

	State of Indiana Indiana Department of Correction	Effective Date 4/1/2022	Page 1 of 7	Number 3.04Y
HEALTH CARE SERVICES DIRECTIVE-YOUTH SERVICES Manual of Policies and Procedures				

Title MANAGEMENT OF HEPATITS C
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Legal References (includes but is not limited to) IC 11-8-2-5	Related Policies/Procedures (includes but is not limited to) 01-02-101	Other References (includes but is not limited to) National Correctional Healthcare Standards
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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. HCV is spread by contact with infected blood and blood products from a person living with HCV (PLWHCV). 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.

HCV can be acute or chronic. Acute HCV can present clinically with a discrete onset of fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain.

It may also present clinically with:

1. Jaundice;
2. A Peak elevated bilirubin levels greater than or equal to 3.0mg/dl;
3. A peak elevated serum alanine aminotransferase (ALT) level greater than 200IU/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

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due to pre-existing chronic Hepatitis C or other causes, such as alcohol exposure, other viral Hepatitis hemochromatosis, etc.

There is a slightly increased risk of transmission of HCV through sexual contact. Surveys have shown the spread of HCV to a spouse or partner in a stable, monogamous relationship occurs in less than 1% of partners per year.

The Centers for Disease Control and Prevention (CDC) reported approximately half of patients 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 later time. The majority of individuals infected with HCV will develop chronic liver disease. 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.

Chronic HCV treatment can be accomplished with medications (interferon, ribavirin or any HCV direct-acting antiviral agents). 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 4.01Y, "Addiction Recovery Services," youths newly diagnosed with Hepatitis C (that is, the diagnosis was made after the youth was committed to the Department) or currently being treated for Hepatitis C shall be referred for substance abuse assessment by Intake personnel or the Treatment Team. Newly diagnosed youth shall be referred for substance use assessment within fourteen (14) days of diagnosis date.

B. Screening for HCV Infection

In accordance with the provisions of HCSD 2.02Y, "Reception Screening," after a youth arrives at an Intake site, the youth must complete the 2-page Health History, State Form 45999. This is a directed

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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 the Health Services vendor.

All incoming and returning youth 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.

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

C. Baseline Evaluation

Initial evaluation of youth living with HCV (PLWHCV) shall include, but is not limited to the following:

1. A baseline history and physical examination within the first 90 days with emphasis on evaluation for other possible causes of liver disease and inquiry regarding prior treatment for HCV infection;
2. Baseline laboratory tests within the first 90 days;
3. Assessment regarding the need for preventive 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 estimate the earliest possible date of infection, including when risk factors for exposures started and stopped.

When HCV diagnoses shall be reported to authorities at the Indiana

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Department of Health (IDOH).

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 and its long-term sequelae, and the pros and cons of the treatment for HCV disease.

All PLWHCV disease shall be offered vaccination against Hepatitis B and Hepatitis A, unless previous infection or vaccination has been documented, or the PLWHCF shall be offered vaccination against pneumococcus once, and against influenza annually.

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

Youths in enrolled chronic care clinic shall be seen at minimum every ninety (90) days, 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 will be obtained every ninety (90) days for monitoring purposes.

All PLWHVC 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 a framework to ensure that youths with the greatest need are identified and treated.

A. Treatment Group One

1. Advanced Hepatic Fibrosis

- a. APRI \geq 2.0;
- b. Metavir or Batts/Ludwig Stage 3 or 4 on liver biopsy; or,
- c. Known or suspected cirrhosis.

2. Liver Transplant Recipients

3. Hepatocellular Carcinoma (HCC)

4. Comorbid medical conditions associated with HCV

- a. Cryoglobulinemia with renal disease or vasculitis;
- b. Certain types of lymphomas or hematologic

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- malignancies; and,
 - c. Porphyria cutanea tarda.

5. Immunosuppressant Medication for a Comorbid Medical Condition

Some immune suppressant medication (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 is 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.

6. Continuity of Care for those already on treatment, including youth newly committed to the Department.

7. Recommended treatment for youths in Treatment Group One includes medications to treat chronic HCV and an Addictions Recovery Services referral.

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

B. Treatment Group Two

1. Evidence for Progressive Fibrosis

- a. APRI Score ≥ 0.7
- b. Stage 2 fibrosis on liver biopsy

2. Comorbid medical conditions associated with more rapid progression of fibrosis

- a. Coinfection with HBV or HIV
- b. Comorbid liver diseases (e.g., autoimmune, hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
- c. Diabetes mellitus

3. Chronic Kidney Disease (CKD) with GFR ≥ 59 ML/min per 1.73 m²

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4. Recommended treatment for youth in Treatment Group Two includes medications to treat chronic HCV and an Addictions Recovery Services referral.

C. Treatment Group Three

1. Stage 0 to Stage 1 fibrosis on liver biopsy
2. APRI < 0.7
3. All other cases of HCV infection meeting the eligibility criteria for treatment, as noted below under *Other Criteria for Treatment*
4. Recommended treatment for youth in Treatment Group Three includes consideration for medications to treat chronic HCV and an Addictions Recovery Services referral.

D. Other Criteria for Treatment

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

1. Have no contraindications to, or significant drug interactions with, any component of the treatment regimen;
2. Not be pregnant, especially for any regimen that would require ribavirin or interferon;
3. Have sufficient time remaining on their commitment in the Department to complete a course of treatment;
4. Have a life expectancy greater than 18 months;
5. Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated; and,
6. Youth with evidence for ongoing high-risk behaviors (e.g., injection drug use) shall be considered for HCV treatment on an 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 youth

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may be moved up from one group based on the attending physicians individualized treatment plan for the youth.

Upon release of a youth from custody they shall be reviewed for health care coverage. Transitional Healthcare Services shall ensure activation of benefits. If Managed Care Entity is known, the youth's information shall be forwarded for coordination of care in the community by a Transition Health Specialist. Youth experiencing a treatment interruption or in need of initial treatment after release shall be referred to the IDOH designee by the site Transitional Healthcare Facilitator for linkage to community care.

PLWVC diagnosis and have successfully completed treatment shall receive educational information about community resources from the Transitional Healthcare Facilitator.

IV. END STAGE LIVER DISEASE:

Youths 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 youth shall be referred to the appropriate off-site provider.

V. APPLICABILITY:

This HCSD is applicable to all facilities providing Health Services to youth.

signature on file

Kristen Dauss, MD
Chief Medical Officer

Date