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Management of Hepatitis C	ACA Standards: 5-ACI-A-25, 5-ACI-6A-27		
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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.

The ODOC Hepatitis C MSRM allows for the selection of those patients who are likely to benefit most from treatment. All inmates with chronic HCV are enrolled in every 6 months chronic clinic provider evaluations at which time indications to treatment are assessed.

At any point during evaluation and treatment, an inmate can decline further evaluation or treatment. Following counseling, a “Waiver of Treatment for Hepatitis C” ([DOC 140137.06 C](#)) will be signed.

II. HEPATITIS C PROTOCOL

A. The 5 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 of inmates who are anti-HCV positive
 - Targeted history and physical examination
 - 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) if last HIV screen was > 1 year
 - Provide HCV Education (“Hepatitis C Frequently Asked Questions” ([DOC 140137.06 B](#))).
3. Step 3: Assess for hepatic cirrhosis/decompensation and priority criteria for treatment, if HCV RNA is detectable
 - Assess for hepatic cirrhosis/decompensation: Calculate APRI and FIB-4 scores if no obvious cirrhosis; Calculate CTP score if cirrhosis is known or suspected. PT/INR (1425) will have to be drawn as part of the CTP calculation.
 - Assess for priority criteria for treatment of HCV and exclude contraindications
 - Complete “Case Manager Review/Medical Treatment Evaluation” ([DOC 140137.06 A](#)).
4. Step 4: Perform a pretreatment assessment, if priority criteria for treatment are met
 - Obtain additional labs to include: HCV Genotype (CPL 4804), Genotype 1a NS5a resistance (CPL 4795) in those that are Genotype 1a, Fibrosure (CPL 3884) may be indicated, Obtain witnessed UDS (CPL 3311) and urine pregnancy test.
 - 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.
 - Complete “Hepatitis C Agreement for Treatment Work-up” ([DOC 140137.06 D](#)).
 - Complete the “HCV Treatment Work-Up Provider Note” ([DOC 140137.06 G](#)) and co-sign note to Bethany Wagener, MHS, PA-C.
5. Step 5: Monitor patient during and after treatment.
 - A “Medical Transfer Request” ([DOC 140113 E](#)) or on-site consultation may be indicated for patients with [decompensated](#) cirrhosis or other comorbidities that complicate HCV treatment.
 - Restrict patient to treating facility only while taking the Direct Acting Antiviral medication (DAA)

- Initiate approved DAA regimen as a Directly Observed Therapy and follow monitoring schedule as directed by the ODOC HCV Clinical Coordinator and/or CMO.
- Schedule Monthly HCV nurse monitoring for the duration of HCV treatment.
- Providers evaluate and complete HCV Post Treatment Notes and co-sign them to the ODOC HCV Clinical Coordinator.
 1. End of Treatment (EOT); un-restrict patients from facility
 2. 12 Week Post Treatment (assess for sustained virologic response 12 weeks after completion of therapy- SVR12).
 3. 48 Week Post Treatment is indicated only for patients with evidence of cirrhosis prior to treatment (assess for sustained virologic response 48 weeks after completion of therapy- SVR48).

III. SCREENING FOR HCV INFECTION

A. Inmate History and Patient Education

A health history should be obtained from all newly incarcerated inmates. In addition, 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 140137.06 B](#)).

An opt-out strategy of voluntary testing for HCV infection at the prevention baseline visit is recommended for all inmates: (a) with risk factors (b) with certain medical conditions and/or birth cohorts, and (c) those that request testing.

1. Risk Behaviors and Exposures:

- 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.
- g. Have ever been incarcerated.

2. 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. All Inmates that request HCV screening

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. The presence of HCV RNA indicates active infection, whereas presence of antibodies with negative HCV RNA indicates resolved infection.

Patients that cleared HCV spontaneously or achieved a sustained virologic response (SVR) with treatment that are at risk of or are suspected to have suffered reinfection will require an HCV RNA test as the initial screening.

4. Screening Method:

Laboratory test: HCV ab with reflex Quant (CPL # 4677)

5. Refusal of Testing

Patients who decline testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits.

