms.

USPSTF Level of Certainty Regarding Net Benefit	
Level of Certainty	Description
High	Available evidence includes consistent results from well-designed, well-conducted studies in representative primary care populations that assess the effects of the preventive service on health outcomes. Conclusions are unlikely to be affected by future studies.
Moderate	Available evidence is sufficient to determine effects of the preventive service on health outcomes, but confidence is limited. As more information becomes available, the observed effects could change and alter conclusions.
Low	Available evidence is insufficient to assess effects on health outcomes.

What are the Implications of USPSTF Recommendations?

1

- The Patient Protection and Affordable Care Act (ACA) requires non-grandfathered, private health plans to cover clinical preventive services given a grade A or B by the USPSTF without cost sharing. It also provides incentives for Medicaid programs to cover these services.

2

- ACA prohibits insurance companies from declining to sell or renew policies because of preexisting conditions such as chronic HCV infection.

3

- The Center for Medicare and Medicaid Services (CMS) is allowed to add coverage of “additional preventive services” if certain statutory requirements are met including a grade 'A' or 'B' recommendation by the US Preventive Services Taskforce.



September 2013, CMS initiated a National Coverage Analysis (NCA) on screening for HCV in Adults. Public comment October 2013 solicited clinical studies and other scientific information that provide evidence for improvement in short and long term outcomes related to this screening service.

A proposed decision memo is expected by March 2014.

For more information visit:

[NCA Tracking Sheet for Screening for HCV in adults \(CAG-00436N\)](#)

Overview of Hepatitis C Screening, Diagnosis and Referral

Testing for hepatitis C infection is a **two-step process**, involving an initial hepatitis C screening test, which detects hepatitis C antibodies in the blood, followed by a hepatitis C diagnostic test, which detects the presence of hepatitis C virus (HCV) in the blood. See Sections 8 and 9 for an overview of a CDC recommended testing sequence for identifying current hepatitis C virus infection and interpretation of test results.

Primary care providers can play an important role in each of these steps: promoting the initial offer to screen, reinforcing the importance of obtaining a diagnostic test, and assisting in preparing the patient for follow-up care and possible treatment.

Step 1

- Hepatitis C Screening Test: detection of HCV antibodies

Step 2

- Hepatitis C Diagnostic Test: detection of HCV virus

Referral

- Evaluation & Monitoring
- Care and Treatment

Hepatitis C Screening Test: detection of HCV antibodies

Initial testing for HCV infection should begin with an FDA approved test for HCV antibody, either a rapid or a laboratory conducted assay for HCV antibody. Tests are reported as reactive or nonreactive. HCV infection can be detected by anti-HCV screening tests (enzyme immunoassay) 4-10 weeks after infection. Anti-HCV can be detected in more than 97% of persons 6 months after exposure.

- A **nonreactive** HCV antibody result indicated that no HCV antibody detected. No further testing is needed, unless there is suspicion of recent exposure. **NOTE:** If the person is immunocompromised, testing for HCV RNA may be considered.
- A **reactive** HCV antibody result indicates one of the following: 1) current HCV infection; 2) past HCV infection that has resolved; or 3) false positivity, meaning the person was never infected. A **reactive** HCV antibody result should be followed by testing for HCV viremia using nucleic acid testing for HCV RNA in order to confirm current/active hepatitis C infection. Patients should presume they are infected until they have the hepatitis C diagnostic testing done.

Hepatitis C Diagnostic Test: detection of HCV virus

A reactive anti-HCV test result should be followed by an FDA-approved nucleic acid test assay intended for detection of HCV RNA in serum or plasma from blood of at-risk patient. Either quantitative or qualitative HCV RNA tests can be used to confirm active infection.

- If HCV RNA is **detected**, results indicate current HCV infection.
- If HCV RNA is **not detected**, results indicate either past, resolved infection or false HCV antibody positivity.

Regardless of serology for HCV antibody, patients with detectable HCV RNA should be considered to have active HCV infection and should be referred for further medical evaluation.

Refer to Section 5, "Interpretation of Results of Tests for Hepatitis C Virus Infection and Further Actions," for additional information.

