# Section 20 – Hepatitis C Protocol

## *Background*

* 1. This Hepatitis C Protocol for the Pennsylvania Department of Corrections (PA DOC) provides clinical guidelines for the diagnosis, management, and treatment of inmate patients with chronic Hepatitis C Virus (HCV).[[1]](#footnote-1)
	2. Introduction
1. HCV is a slowly progressive disease, usually requiring decades to progress to cirrhosis; however, the natural history of HCV is variable and not all patients with chronic HCV will develop cirrhosis during their lifetime. Of every 100 persons infected with HCV, approximately: 15-25 will clear the virus from their body and be naturally cured with no risk of future liver disease; 75-85 will develop chronic infection; 60-70 with chronic infection will develop chronic liver disease; 5-20 with chronic infection will develop cirrhosis of the liver over a period of 20-30 years; and 1-5 will die from the consequences of chronic infection, such as end-stage cirrhosis or liver cancer (for content references, please see **Subsection *H*.1. below**).
2. The goal of Hepatitis C anti-viral treatment is to achieve a sustained virological response (SVR), defined as undetectable HCV virus in the blood, 12 or more weeks after completing anti-viral treatment.

## Screening

1. All new intakes will be screened at their home institutions utilizing the Hepatitis C Antibody test.[[2]](#footnote-2) Anyone may refuse testing by signing a **DC-462, Release from Responsibility for Medical Treatment Form.**
2. The Infection Control Nurse (ICN) will review positive antibody results with all inmates, whether it be at intake or later during incarceration. The Medical Director/designee will order a confirmatory Hepatitis C Ribonucleic Acid (RNA) Quantitative Polymerase Chain Reaction (PCR) test (viral load).[[3]](#footnote-3) Recommended immunizations ***(Hepatitis A and B)***, counseling/***education regarding this disease***, and literature ***explaining transmission of Hepatitis C*** will be provided during that encounter. ***The patient will be placed on the annual Influenza vaccination list maintained by the ICN.***
3. Inmate patients with documented (+) Hepatitis C Antibody test should not be retested, but entered into tracking.
4. Inmate patients who have a documented undetectable Hepatitis C Quantitative PCR may become re-infected while out on parole. If they return to the PA DOC, the Medical Director/designee shall order a repeat viral load on intake.

## Tracking

For all patients with a positive HCV antibody test, the ICN will maintain a current **Hepatitis C Tracking Spreadsheet (Attachment 20-A)** in Excel format. This spreadsheet will be forwarded to the Bureau of Health Care Services (BHCS) Infection Control Coordinator (ICC) on a monthly basis.

## Chronic Care Clinic[[4]](#footnote-4)

# All patients who have chronic Hepatitis C (confirmed by a detectable viral load) will be entered into the Liver Disease Chronic Care Clinic. *Initial screening will utilize the APRI (AST [Aspartate Aminotransferase] to Platelet Ratio Index)*. The ICN will confer with the Site Medical Director to determine if the patient’s diagnosis is:

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# F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis). *APRI < 1.5 unless otherwise documented*;

# F3 (advanced fibrosis). *APRI 1.5-2.0 unless otherwise documented*; *and/or*

# F4 (cirrhosis). *APRI > 2.0 unless otherwise documented*.

# Patients who are antibody positive only (confirmed by an undetectable viral load) do not have chronic Hepatitis C and will be followed in Chronic Care Clinic at the discretion of the Site Medical Director, if the patient exhibits signs or symptoms of liver disease. Patients who have been treated with medication will continue to be followed in Chronic Care Clinic, whether or not they achieved an SVR.

# At a minimum, the following will be documented in a Progress Note during the Chronic Care Clinic encounter:

1. Subjective:
2. symptoms of cirrhosis or liver failure;
3. history of ascites, encephalopathy, or esophageal varices (bleeding or not);
4. estimated date of contracting the disease; and
5. any recent admissions to the Infirmary, emergency room (ER), or hospital.
6. Objective:

