Management of Hepatitis C

I. PURPOSE AND OVERVIEW

The Oklahoma Department of Corrections Treatment of Hepatitis C MSRM provides the most current recommendations for the evaluation and treatment of chronic HCV infection in the Oklahoma inmate population. As stated by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), in collaboration with the International Antiviral Society-USA (IAS-USA), the goal of treatment of HCV infected persons is to reduce all-cause mortality and liver related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.

All patients with chronic HCV are enrolled in chronic clinic provider evaluations every 6 months at which time indications to treatment are assessed.

At any point during evaluation and treatment, a patient can decline further evaluation or treatment. Following counseling, a "Waiver of Treatment for Hepatitis C" (**DOC 140137.06C**) will be signed.

II. HEPATITIS C PROTOCOL

A. The 4 Stepped Approach to Evaluation and Treatment of HCV:

1. Step 1: Test for HCV infection with anti-HCV (HCV ab) test with reflex to HCV RNA (CPL 4677)

2. Step 2: Perform a baseline evaluation on those with chronic HCV infection

   a. Targeted history and physical examination

   b. CPL Lab tests: CBC (1000), CMP (9179), hepatitis A and hepatitis B serology including HBsAg, anti-HBs, anti-HBc, anti-HAV (CPL 162), and HIV AB (3540), witnessed UDS (CPL 3311)

   c. Provide HCV Education ("Hepatitis C Frequently Asked Questions (**DOC 140137.06B**).

   d. Assess for hepatic fibrosis and cirrhosis: Calculate APRI and FIB-4 scores. Draw Fibrosure (CPL 3884) in Metavir 3 or Metavir 4. Calculate CTP score in advanced fibrosis and cirrhosis. PT/INR (1425) will have to be drawn as part of the CTP calculation.

3. Step 3: Perform HCV Treatment assessment

   a. Exclude Treatment contraindications

   b. Complete "Case Manager Review/Medical Treatment Evaluation" (**DOC 140137.06A**)

   c. Complete "HCV Treatment Work-up Order Note" (**DOC 140137.06 L**) (to ensure all necessary labs, imaging, and documents are completed and scanned into the EHR.

   d. Obtain additional labs: HCV Genotype (CPL 4804) and urine pregnancy test.

   e. Exclude Hepatocellular Carcinoma (HCC) in those with a Fibrosure F3 or F4 to include AFP (CPL 2625) and Right Upper Quadrant (RUQ)/splenic Ultrasound.

   f. Complete "Hepatitis C Agreement for Treatment Work-up" (**DOC 140137.06D**)

   g. Complete the "HCV Treatment Work-Up Provider Note" (**DOC 140137.06G**)

4. Step 4: Monitor patient during and after treatment.

   a. A "Medical Transfer Request" (**DOC 140113E**) or expert consultation may be indicated for patients with decompensated cirrhosis or other comorbidities that complicate HCV treatment.

b. Restrict patient to treating facility **only** while taking the Direct Acting Antiviral medication (DAA)

c. Initiate approved DAA regimen as Directly Observed Therapy.

d. Schedule Monthly HCV nurse monitoring for the duration of HCV treatment.

(1) Schedule with an On-Site Provider for medication compliance counseling if the patient is not compliant with pill line medication adherence and complete the "Provider HCV Medication Compliance Counseling Note (**DOC 140137.06 P**)."

e. Providers evaluate and complete HCV Post Treatment Notes

(1) End of Treatment (EOT) and un-restrict patients from facility

(2) 12 Week Post Treatment (assess for sustained virologic response 12 weeks after completion of therapy- SVR12).

III. SCREENING FOR HCV INFECTION

A. Universal and annual HCV screening: CPL 4677

Universal, opt-out HCV screening will be completed on all those newly incarcerated. These patients should be provided with educational information regarding prevention and transmission, risk factors, testing, and medical management of HCV infection. "Hepatitis C Frequently Asked Questions" (**DOC 140137.06B**).