Counseling Messages for Screening Test Results

All patients should be provided information on the meaning of their test results:

For a non-reactive hepatitis C screening test:

- Explain the meaning of the non-reactive antibody test, ensuring that the patient understands a negative antibody test does not protect him/her from future infection in the event of risk-taking behaviors.
- Discuss that if the patient was recently exposed (6 months), he/she may be in a window period and recommend repeat screening in 6 months, and provide information on hepatitis C prevention, risk and harm reduction.
- Encourage the patient to make healthy choices and to get vaccinated against hepatitis A and B, if appropriate.

For a reactive hepatitis C screening test:

- Explain the meaning of the reactive antibody test and counsel on the need for diagnostic testing (hepatitis C RNA test) to confirm a diagnosis of chronic hepatitis C.
- Explain that the patient is most likely chronically infected and provide basic hepatitis C disease and treatment information.
- Discuss the importance of minimizing risk behaviors to avoid transmitting hepatitis C infection to others, and encourage notification and screening of needle sharing and sexual partners.
- Discuss healthy liver practices, including stopping or reducing alcohol intake and getting vaccinated against hepatitis A and B, if appropriate.
- Encourage the patient to make these healthy choices, and describe the importance of regular medical care.

Management of Persons with Hepatitis C Infection

CDC recommends that all persons identified with HCV infection should receive:

- A brief alcohol screening and intervention as clinically indicated; and
- Referral to appropriate care and treatment services for HCV infection.

While patients identified with chronic hepatitis C infection should be referred to a provider experienced in treating hepatitis C, there is often a delay before the patient can be seen. Primary care providers can play a crucial role in facilitating ongoing medical care and helping prepare patients for treatment, if appropriate.

Engage a referent specialist in developing a plan for the patient while waiting for the referral appointment. Furthermore, primary care providers can assist in identifying and addressing any existing mental health or alcohol/substance abuse issues following diagnosis so these conditions are well controlled prior to initiation of treatment. The table below outlines recommended additional testing and management in which primary providers may be involved.

For the most updated recommendations on testing, management and treatment of hepatitis C, please visit <http://www.hcvguidelines.org>.

Laboratory tests

Liver Health/HCV-related Assessments	Basic Health Assessments
<ul style="list-style-type: none"> - ALT, AST, total and direct bilirubin, albumin - Prothrombin time, including INR - HAV and HBV - Quantitative HCV RNA, HCV genotype 	<ul style="list-style-type: none"> - CBC - Creatinine and GFR - Glucose or hemoglobin A1c - TSH - HIV

Management

Patient Counseling	Clinical Management
<ul style="list-style-type: none"> - Preventing HCV transmission - HCV antibodies are not protective - Avoid alcohol - Avoid illicit drugs - Avoid new medicines, including over-the counter and herbal agents, without first checking with their healthcare provider - Maintain a healthy diet and lose weight if necessary - Sources of support (e.g., social, emotional, financial) 	<ul style="list-style-type: none"> - HAV and HBV vaccinations - Comorbidity management (depression, diabetes, and hypertension) - Ophthalmoscopic exam (for interferon-based therapies) - Medication assessment (for any products that may harm the liver)

[AASLD Practice Guidelines](#)

For the most updated recommendations on testing, management and treatment of hepatitis C, please visit <http://www.hcvguidelines.org>

Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
HCV antibody nonreactive	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required. If recent exposure in person tested is suspected, test for HCV RNA.*
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations,‡ follow up with HCV RNA testing and appropriate counseling.

* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

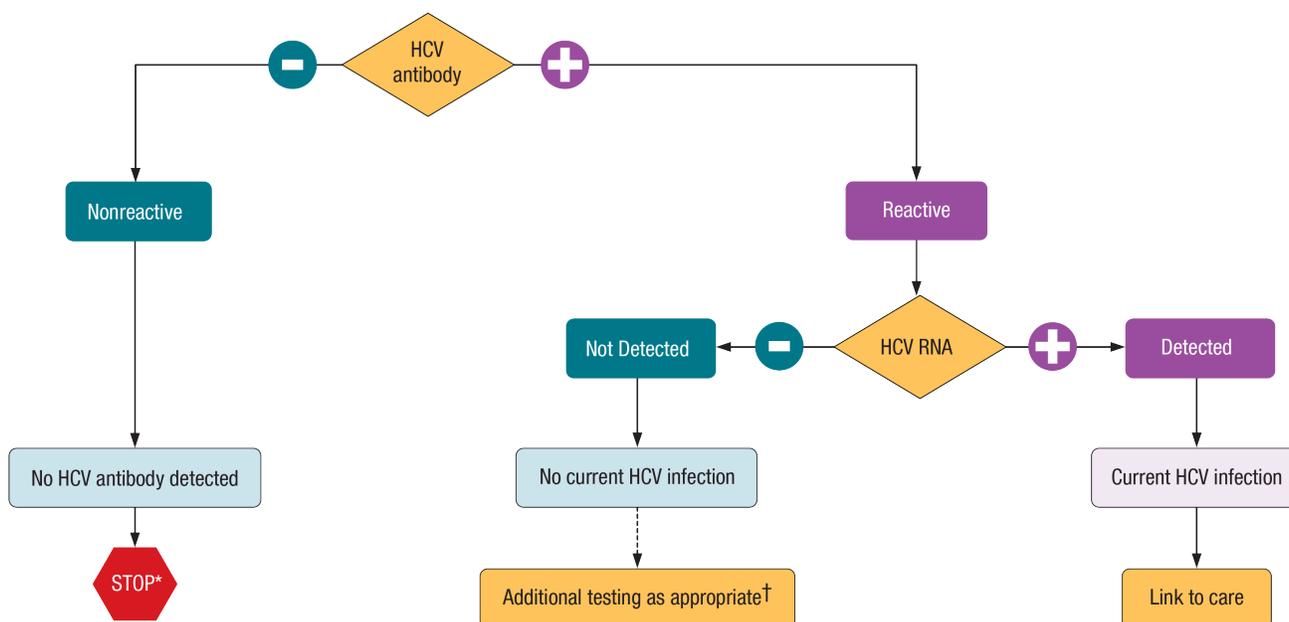
‡ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Testing For Hepatitis C Viral Infections:

FREQUENTLY ASKED QUESTIONS

In May 2013, the Centers for Disease Control and Prevention released [Testing for HCV Infections: An Update of Guidance for Clinicians and Laboratorians](#). The updated guidelines emphasize identifying persons with current hepatitis C virus (HCV) infections and incorporate recent changes in the availability of certain commercial HCV antibody tests. The new recommended testing sequence includes an initial test with an FDA-approved test for HCV antibodies, followed by an FDA-approved diagnostic nucleic acid test (NAT) intended for the detection of HCV RNA in serum or plasma if the initial HCV antibody test is reactive (Figure 1). This document intends to provide answers to some frequently asked questions regarding the recommended testing sequence and outlines FDA-approved diagnostic HCV RNA tests (Table 1).

Figure 1: Recommended testing sequence for identifying current HCV infection¹



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

1 <http://www.cdc.gov/hepatitis/hcv/labtesting.htm>

FREQUENTLY ASKED QUESTIONS

- 1. Our laboratory's requisition specifies HCV antibody testing and HCV RNA testing as separate tests. Is the clinician required to order both types of tests in order for the laboratory to perform the full algorithm?** If the requisition specifies antibody testing only, it may be necessary for the clinician to order an HCV RNA test, as needed. A reflex option for an RNA test may be offered for positive antibody tests. Laboratories are encouraged to review their requisition process and consider revising the test menu to indicate HCV diagnostic testing without specifying the type of test.
- 2. The new algorithm begins with an HCV antibody test. Can a rapid test that detects HCV antibodies be used for this step?** Yes, a test that has been approved by the FDA to screen for HCV antibodies for diagnostic purposes may be used for the HCV antibody test step at the beginning of the algorithm. This may be an FDA-approved HCV rapid test or a conventional HCV antibody immunoassay. If the laboratory receives an appropriate specimen from a patient who has already tested reactive on a rapid test, no additional testing to confirm antibodies is needed. A suitable specimen may be submitted directly for RNA testing to determine current infection status.
- 3. In the past, laboratories were encouraged to report the signal-to-cutoff ratios from laboratory-based HCV enzyme immunoassays (IA). Should laboratories continue to report signal-to-cutoff ratios?** The signal-to-cutoff ratio is not needed to interpret results in the newly recommended testing sequence. However, package inserts for some HCV IAs may recommend reporting signal-to-cutoff ratios. For information on reporting the signal-to-cutoff ratio, refer to the package inserts of assays and consider your jurisdiction's individual surveillance needs. Note: An HCV RNA test is indicated when an HCV IA test is reactive, regardless of signal-to-cutoff ratio.
- 4. The algorithm indicates that an HCV RNA test should be performed for all patients who have a reactive HCV antibody test result. Are laboratories allowed to reflex directly to the RNA test?** If the specimen submitted to the laboratory is acceptable for the HCV RNA test, the laboratory may reflex directly to the HCV RNA test. In some cases, a separate sample tube or a pristine aliquot may be submitted and processed for RNA testing if needed. If the original specimen is not suitable for RNA testing, or if insufficient volume remains, the laboratory should request another blood specimen and provide appropriate collection instructions. Laboratories may need to alter their requisition forms to include an option to specifically request an HCV RNA test or to reflex to HCV NAT following a positive antibody test according to the algorithm.
- 5. Can a quantitative HCV RNA test (i.e. a viral load test) be used in the HCV RNA test step of the algorithm?** Currently, available HCV quantitative RNA tests are approved by FDA for the management of patients undergoing antiviral therapy and should only be performed after a confirmed diagnosis of active HCV. Quantitative HCV RNA tests are not intended for diagnostic use, and any use in the diagnostic algorithm would be off-label. To use a quantitative HCV RNA test in the diagnostic algorithm, the laboratory must have performed an appropriate validation study. Quantitative HCV RNA tests should only be used after the