1. vital signs, weight, and Body Mass Index (BMI);
2. examination of the sclera for jaundice;
3. examination of the abdomen, including both ascites and the size and character of either hepatomegaly or splenomegaly;
4. examination of the skin for changes suggestive of cirrhosis (jaundice, spider angiomata/telangiectasia, palmar erythema, and caput medusae);
5. examination of the neurological system for the presence of asterixis (“liver flap”);
6. fibrosis stage, if known, and method used to determine the fibrosis stage (e.g. liver biopsy or elastography);
7. calculation of the APRI, using the calculator located in the Resource Section of the electronic health record;
8. calculation of the Model of End Stage Liver Disease (MELD) score and the (Child-Turcotte-Pugh) CTP score for patients with cirrhosis, using the calculator located in the Resource Section of the electronic health record;
9. review of any results of the esophagogastroduodenoscopy (EGD), elastography, or abdominal ultrasound; and
10. examination of pertinent laboratory results.
11. Assessment:
12. F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis);
13. F3 (advanced fibrosis); or
14. F4 (cirrhosis).
15. Plan of Treatment:[[5]](#footnote-5)
16. schedule the follow-up Clinic appointment according to the assessment:

(a) F0-F2 (six months);

(b) F3 (three months); or

(c) F4 (one month).

1. diagnostics ordered will include the following:
2. initial Chronic Care Clinic for all patients: Comprehensive Metabolic Profile (CMP), Complete Blood Count (CBC), Chronic Hepatitis Panel, and Prothrombin Time (PT)/International Normalized Ratio (INR);

(b) yearly labs for all patients: CMP, CBC, and PT/INR. Quantitative PCR (viral load) for those who have completed treatment;

(c) every six month labs for patients with cirrhosis (F4): CMP, CBC, PT/INR, and abdominal ultrasound to evaluate for Hepatocellular Carcinoma (HCC);

(d) every six month labs for patients without cirrhosis (F0-F3): Liver Function Tests (LFTs) and CBC; and

(e) monthly visits for patients with cirrhosis (F4): No labs required.

1. ***education regarding the natural progression of this disease, transmission of Hepatitis C, and the importance of immunizations and annual Influenza vaccination.***
2. ***Additional Interventions for Inmates with Cirrhosis: (for content reference, please see Subsection H.2. below)***

***pneumococcal vaccine: Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age;***

***HCC screening: Liver ultrasound is recommended every six months for patients with cirrhosis (F4) or advanced fibrosis (F3);***

***esophageal varices screening: Screening for esophageal and gastric varices with EGD is recommended for patients diagnosed with cirrhosis;***

***other health care interventions recommended for patients with cirrhosis may include:***

***non-selective beta blockers for prevention of variceal bleeding in patients with esophageal varices;***

***antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis;***

***optimized diuretic therapy for ascites; and***

***lactulose and rifaximin therapy for encephalopathy.***

1. ***In general, Non-Steroidal Anti-Inflammatory Drugs (NSAID) should be avoided in advanced liver disease/cirrhosis, and metformin should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of these*** ***guidelines. Other resources should be consulted for more specific recommendations related to this condition.***

## Evaluation for Treatment with Anti-Viral Medication[[6]](#footnote-6)

1. The PA DOC will utilize the Federal Bureau of Prisons (FBOP) Priority Criteria as listed in the “Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection Clinical Practice Guidelines, ***January 2018***.” (please refer to **Subsection *H*.2. below**)
2. Determining whether PA DOC priority criteria for treatment are met is an important part of the initial evaluation and ongoing management of inmates with chronic HCV infection. Although all patients with chronic HCV infection may benefit from treatment, certain cases are at higher risk for complications or disease progression and require more urgent consideration for treatment.
3. The PA DOC will use Fibrosure to determine fibrosis scoring for patients without a diagnosis of cirrhosis who have an APRI > ***0.7*** or select patients as clinically indicated.
4. The DOC has established priority criteria to ensure that those with the greatest need are identified and treated first (for content reference, please see **Subsection *H*.2. below**). The DOC Chief of Clinical Services will provide periodic guidance on specific strategies for implementing these priority levels:
	1. Priority Level 1 – High Priority for Treatment
5. Advanced hepatic fibrosis:

(a) APRI > 2.0;

(b) Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, Elastography, or Fibrosure; or

(c) known or suspected cirrhosis.