A single, once in every patient's lifetime screening for HCV infection is recommended. The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, with a reflex to HCV RNA (HCV Antibody with reflex Quant, CPL 4677). The presence of HCV RNA (> 15 IU/mL) indicates active infection. Medical staff may utilize the Inmate Notification (DOC 140137.16 O): Chronic HCV infection to inform his/her patients of this laboratory fin~~ding and enroll the~~ patient in chronic clinic. The presence of antibodies with negative HCV RNA indicates resolved infection. Medical staff may utilize the Inmate Hepatitis C Notification (**DOC 140137.16 O):** Spontaneous Clearance of HCV to inform his/her patients of this laboratory finding. These patients will not need enrolled in HCV Chronic Clinic.

Annual HCV screening is indicated for all with ongoing risk behaviors or exposures. The HCV Screening – Laboratory Testing Results (**DOC 140137.06M**) can be utilized to inform patients of his/her HCV screening results.

1. <u>HCV Risk Behaviors and Exposures:</u>

a. Ever injected illegal drugs or shared equipment (including intranasal use of illicit drugs).

b. Received tattoos or body piercings while in jail or prison, or from an unregulated source.

c. Received a blood transfusion or an organ transplant before 1992, received clotting factor transfusion prior to 1987, or received blood from a donor who later tested positive for HCV infection.

d. History of percutaneous exposure to blood.

e. Ever received hemodialysis.

f. Born to a mother who had HCV infection at the time of delivery.

2. HCV Clinical Conditions and birth cohort:

a. A reported history of HCV infection without prior medical records to confirm the diagnosis.

b. HIV or chronic hepatitis B virus (HBV) infection.

c. Cirrhosis

d. Chronic hemodialysis – screen alanine aminotransferase (ALT) monthly and anti-HCV semiannually.

e. Elevated ALT levels of unknown etiology.

f. Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis.

g. Born between 1945 and 1965.

3. Refusal of Testing

Those that decline testing should be counseled about and offered HCV testing during periodic preventive health visits.

IV. Initial Evaluation in Chronic HCV Infection

Initial evaluation in chronic HCV infection includes a baseline history and physical examination and laboratory tests. Preventive health interventions such as vaccines and screening for other conditions, as well as counseled with information on HCV infection. “Hepatitis C Frequently Asked Questions “ (**DOC 140137.06 B**)

A. Targeted History and Physical Examination:

1. Evaluate for signs and symptoms of liver disease and determine risk behaviors for acquiring HCV infection. Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped.

2. Evaluate for other possible causes of liver disease including alcoholism, illicit drug use (including marijuana), Metabolic dysfunction-associated steatotic liver disease (MASLD; previously termed nonalcoholic fatty liver disease [NAFLD]), iron overload, and autoimmune hepatitis. Quantify current and/or prior illicit drug and alcohol consumption.

3. Inquire about prior treatment for HCV infection, specific medications used, dosages and duration of treatment, and outcomes.

4. Laboratory Tests:
   a. CBC (CPL # 1000), CMP (CPL # 9179) - Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated
   b. Hepatitis A and B serology (CPL 162) and HIV screen (CPL 3540) within the last year
   c. A urine drug screen to determine the need for referral to Substance Abuse Treatment (CPL3311).
5. Preventive Health Measure:

   All patients with chronic HCV should assessed for preventive health interventions including the Hepatitis A, Hepatitis B, and Influenza vaccines.
6. Patient and Provider HCV Education:

   Patients diagnosed with chronic HCV infection should be educated regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting HCV infection to others (both during incarceration and upon release). "Hepatitis C Frequently Asked Questions" (**DOC 140137.06 B**)*; Additional Educational Resources:*

   For Patients:

   1. *American Liver Foundation (ALF)* https://liverfoundation.org/
   2. *Centers for Disease Control and Prevention (CDC)* https://www.cdc.gov/hepatitis-c/about/?CDC_AAref_Val=https://www.cdc.gov/hepatitis/hcv/cfaq.htm

   For Providers:

   1. *American Association for the Study of Liver Diseases and Infectious Disease Society of America Hepatitis C Guidance* http://www.hcvguidelines.org
   2. University of Washington Infectious Diseases Education & Assessment (IDEA) Program https://www.hepatitisc.uw.edu/

B. Assess for Hepatic Fibrosis and Cirrhosis

Grading fibrosis and cirrhosis is recommended in all patients with HCV infection to determine the need for additional health care interventions. Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement of fibrotic scar tissue. The natural history of HCV is such that 50-80 % of HCV infections become chronic. Most complications from HCV infection occur in people with cirrhosis.

Cirrhosis may be diagnosed in several ways:

1. Symptoms and signs that support the diagnosis of cirrhosis may include Low albumin or platelets, elevated bilirubin or INR or esophageal varices.
2. Decompensated cirrhosis is evidenced by ruptured varices, ascites, jaundice, hepatic encephalopathy, spontaneous bacterial peritonitis and HCC.

3. Fibrosure is a proprietary test that involves assessment of alpha-2-macroglobulin, alpha-2-globulin (haptoglobin), gamma globulin, apolipoprotein A1, GGT, and total bilirubin. It also takes into account the patient's age and sex. Results from the individual assays are combined and are used to classify patients having mild fibrosis (F0 to F1), significant fibrosis (F2 to F4), or an indeterminate stage of fibrosis. The sensitivity for detection of significant fibrosis is approximately 60 to 75 and the specificity is approximately 80 to 90 percent,

4. The AST-Platelet Ratio Index (APRI) and FIB-4 score are validated non-invasive assessments of hepatic fibrosis and cirrhosis. An APRI score 2.0 has a sensitivity of 48 %, but a specificity of 94 %, for predicting cirrhosis. Most experts recommend using 40 IU/L as the value for the AST upper limit of normal when calculating an APRI value. A FIB-4 score of ≥3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. If a person is known to have cirrhosis, the APRI and FIB-4 score is irrelevant and unnecessary.

   https://www.hepatitisc.uw.edu/page/clinical-calculators/apri

   https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4

5. Abdominal imaging studies such as ultrasound or CT scan may identify findings consistent with or suggestive of the following: cirrhosis (nodular contour of the liver), portal hypertension (ascites, splenomegaly, varices), or hepatocellular carcinoma (HCC). Abdominal US is routinely performed in cases of known or suspected cirrhosis, and as clinically indicated on a case-by-case basis.

C. Assess for Hepatic Decompensation in those with Cirrhosis

Assessing hepatic decompensation in those with cirrhosis is important for determining the most appropriate HCV treatment regimen.

The Child-Turcotte-Pugh (CTP) score is a useful tool in determining the severity of cirrhosis and in distinguishing between compensated and decompensated liver disease. Further, this score helps predict overall mortality and serves as a guide for the clinical recommendation for medical parole.

PT/INR (CPL # 1425) will have to be drawn to calculate the CTP score.

https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp

The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score. A score of 5 to 6 is considered class A (well-compensated disease); 7 to 9 is class B (significant functional compromise); and 10 to 15 is class C (decompensated disease). These classes correlate with one- and two- year patient survival: class A: 100 and 85 percent; class B: 80 and 60 percent; and class C: 45 and 35 percent.

Child-Turcotte-Pugh classification

Parameter		Points assigned	
	1	2	3
Ascites	Absent	Slight	Moderate
Bilirubin	<2 mg/dL	2 to 3 mg/dL	>3 mg/dL
Albumin	>3.5 g/dL (35 g/liter)	2.8 to 3.5 g/dL (28 to 35 g/liter)	<2.8 g/dL (<28 g/liter)
INR	<1.7	1.7 to 2.3	>2.3
Encephalopathy	None	Grade 1 to 2	Grade 3 to 4

Notes:

1. Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher.
2. Patients with CTP class C who have survival probability of 6 months or less or severe ADL disability requiring significant ADL caretaker assistance are eligible for submission for consideration of medical parole if they are not serving a life sentence.