B. Initial Evaluation of Anti-HCV Positive Inmates

Initial evaluation of anti-HCV positive patients includes (a) a baseline history and physical examination, and (b) baseline lab tests. The patient should also be (c) assessed regarding the need for preventive health interventions such as vaccines and screening for other conditions, as well as (d) counseled with information on HCV infection. “Hepatitis C Frequently Asked Questions “([DOC 140137.06 B](#)).

1. Determining whether the patient meets ODOC priority criteria for treatment is an important part of the initial evaluation of anti-HCV positive inmates:
 - a. If cirrhosis is present, see Section 4, Assess for Hepatic Cirrhosis and Decompensation, to determine whether the liver disease is compensated or decompensated.
 - b. Section 5, ODOC Priority Criteria for Treatment, lists the clinical scenarios that will be used in the ODOC to prioritize patients for treatment.

C. Baseline Evaluation

A baseline provider evaluation should be conducted for all inmates who are anti-HCV positive with confirmatory PCR. At a minimum, this evaluation should include the following elements:

1. Targeted History and Physical Examination:

- a. Evaluate for signs and symptoms of liver disease, and determine risk behaviors for acquiring HCV infection (see the section on risk factors under screening criteria above). Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped.
- b. Evaluate for other possible causes of liver disease, especially alcoholism, illicit drug use (including marijuana use), nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), iron overload, and autoimmune hepatitis. Quantify current and/or prior alcohol consumption and illicit drug use including marijuana.
- c. Inquire about prior treatment for HCV infection, specific medications used, dosages and duration of treatment, and outcomes, if known.

2. Laboratory Tests:

- a. CBC (CPL # 1000), CMP (CPL # 9179)
 1. Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated, to determine the underlying cause, e.g., low hemoglobin / platelet count or GFR.
- b. Hepatitis A and B serology and HIV screen within the last year – Hepatitis Panel (CPL 162) and HIV antibody (CPL # 3540).
- c. Unless otherwise clinically indicated, testing for other causes of liver disease- e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin- are not routinely ordered in the evaluation of a positive HCV Ab test.
- d. A urine drug screen is recommended to determine the need for referral to Substance Abuse Treatment. (CPL # 3311).

3. Preventive Health Measure:

All inmates who are anti-HCV positive should be evaluated to assess the need for the preventive health interventions, including the following:

- a. **Hepatitis B Vaccine:** Indicated for susceptible patients with chronic HCV infection. Patients with evidence of liver disease should be priority candidates for HBV vaccination.
- b. **Hepatitis A Vaccine:** Indicated for susceptible patients with chronic HCV infection.

- c. **Influenza vaccine:** Offer to all HCV infected patients annually. Patients with cirrhosis are high priority for influenza vaccine.
- d. **COVID-19 vaccine:** All patients with chronic liver disease should receive one of the available COVID-19 vaccines, unless contraindicated for other reasons (e.g., hypersensitivity to the vaccine or its components). Chronic liver disease is a risk factor for adverse outcome with COVID-19 infection.

4. Patient Education:

Inmates diagnosed with chronic HCV infection should be counseled by a health care provider 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/hcv/cfaq.htm>
3. *Hepatitis Foundation International (HFI)* <https://hepatitisfoundation.org/>

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. *Centers for Disease Control and Prevention*
<https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>
3. <https://www.hepatitisc.uw.edu/>

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

Patients that are found to have positive HCV antibodies with non-detectable viral loads either spontaneously cleared the virus or have been treated successfully for HCV. These patients still require a provider visit to discuss these laboratory results. Providers should enter the ICD-9 code (070.70) into the patients EHR and indicate the problem is “resolved” with an explanation (successful treatment versus spontaneous resolution). Patients should be educated that they can re-infect themselves if they engage in high-risk behavior. They will require HCV screening by PCR (as they can remain anti-HCV positive lifelong) if they do engage in high-risk behavior. They do not require enrollment in Chronic Clinic for HCV as long as they have no evidence of cirrhosis. If they have evidence of cirrhosis, they should be enrolled in Chronic Clinic and require 571.5 (Cirrhosis) but not 070.70 (HCV).

E. Assess for Hepatic Fibrosis and Cirrhosis

Assessing for fibrosis and cirrhosis is recommended in all patients with HCV infection in order to prioritize for treatment and 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.

