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<b>Management of Hepatitis C</b>	<b>ACA Standards: 4-4356M, 4-4367</b>		
<b>Donald Sutmiller, D.O., Chief Medical Officer Oklahoma Department of Corrections</b>		<b>Signature on File</b>	

## Management of Hepatitis C

Oklahoma Department of Corrections, Medical Services recognizes that Hepatitis C virus infection represents a potentially serious problem within the correctional environment. It is widely recognized that Hepatitis C infection often results in chronic infection. This could be the case in 60% - 85% of infected individuals. It is also widely recognized that incarcerated individuals have a considerably higher prevalence of Hepatitis C infection than the general population.

What is not so clear is how to predict the outcome of chronic Hepatitis C infection in an individual case. Most studies show that 85% - 90% of persons with chronic Hepatitis C infection will have a mild course without the development of cirrhosis or death from their infection. The remaining 10% -15% will develop cirrhosis; some mild, some severe. A small percentage of those who develop cirrhosis will develop liver cancer. It is this small percentage of persons with severe cirrhosis and cancer who are most likely to benefit from interventions to reduce their risk. Unfortunately there are no clear predictors of who is most likely to benefit from current treatments.

Currently available medication treatments for Hepatitis C infection are fraught with complications. Side effects can be incapacitating, and even fatal. In particular, persons with certain medical and mental health conditions are at high risk for fatal complications of the medications. For these reasons, the Oklahoma Department of Corrections strives to select those people most likely to benefit from the medications and to prevent harm to those most likely to be harmed by the medications.

### I. Hepatitis C Protocol

The Hepatitis C Management Protocol addresses the diagnosis of chronic Hepatitis C, the identification of other types of liver disease, the screening process for medical and mental health contraindications, offender educational materials, and

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treatment guidelines. Medication treatment will take place at one of the four centers of excellence for Hepatitis C treatment (DCCC, JEHCC, MBCC or OSP), or at private prison facilities according to their contract. If an offender is transferred to another facility during the evaluation phase (Step 1-6) the “Hepatitis C Protocol Workup Checklist” (Attachment D) will be initiated. At any point during evaluation and treatment, an offender can decline further evaluation or treatment. A “Waiver of Treatment for Hepatitis C” (DOC 14-137.6l) will be signed.

A. Step 1 – Diagnosis of Chronic Hepatitis C Infection

1. HCV Antibody test (DLO # 8472) can be ordered at the medical providers discretion for any of the following indications:
  - a. Signs or symptoms of liver disease
  - b. Elevated liver enzyme tests
  - c. Known risk factors for HCV infection
  - d. To document a claim of HCV seropositivity prior to incarceration
  - e. Offenders requests HCV testing
2. If HCV antibody test is positive, check for ongoing, chronic infection:
  - a. Check ALT (DLO # 823) every 3 months X3
  - b. If all ALT tests are within normal limits, enroll in Chronic Liver Disease chronic clinic. Check ALT every 6-12 months.
  - c. If any ALT test is above normal, proceed to Step 2.

B. Step 2 – Case Manager Review

1. Send Form A. entitled “Case Manager Review/Medical Treatment Evaluation” (DOC 14-137.6 A) to the offender’s assigned case manager for completion (fill in offender name and DOC #)
2. Must have greater than 24 months remaining prior to earliest release date
3. If greater than 24 months remain until earliest release date, proceed to Step 3
4. If less than 24 month remain until earliest release date, refer to “Conservative Treatment” (Attachment B), and provide offender education Step 3, and enroll offender in Chronic Liver Disease chronic clinic

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- C. Step 3 – Consents and Offender Education
1. Review Video on Hepatitis C Treatment
  2. Review, complete and sign Hepatitis C “Frequently Asked Questions” (DOC 14-137.6 B)
  3. Review, complete and sign “Offender Information about Interferon/Ribavirin combination therapy” (DOC 14-137.6 C)
  4. Review, complete and sign a “Consent for Liver Biopsy” form (DOC 14-137.6 D, attached)
  5. Review, complete and sign an “Agreement to Accept Treatment Plan” (DOC 14-137.6 E)
  6. When all forms are signed by a offender and provider, proceed to Step 4.
- D. Step 4 – Evaluation for Contraindications to Treatment
1. Order lab tests –
    - Hepatitis C differential Diagnosis Panel ( DLO# 326/457/7573)
    - AFP (DLO#237)
    - CBC (DLO#1759)
    - INR (DLO#8847)
    - TSH (DLO#899)
    - HgbA1C (DLO#496)
    - CRP (DLO#4420)
  2. Medical Evaluation – complete and sign a “Medical Contraindications to Treatment” form (DOC 14-137.6 F)
  3. Mental Health Evaluation – complete and sign a “Mental Health Contraindications to Treatment” form (DOC 14-137.6 G)
  4. Verification of at least 24 months remaining in sentence
  5. If no contraindications exist and >24 months remain in sentence, proceed to Step 5

6. If contraindications exist, refer to “Conservative Treatment” (Attachment B, attached), and enroll offender in Chronic Liver Disease chronic clinic.

E. Step 5 – Liver Biopsy

1. Fax Attachment D “Hepatitis C Protocol Workup Checklist” showing completion of steps 1-4 to Regional Lead Physician for approval.
2. Prior to liver biopsy, check quantitative HCV RNA (DLO#10565). If negative, no treatment is necessary. If positive, refer for liver biopsy.
3. Prior to liver biopsy, check HCV Genotype (DLO#37811). **If genotype 2 or 3, no biopsy is necessary: Proceed to Step 6. If genotype 1 or 4, schedule biopsy at LMH.**
4. After liver biopsy is performed, review results with offender. Biopsy report will include a Stage (0-4 – degree of fibrosis) and a Grade (0-4 – degree of inflammation).
  - a. Grade 2, 3 or 4 – qualifies for treatment, regardless of grade
    - If Stage 4 with uncompensated cirrhosis, treatment is contraindicated. Enroll in Chronic Liver Disease chronic clinic.