D. Additional Interventions for patients with (Decompensated) Cirrhosis

The following recommendations apply to all patients with cirrhosis, whether they have chronic or resolved HCV infection.

1. Ensure these patients have an active ICD-9 cirrhosis code (571.5) and remain enrolled in chronic clinic: cirrhosis.
2. Pneumococcal vaccine: Offer to all HCV-infected patients with cirrhosis who are 19 through 64 years of age.
3. Lifelong Hepatocellular Carcinoma screening: Liver ultrasound with AFP is recommended every 6 months for patients with advanced fibrosis or cirrhosis.
4. Esophageal Varices Screening and management: Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended every 2-3 years in those with CTP Class A and B and annually in those with a CTP score class C. NSAIDs should be avoided in those with esophageal varices and/or Thrombocytopenia. Nonselective beta blockers are used for prevention of variceal bleeding in patients with known esophageal varices.
5. Ascites: Optimize diuretic therapy for ascites (maintain ratio of Spironolactone 100 mg: Furosemide 40 mg with max doses of 400:160.) with sodium restriction (< 2 G daily Sodium diet) Fluid restriction only if Na <120 mEq/L or symptomatic.
6. Hepatic Encephalopathy (HE): Diagnosed clinically based on the combination: Impaired mental status graded by the West Haven Criteria and Impaired neuromotor function, such as hyperreflexia, hypertonicity, and asterixis. **There is no clinical indication for routine ammonia levels in the diagnosis of HE.** HE prophylaxis includes: avoiding precipitating factors, Xifaxin 550 mg BID, and/or Lactulose 10-30 G PO 2-4 X daily (titrated to 2-4 soft stools daily). MiraLAX 17 grams daily can also be used in conjunction with these medications.

7. These patients should also be counseled on the importance of lifelong drug and alcohol sobriety to prevent further hepatic insult.

V. Anti-HCV Positive Inmates with Non-Detectable Viral loads:

Patients that are found to have positive HCV antibodies with non-detectable viral loads (or < 15 IU/mL) either spontaneously cleared the virus or have been successfully treated. Providers should enter the ICD-9 code (070.70) and change it to "resolved" with an explanation (successful treatment versus spontaneous resolution). They do not require enrollment in Chronic Clinic for HCV

Medical staff may utilize inmate notifications to inform his/her patients of this laboratory finding: "Inmate Hepatitis C Notification." (**DOC 140137.06O**): Spontaneous Clearance of HCV or successful treatment in the past. These patients should be educated regarding re-infection if they engage in high-risk behaviors. They will require repeat screening with HCV Antibody with reflex RNA (CPL 4677) if they do engage in high-risk behaviors.

VI. ASSESSMENT FOR HCV TREATMENT

Assessing HCV treatment is an important part of the initial evaluation and ongoing management of patients with chronic HCV Infection.

Certain cases of HCV are at a higher risk for complications or disease progression and require more urgent consideration for treatment. Patients with decompensated cirrhosis, HCC, or comorbidities that can complicate HCV treatment may require expert consultation regarding treatment regimens and monitoring.