1. Patients with advanced hepatic fibrosis (stage 3) have a 10 % per year rate of progressing to cirrhosis (stage 4).
2. Those with cirrhosis have a 4 % per year rate of developing decompensated cirrhosis and a 3 % per year rate of developing hepatocellular carcinoma.

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. The AST-Platelet Ratio Index (APRI) and FIB-4 score are validated non-invasive assessments of hepatic fibrosis and cirrhosis.

- a. The APRI score, a calculation based on results from 2 blood tests- the AST and the platelet count; and the FIB-4 score, a calculation based on results from 3 blood tests, the AST, ALT, platelet count and patients age- are less invasive and less expensive means of assessing fibrosis than a liver biopsy. **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>

- b. **An APRI score of ≥ 2.0 may be used to predict the presence of cirrhosis.** At this cutoff, the APRI score has a sensitivity of 48 %, but a specificity of 94 %, for predicting cirrhosis. Inmates with an APRI score of ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see *abdominal imaging studies* bullet below in this list). **The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4).** Using a cutoff of ≥ 0.7 , the sensitivity is 77 % and specificity is 72 % for significant fibrosis.
- c. **A FIB-4 score of ≥ 3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis.** A FIB-4 score <1.45 has a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25 . Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

- d. **The APRI and FIB-4 scores may be invalidated in cases of splenectomy or thrombocytosis.**
- e. **Liver biopsy is no longer required** unless otherwise clinically indicated (e.g., to assess for other of liver diseases that may co-exist with HCV infection, including both hereditary and acquired conditions including: NAFLD, Auto-Immune Hepatitis, Hemochromatosis, or Alpha 1 Anti-trypsin Deficiency) or as per the direction of the Hepatologist.
- f. Although a combination of direct biomarkers and transient elastography is emerging as an accurate non-invasive assessment of fibrosis, the data is insufficient at this time to establish it as the new standard over validated indirect biomarkers such as the APRI and FIB-4 scores (especially when combining these scores).
- g. **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.

F. Assessment for Hepatic Decompensation in those with Cirrhosis

Assessing for hepatic decompensation in those with cirrhosis is important for determining the most appropriate HCV treatment regimen; as the regimen may differ depending on whether the cirrhosis is compensated or decompensated.

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 (<34.2 micromol/liter)	2 to 3 mg/dL (34.2 to 51.3 micromol/liter)	>3 mg/dL (>51.3 micromol/liter)
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)
Prothrombin time			
Seconds over control	<4	4 to 6	>6
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. Inmates w/ 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.

G. Additional Interventions for Inmates with Cirrhosis

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

1. Ensure these patients have an active ICD-9 cirrhosis code (571.5)
2. Pneumococcal vaccine: Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age.
3. Covid-19 vaccine: Offer to all HCV-infected inmates Covid-19 vaccine with booster if not contraindicated.
4. Hepatocellular Carcinoma screening: Liver ultrasound with AFP is recommended every 6 months for patients with both HCV *and* cirrhosis.
5. Esophageal Varices Screening: 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.

H. Other Healthcare Interventions Recommended for Patients with Cirrhosis may include:

1. Nonselective beta blockers for prevention of variceal bleeding in patients with known esophageal varices.
 - a. Propranolol Max dose 80 mg. Initial dose of 20 mg BID

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- b. Carvedilol Max dose 6.25 mg BID. Initial dose of 3.125 mg twice daily or 6.25 mg once daily
- c. Titrate according to resting heart rate (target 55 to 60 beats per minute) while maintaining blood pressure (e.g., systolic blood pressure \geq 90 mm Hg)
2. Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
3. Optimized 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.
4. HE prophylaxis: but only with clear history of HE or Clinical evidence of overt HE: based on the combination:
 - a. Impaired mental status which is commonly graded by the West Haven Criteria.
 - b. Impaired neuromotor function, such as hyperreflexia, hypertonicity, and asterixis.
5. HE prophylaxis includes: avoiding precipitating factors, Neomycin 250 mg 2-4 times daily (titrate to reduce HE sx's), Xifaxin 550 mg BID, and/or Lactulose 10-30 G PO 2-4 X daily (titrated to 2-3 soft stools daily). Miralax 17 grams daily can also be used in conjunction with these medications. There is no clinical indication for routine ammonia levels.
6. In general, NSAIDs 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 this document. Other resources should be consulted for more specific recommendations related to this condition which includes: MSRM 140125-01 (Management of Viral Hepatitis).

