

	State of Indiana Indiana Department of Correction	Effective Date	Page 1 of	Number
HEALTH CARE SERVICES DIRECTIVE-ADULT Manual of Policies and Procedures		4/1/2022	8	3.04A

Title MANAGEMENT OF HEPATITIS C

Legal References (includes but is not limited to)	Related Policies/Procedures (includes but is not limited to)	Other References (includes but is not limited to)
Indiana Code: 11-8-2-5 11-8-5-2 11-10-1-2	01-02-101	National Correctional Healthcare Standards

I. PURPOSE:

The purpose of this Health Care Services Directive (HCSD) is to provide information and guidelines concerning the management of Hepatitis C Virus (HCV) infections.

II. GUIDELINES:

A. General Information

HCV is the most common chronic bloodborne viral infection in the United States and correctional facilities have a disproportionate number of infected individuals. Within the Department, approximately 15-20% of arriving incarcerated individuals at Intake are HCV-Antibody positive.

HCV is spread by contact with infected blood and blood products from a person living with HCV (PLWHCV). Currently, the majority of PLWHCV become infected by sharing needles or other equipment used in injectable drugs. Other common risk factors include receiving a blood transfusion prior June 1992, receiving clotting factor concentrates before 1987, hemodialysis, birth to an HCV-infected mother, tattooing and suffering a needle-stick accident from a person with HCV. However, some individuals who acquire HCV have no known risk factors.

Hepatitis C Virus can be acute or chronic.

Acute HCV can present clinically with a discrete onset of fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and/or abdominal pain; and,

1. jaundice;

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2. Peak elevated bilirubin levels greater than or equal to 3.0 mg/dl;
3. a peak elevated serum alanine aminotransferase (ALT) level greater than 200 IU/L during the period of acute illness; and,
4. The absence of a more likely diagnosis which may include evidence of acute liver disease due to other causes of advanced liver disease due to pre-existing chronic hepatitis C or other causes, such as alcohol exposure, other viral hepatitis hemochromatosis, etc.

Laboratory criteria for an acute probable HCV diagnosis includes a positive/reactive test for antibodies to Hepatitis C virus (anti-HCV). An acute confirmed HCV diagnosis includes a positive Hepatitis C virus detection test. These tests could also be utilized to determine an acute confirmed case (e.g., Nucleic Acid Test [NAT] for HCV RNA positive [including qualitative, quantitative, or genotype testing]).

The Centers for Disease Control and Prevention (CDC) report that half of the PLWHCV will clear the virus spontaneously. In at least two-thirds of patients who spontaneously clear acute HCV infection, this occurs within 6 months of the estimated time of infection. Only 11% of those who remain viremic at 6 months will spontaneously clear the infection at a later time. Thus, detectable HCV RNA at 6 months after the time of infection may signify chronic HCV. Once established, the chronic infection rarely resolves spontaneously. The clinical course of HCV varies greatly; some individuals have no signs or symptoms and normal levels of serum enzymes, some have mild to moderate elevations in liver enzymes with an uncertain prognosis, and some have severe disease with symptoms, high viral load, and elevated serum enzymes.

The standard of care for HCV treatment is with direct acting virals and in some cases may require the use of interferon, peginterferon, ribavirin or any HCV direct-acting antiviral agents (DAA). Antiviral medication regimen choice should be determined based on patient-specific data, including drug-drug interactions. Patients receiving antiviral therapy require careful pretreatment assessment for comorbidities that may influence treatment response or reactivate hepatitis B infection. All patients require careful monitoring during treatment.

Another component of treatment for PLWHCV is substance use treatment. In accordance with HCSD 4.01, "Addiction Recovery Services", all patients newly diagnosed with Hepatitis C (that is, the diagnosis was made after the patient was committed to the Department) or the patient currently being treated for Hepatitis C shall be referred for substance abuse assessment by Unit Team personnel. Newly diagnosed patients shall be referred for substance abuse assessment within fourteen (14) days of diagnosis date.

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B. Screening for HCV Infection

In accordance with the provisions of HCSD 2.02 , “Reception Screening,” after an incarcerated individual arrives at an Intake site, the incarcerated individual must complete State Form 45999, “Offender Health History.” This is a directed screening history designed to identify serious health conditions, and to provide staff with information that will be useful in managing and anticipating serious health conditions. The health history should be completed after the Point of Entry screening and prior to or during the Arrival Health Screening completed with Health Services staff.

All incoming and returning incarcerated individuals shall have mandatory Hepatitis C antibody testing completed in accordance with State statute.