A. Highest Priority:

1. Moderate Fibrosis to Advanced Hepatic Fibrosis/Cirrhosis
    a. APRI $\geq$ 0.7
    b. FIB-4 $\geq$ 1.45
    c. Metavir score of F2, F3, or F4
2. Known or suspected cirrhosis Hepatocellular Carcinoma (HCC) - on a case-by-case basis as approved and with expert guidance.
3. Comorbid Medical Conditions associated with more rapid progression of fibrosis including:
    a. Coinfection with HBV or HIV (with expert guidance).
    b. Comorbid Liver Diseases (e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
    c. Diabetes Mellitus
    d. Chronic Kidney Disease (CKD) with GFR $\leq$ 59 mL/min
    e. Cryoglobulinemia with or without vasculitis
    f. Certain types of Lymphomas or hematologic malignancies
    g. Porphyria Cutanea Tarda or Lichen Planus

4. Immunosuppressant Medication for a Comorbid Medical Condition.
5. Continuity of Care for Those Already Started on Treatment.
6. Patients serving extended sentences, regardless of disease severity or comorbid conditions

B. Additional Criteria for HCV Treatment

Patients being considered for treatment of HCV infection should:

1. Have no contraindications to or significant drug interactions with any component of the treatment regimen.
2. Not be pregnant.
3. Have a life expectancy > 18 months.
4. Not have active cancer or be receiving Chemotherapy (Excluding Lymphomas, HCC and certain Hematologic malignancies) unless otherwise indicated following expert consultation.
5. Not have active HBV infection evidenced by: +HBsAg with a positive HBV PCR DNA. As these patients need to have an undetectable HBV viral load prior to the initiation of HCV treatment unless otherwise indicated following expert consultation.
6. Have sufficient time remaining on his/her sentence to complete the full course of treatment and assessment for SVR and demonstrate a willingness and an ability to adhere to the treatment regimen. Ideally, patients should abstain from high-risk behaviors.
    a. Patients with insufficient time remaining in ODOC custody may be considered for treatment if they have access to linkage to care at the time of release.
    b. To prevent HCV re-infection and reduce the risk of progression of liver disease, patients should be provided harm reduction and evidence-based treatment for underlying substance use disorders (SUD) as specified by the AASLD

VII. HCV Treatment Work-Up

Prior to starting treatment for HCV infection, patient education is recommended including but not limited to how to take the medication, the importance of adherence, monitoring and follow-up, and potential medication side effects. All of this information can be found at:

https://www.hepatitisc.uw.edu/page/treatment/drugs

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

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

1. Complete the ODOC “Hepatitis C Frequently Asked Questions” (**DOC 140137.06B**)
2. Complete the “Hepatitis C Agreement for Treatment Work-up” (**DOC 140137.06D**)

3. Complete “Case Manager Review/Medical Treatment Evaluation” (**DOC 140137.06A**)

4. Providers complete “HCV Treatment Provider Work-up Order Note” (**DOC 140137.06L**) to ensure all necessary labs, imaging, and documents are completed and scanned into the EHR to include:

    a. Labs within 6 months of HCV treatment start date include: CBC, CMP, Witnessed Urine Drug Screen

    b. Urine Pregnancy Test within 30 days

    c. Labs within 1 year of HCV treatment start date include: HCV antibody with reflex RNA (CPL 4677), Hepatitis profile (that includes HBsAg and anti-HBc), HBV PCR DNA (if HBsAg is positive), HIV antibody, HCV genotype, and Fibrosure in a Metavir 3 or Metavir 4.

5. Providers complete the full “HCV Treatment Work-Up Clinical Note” (**DOC 140137.06G**). This work-up includes:

    a. APRI and FIB-4, Calculations. Fibrosure in those that are a Metavir 3 or Metavir 4.

    b. Child Pugh Score and HCC screening with RUQ US and AFP in those that are confirmed Metavir 3 or Metavir 4 by Fibrosure

    c. History of Previous HCV treatment to include: treatment regimen, duration, and treatment outcomes.

    d. High Risk Behavior/Mode of Transmission/risks of disease progression

    e. Extra- Hepatic Manifestations of HCV.

    f. Physical Examination findings consistent with cirrhosis.

    g. Hepatic Decompensation history.