IV. PRIORITY CRITERIA FOR HCV TREATMENT

Assessing for treatment priority is an important part of the initial evaluation and ongoing management of patients 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. The ODOC has established criteria, ensuring all patients are considered for treatment and those with the greatest need are identified and treated first. Exceptions will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment. Patients with decompensated cirrhosis, HCC, or comorbidities that can complicate HCV treatment may require consultation for expert guidance regarding treatment regimens and monitoring.

A. Priority Level 1:

1. Moderate Fibrosis to Advanced Hepatic Fibrosis/Cirrhosis
 - a. APRI \geq 0.7
 - b. FIB-4 \geq 1.45

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- c. \geq Stage 2 fibrosis on liver biopsy
 - d. Known or suspected cirrhosis (see above section “assessing for hepatic fibrosis/cirrhosis).
2. Hepatocellular Carcinoma (HCC) - on a case-by-case basis as approved and with expert guidance by Hepatology.
 3. Comorbid Medical Conditions associated with more rapid progression of fibrosis including:
 - a. Coinfection with HIV (with expert guidance).
 - b. Coinfection with HBV. HCV has a suppressive effect on HBV. Therefore, if HCV viremia is resolved, patients co-infected with HBV could decompensate. Therefore, unless otherwise directed, HBV must be treated first and patients (although don't require seroconversion) need to have an undetectable HBV viral load prior to the initiation of HCV treatment.
 - c. Comorbid Liver Diseases (e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
 - d. Diabetes Mellitus
 - e. Chronic Kidney Disease (CKD) with GFR \leq 59 mL/min
 - f. Cryoglobulinemia with or without vasculitis
 - g. Certain types of Lymphomas or hematologic malignancies
 - h. Porphyria Cutanea Tarda or Lichen Planus
 4. Immunosuppressant Medication for a Comorbid Medical Condition: Some immunosuppressant medications may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. Such cases will be considered for prioritized treatment of HCV on an individual basis.
 5. Continuity of Care for Those Already Started on Treatment, including inmates who are newly incarcerated.
 6. Patients serving extended sentences, regardless of disease severity or comorbid conditions

B. Priority Level 2:

- a. Stage 0 to 1 fibrosis on liver biopsy
- b. APRI < 0.7
- c. FIB-4 < 1.45

C. 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, especially for any regimen that would require ribavirin.
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 by the CMO and/or ODOC HCV Clinical Coordinator 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 (as specified above) unless otherwise indicated by the CMO and/or ODOC HCV Clinical Coordinator 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 a rigorous treatment regimen. Ideally, patients should abstain from high-risk activities while incarcerated.
 - a. Patients with high priority but 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.

V. PRE-TREATMENT ASSESSMENT

- A. 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>

- B. Complete the ODOC “Hepatitis C Frequently Asked Questions” ([DOC 140137.06 B](#)).
- C. Complete the “Hepatitis C Agreement for Treatment Work-up” ([DOC 140137.06 D](#)).

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- D. Complete “Case Manager Review/Medical Treatment Evaluation” ([DOC 140137.06 A](#))
- E. Consult the Oklahoma Department of Corrections Hepatitis C Clinical Coordinator.
- F. Providers complete “HCV Treatment Provider Work-up Order Note” ([DOC 140137.06 L](#)) to ensure all necessary labs, imaging, and documents are completed and scanned into the EHR to include:
1. Labs within 6 months of HCV treatment start date include: CBC, CMP
 2. Urine Pregnancy Test within 30 days
 3. Labs within 1 year of HCV treatment start date include: HCV PCR RNA, Hepatitis profile (that includes HBsAg and anti-HBc), HBV PCR DNA (if either HBsAg or anti-HBc positive), AFP, INR, and TSH, HIV antibody, and HCV genotype, Genotype 1a NS5a resistance in those that are Genotype 1a, Fibrosure may be indicated.
 4. Providers complete the full “HCV Treatment Work-Up Provider Note” ([DOC 140137.06 G](#)) and co-sign the note to the ODOC HCV Clinical Coordinator. This work-up includes:
 5. APRI, FIB-4, and Child Pugh Calculations in those with cirrhosis.
 6. History of Previous HCV treatment to include: treatment regimen, duration, and treatment outcomes.
 7. High Risk Behavior/Mode of Transmission/risks of disease progression
 8. Extra- Hepatic Manifestations of HCV.
 9. Physical Examination findings consistent with cirrhosis.
 10. Hepatic Decompensation history.
 11. HCC screen (includes RUQ/splenic Ultrasound and AFP).