Initial testing with an HCV RNA test is recommended for cases with a known prior positive HCV Ab if they are at risk for reinfection or suspected of reinfection, and if they previously cleared the HCV spontaneously or achieved a sustained virologic response with treatment.

Patients who decline testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventative health visits. A treatment refusal form must be completed for every testing and treatment refusal.

C. Baseline Evaluation

Initial evaluation of anti-HCV positive patients shall include, but is not limited to the following:

1. A baseline history and physical examination within the first ninety (90) days with emphasis on evaluation for other possible causes of liver disease and inquiry regarding prior treatment and testing for HCV infection;
2. Baseline laboratory tests within the first ninety (90) days;
3. Assessment regarding the need for preventative health interventions, such as vaccines, and screenings for other conditions;
4. Counseling with information on HCV infection;
5. Enrollment in HCV Chronic Care Clinic; and,
6. An attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped.

All positive HCV labs and new HCV diagnoses shall be reported to authorities at Indiana Department of Health (IDOH).

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III. MANAGEMENT OF HCV:

All PLWHCV, regardless of liver inflammation, shall be counseled regarding HCV disease. This counseling shall include information on HCV infection, transmission, avoiding transmission, the nature of the HCV disease, its long-term sequelae, and the pros and cons of the treatment for HCV disease.

All PLWHCV shall be offered vaccination against Hepatitis B and Hepatitis A, unless previous infection or vaccination has been documented, or the attending physician believes that vaccination is unnecessary or contraindicated. All PLWHCV disease shall be offered vaccination against pneumococcus once, and against influenza annually. Any refusals shall be signed and scanned into the patient's health record.

Informed consent for treatment must be obtained prior to initiating treatment in accordance with HCSD 2.12, "Consent and Refusal."

A. Acute Hepatitis C Monitoring and Management

This section provides guidance on the diagnosis and medical management of acute HCV infection, which is defined as presenting within six (6) months of the exposure

1. Counseling is recommended for PLWHCV acute infection to avoid hepatotoxic insults, including hepatotoxic drugs (e.g., acetaminophen) and alcohol consumption, and to reduce the risk of HCV transmission to others;
2. A referral to Addictions Recovery Services shall be completed;
3. Regular clinical monitoring, including routine laboratory testing, is recommended in the setting of acute HCV infection for six (6) months to determine spontaneous clearance versus persistence of HCV infection.

Laboratory monitoring should continue until the ALT level normalizes and HCV RNA becomes repeatedly undetectable, suggesting spontaneous resolution. If this does not occur, frequency of laboratory monitoring for patients with persistently detectable HCV RNA and elevated ALT levels should follow recommendations for monitoring PLWHCV as outlined in Section III, B.

B. Chronic Hepatitis C Treatment

All sentenced PLWHCV infection are eligible for consideration of treatment.

Certain cases are at higher risk for complications or disease progression and may require more urgent consideration for treatment. The Department has established

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a framework to ensure that patients with the greatest need are identified and treated. (AST PLATELET RATIO INDEX-APRI)

1. Treatment Group One
 - a. Advanced Hepatic Fibrosis
 - 1) APRI ≥ 1.5 , or;
 - 2) Metavir or Batts/Ludwig Stage 3 or 4 on liver biopsy, or as indicated by transient elastography; or,
 - 3) Known or suspected cirrhosis.
 - b. Liver Transplant Recipients
 - c. Hepatocellular Carcinoma (HCC)
 - d. Comorbid Medical Conditions Associated with HCV
 - 1) Cryoglobulinemia with renal disease or vasculitis;
 - 2) Certain types of lymphomas or hematologic malignancies; and,
 - 3) Porphyria cutanea tarda
 - e. Immunosuppressant Medication for a Comorbid Medical Condition

Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition but are not recommended for use when infection is present. Although data are insufficient and current guidelines are inconsistent regarding treatment of HCV in this setting, such cases shall be considered for prioritized treatment on an individual basis.
 - f. Continuity of Care for those already started on treatment, including patients newly incarcerated in the Department. These patients shall be immediately added to the HCV Comprehensive Log and reported to the Executive Director of Physical Health and the Department's Epidemiologist.

Recommended treatment for patients in Treatment Group One includes medications to treat chronic HCV and an Addictions Recovery Services referral. Patients in Treatment Group One shall be seen at minimum every thirty (30) days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for

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signs and symptoms of liver disease shall be completed each visit. Labs shall be obtained at least every thirty (30) days for monitoring purposes.