VIII. TREATMENT MONITORING

A. **On Treatment Monitoring**:

After initiating Directly Observed Therapy (DOT), Direct Acting Anti-viral (DAA) therapy, the patient is scheduled clinic appointments every 4 weeks during the course of the treatment duration.

The primary focus of these visits is assessment for medication adherence, side effects, and symptoms of hepatic decompensation..

1. Upon receipt at the treating facility, DAAs will be counted, ensuring the correct number of doses have been received and initiate the DAA regimen and follow the monitoring schedule.

2. In addition to monitoring patient compliance via the Electronic Medication Administration Records (eMAR), All DAA HCV medications will be counted in a perpetual inventory system on the "HCV Medication Regimen and Documentation" (**DOC 140137.06H**). This document is to be scanned into the patients EHR upon completion of the regimen.
3. Once DAA treatment is initiated, patients will be restricted to his/her current facility, as indicated on the Activity Housing Summary (IHAP) (**DOC 140113C**). If a patient must be transferred to another facility while on HCV medications including to another ODOC facility, a hospital, or county jail, the HCV Treatment Coordinator and receiving facility must be notified that a patient on HCV medications is transferring.. The "Medication Chain of Custody" (**DOC 140137.06 N**) will be completed in its entirety, scanned into the EHR and sent with the transporting officer along with the HCV medication.
4. The receiving ODOC facility will ensure all on and post treatment appointments are scheduled within their clinic. A "Medical Transfer Request" (**DOC 140113E**) or on-site consultation may be indicated for patients with decompensated cirrhosis or other comorbidities that complicate HCV (re)treatment.
5. Educate patients regarding the need for strict avoidance of all hepatotoxic substances including illicit drug use and alcohol while on HCV treatment. Patients that failed the pre-treatment urine drug screen or are high risk for ongoing illicit drug use will be referred to Substance Abuse Treatment.
6. A CMP will be drawn every 4 weeks while on medications for all at risk of hepatoxicity and/or those that have a positive baseline Hepatitis B Surface Antigen.
7. Monitoring patients with Diabetes is indicated during HCV treatment as rapid reduction in the hepatitis C viral load can lead to improvement in glucose metabolism, potentially resulting in symptomatic hypoglycemia if antidiabetic agents are continued at the same dose.
8. Patients with advanced fibrosis (Metavir 3) or cirrhosis (Metavir 4) should be monitored for the development of clinical complications including jaundice, ascites, and hepatic encephalopathy as well as laboratory testing to identify hepatic dysfunction including hypoalbuminemia, hyperbilirubinemia, or hypoprothrombinemia.

B. On-Treatment Direct Acting Antiviral Non-adherence

If a patient misses 2 consecutive doses or 4 total doses of medication during treatment, the patient will be scheduled with an on-site provider to address the medication non-adherence. Specifically, the on-site provider will educate the patient that the HCV medication may be stopped to protect against the development of drug resistance and lower SVR (cure) rates, which complicates future treatment decisions.

1. The on-site provider will complete the "**Provider HCV Medication Compliance Counseling"** (**DOC 140137.06O**), The HCV Treatment Coordinator and/or Chief Medical Officer must be consulted before the HCV Medication is discontinued due to noncompliance.

2. If the HCV Treatment Coordinator and/or the Chief Medical Officer determine it is best to discontinue the HCV Medication, package the HCV medication with the ODOC Chain of Custody (DOC140137.6 N) and mail to Dick Conner Correctional Center for the addition of this medication to Stock Supply.

IX. POST TREATMENT MONITORING:

A. After patients complete HCV medications, he/she will be un-restricted from the current (treating) facility, as indicated on the Activity Housing Summary (IHAP) **(DOC 140113C)**. If the patient required a medical transfer for HCV Treatment, a medical transfer back to the pre-treatment facility may be indicated.

B. Providers Complete the "HCV End of Treatment Note" (**DOC 140137.06F**) and educate patients on risks of re-infection. Providers may utilize the "Inmate Hepatitis C Notification" (**DOC 140137.06O**): HCV End of Treatment if a patient is unable to be scheduled in clinic for follow-up.