VI. 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, and adverse drug reactions.

1. Initiate approved DAA regimen and follow the monitoring schedule as directed by the ODOC HCV Clinical Coordinator and/or CMO

2. Upon receipt at the treating facility, DAAs for HCV treatment will be counted, ensuring the correct number of doses have been received.
3. 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 140137.06 H](#)). The “HCV Medication Regimen and Documentation” ([DOC 140137.06 H](#)) is to be scanned into the inmates EHR upon completion.
4. Once DAA treatment begins, patients will be restricted to his/her current facility, as indicated on the Activity Housing Summary (IHAP) ([DOC 140113C](#)). This restriction can be lifted after the patient completes his/her full medication treatment course.
5. Schedule HCV Monthly nurse monitoring for the duration of HCV treatment. “HCV Monthly Monitoring” ([DOC 140137.06 E](#)).
6. A “Medical Transfer Request” ([DOC 140113E](#)) or on-site consultation may be indicated for patients with decompensated cirrhosis or other comorbidities that complicate HCV treatment.
7. If a patient misses 2 consecutive doses or 4 total doses of medication during treatment, the medication ordering provider needs to be notified promptly. Additional follow-up appointments may be indicated if compliance is compromised.
8. A CMP will be drawn every 4 weeks during medication treatment for all patients that have a positive baseline HBsAg and/or anti-HBc. HBV PCR DNA will need to be repeated if the AST or ALT doubles.
9. 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 or other hepatotoxicity will be referred to Substance Abuse Treatment and a CMP will be drawn every 4 weeks during medication treatment. A witnessed Urine Drug Screen will need to be repeated if the AST or ALT doubles.
10. Additional labs may be indicated as per the directive from the CMO and/or HCV Clinical Coordinator.
11. Telehepatology or other expert Consultation may be indicated in patients with decompensated cirrhosis or other comorbidities that complicate HCV treatment.

VII. POST TREATMENT MONITORING:

- G. 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)
- H. An End of Treatment (EOT) provider assessment is indicated for all patients that complete HCV treatment. Providers should educate patients on risks of re-infection.
- I. Complete the “HCV End of Treatment Note” ([140137.06 F](#)) and co-sign to the ODOC HCV Clinical Coordinator.

