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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 modeled by the Federal Bureau of Prisons Clinical Guidance on Chronic HCV infection. 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 semi-annual 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
 - a. See section III, Screening for HCV infection.
2. Step 2: Perform a baseline evaluation of inmates who are anti-HCV positive
 - a. See section III C, Initial Evaluation of Anti-HCV Positive Inmates with confirmatory reflexed RNA.
 - b. Targeted history and physical exam.
 - c. Lab tests – CBC, CMP, PT/INR, hepatitis B serology (HBsAg, anti-HBs, anti-HBc), HIV AB.
 - d. 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
 - a. Assess for hepatic cirrhosis/decompensation: Calculate APRI and/or FIB-4 scores if no obvious cirrhosis; Calculate CTP score if cirrhosis is known or suspected; Fibrosure may be indicated if APRI and/or FIB-4 scores vary widely between samples or are contradictory (section III D).
 - b. Assess for priority criteria for treatment of HCV (see section IV).
 - c. Exclude Contraindications to treatment.
 - d. 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 (Section V).
 - a. Obtain HCV Genotype.
 - b. Complete “Hepatitis C Agreement for Treatment Work-up” ([DOC 140137.06 D](#)).
 - c. Consult the Oklahoma Department of Corrections Hepatitis C Clinical Coordinator.
 - d. Providers complete the full “HCV Treatment Provider Work-Up for Treatment Note” ([DOC 140137.06 G](#)) and co-sign note to Bethany Wagener, MHS, PA-C.

5. Step 5: Monitor patient during and after treatment (Section VI).

- a. Initiate approved DAA regimen as a Directly Observed Therapy and follow monitoring schedule as directed by the ODOC HCV Clinical Coordinator and/or CMO.
- b. Schedule Bi-Monthly HCV nurse monitoring for the duration of HCV treatment.
- c. 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.
- d. Telehepatology Consultation may be indicated in patients with decompensated cirrhosis or other comorbidities that complicate HCV treatment.
- e. Providers evaluate and complete “HCV Post Treatment Note” ([DOC 140137.06 E](#)) and co-sign them to the ODOC HCV Clinical Coordinator.
 1. End of Treatment (EOT).
 2. 12 Week Post Treatment (assess for sustained virologic response 12 weeks after completion of therapy- SVR12).
 3. 24 Week Post Treatment is indicated for inmates without evidence of cirrhosis prior to treatment (assess for sustained virologic response 24 weeks after completion of therapy- SVR24).
 4. 48 Week Post Treatment is indicated for inmates 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 inmates 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.

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

4. Screening Method:

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

5. Refusal of Testing

Inmates 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 inmates includes (a) a baseline history and physical examination, and (b) baseline lab tests. The inmate 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](#)).

Determining whether the patient meets ODOC priority criteria for treatment is an important part of the initial evaluation of anti-HCV positive inmates:

1. If cirrhosis is present, see Section 4, Assess for Hepatic Cirrhosis and Decompensation, to determine whether the liver disease is compensated or decompensated.
2. Section 5, ODOC Priority Criteria for Treatment, lists the clinical scenarios that will be used in the ODOC to prioritize inmates 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, quantify prior alcohol consumption, 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.
- 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), PT/INR (CPL # 1425)
 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 - HBsAg, anti-HBs, anti-HBc, anti-HAV (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 only if ongoing substance use is suspected or if it is otherwise clinically indicated. (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 inmates with chronic HCV infection. Inmates with evidence of liver disease should be priority candidates for HBV vaccination.
- b. **Hepatitis A Vaccine:** Indicated for susceptible inmates with chronic HCV infection.
- c. **Influenza vaccine:** Offer to all HCV infected inmates annually. Inmates with cirrhosis are high priority for influenza vaccine.