1. Liver Transplant Recipients
2. HCC
3. Comorbid Medical Conditions Associated with HCV, including:

(a) Cryoglobulinemia with renal disease or vasculitis;

1. certain types of lymphomas or hematologic malignancies; and/or
2. Porphyria cutanea tarda.
3. Immunosuppressant Medication for a Comorbid Medical Condition

For example, certain chemotherapy agents and tumor necrosis factor inhibitors. Such cases will be considered for prioritized treatment on an individual basis.

1. Continuity of Care for those already started on treatment, including inmates who are newly incarcerated in the PA DOC.
	1. Priority Level 2 – Intermediate Priority for Treatment
2. Evidence of progressive fibrosis.
3. APRI > 0.7.
4. Stage 2 fibrosis on liver biopsy, Elastography, or Fibrosure.
5. Comorbid medical conditions associated with more rapid progression of fibrosis.
6. Coinfection with Hepatitis B Virus (HBV) or Human Immunodeficiency Virus (HIV).
7. Comorbid liver disease (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis).
8. Diabetes Mellitus.
9. Chronic Kidney Disease (CKD) with Glomerular Filtration Rate (GFR) < 59 mL/min per 1.73 m squared.
	1. Priority Level 3 – Low Priority for Treatment

(1) Stage 0 to stage 1 fibrosis on liver biopsy, Elastography, or Fibrosure.

(2) APRI < 0.7.

(3) All other cases of HCV infection meeting criteria for treatment, as noted below under Other Criteria for Treatment.

1. Other Criteria for Treatment: In addition to meeting the above criteria for Priority 1–3, inmates being considered for treatment of HCV infection should:
2. have no significant or unstable medical conditions, to include, but not limited to, cardiopulmonary, cancer, and diabetes;
3. have no contraindications to, or significant drug interactions with, any component of the treatment regimen;
4. not be pregnant, especially for any regimen that would require ribavirin or interferon;
5. ~~have been in the DOC at least six months and~~ have at least ***20 weeks*** until expected release. Inmates with Priority Level 1 criteria who are outside these parameters may be considered on an individual basis;
6. have a life expectancy > ***12*** months;
7. demonstrate a willingness and an ability to adhere to a rigorous treatment regimen. Inmates with a history of non-compliance may be offered a one month trial of taking a multi-vitamin daily under direct observation. If successful, they may be considered for treatment on an individual basis; and
8. demonstrate a willingness and an ability to abstain from high-risk activities while incarcerated. Inmates with evidence for ongoing high-risk behavior, e.g. misconducts for illicit drug use or tattoos, will be considered for treatment on an individual basis. Referral for evaluation and treatment of substance abuse is required.
9. The first level of screening patients for treatment with anti-viral medications will occur at the patient’s home site, ***during Chronic Care Clinics***. The review will be conducted utilizing the **Hepatitis C Treatment Referral Form *in the electronic health record*** and will be conducted by the Corrections Health Care Administrator (CHCA), ICN, and Site Medical Director, who will look for the presence of any exclusionary indications listed above.
10. If the CHCA determines that there are no exclusionary indications to anti-viral treatment ***(see Subsection E.4. above)***, ***and the APRI > 0.7***,a Fibrosure test needs to be ordered ***by on-site providers***. If the Fibrosure test indicates F-2, F-3, or F-4***,*** the **Hepatitis C Treatment Referral Form** shall be forwarded to the BHCS ICC for further evaluation, possible recommendations for further testing, and initial determination. ***All patients who are co-infected with HIV or Hepatitis B, or who have co-morbidities listed in Subsection E.4. above, or who have previously failed treatment for Hepatitis C, will also be forwarded to the BHCS ICC.***
11. ***If the APRI < 0.7 and the patients meet the criteria above for Priority Level 3, or if the Fibrosure indicates F0 or F1, the Hepatitis C Treatment Referral Form will be returned to the ICN for coordination of treatment on-site. This on-site treatment will be ordered by the medical vendor providers (physician, physician assistant, or nurse practitioner) trained in the prescribing of Direct Acting Antiviral medication for patients with minimal or no fibrosis. If a particular case is complicated, it can be forwarded to BHCS for appropriate referral.***
12. **Bureau of Health Care Services Review**[[7]](#footnote-7)
	1. The BHCS will use the Fibrosure score ***if available*** as its main determinant of fibrosis to be used within the FBOP prioritization levels as outlined in **Subsection *E*.4. above**.
	2. Fibrosis Stage 0-1

(1) ***If the patient meets all criteria for Priority Level 3, refer the case to the site ICN to coordinate on-site treatment.*** Repeat Fibrosure in one year ***if not yet treated***.