2. Treatment Group Two

Patients in Treatment Group Two have been identified as being at increased risk for liver disease, yet stable. This Group requires prompt consideration for treatment, including antiviral medications. Treatment groups are mutually exclusive, thus patients in Treatment Group Two would not possess any of the clinical indicators listed in Treatment Group One, but can possess one or more of the following:

- a. Evidence for Progressive Fibrosis
 - 1) APRI Score ≥ 0.7
 - 2) Stage 2 fibrosis on liver biopsy or as indicated by transient elastography
- b. Comorbid medical conditions associated with more rapid progression of fibrosis
 - 1) Coinfection with HBV or HIV
 - 2) Comorbid liver diseases (e.g., autoimmune, hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
 - 3) Diabetes mellitus
- c. Chronic Kidney Disease (CKD) with GFR ≥ 59 ML/min per 1.73 m²
- d. Birth Cohort 1945-1965

Recommended treatment for patients in Treatment Group Two includes medications to treat chronic HCV and an Addictions Recovery Services referral. Patients in group two shall be seen at minimum every ninety (90) days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for signs and symptoms of liver disease shall be completed each visit. Labs shall be obtained at least every ninety (90) days for monitoring purposes.

3. Treatment Group Three

Patients in Treatment Group Three have been identified as being at a lower risk for liver disease. This Group requires consideration for treatment, including antiviral medications. Patients in Treatment Group Three would

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not have any of the clinical indicators listed in Treatment Group One or Two, but would have one or more of the following:

- a. Stage 0 to Stage 1 fibrosis on liver biopsy
- b. APRI < 0.7
- c. All other cases of HCV infection meeting the eligibility criteria for treatment, as noted below under *Other Criteria for Treatment*.

Recommended treatment for patients in Treatment Group Three includes consideration for medications to treat chronic HCV and an Addictions Recovery Services referral. Patients in Treatment Group Three shall be seen at a minimum of every ninety (90) days in chronic care clinic, unless otherwise clinically determined. A targeted history and physical examination to evaluate for signs and symptoms of liver disease shall be completed each visit. Labs shall be obtained every ninety (90) days for monitoring purposes.

4. Other Criteria for Treatment

In addition to the above groups, HCV infected patients being considered for treatment with antiviral medications should:

- a) Have no contraindications to, or significant drug interactions with, any component of the treatment regimen;
- b) Not be pregnant, especially for any regimen that would require ribavirin or interferon;
- c) Have sufficient time remaining on their incarceration in the Department to complete a course of treatment;

Patients in Treatment Group One that have insufficient time remaining in Department custody, may be considered for treatment if they will have access to antiviral medications and health care providers for continuity of care at the time of release;

- d) Have a life expectancy > 18 months;
- e) Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated; and,
- f) Patients with evidence for ongoing high-risk behaviors (e.g., injection drug use) shall be considered for HCV treatment on an

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individual basis. Referral for evaluation and treatment with Addictions Recovery Services shall be completed.

Treatment of HCV will be based on clinical indication. At any time, a patient can be moved up from one treatment group based on the attending physicians individualized treatment plan for the patient.

Upon release of a patient from Department custody, the patient shall be reviewed for healthcare coverage. Transitional Healthcare Services shall ensure activation of benefits if managed care entity is known. Patient information shall be sent for coordination of care in the community by Transitional Health Specialist. A patient experiencing a treatment interruption or in need of initial treatment after release shall be referred to IDOH designee by site Transitional Healthcare Facilitator for linkage to care in the community. .

IV. END STAGE LIVER DISEASE:

Patients in end stage liver disease secondary to HCV shall be provided with off-site consultation with a hepatologist or GI specialist for recommendations. If a liver transplant is recommended, the patient shall be referred to the appropriate off-site provider.

V. HCV COMPREHENSIVE LOG:

The HCV Comprehensive Log contains health information on currently patient with HCV diagnosis/known HCV antibodies. The HCV Comprehensive Log is maintained by the Department's Data Analytics team and the Department Epidemiologist. This Log shall be updated weekly by the Epidemiologist and health services vendor Infection Control Nurse. This Log shall be distributed weekly by the Epidemiologist to Health Services Division Executives and health services vendor personnel.

All patients newly diagnosed with HCV who appear on the HCV Comprehensive Log shall be reported to the Executive Director of Behavioral Health for Addiction Recovery Services. This shall be reported on a weekly basis.

VI. APPLICABILITY:

This HCSD is applicable to all facilities providing health services to incarcerated adults.

signature on file

Kristen Dauss, MD
Chief Medical Officer

Date