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)* <http://www.liverfoundation.org>
2. *Centers for Disease Control and Prevention (CDC)*
<http://www.cdc.gov/odu/hepatitis/index.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 National Center for Infectious Diseases—Hepatitis Branch* <http://www.cdc.gov/ncidod/diseases/hepatitis/>
3. <https://www.hepatitisc.uw.edu/>

Anti-HCV Positive patients 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 in the past. 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. These patients will require HCV screening by PCR (as they can remain anti-HCV positive lifelong) if they do engage in high risk behavior. These patients do not require enrollment in Chronic Clinic for HCV or Chronic Liver Disease as long as they have no evidence of cirrhosis. If they have evidence of cirrhosis, they should be enrolled in Chronic Clinic and require ICD-9 codes 571.9 (Chronic Liver Disease) and 571.5 (Cirrhosis) but not 070.70 (HCV).

D. Assess for Hepatic Fibrosis and Cirrhosis

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

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- 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.
 - h. Fibrosure (CPL 3884) is a proprietary laboratory test primarily studied in patients with hepatitis B and C. It 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, respectively. This test may be indicated if APRI and/or FIB-4 scores vary widely between samples or are contradictory. This test should only be ordered if recommended by the ODOC Chief Medical Officer, ODOC HCV Clinical Coordinator or through expert Telehepatology guidance.
- E. 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.

<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 with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for medical parole/Commutation.

F. Additional Interventions for Inmates with Cirrhosis

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

1. Pneumococcal vaccine: Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age.
2. Hepatocellular Carcinoma screening: Liver ultrasound with AFP is recommended every 6 months for patients with both HCV *and* cirrhosis.
3. 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.

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

1. Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
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 hx 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

Determining whether 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. The ODOC has established criteria (as adopted from the Federal Bureau of Prisons HCV treatment priority policy). This ensures that those with the greatest need are identified and treated first. The ODOC Chief Medical Officer in collaboration with the ODOC HCV Clinical Coordinator will provide guidance on specific strategies for implementing these priority levels. Exceptions to the following criteria for Priority levels 1-3 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities. Patients with decompensated cirrhosis, HCC, or comorbidities that can complicate HCV treatment will require consultation for expert guidance regarding treatment regimens and monitoring.

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A. Priority Level 1: High Priority for Treatment

1. Advanced Hepatic Fibrosis/Cirrhosis
 - a. APRI \geq 2.0 or
 - b. FIB-4 \geq 3.25 or
 - c. Fibrosure \geq F3 or F4
 - d. Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy or
 - e. 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 HCV including:
 - a. Cryoglobulinemia with renal disease or vasculitis
 - b. Certain types of Lymphomas or hematologic malignancies
 - c. 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.

B. Priority Level 2: Intermediate Priority for Treatment

1. Evidence For Progressive Fibrosis
 - a. APRI score \geq 0.7
 - b. FIB-4 score \geq 1.45
 - c. Fibrosure F2
 - d. Stage 2 fibrosis on liver biopsy
2. Comorbid Medical Conditions associated with more rapid progression of fibrosis
 - a. Coinfection with HIV (with expert guidance).
 - b. Coinfection with HBV (with expert guidance). 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.

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- c. Comorbid Liver Diseases (e.g. autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis)
- d. Diabetes Mellitus

3. Chronic Kidney Disease (CKD) with GFR \leq 59 mL/min

C. Priority Level 3: Low Priority for Treatment

- a. Stage 0 to 1 fibrosis on liver biopsy
- b. APRI < 0.7
- c. FIB-4 < 1.45
- d. Fibrosure < F2
- e. All other cases of HCV infection meeting the eligibility criteria for treatment as noted right below under *Other Criteria for Treatment*

D. Additional Criteria for HCV Treatment

In addition to meeting the above criteria for priority levels 1-3, inmates 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 severe liver decompensation (evidenced by CTP Class C) as these patients qualify for medical parole (as specified above) unless otherwise indicated by the CMO and/or ODOC HCV Clinical Coordinator following expert consultation.
6. 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.
7. Have sufficient time remaining on their 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. Inmates with high priority criteria (**Priority Level 1**) but insufficient time remaining in ODOC custody, may be considered for treatment if they will have access to medications and linkage to care at the time of release.