validation is completed or if a physician has specifically ordered the test.

6. **If the laboratory performs HCV antibody testing on serum specimens, can the same serum specimen be used for the HCV RNA test step?** Laboratories must adhere to the specimen collection, processing and storage criteria for the RNA test as approved by the FDA. Specimens must be handled with care to minimize the chance of cross contamination. If serum is an acceptable specimen type listed in the package insert, then it may be used.
7. **What testing should be recommended if an individual has a reactive HCV antibody test, but the HCV RNA test is negative?** If the HCV antibody test is reactive, but HCV RNA is not detected, the laboratory should report the results with an interpretation of “HCV RNA not detected.” The laboratory may recommend further actions that include re-testing with a different HCV antibody test, repeat testing if the person may have had a recent (within 6 months) exposure or has clinical evidence of HCV disease.

Table 1: FDA Approved Diagnostic HCV RNA Tests

	Test Name	Manufacturer	Intended Use	LOD/LLOQ	Specimen Type
Qualitative HCV RNA Tests	VERSANT HCV RNA Qualitative Assay/APTIMA HCV RNA Qualitative Assay	Gen-Probe	Diagnostic	7.5 IU/mL (genotype 1) 9.6 IU/mL overall	Serum or plasma (EDTA, sodium heparin, sodium citrate, and ACD)
	COBAS Amplicor HCV Test, v2.0 and COBAS AmpliPrep/COBAS Amplicor HCV Test, v2.0	Roche	Diagnostic	100 IU/mL	Serum or plasma (EDTA)
	AMPLICOR HCV Test, v2.0	Roche	Diagnostic	50 IU/ml	Serum or plasma (EDTA)
Quantitative HCV RNA Tests	Abbott RealTime HCV	Abbott	Aids in the management of HCV-infected patients undergoing antiviral therapy	12/12 IU/mL	Serum and plasma (EDTA)
	COBAS AmpliPrep/COBAS TaqMan HCV Test and COBAS TaqMan HCV Test For Use With The High Pure System	Roche	Aids in the management of HCV-infected patients undergoing antiviral therapy	15/15 IU/mL 20/25 IU/mL	Serum and plasma (EDTA)
	VERSANT HCV RNA 3.0 bDNA	Siemens	Aids in the management of HCV-infected patients undergoing antiviral therapy	LOD 988 (340 system) 1,100 IU/mL (440 system) Detection Cutoff 615 IU/mL	Serum and plasma (EDTA, ACD)

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Coding Guide for HCV Screening and Diagnosis

Coverage and actual dollar reimbursements often vary among insurers, as well as a patient's individual insurance plan. The actual reimbursement may also depend on whether or not the patient has met his or her annual deductible.

Below are some guidelines for seeking reimbursement for hepatitis C screening and diagnosis.

Appropriate Current Procedure Terminology (CPT) and International Classification of Diseases (ICD) codes are required for each claim submission for the performance of a hepatitis related test.