(2) Follow in Chronic Care Clinic every six months.

* 1. Fibrosis Stage 2
1. Refer to Temple University for final review and the ordering of Direct Acting Antivirals (DAA) medications unless there are contraindications.
2. Follow in Chronic Care Clinic every six months.
	1. Fibrosis Stage 3
3. Refer to Temple University for final review and the ordering of DAA medications unless there are contraindications.
4. Order full ultrasound screening for HCC every six months.
5. Follow in Chronic Care Clinic every three months.
	1. Fibrosis Stage 4
6. Order full ultrasound screening for HCC every six months.
7. Order baseline EGD for esophageal varices surveillance.
8. Refer to Temple University for final review and the ordering of DAA medications unless there are contraindications.
9. Follow in Chronic Care Clinic every month.
	1. The Chief of Clinical Services will render a decision and forward the determination, along with follow-up recommendations for those not meeting current priority criteria for greatest need of treatment with anti-viral medications, to the ICN and Site Medical Director, who will then discuss the results with the patient and document the encounter in the **DC-472, Progress Notes**.[[8]](#footnote-8)
	2. If the Chief of Clinical Services recommends treatment with anti-viral medication, the ***BHCS ICC*** will refer the patient to Temple University who will direct the anti-viral treatment. The referral will be made utilizing a **Hepatitis C Treatment Referral Form**, to include the following updated laboratory results:
10. genotype, no time limit if completed during this incarceration; otherwise, one year;
11. viral load (within ***six*** months);
12. HIV (within one year);
13. CMP (within one month);
14. CBC (within one month);
15. abdominal sonogram for patients with ***F3 or F4*** (within six months); and
16. the treatment of HCV with anti-viral medications is rapidly evolving. New medications are being approved by the Federal Drug Administration (FDA) frequently. The regimens currently approved by PA DOC will be included in the Diamond Pharmacy Services Formulary for this contract. The Formulary will include all necessary prescribing information and will be updated quarterly via the PA DOC Pharmacy and Therapeutics Committee.
17. **American Correctional Association (ACA) Accreditation**

As part of the audit for ACA accreditation, each site is required to submit data representing Outcome Measures. This information is available on the **Hepatitis C Tracking Spreadsheet** and includes all inmates who are diagnosed with chronic Hepatitis C infection at a given point in time. ACA recommends selecting June as the midpoint of a calendar year.

1. Include all inmates within the facility with a current laboratory test indicative of Hepatitis C viral infection whether or not they have received antiviral treatment.
2. Exclude inmates diagnosed with chronic Hepatitis C infection, but housed in another correctional system, community-based facility, or home detention.
3. Exclude inmates with suspected acute Hepatitis C viral infection who are currently under evaluation for clearance of their infections (in other words, viremia).
4. **References**
5. Centers for Disease Control and Prevention. “Hepatitis C FAQs for health professionals,” accessed ***February 12, 2019***, at [www.cdc.gov/hepatitis/hcv/hcvfaq.htm](http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm).
6. Federal Bureau of Prisons, January 2018, “Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection,” accessed ***February 12, 2019***, at <https://www.bop.gov/resources/pdfs/012018_hcv_infection.pdf>.
7. AASLD and IDSA, “Recommendations for Testing, Managing, and Treating Hepatitis C,” accessed ***February 12, 2019***, at <http://www.hcvguidelines.org>.
1. 5-6A-4350, 5-6A-4356, 5-6A-4359 [↑](#footnote-ref-1)
2. 5-6A-4359 [↑](#footnote-ref-2)
3. 5-6A-4359 [↑](#footnote-ref-3)
4. 5-6A-4350, 5-6A-4359 [↑](#footnote-ref-4)
5. 5-6A-4350, 5-6A-4359 [↑](#footnote-ref-5)
6. 5-6A-4359 [↑](#footnote-ref-6)
7. 5-6A-4350, 5-6A-4359 [↑](#footnote-ref-7)
8. 5-6A-4359 [↑](#footnote-ref-8)