- J. If the patient required a medical transfer for HCV treatment, co-sign this EOT note to the ODOC HCV treatment transfer coordinator (Judy Brinkley, RN), so the patient can be transferred back to the pre-treatment facility.
- K. A quantitative HCV RNA viral load assessment is indicated at 12 weeks after completion of the HCV medication; if this HCV RNA is undetectable, it defines a sustained virologic response (SVR12).
- L. Schedule HCV PCR RNA (CPL 4571)12 weeks after the completion of HCV treatment.
- M. Complete the “HCV 12 Week Post Treatment - Assess for Sustained Virologic Response (SVR12)” ([DOC 140137.06 I](#)) and co-sign to the ODOC HCV Clinical Coordinator.
- H. If the patient’s 12-week post treatment viral load is undetectable, and does not have cirrhosis (Metavir 4), he or she is considered cured. Change ICD-9 code 070.70 to “resolved” and remove from Chronic Clinic: HCV.
- J. All patients with a Metavir 3 will require HCC screening with an AFP and RUQ ultrasound every 6 months.
- K. Provider delivered patient education indicated including: behaviors that risk re-infection and hepatotoxicity; future screening for re-infection necessitates PCR testing as opposed to antibody screening.
- L. A quantitative HCV RNA viral load assessment is indicated 1 year after completion of HCV medication (SVR48) only in those with evidence of cirrhosis prior to treatment (Metavir 4). If this HCV RNA is undetectable, it defines a sustained virologic response (SVR48).
- M. Schedule HCV PCR RNA 48 weeks after the completion of HCV treatment.
- N. Complete the “HCV 48 Week Post Treatment - Assess for Sustained Virologic Response (SVR48)” ([DOC 140137.06 J](#)) and co-sign to the ODOC HCV Clinical Coordinator.
- O. Provider delivered patient education indicated including: behaviors that risk re-infection and hepatotoxicity; future screening for re-infection necessitates PCR testing as opposed to antibody screening.
- P. Change ICD-9 code 070.70 to “resolved.” Patient will remain in Chronic Clinic for Cirrhosis and ICD-9 code 571.5 will remain active lifelong. These patients will require lifelong HCC screening.
- R. Recurrent viremia following an SVR may be due to treatment failure or reinfection. To help distinguish between the two in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained in an attempt to distinguish treatment failure from reinfection.

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VIII. ONGOING MONITORING

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

- a. For cases without advanced fibrosis, cirrhosis, or complications every 6 month assessment during Chronic Clinic visits is indicated. This evaluation should include a focused review of systems and patient educations relevant to HCV, vital signs and a focused physical examination. Lab monitoring including (CBC, CMP, and calculation of APRI and FIB-4) are indicated annually.
- b. For patients with cirrhosis or significant comorbidities, every 6 month assessments during Chronic Clinic visits are indicated along with every 6 month lab monitoring including: (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 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 may be deferred to allow for spontaneous clearance of viremia. However, in some cases 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 unprotected sex, HCV PCR RNAs are indicated annually.

IX. SPECIAL CONSIDERATIONS

a. Expert Guidance

Some patients may require expert guidance from Hepatology or Infectious Disease prior to the initiation of HCV treatment.

b. HBV Coinfection

In patients coinfecting with HBV and HCV, HBV reactivation may occur during or after treatment with HCV DAAs. Testing for HBV infection – including HBsAg, anti-HBs, and anti-HBc, as well as HBV DNA levels in those with a reactive HBsAg or anti-HBc is recommended for all patients being considered for treatment of HCV infection. If the patient is found to have a negative anti-HBs, he/she should be offered the 3 dose HBV Vaccine Series.

c. HIV Coinfection

1. Currently recommended HCV regimens are equally effective for HCV mono-infection and coinfection with HIV. However, an alternative HCV regimen or an alternative antiretroviral medication regimen may be necessary due to potential drug interactions between the HCV DAAs and certain antiretrovirals.

2. OUHSC Infectious Disease serves as ODOC's expert guidance via scheduled Telemedicine clinic in patients coinfecting with HCV and HIV.
 - d. Linkage to Care

Some patients may benefit from HCV treatment, but 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. All patients with impending discharge dates will be identified. Providers should assess and work-up these patients for HCV treatment as part of the "Linkage to Care" ([Attachment A](#)).
 - e. Providers will complete the "HCV Linkage to Care Work-up Note" ([DOC 140137.06 K](#)). This note can replace the patient's last Chronic Clinic note.
 - f. Print the "HCV Linkage to Care Work-up Note" ([DOC 140137.06 K](#)) along with the "Linkage to Care" ([Attachment A](#)) document and issue both to these patients.

X. REFERENCES

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https://www.bop.gov/resources/pdfs/012018_hcv_infection.pdf

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

<https://www.aasld.org/publications/practice-guidelines>

XI. 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 May 29, 2019.

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

Referenced Forms	Title	Located
DOC 140137.06 I	"HCV 12 Week Post Treatment - Assess for Sustained Virologic Response (SVR12)"	Attached
DOC 140137.6 J	"HCV 48 Week Post Treatment - Assess for Sustained Virologic Response (SVR48)"	Attached
DOC 140137.6 K	"HCV Linkage to Care Work-up Note"	Attached
DOC 140137.6 L	"HCV Treatment 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