CPT Codes		
86803	Hepatitis C antibody	Testing Codes
86804	Hepatitis C antibody; confirmatory test (e.g., immunoblot or RIBA)	
87520	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, direct probe technique	
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique	
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, quantification	
87533	Quantitative PCR	
90201-99205	Office or outpatient visit for the evaluation or management of a new patient	E & M Codes
36415	Collection of venous blood by venipuncture	

CPT copyright 2008 American Medical Association. All rights reserved.¹

ICD-9 Diagnosis Codes	
V01.7	Contact with or exposure to communicable diseases, other viral diseases
V05.3	Need for prophylactic vaccination and inoculation against single disease: viral hepatitis
V69.2	High-risk sexual behavior
571.8	Other chronic nonalcoholic liver disease
571.9	Unspecified chronic liver disease without the mention of alcohol
070.51	Acute hepatitis c without hepatic coma
070.54	Chronic hepatitis C without hepatic coma
070.7	Unspecified viral hepatitis C
070.70	Unspecified viral hepatitis C without hepatic coma



ICD-9 code will be transitioning to ICD-10 by October 2014.

For more information visit:

<http://www.cdc.gov/nchs/icd/icd1>

¹ Adapted from the California Department of Public Health

Persons in these groups are at risk for hepatitis A virus or B virus infection and should be vaccinated:

Hepatitis A high-risk groups

- Men who have sex with men.
- People with chronic liver disease, including people with hepatitis B and hepatitis C
- Illicit drug users
- People with clotting-factor disorders
- Children living in areas with historically high rates of hepatitis A infections (see www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_a/slide_40.htm)
- People who work with hepatitis A virus in experimental lab settings (not routine medical laboratories)
- People who travel outside of the U.S. (except for Western Europe, New Zealand, Australia, Canada and Japan)
- Food handlers when health authorities or private employers determine vaccination to be cost effective

Hepatitis B high-risk groups

- Men who have sex with men
- Household contacts and sex partners of HBsAg-positive persons
- Users of illicit injectable drugs
- Heterosexuals with more than one sex partner in six months
- People with recently diagnosed STDs
- Patients receiving hemodialysis and patients with renal disease that may result in dialysis
- Recipients of certain blood products
- Health care and public safety workers who are exposed to blood
- Clients and staff of institutions for the developmentally disabled
- Inmates of long-term correctional facilities
- Certain international travelers
- Immigrants/refugees from areas with high endemic rates of hepatitis B infection (Asia, Pacific Islands, Sub-Saharan Africa, Amazon Basin, Eastern Europe, Middle East)
- Asian and Pacific islanders (pre-vaccination screening may be appropriate)
- Adopted children from countries where hepatitis B is endemic (see above list)
- All adolescents

Resources

Centers for Disease Control and Prevention Hepatitis Home Page
www.cdc.gov/ncidod/diseases/hepatitis/index.htm

American College of Gastroenterology:
Chronic Liver Disease: A Primer on Vaccinations
www.acg.gi.org/physicianforum/publications/index.html

American Academy of Family Physicians:
Preventive Strategies in Chronic Liver Disease
www.aafp.org/afp/20011101/1555.html

National Institute of Health Consensus Statement –
Management of Hepatitis C: 2002
consensus.nih.gov/cons/116/116cdc_intro.htm

American Medical Association CPT Home Page
www.ama-assn.org/go/CPT

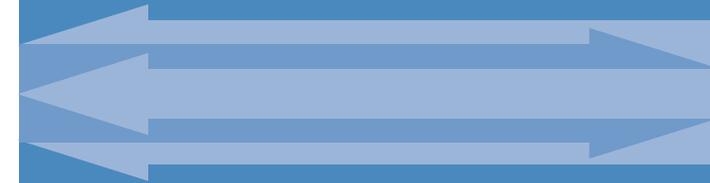
These guidelines were produced by the American Medical Association (AMA) to complement the Centers for Disease Control and Prevention outreach program to combat VPH in high-risk populations, such as men who have sex with men. Please visit the AMA Web site at www.ama-assn.org/go/infectious to download these materials.

Current Procedural Terminology (CPT®) is copyright 2003 American Medical Association. All Rights Reserved. This pamphlet contains selected codes for Hepatitis B vaccine procedures. For complete coding and guidelines, please always refer to AMA's *Current Procedural Terminology* (CPT®). CPT is a registered trademark of the American Medical Association



Coding Guidelines for Vaccine-Preventable Hepatitis (VPH)

High-risk populations, including men who have sex with men



Many insurers offer coverage for protection against vaccine-preventable hepatitis (VPH)—hepatitis A and hepatitis B—for high-risk populations, including men who have sex with men (MSM).

