

HS-19.09, "Hepatitis C,"

SCDC POLICY

Change 1 to HS-19.09: 4.2.1

NUMBER: HS-19.09

TITLE: HEPATITIS C

ISSUE DATE: MAY 27, 2016

RESPONSIBLE AUTHORITY: DIVISION OF HEALTH SERVICES

OPERATIONS MANUAL: HEALTH SERVICES

SUPERSEDES: NONE- NEW POLICY

RELEVANT SCDC FORMS/SUPPLIES: M-174; M-175; M-176

ACA/CAC STANDARDS: 4-4354, 4-4356

HEALTH SERVICES PROCEDURES: NOT ANNOTATED

STATE/FEDERAL STATUTES: OSHA Regulation 29 CFR 1910.1030; S.C. Code of Laws Sections 24-1-130, 140

PURPOSE: The South Carolina Department of Corrections (SCDC) has recommended the following protocol be put in place for guidance in treatment of chronic Hepatitis C (HCV). These guidelines were written in conjunction with the University of South Carolina Department of Medicine, Division of Infectious Disease. Information and/or procedures in this policy will change as treatment regimens evolve and/if funding increases for the treatment and management of HCV. (4-4356)

POLICY STATEMENT: The SCDC will strive to render the optimum standard of care to inmates who are infected with Hepatitis C. Every effort will be made by the Agency to ensure those inmates, who meet the criteria outlined in the policy, be placed on a list for evaluation and possibly treatment. In addition, those inmates who are waiting to be treated, will be followed by the SCDC Infectious Disease Physician to maintain optimum health.

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SPECIFIC PROCEDURES:

1. SCREENING FOR HCV INFECTION:

1.1 A health history should be obtained from all newly incarcerated SCDC inmates. In addition, these inmates should be provided with educational information regarding prevention and transmission, risk factors, testing, and medical management of Hepatitis C Virus (HCV) infection during the intake process. (video or brochure)

1.2 Testing for HCV infection, at this time, is recommended for the following:

- HIV positive inmates.
- Inmates on hemodialysis.
- Inmates with chronic Hepatitis B (HBV) Infection. (The inmate is considered chronic if the Hepatitis B positive surface antigen is positive).
- Inmates with percutaneous exposure to blood.
- A reported history of HCV infection without prior medical records to confirm the diagnosis.
- Elevated ALT levels of unknown etiology.
- As requested by a provider for extrahepatic manifestations.

1.3 The preferred screening test for HCV infection is an immunoassay test that measures the presence of antibodies to HCV antigen, referred to as HCV AB or anti-HCV.

1.4 Inmates who have the above risk factors for HCV, but who refuse testing, should be counseled about and offered HCV testing periodically. (4-4356)

2. BASELINE EVALUATION FOR TREATMENT OF ANTI-HCV POSITIVE INMATES:

2.1 A baseline evaluation should be performed on all inmates who are anti-HCV positive. This evaluation will be documented on SCDC Form M-174, "Evaluation: Hepatitis C Treatment."

2.2 The inmate's max out date will be discussed. If the inmate has less than 12 months left on his/her sentence, educational material will be given to the inmate about HCV. The inmate will also be tested for Hepatitis B Surface Antibody to detect immunity to HBV (>10). If the HBV value indicates immunity,

nothing else will be done. If the HBV does not indicate immunity, a Twinrix vaccine (course of 3 injections per protocol) will be administered. (Immunity testing will not be performed if documentation of vaccination administration is found.) No further evaluation will be done.

2.3 If the inmate's max out date is greater than 12 months, educational material will be given to the inmate about HCV. The inmate will also be tested for Hepatitis B Surface Antibody to detect immunity to HBV (>10). If the HBV value indicates immunity, nothing else will be done. If the HBV does not indicate immunity, a Twinrix vaccine (course of 3 injections per protocol) will be administered. (Immunity testing will not be performed if documentation of vaccination administration is found.) the inmate will then proceed to the next step in the evaluation process.

