Hepatitis C Testing and Treatment

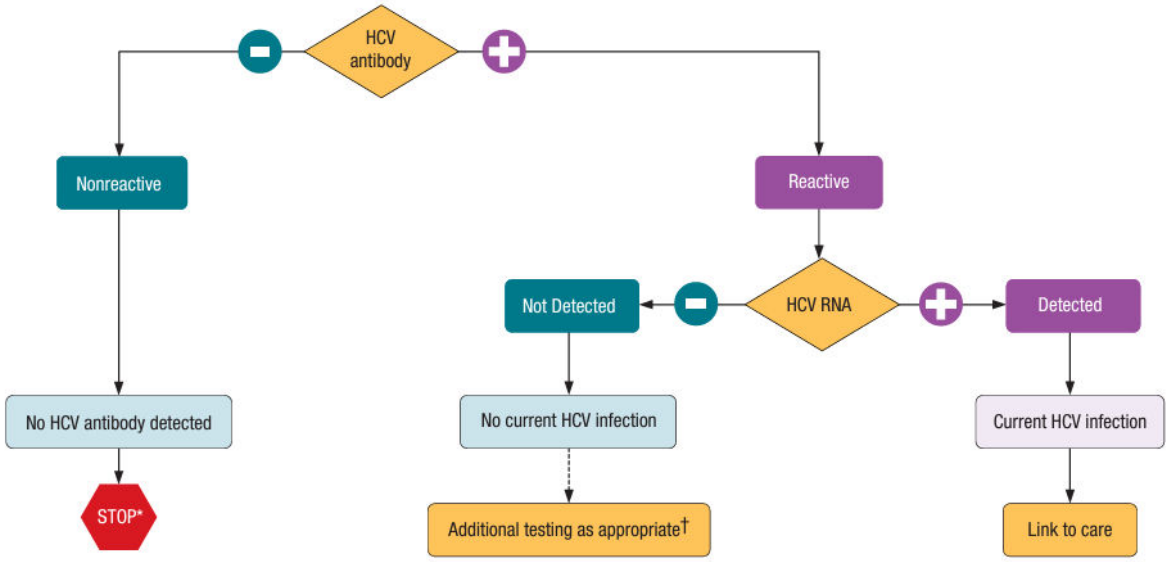
Adult Care Guideline – USPSTF Level B

Approved: Ambulatory QAPI 3/32/2024

Summary of the rational for testing for Hepatitis C

The United States Preventive Task Force (USPSTF) recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years. In the absence of risk factors (for example patients with past or current injection drug use) the recommendation is for one time screening. The current recommendation is based on the conclusion by the USPSTF that in adults aged 18-79 there is substantial net benefit. Currently recommended direct-acting antiviral (DAA) regimens are associated with fewer harms than older interferon containing therapies, they have a shorter duration of treatment (8-12 weeks), and evidence shows a sustained virologic response (>95%) in adults aged 18-79 to these therapies. Further, this response is associated with improved health outcomes of decreased risk for all-cause mortality, mortality to liver disease, cirrhosis and hepatocellular carcinoma. (1).

Testing algorithm



* 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.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

(2)

Current Management Guidance and Key Recommendations (4)

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Complicated or complex cases of HCV should be treated by the appropriate specialist. For noncomplicated Hepatitis C, a simplified HCV treatment is available for treatment-naïve adults without cirrhosis. Assessment and treatment as well as eligibility and exclusion are listed below:

Who Is Eligible for Simplified Treatment
Adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment

Who Is *NOT* Eligible for Simplified Treatment (Without Cirrhosis)
Patients who have any of the following characteristics: • Prior hepatitis C treatment • Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis) • HBsAg positive • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation (see HCV guidance for treatment recommendations for these patients)

Pretreatment Assessment*

- Calculate FIB-4 score.
- **Cirrhosis assessment:** Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 **or** any of the following findings from a previously performed test.
    - Transient elastography indicating cirrhosis (eg, FibroScan stiffness >12.5 kPa)
    - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (eg, FibroSure, Enhanced Liver Fibrosis Test, etc)
    - Clinical evidence of cirrhosis (eg, liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm^3, etc)
    - Prior liver biopsy showing cirrhosis
- **Medication reconciliation:** Record current medications, including over-the-counter drugs and herbal/dietary supplements.

- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
    - Drug-drug interactions are particularly important in HIV co-infection
    - In those with HIV, the simplified treatment approach should not be used in those on TDF containing regimens with eGFR <60 ml/min because of the need of additional monitoring.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.
- **Pretreatment laboratory testing:**
    - *Within 6 months of initiating treatment:*
        - Complete blood count (CBC)
        - Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], aspartate aminotransferase [AST])
        - Calculated glomerular filtration rate (eGFR)
    - *Any time prior to starting antiviral therapy:*
        - Quantitative HCV RNA (HCV viral load)
        - HIV antigen/antibody test
        - Hepatitis B surface antigen
    - *Before initiating antiviral therapy*:
        - Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

Recommended Regimens*

- Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks
- Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

On-Treatment Monitoring

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

Post-Treatment Assessment of Cure (SVR)

- Assessment of quantitative HCV RNA and a hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

Follow-Up After Achieving Virologic Cure (SVR)

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (eg, intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Advise patients to avoid excess alcohol use.

Follow-Up for Patients Who Do *Not* Achieve a Virologic Cure

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- Until retreatment occurs, assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Advise patients to avoid excess alcohol use

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ECU HEALTH

Resources:

From https://www.hcvguidelines.org/treatment-naive/simplified-treatment HCV Guidance: Recommendations for Testing Managing and Treating Hepatitis C by IDSA (Infectious Diseases Society of America) and AASLD (American Association for the Study of Liver Diseases) accessed 03/06/2024

Current treatment recommendations may also be accessed at:

https://www.hcvguidelines.org/treatment-naive

https://www.dynamedex.com/management/hepatitis-c-treatment-of-genotype-1 and

https://www.dynamedex.com/management/hepatitis-c-treatment-of-genotypes-2-6

Further References cited:

(1) From: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening#bootstrap-panel--6 accessed 03/06/2024

(2) From: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf accessed 03/06/2024

(3) Maness D, Riley E, AND Studebaker G, Hepatitis C: Diagnosis and Management, *Am Fam Physician.* 2021; 104(6):626-635

(4) From https://www.hcvguidelines.org/treatment-naive/simplified-treatment HCV Guidance: Recommendations for Testing Managing and Treating Hepatitis C by IDSA (Infectious Diseases Society of America) and AASLD (American Association for the Study of Liver Diseases)