Coverage and actual dollar reimbursements often vary among insurers, as well as on the patient's individual insurance plan. The actual reimbursement may also depend on whether or not the patient has met his or her annual deductible and/or co-pay requirements.

Below are some guidelines for seeking reimbursement for immunization against VPH for high-risk patients. For answers to reimbursement questions on a patient-by-patient basis, contact the VACCRIX Reimbursement Hotline at 888-VACCRIX (888-822-2749). (Service underwritten by GlaxoSmithKline; information given regardless of the vaccine used.)*

Note: Medicaid and some state-administered programs for underserved patients may also cover protection against VPH for high-risk patients. Check with your individual state offices to determine the eligibility requirements and reimbursement policies in your area.

Appropriate coding for immunization against VPH

Appropriate CPT® and ICD-9 codes are required for each claim submission for the performance of an immunization against VPH. Even if immunization against VPH (along with other vaccinations) is considered a routine service by the insurer, appropriate coding will be required for payment.

* The use in this brochure of any company name or mention of any company product or service is for identification purposes only and does not imply endorsement by the American Medical Association.

CPT Codes

There are separate CPT codes for the vaccine product, for the administration of the vaccine and for patient evaluation and management services. AMA members may call 800-634-6922 for CPT coding advice.

90632	Monovalent hepatitis A vaccine for adult dosage	Vaccine Codes
90633	Monovalent hepatitis A vaccine for pediatric/adolescent use (2-dose schedule)	
90634	Monovalent hepatitis A vaccine for pediatric/adolescent use (3-dose schedule)	
90746	Monovalent hepatitis B vaccine for adult dosage	
90743	Monovalent hepatitis B vaccine for adolescent use (2-dose schedule)	
90745	Monovalent hepatitis B vaccine for pediatric use (3-dose schedule)	
90636	Combination hepatitis A/hepatitis B vaccine for adult dosage	
90740	Hepatitis B vaccine for dialysis or immunosuppressed patient (3-dose schedule)	
90747	Hepatitis B vaccine for dialysis or immunosuppressed patient (for 40 mcg dosing and 4-dose schedule)	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, intramuscular and jet injections), one vaccine (single or combination vaccine/toxoid)	Administration Codes
90472	Each additional vaccine (single or combination vaccine) List separately in addition to the code for primary procedure	
90201-99205	Office or outpatient visit for the evaluation or management of a new patient	E & M Codes

ICD-9 Codes

A number of ICD-9 diagnosis codes can be used to identify the VPH high-risk population. To protect the patient's confidentiality, you may wish to discuss using a code that indicates a specific risk factor/group with the patient prior to contacting the insurer.

V01.7	Contact with or exposure to communicable diseases, other viral diseases
V05.3	Need for prophylactic vaccination and inoculation against single disease: viral hepatitis
042	Human immunodeficiency virus (HIV) disease
V08	Asymptomatic HIV infection status
V69.2	High-risk sexual behavior
571.8	Other chronic nonalcoholic liver disease
571.9	Unspecified chronic liver disease without mention of alcohol
070.54	Chronic hepatitis C without mention of hepatic coma

Example with an HIV-positive patient: Most insurers cover immunization against VPH in an HIV positive patient because of the high risks and costs associated with VPH in these patients. To bill, use the ICD-9 diagnosis code to identify HIV (ICD-9 code 042) along with the appropriate CPT code (90747 for hepatitis B vaccine for immunosuppressed patient or 90632 for hepatitis A vaccine) plus the appropriate CPT administration code (90471 for immunization administration).

Example with an HIV-negative patient exposed to viral hepatitis: Insurers will consider payment for hepatitis A and B vaccines if a patient is exposed to hepatitis A or B but does not show signs of disease. To bill, use the ICD-9 diagnosis code for contact with or exposure to communicable disease, other viral diseases (ICD-9 code V01.7) along with the appropriate CPT code (90746 for hepatitis B vaccine or 90632 for hepatitis A vaccine) plus the appropriate CPT administration code (90471 for immunization administration).

If denied by the insurer

Contact the insurance company and request a review of the initial claim submission. Be sure to identify the appropriate high-risk population for your patient. An effective claim appeals letter will need to be developed if the telephone call to reverse the claim denial is unsuccessful.

Request a pre-treatment benefit verification before the immunization against VPH is to be incurred by a patient to reduce the number of instances when the insurance company will not cover the service. Once a claim is received and denied, it may take more effort to receive payment from the insurance company.