- b. Complete “Case Manager Review/Medical Treatment Evaluation” ([DOC 140137.06 A](#)).
- c. To prevent HCV re-infection and reduce the risk of progression of liver disease, inmates should be provided harm reduction and evidence-based treatment for underlying substance use disorders (SUD) as specified by the AASLD. Therefore, inmates with evidence for ongoing high-risk behaviors are considered for HCV treatment on an individual basis as approved by the CMO and/or ODOC HCV Clinical Coordinator when treatment can be delivered along with SUD treatment.

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](#)).
- D. Consult the Oklahoma Department of Corrections Hepatitis C Clinical Coordinator.
 1. Providers complete the full “HCV Treatment Provider Work-Up for Treatment Note” ([DOC 140137.06 G](#)) and co-sign the note to the ODOC HCV Clinical Coordinator. This work-up includes:
 2. Labs within 3 months of HCV treatment start date include: CBC, CMP, AFP, INR, TSH, and Urine Pregnancy Test.
 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 (CPL4286- if either HBsAg or anti-HBc positive), HIV antibody, and HCV genotype (CPL 4804).
 - a. APRI and Child Pugh Calculations.
 - b. History of Previous HCV treatment to include: treatment regimen, duration, and treatment outcomes.
 - c. High Risk Behavior/Mode of Transmission.
 - d. Extra- Hepatic Manifestations of HCV.
 - e. Physical Examination findings consistent with cirrhosis.
 - f. Hepatic Decompensation history.
 - g. HCC screen (includes RUQ/splenic Ultrasound).

- h. IHAP completed within the last 3 months (for inmates that may require transfer to another facility for HCV treatment).

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 2 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 as a Directly Observed Therapy and follow 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](#)). Doses of medication are not counted if they are missed, refused, held or not taken for any reason. 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 treatment course.
5. Schedule HCV Bi-Monthly nurse monitoring for the duration of HCV treatment. "HCV Bi-Monthly Monitoring" ([DOC 140137.06 E](#)).
6. 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.
7. Labs drawn at 4 weeks after the start of therapy should include a CMP (only if the patient had a positive baseline HBsAg and/or anti-HBc). Monthly CMPs are indicated during HCV treatment for these patients. Additional labs may be indicated as per the directive from the CMO and/or HCV Clinical Coordinator.
8. End of Treatment (EOT) assessment is indicated for all inmates that complete HCV treatment.
 - a. Complete the "HCV Post Treatment Note" ([DOC 140137.06 F](#)) for EOT and co-sign to the ODOC HCV Clinical Coordinator.
9. Telehepatology or other expert Consultation may be indicated in patients with decompensated cirrhosis or other comorbidities that complicate HCV treatment.
 - a. "Integris TeleHepatology New Patient Information" ([Attachment A](#)).
 - b. "Integris TeleHepatology New Patient Labs" ([Attachment B](#)).

- c. "Integris TeleHepatology Lab and Treatment Flow Sheet" ([Attachment C](#)).
- d. "Integris TeleHepatology New Patient Recommendations" ([Attachment D](#)).
- e. "Integris TeleHepatology Existing Patient Follow-Up Information" ([Attachment E](#)).