2.4 The inmate will then be evaluated for the following, and if any of the questions have a "yes" answer, the evaluation will be stopped. If the answers are no to the following questions, the evaluation will continue. Note: all yes answers to the following questions should have documentation supporting the answer sent to the Hepatitis C Coordinator along with the evaluation. The Hepatitis C Coordinator and the infectious disease physician will review.

- Does the inmate have any major medical condition to include metastatic cancer, life expectancy of less than 12 months, pregnancy, or previous history of Hepatitis C treatment?
- Does the inmate have a history of IV drug or alcohol use in the prior 12 months? The inmate's disciplinary records should be checked to see if any charge for alcohol and/or drugs has been made along with the inmate's answers.
- Does the inmate have a history of poor compliance with standard prescribed medical regimen?
- Does the inmate have evidence of tattoo or body piercing received during incarceration in the last 12 months? The inmate's disciplinary record may be reviewed in addition to the physical assessment.

2.5 The inmate will read, or have read to him/her, SCDC Form M-175, "Consent To Hepatitis C Evaluation And/Or Treatment." This is made part of the evaluation to ensure that he/she will adhere to appointments, laboratory scheduling, and medication during both the evaluation phase and if selected for treatment. It is essential that this become a high priority for the inmate, due to the specific times of testing and the exact dosing of medication for the treatment of HCV. If the inmate is not willing to accept these terms, the evaluation will not continue. If the inmate agrees to the terms, the evaluation will continue.

2.6 Laboratory Testing to include a CBC, AST, GFR, and APRI will be performed in the next step of the evaluation. If the inmate has an APRI of <2.0, the evaluation will be stopped.

2.7 If the APRI >2, then a Hepatitis C viral load with reflex genotype should be performed. If the viral load is <43, no genotype will be performed and the inmate does not qualify for treatment.

2.8 If the viral load is >43, the evaluation and results of all tests will be sent to the Hepatitis C Coordinator. The inmate will then be evaluated by the infectious disease physician who may order additional testing such as a liver ultrasound and alfa-feto protein.

2.9 If the inmate does not qualify for treatment at the time of evaluation, the inmate may be reevaluated in one (1) year. All evaluations, even if the inmate does not meet the criteria, should be forwarded to the Hepatitis C Coordinator for review. (4-4356)

3. EVALUATION BY INFECTIOUS DISEASE PHYSICIAN:

3.1 All evaluation information will be given to the Infectious Disease Physician to evaluate for possible treatment.

3.2 Additional laboratory tests, ultrasound, staging, referrals, or other procedures may be needed to further evaluate the inmate for best outcomes.

3.3 The Infectious Disease Physician will choose treatment regimen depending on genotype, drug interactions, co-morbidities, previous treatment, stage of liver, and based on updated HCV national guidelines. (4-4354)

4. TREATMENT FOR HCV:

4.1 Treatment evaluation will begin with current inmates who are already in the SCDC HCV data base. The inmates will be evaluated and then treatment will be initiated based on the priority steps listed below. After all of these inmates are treated, the next phase of antibody testing will begin to include those with a history of IV drug use, diabetics, and other inmates that meet national standards for HCV screening.

4.2 Priority Level 1 - Highest Priority for Treatment: (Changes in RED below are amended by Change 1, dated January 10, 2017.)

4.2.1 ~~Those with an APRI score >2.0 and one of the following:~~ Two or more of the following:

- >2.0 APRI.
- Cirrhosis - This includes cases of known cirrhosis or clinical findings consistent with cirrhosis.
- Liver Transplant candidates or recipients. Other types of transplant candidates or recipients may be appropriate to prioritize for treatment and will be considered individually on a case by case basis.
- Hepatocellular carcinoma (HCC) - At least one third of all cases of HCC occur in association with HCV infection, with most cases occurring in those with advanced fibrosis or cirrhosis. This will be determined on an individual basis by the infectious disease physician.
- Extra-hepatic manifestations related to HCV such as Cryoglobulinemia, membranoproliferative GN, nephrotic syndrome.
- Continuity of care for those already started on treatment, including inmates who are newly incarcerated in SCDC. Inmates who may have had a break in treatment due to being in a county facility or who involuntarily or voluntarily stopped treatment will be evaluated on a case by case basis by the Infectious Disease Physician.