Note: None of the above information is a guarantee of coverage. All claims are subject to individual plan coverage, guidelines and the submission of the actual claim. There are also many variables that determine claim payment. Coverage and reimbursement amounts are specific according to the individual plan that a member or their employee has purchased, as well as the negotiated contract for each provider. Blanket statements regarding coverage may not be accurate and this information is intended as a guideline only.

Educational Resources for Medical Providers

CDC Division of Viral Hepatitis:

The Division of Viral Hepatitis (DVH) is part of the [National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention](#) at CDC. In collaboration with domestic and global partners, DVH provides the scientific and programmatic foundation and leadership for the prevention and control of hepatitis virus infections and their manifestations.

DVH consists of three branches — the Epidemiology and Surveillance Branch, the Prevention Branch, and the Laboratory Branch — that work collaboratively to prevent viral hepatitis infections and associated liver disease.

www.cdc.gov/hepatitis

CDC Morbidity and Mortality Weekly Report (www.cdc.gov/mmwr/)

This weekly report provides updated information on specific diseases as reported by state and territorial health departments. It is a good source for updated CDC recommendations, reports and other items of interest to the public health community.

The following link provides a shortcut to all of the Morbidity and Mortality Weekly reports (MMWR) that relate directly to viral hepatitis.

<http://www.cdc.gov/hepatitis/Resources/Professionals/MMWRs.htm>

CDC Advisory Council on Immunization Practices

(<http://www.cdc.gov/vaccines/acip/recs/index.html>) develops written recommendations for the routine administration of vaccines to children and adults. A complete listing of these recommendations as well as the recommended immunization schedules can be found at the link below.

Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis

(<http://aids.gov/pdf/viral-hepatitis-action-plan.pdf>)

The 2014-2016 update for the Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis was released in April 2014. This Action Plan was developed across multiple Federal agencies, including the Department of Health and Human Services, Department of Justice, Department of Housing and Urban Development, and Veteran Affairs. This Action Plan aims to prevent new infections and improve the diagnosis, care and treatment of those living with chronic hepatitis C in the U.S.

A two-page fact sheet about the updated Viral Hepatitis Action Plan can be found at

<http://aids.gov/pdf/2014-vhap-at-a-glance.pdf>.

American Liver Foundation: Hep C 123 (<http://hepc123.com>) is an online resource center for hepatitis C created by the American Liver Foundation to provide information and resources to those affected by hepatitis C as well as educational resources for healthcare professionals.

Hepatitis C Education for Health Care Professionals (<https://www.cthervirus.com>) was created by AbbVie, Inc. to provide clinical information about hepatitis C infection.

Clinical Education, Guidelines and Resources:

AASLD Curriculum and Training (ACT) is an initiative through the American Association for the Study of Liver Disease to provide strategies and mentoring for managing HCV and is designed for health care professionals that are new to providing HCV care to their patients. This free course offers CME's and can be accessed at <http://www.aasld.org/act/Pages/default.aspx>.

Hepatitis C Online (<http://hepatitisc.uw.edu/>) is a free educational web site from the University of Washington. The site is a comprehensive resource that addresses the diagnosis, monitoring, and management of hepatitis C virus infection. It includes course modules, slide lectures, medical summaries of the latest hepatitis C treatments and several clinical calculators, including tools to screen and counsel around alcohol use (CAGE and Audit-C questionnaire).

A new section on **Medications to Treat HCV** is now available at <http://hepatitisc.uw.edu/page/treatment/drugs>. Free CME and CNE credits are available.

Hepatitis Web Study (<http://depts.washington.edu/hepstudy/>) provides free interactive, case-based modules related to the clinical care of persons with viral hepatitis developed by the Seattle STD/HIV Prevention Training Center and the University of Washington. This site is intended for healthcare workers involved with the care of patients at risk for infection with hepatitis.

The CHB Treatment Guideline Navigator (<http://www.chbnavigator.com/>) offers an Online Interactive Review of current treatment guideline recommendations from the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) on testing, treatment, and monitoring of chronic hepatitis B and downloadable summary sheets for providers who care for patients at risk for, or infected with hepatitis B. CME/CE are available.

Clinical Care Options (<http://www.clinicaloptions.com/Hepatitis.aspx>)

Experts in the development of interactive medical education programs for healthcare professionals create and publish original CME and information resources that translate the latest developments in science and medicine to clinically useful information.