VII. POST TREATMENT MONITORING:

- A. A quantitative HCV RNA viral load assessment is recommended at 12 weeks after completion of treatment; if HCV is undetectable, it defines a sustained virologic response (SVR12).
 - 1. SVR12 is indicated on ALL inmates that complete HCV treatment.
 - a. Schedule HCV PCR RNA 12 weeks after the completion of HCV treatment.
 - b. Complete the "HCV Post Treatment Note" ([DOC 140137.06 F](#)) for SVR12 and co-sign to the ODOC HCV Clinical Coordinator.
- B. If the HCV viral load is again undetectable at 6 months (SVR24) to 12 months (SVR48) after the end of treatment, the inmate may be removed from the chronic care clinic for this condition, so long as he or she has no cirrhosis, complications, or related comorbidities.
 - 1. SVR24 is indicated on ALL inmates that complete HCV treatment and have NO evidence of cirrhosis prior to treatment.
 - a. Schedule HCV PCR RNA 24 weeks after the completion of HCV treatment
 - b. Complete the "HCV Post Treatment Note" ([DOC 140137.06 F](#)) for SVR24 and co-sign to the ODOC HCV Clinical Coordinator.
 - c. 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.
 - d. Change ICD-9 code 070.70 to "resolved" and remove from Chronic Clinic: HCV.
 - 2. SVR48 is indicated only in those inmates with evidence of cirrhosis prior to treatment.
 - a. Schedule HCV PCR RNA 48 weeks after the completion of HCV treatment.
 - b. Complete the "HCV Post Treatment Note" ([DOC 140137.06 F](#)) for SVR48 and co-sign to the ODOC HCV Clinical Coordinator.
 - c. 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.
 - d. Change ICD-9 code 070.70 to "resolved." Patient, however will remain in Chronic Clinic for Cirrhosis and will require lifelong HCC screening.
 - 3. Recurrent viremia following an SVR may be due to relapse or reinfection. To help distinguish between the two in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained. If the post –SVR genotype is the same as the pre-treatment genotype, it is not possible to distinguish relapse from reinfection.

VIII. ONGOING MONITORING

- A. Periodic monitoring is recommended for all those with active infection, including acute HCV infection, HCV treatment failures, relapse of HCV infection or reinfection, and those with chronic HCV infection who are not yet treated or refuse treatment.
1. For cases without advanced fibrosis, cirrhosis, or complications semi-annual 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, PT/INR, CMP, and calculation of APRI and FIB-4) is only indicated annually.
 2. For patients with cirrhosis or significant comorbidities, semi-annual assessments during Chronic Clinic visits is indicated along with semi-annual lab monitoring including: (CBC, PT/INR, CMP, and calculation of CTP score along with HCC screening (RUQ/Splenic US and AFP).
 3. In cases of acute HCV infection, monitoring for spontaneous clearance of the infection with ALT and quantitative HCV RNA levels every 4-8 weeks, for 6-12 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.
 4. For patients with evidence of ongoing illicit drug use before or after HCV treatment, HCV PCR RNAs are indicated annually.

IX. SPECIAL CONSIDERATIONS

- A. The patients specified below will require expert guidance from Hepatology or Infectious Disease prior to the initiation of HCV treatment.
1. HCV Infection with more than one Genotype
 - a. Very little data are available to guide the selection of a DAA regimen when more than one HCV genotype are present at the same time. In such cases, selection of a regimen that is effective against both of the existing genotypes is appropriate.
 2. HBV Coinfection
 - a. 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.

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3. HIV Coinfection

- a. 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.
- B. OUHSC Infectious Disease serves as ODOC's expert guidance via scheduled Telemedicine clinic in patients coinfecting with HCV and HIV.

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 January 9, 2020.

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 Bi-Monthly Monitoring”	Attached
DOC 140137.06 F	“HCV Post 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 140113 E	“Medical Transfer Request”	OP 140113
DOC 140113 C	“Activity Housing Summary (IHAP)”	OP 140113
DOC 140701D	“Informed Consent for Telemedicine Services”	OP-140701

Referenced Attachments	Title	Location
Attachment A	“Integrus TeleHepatology New Patient Information”	Attached
Attachment B	“Integrus TeleHepatology New Patient Labs”	Attached
Attachment C	“Integrus TeleHepatology Lab and Treatment Flow Sheet”	Attached
Attachment D	“Integrus TeleHepatology “New Patient Recommendations”	Attached
Attachment E	“Integrus TeleHepatology Existing Patient Follow-Up Information”	Attached
Attachment F	“Hepatitis C Treatment Monitoring Schedule”	Attached