4.3 Priority Level 2 - High Priority for Treatment:

- APRI score >2;
- HBV co-infection;
- HIV co-infection;
- Comorbid liver diseases; and
- Porphyria cutanea tarda.

4.4 Priority Level 3 - Intermediate Priority for Treatment:

- APRI Score 1.5 to <2;
- Diabetes mellitus.

4.5 Priority Level 4 - Routine Priority for Treatment:

4.5.1 All other cases of HCV infection meeting the eligibility criteria from those inmates already known to be HCV positive.

4.6 In addition to meeting the above criteria, inmates being considered for treatment of HCV infection should:

- Have no contraindications to, or significant drug interactions with, any component of treatment regimen.
- Not be pregnant, especially for any regimen that would require ribavirin or interferon.
- Have a sufficient time (12 months) remaining on their sentence in SCDC.
- Have a life expectancy >12 months.
- Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated.

(4-4356)

5. RECOMMENDED TREATMENT REGIMENS:

5.1 Recommendations for preferred HCV treatment regimens continue to evolve but still depend on several factors such as HCV Genotype, prior HCV treatment history, compensated vs. decompensated liver disease.

5.2 Treatment choice will be dependent on infectious disease doctor consultant and inmate consent.

5.3 In addition to the genotype, previous HCV treatment history and status of hepatic compensation, it is essential to review each treatment candidate for potential drug interactions prior to selecting the most appropriate regimen for HCV treatment. Adjustments of the inmate's current medications may be needed prior to starting treatment for HCV. (4-4356)

6. LABORATORY MONITORING:

6.1 The following are recommended within 12 weeks prior to starting therapy: CBC, INR, LFT, BMP, and eGFR or any other test the infectious disease doctor deems necessary.

6.2 After 4 weeks of treatment, a CBC, Liver function test, eGFR, and Hepatitis C viral load should be collected and results sent to the Hepatitis C Coordinator. This information will be documented on SCDC Form M-176, "SCDC Hepatitis C Treatment Monitoring Schedule."

6.3 After 8 weeks of treatment, a CBC, Liver function test, and eGFR, should be collected and results sent to the Hepatitis C Coordinator. This information will be documented on SCDC Form M-176, "SCDC Hepatitis C Treatment Monitoring Schedule."

6.4 At completion of the 12 weeks of treatment, a HCV viral load, CBC, and Liver function test should be collected and results sent to the Hepatitis C Coordinator. This information will be documented on SCDC Form M-176, "SCDC Hepatitis C Treatment Monitoring Schedule."

6.5 If interferon and ribavirin are used, a CBC should also be collected and results sent to the Hepatitis C Coordinator at 2 weeks, 4 weeks, 8 weeks, and 12 weeks after starting therapy.

6.6 Pregnancy test is indicated prior to first dose and at 4 weeks, 8 weeks, and 12 weeks after starting therapy. Results should be sent to the Hepatitis C Coordinator. A positive test should immediately be called to the Hepatitis C Coordinator. (4-4354)

6.7 More frequent monitoring for drug related toxic effects should be done as clinically indicated.

7. POST-TREATMENT MONITORING:

7.1 A quantitative HCV Viral load assessment is recommended at 12 weeks after completion of treatment. If the HCV is undetectable, it defines a sustained virologic response (SVR).

7.2 The inmate should be counseled on risk factors that could cause re-infection of the Hepatitis C virus.

8. ONGOING MONITORING;

8.1 Periodic monitoring is recommended for those with active infection, including acute HCV infection, HCV treatment failures, relapse of HCV infection, re-infection, and those with chronic HCV infection who are not yet treated.

8.2 For cases without advanced fibrosis, cirrhosis, or complication, annual evaluation is appropriate. The evaluation should include a focused review of symptoms and inmate education relevant to HCV, vital signs and a focused physical examination, and lab monitoring (CBC, PT/INR, liver panel, eGFR, and calculation of APRI).

8.3 At any point during the evaluation or treatment process, an inmate may request through institution medical staff to be seen by a mental health professional. (4-4356)

SIGNATURE ON FILE

—
s/Bryan P. Stirling, Director

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Date of Signature

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