American Association for the Study of Liver Diseases

(<http://www.aasld.org/practiceguidelines/Pages/guidelinelisting.aspx>)

AASLD is a nonprofit, member organization for physicians and others striving to prevent and cure diseases of the liver. AASLD develops clinical practice guidelines, based on a formal review and analysis of relevant published data to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

AASLD – IDSA Recommendations for Testing, Managing and Treating Hepatitis C

(<http://www.hcvguidelines.org/>)

The Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management to provide healthcare professionals with timely guidance, as new therapies are available and integrated into HCV regimens. This Guidance should be considered a "living document" in that new sections will be added and updated frequently as new information and treatments become available.

Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment

(PREP-C) (<https://prepc.org/>) is a free interactive online tool that enables you to provide a thorough assessment of a patient's psychosocial readiness to begin hepatitis C treatment, and make a treatment plan to improve treatment readiness.

Center Watch: Clinical Trials Listing Service

(<http://www.centerwatch.com/patient/studies/cat79.html>)

This website offers a state by state listing of clinical trials for viral hepatitis.

HIV and Hepatitis (<http://www.hivandhepatitis.com>) provides information on HIV and viral hepatitis sponsored by pharmaceutical companies. The focus is on clinical issues related to HIV, viral hepatitis, and co-infection.

Harm Reduction Journal (<http://www.harmreductionjournal.com/home>) is an open access, peer-reviewed, online journal whose focus is prevalent patterns of psychoactive drug use, the public policies meant to control them, and the search for effective methods of reducing the adverse medical, public health, and social consequences associated with both drugs and drug policies.

Hepatitis Foundation International (<http://www.hepfi.org>) educates the public and healthcare providers about viral hepatitis and its prevention, diagnosis, and treatment. Educational videos and other resources are available. HFI offers a free discount prescription drug card, "*Hepatitis Foundation International Health Savings Card*," with discounts of roughly 30% in select pharmacies nationwide.

Patient Resources

Centers for Disease Control and Prevention, Division of Viral Hepatitis: Patient Education Resources (<http://www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm>)

CDC Know More Hepatitis

Know More Hepatitis is a joint project of the NCHHSTP and the CDC Foundation to increase awareness of viral hepatitis and promote screening for viral hepatitis. The site offers a wealth of materials to support community awareness, including an online risk assessment, fact sheets, buttons, badges, and posters.

<http://www.cdc.gov/KnowMoreHepatitis/> (Hepatitis C)

<http://www.cdc.gov/knowhepatitisb/> (Hepatitis B)

Hepatitis C Support Project (www.hcvadvocate.org)

The Hepatitis C Support Project (HCSP) is a registered non-profit organization founded in 1997 by Alan Franciscus and other HCV-positive individuals to address the lack of education, support, and services available at that time for the HCV population. HCSP's mission is to provide unbiased information, support, and advocacy to all communities affected by HCV and HIV/HCV coinfection, including medical providers.

American Liver Foundation (<http://www.liverfoundation.org/>)

This website provides information on liver diseases, advocacy for education, treatment and research funding.

Hepatitis C Caring Ambassadors (<http://www.hepcchallenge.org/>)

The Hepatitis C Caring Ambassadors Program mission is to improve the lives of people living with hepatitis C, through information and awareness.

Harm Reduction Coalition (<http://www.harmreduction.org/>)

The website offers a variety of tools and resources that reflect the most current and innovative information on methods for reducing drug related harm, including brochures, fact sheets, manuals, posters, training curricula, videos, bulletins and podcasts that span all aspects of harm reduction.

Help 4 Hep (<http://help4hep.org/>) is a free helpline for those with concerns and questions about hepatitis C. The toll-free number for Help4Hep is **1-877-Help-4-Hep** (1-877-435-7443)

Center Watch (<http://www.centerwatch.com/>) offers a state by state listing of clinical trials for viral hepatitis.

Patient Advocate Foundation Co-Pay Relief (<http://www.copays.org/diseases/hepatitis-c>) is a patient assistance program that may be helpful for those in need of financial assistance for hepatitis C care and treatment.

Hepatitis C Guide: Forward Motion (<https://www.hepcinfo.com/>) was created by AbbVie, Inc. to provide hepatitis C educational information and resources for patients.

Hep C 123 (<http://hepc123.com/>) is an online resource center for hepatitis C created by the American Liver Foundation to provide information and resources to those affected by hepatitis C.