Cirrhosis	
Decompensated	Compensated
Bilirubin > 1.5 mg/dL	Bilirubin normal
INR > 1.5	Albumin normal
Ascites present	No Ascites
Encephalopathy present	No encephalopathy

b. Stage 1

- Grade 3 or 4 qualifies for treatment
- Grade 0, 1 or 2 – treatment not indicated – repeat Biopsy in 3 – 5 years and enroll in Chronic Liver Disease chronic clinic.

c. Stage 0

- Grade 3 or 4 qualifies for treatment
- Grade 0, 1 or 2 – treatment not indicated – repeat Biopsy in 5 – 10 years and enroll in Chronic Liver

Disease chronic clinic.

5. If offender qualifies for treatment based on biopsy results and absence of contraindications, proceed to Step 6.
6. Transfer offender to a Center of Excellence for HCV treatment. Arrange medical transfer with Medical Services Administrative Office.

F. Step 6 – Pretreatment Evaluation

1. Verify that Steps 1-5 have been done and all forms are completed and signed.
2. Measure weight and vital signs
3. Perform limited physical exam
  - a. Skin and eye exam for jaundice
  - b. Abdominal exam for organomegaly, ascites, tenderness
  - c. Appropriate exam for coexisting medical conditions
4. Proceed to Step 7

G. Step 7 – Treatment

1. Genotype 2 or 3 – 24 weeks of combination drug therapy
2. Genotype 1 – begin combination therapy and check quantitative HCV RNA at 12 wks (DLO#10565)
  - a. If HCV RNA has decreased by 2 log (100 times lower), continue therapy for total of 48 weeks
  - b. If HCV RNA has not decreased by 2 log (100 times lower), discontinue therapy
3. Fax “Non-Formulary Exception Report” (DOC 140130F) to pharmacy (Centers of Excellence only) to obtain medication – indicate under justification section that all forms are complete per Hepatitis C protocol.
4. Combination therapy:
  - a. >75 kg
    - (1) Ribavirin – 3 X 200mg BID

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- (2) Pegylated Interferon alpha 2a (Pegasys) 180 mcg weekly SQ
  - b. 75kg or less
    - (1) Ribavirin – 2 X 200mg AM / 3 X 200mg PM
    - (2) Pegylated Interferon alpha 2a – 180 mcg SQ weekly
  - c. Genotype 2 or 3
    - (1) Ribavirin 2 x 200 mg BID
    - (2) Pegylated Interferon alpha 2a 180 mg SQ weekly
- 5. Follow-up during treatment
  - a. Visits at weeks 1,2,4,8,12,16,20,24,28,32,36,40,44,48
    - (1) Vital signs and weight
    - (2) Liver examination
    - (3) Review of adverse events
    - (4) Lab – Hepatitis C monitoring panel at each visit – (DLO#34704/6399) plus CBC with platelets (DLO#1759) and (urine pregnancy test (DLO#396) for women of childbearing age)
      - (a) Quantitative HCV-RNA at week 12 if genotype 1 or 4 (DLO#10565)
      - (b) Qualitative HCV-RNA at week 48 (DLO# 34024)
      - (c) Random urine drug screens
      - (d) Laboratory results and offenders response to therapy will be documented on “Medication Treatment Tracking” (DOC 14-137.6 H)
  - b. Mental Health follow-up required at weeks 4,8,12,24,36 and 48 refer to “Components of Psychosocial Evaluation” (Attachment C).
  - c. Dose modifications – based on follow-up lab. Refer to “Dose Modification” (Attachment A).

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H. Step 8 – Post-treatment Follow-up

1. 6 months after completion of treatment
  - a. Vital signs / Weight
  - b. Liver examination
  - c. Adverse events
  - d. Lab – CBC, Qualitative HCV-RNA (DLO#34024), (urine pregnancy test for women of childbearing age)
2. If offender has a positive HCV-RNA at end of treatment or 6 months after treatment, enroll offender in Chronic Liver Disease chronic clinic.

II. References

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III. Action

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

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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 June 24, 2008

Distribution: Medical Services Resource Manual

Referenced Forms	Title	Located
<a href="#">DOC 140130F</a>	“Non-Formulary Exception Report“	OP-140130
<a href="#">DOC 14-137.6 A</a>	“Case Manager Review/Medical Treatment Evaluation”	
<a href="#">DOC 14-137.6 B</a>	“Hepatitis C Frequently Asked Questions”	
<a href="#">DOC 14.137.6 C</a>	“Offender Information About Interferon/ Ribavirin Combination Therapy”	
<a href="#">DOC 14-137.6 D</a>	“Consent for Liver Biopsy”	
<a href="#">DOC 14-137.6 E</a>	“Agreement to Accept Treatment Plan”	
<a href="#">DOC 14-137.6 F</a>	“Medical Contraindications to Treatment“	
<a href="#">DOC 14-137.6 G</a>	“Mental Health Contraindications to Treatment”	
<a href="#">DOC 14-137.6 H</a>	“Medication Treatment Tracking“	
<a href="#">DOC 14-137.6 I</a>	“Waiver of Treatment for Hepatitis C”	

Attachments	Title	Location
<a href="#">Attachment A</a>	“Dose Modification”	
<a href="#">Attachment B</a>	“Conservative Treatment”	
<a href="#">Attachment C</a>	“Components of Psychosocial Evaluation”	
<a href="#">Attachment D</a>	“Hepatitis C Protocol Workup Checklist”	