C. Schedule HCV Antibody with reflex RNA (CPL 4677) 12 weeks after the completion of HCV treatment and complete the "HCV 12 Week Post Treatment-Assess for Sustained Virologic Response (SVR12) (**DOC 140137.06I**). If this HCV RNA is undetectable (or less the 15 IU/mL), it defines a sustained virologic response (SVR12) or cure. Change the ICD-9 code 070.70 to "resolved" and remove from Chronic Clinic: HCV. Educate patients on behaviors that risk re-infection. Providers may utilize the "Inmate Hepatitis C Notification" (**DOC 140137.06O**): HCV SVR12 without cirrhosis if a patient is unable to be scheduled in clinic for follow-up.

D. Recurrent viremia following an SVR may be due to treatment failure (relapse) or reinfection. To help distinguish between the two, an HCV genotype, along with subtyping for genotype 1, should be obtained in an attempt to distinguish treatment relapse from reinfection. Providers must specifically question his/her patient regarding high-risk behaviors during and following HCV treatment. Additionally, medication adherence should be assessed in all patients that have a history of HCV Treatment.

X. ONGOING MONITORING

Periodic monitoring is recommended for all those with active infection, including acute HCV infection, HCV treatment relapses or reinfection, and those with chronic HCV infection not yet treated or refuse treatment.

A. Chronic Clinic visits every 6 months are indicated for patients without advanced fibrosis, cirrhosis, or complications. This evaluation should include vital signs, a focused review of systems, physical examination, patient education relevant to HCV, and annual lab monitoring including (CBC, CMP, PT/INR and calculation of APRI and FIB-4). Most experts recommend using 40 IU/L as the value for the AST upper limit of normal when calculating an APRI value.

B. For patients with cirrhosis or significant comorbidities, Chronic Clinic assessments are indicated every 6 months along with lab monitoring every 6 months to include: (CBC, PT/INR, CMP, and calculation of CTP score). Patients with advanced fibrosis and cirrhosis require HCC screening to include a Right Upper Quadrant Ultrasound and AFP every 6 months.

C. In cases of acute HCV infection, monitoring for spontaneous clearance of the infection with ALT and quantitative HCV RNA levels (HCV Antibody with reflex RNA, CPL 4677) every 12 weeks, for 12 months, is recommended. If viremia persists after that time, continue to monitor and manage the case as a chronic infection. In most cases of acute HCV infection, treatment should be deferred to allow for spontaneous clearance of viremia. However, rarely there may be a compelling reason to treat the acute infection in order to prevent severe complications, e.g., HCV infection superimposed on established cirrhosis or advanced fibrosis.

D. For patients that achieve cure following treatment or spontaneous clearance of HCV but continue to engage in high-risk behavior including illicit drug use, prison tattooing or piercings, or unprotected sex, screening with HCV Antibody with reflex RNA (CPL 4677) are indicated annually.

XI. SPECIAL CONSIDERATIONS

A. Linkage to Care

Some patients will have insufficient time remaining on his/her sentence to deliver the full DAA regimen while in our custody. These patients should be linked to community clinics for continuity of care and potential treatment after discharge. Providers should assess these patients for HCV treatment after discharge as part of the "Linkage to Care" (**Attachment A**). Providers will complete the "HCV Linkage to Care Note" (**DOC 140137.06K**). Print the "HCV Linkage to Care Note" (**DOC 140137.06K**) along with the "Linkage to Care" (**Attachment A**) document and issue both to these patients.

B. Ongoing Risk Behaviors

HCV Treatment should be deferred in those still receiving prison tattoos and piercings. Some patients continue to use illicit drugs complicating the treatment process including compliance, adverse effects including hepatoxicity during treatment and reinfection risk following successful treatment. These patients benefit from Substance Abuse Treatment before and/or during and after treatment.

Substance Abuse Patient and Provider Education:

For Patients:

- Patient education: Cannabis use disorder (The Basics) attachment
- Patient education: Opioid use disorder (The Basics) attachment
- Stimulant Use Disorder (The Basics) attachment
- Patient education: Substance Use Disorder (The Basics) attachment

For Providers:

- American Society of Addiction Medicine (ASAM)/American Academy of Addiction Psychiatry (AAAP): Clinical practice guideline on the management of stimulant use disorder (2024)
- Substance Abuse and Mental Health Services Administration (SAMHSA): A Treatment Improvement Protocol (TIP) for treatment of stimulant use disorders (2021)

- World Federation of Societies of Biological Psychiatry (WFSBP): Guidelines for the biological treatment of substance use and related disorders, part 2 − Opioid dependence (2011)
- American Society of Addiction Medicine (ASAM): National practice guideline for the treatment of opioid use disorder, focused update (2020)
- US Department of Veterans Affairs (VA)/Department of Defense (DoD): Clinical practice guidelines for the management of substance use disorder (SUD) (2021)
- US Preventive Services Task Force (USPSTF): Final recommendation statement on unhealthy drug use – Screening (2020)
- Substance Abuse and Mental Health Services Administration (SAMHSA): A Treatment Improvement Protocol (TIP) for detoxification and substance abuse treatment (2006, revised 2015)
- American College of Physicians (ACP): Position paper on health and public policy to facilitate effective prevention and treatment of substance use disorders involving illicit and prescription drugs (2017)

XII. REFERENCES

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http://hcvguidelines.org/

https://www.hepatitisc.uw.edu/

XIII. Action

The chief medical officer will be responsible for compliance with this procedure.

Any exceptions to this procedure will require prior written approval from the director. This procedure will be effective as indicated.

Replaced: Medical Services Resource Manual 140137-06 entitled “Management of Hepatitis C” dated February 2, 2024.

Distribution: Medical Services Resource Manual

Referenced Forms	Title	Located
DOC 140137.06 A	"Case Manager Review/Medical Treatment Evaluation"	Attached
DOC 140137.06 B	"Hepatitis C Frequently Asked Questions"	Attached
DOC 140137.06 C	"Waiver of Treatment for Hepatitis C"	Attached
DOC 140137.06 D	"Hepatitis C Agreement for Treatment Work-Up"	Attached
DOC 140137.06 E	"HCV Monthly Monitoring"	Attached
DOC 140137.06 F	"HCV End of Treatment Note"	Attached
DOC 140137.06 G	"HCV Treatment Work-Up Provider Note"	Attached
DOC 140137.06 H	"HCV Medication Regimen and Documentation"	Attached
DOC 140137.06 I	"HCV 12 Week Post Treatment - Assess for Sustained Virologic Response (SVR12)"	Attached
DOC 140137.06 M	"HCV Laboratory Testing and Patient Education Notification"	Attached
DOC 140137.06 N	"Medication Chain of Custody"	Attached
DOC 140137.06 P	"Provider HCV Medication Compliance Counseling"	Attached
DOC 140137.06 Q	"HCV Providers Retreatment Work-Up Clinical Note"	Attached
DOC 140137.06 R	HCV Retreatment Work-up Order Note	Attached
DOC 140113 E	"Medical Transfer Request"	OP 140113
DOC 140113 C	"Activity Housing Summary (IHAP)"	OP 140113

Referenced Attachments	Title	Location
Attachment A	"Linkage to Care"	Attached
Attachment C	"Patient Education: Cannabis Use Disorder (The Basics)"	Attached
Attachment D	"Patient Education: Opioid Use Disorder (The Basics)"	Attached
Attachment E	"Patient Education: Stimulant Use Disorder (The Basics)"	Attached
Attachment F	"Patient Education: Substance Use Disorder (The Basics)"	Attached