

HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Public Safety Prisons
Health Services

SECTION: Clinical Practice Guidelines

POLICY # CP-7

SUBJECT: Hepatitis C

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EFFECTIVE DATE: June 2013

SUPERCEDES DATE: September 2009

PURPOSE

To provide guidance to primary care physicians in the Division of Prisons Health Services on how to appropriately manage hepatitis C.

POLICY

DOP Primary Care Providers are expected to follow this guideline except when in their professional judgment on a case-by-case basis there is reason to deviate from these guidelines. If a deviation is made the PCP will document in the medical record any deviations from this guideline and the reasoning behind the need for any deviation.

Natural History of Chronic HCV Infection

Most persons infected with HCV develop chronic infection; however, a small subset of newly infected persons are able to clear the virus spontaneously. Chronic HCV infection frequently results in high levels of HCV RNA in the blood, ranging from 10^5 to 10^7 international units (IU)/mL, despite the presence of HCV antibodies. The majority of persons with chronic HCV infection are asymptomatic. Chronic HCV infection has an unpredictable course, frequently characterized by fluctuations in ALT levels that may or may not be associated with significant liver disease. Approximately one-third of persons with chronic HCV infection have no laboratory or biopsy evidence of liver disease.

A small, but significant subset of persons with chronic HCV infection develop progressive fibrosis of the liver that leads to cirrhosis. Transfusion-acquired HCV, high levels of alcohol consumption, older age at the time of infection, HIV infection, chronic HBV infection, the presence of HCV genotype 3, and male gender are associated with an increased risk of disease progression. However, the degree of viremia (“viral load”) does not affect the progression of liver disease. Other factors that appear to increase the risk of cirrhosis, and decrease the response to antiviral therapy, include: hepatic steatosis, marked necroinflammation on biopsy, and certain host immunologic characteristics. Once cirrhosis develops in persons with chronic HCV infection, the risk of hepatocellular carcinoma (HCC) is about 1–4% per year. HCV accounts for one-third of the cases of HCC in the U.S. each year.

PROCEDURE

Stepwise Approach for Detecting, Evaluating, and Treating Chronic Hepatitis C

Current antiviral treatment for hepatitis C has some limitations in terms of both efficacy and toxicity. With this in mind, the North Carolina Department of Public Safety, Adult Correction Division/Health Services Section has adopted the stepwise approach used by the Federal Bureau of Prisons to detect, evaluate, and treat Hepatitis C. **Table 1** below lists the steps in this process.

Following **Table 1**, the policy will outline the components that are to be addressed at each step in the process. Although, this stepwise approach has been adopted, the judgment of the clinician remains the hallmark for appropriate care and management in all cases of Hepatitis C. Any deviation from this approach, however, must be clearly documented in the patient record and notes written to reflect reasoning for deviation.

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Table 1

Steps for Detecting, Evaluating, and Treating Chronic Hepatitis C

Step 1. Appropriately screen inmates for hepatitis C.

Step 2. Provide initial medical follow-up for anti-HCV positive inmates. All anti-HCV positive inmates should be counseled about the natural history of HCV, risks of transmission to others, lifestyle changes that can minimize disease progression.

Step 3. Conduct a pre-treatment evaluation.

Step 4a. Determine if hepatitis C treatment is *contraindicated*.

Step 4b. Monitor HCV-infected inmates who are *not* on treatment.

For inmates who may be eligible for hepatitis C treatment, proceed as follows:

Step 5. Obtain HCV RNA assay and HCV genotype.

Step 6. Determine if treatment should be initiated and obtain Informed Consent.

Step 7. Initiate UR and refer to Hepatology Clinic.

Components for each step:

Step 1.

Appropriately screen for Hepatitis C.

Discuss risk factors and if present, consider testing for Hepatitis C.

Presence of following increases risk for Hepatitis C

- Chronic hemodialysis or ever received hemodialysis
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV (mixed cryoglobulinemia, membranoproliferative glomerulonephritis, or porphyria cutanea tarda)
- Ever injected illegal drugs or shared equipment
- Received tattoos or body piercings **while in jail or prison**
- HIV-infected or chronic HBV infection
- Received a blood transfusion or organ transplant before 1992, or received clotting factor transfusion prior to 1987
- History of percutaneous exposure to blood

Step 2.

Provide initial medical follow-up for anti-HCV positive inmates.

- Take a medical history and perform a physical examination.**
- Try to establish duration of HCV infection by history, e.g., time period of injection drug use**
- Obtain baseline labs**

HIV
HBsAb, HBsAg, HBcAb*
Anti HAV(IgG)
CBC with diff
ALT, AST
Bilirubin, Alk Phos

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Albumin
INR
Creatinine
Ferritin, Iron Saturation
ANA*(Further w/u of other liver diseases such as Wilson disease,
hemochromatosis, etc may be considered if clinically warranted)

* HBsAg to determine current infection and HBcAb to determine if prior exposure. Anti-HBs to determine immunity..

- Evaluate inmate for other potential causes of liver disease.
- Initiate patient counseling
- Initiate preventive health measures listed below:

• **Hepatitis B vaccine:** Indicated for inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination. *Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.*

• **Hepatitis A vaccine:** Indicated for inmates with chronic HCV infection who have other evidence of liver disease. For foreign-born inmates, consider prescreening for hepatitis A immunity prior to vaccination.

• **Pneumococcal vaccine:** Offer to all HCV-infected inmates with cirrhosis.

• **Influenza vaccine:** Offer to all HCV-infected inmates annually. Inmates with cirrhosis are high priority for influenza vaccine.

Step 3.

Conduct a pre-treatment evaluation.

Assure that all recommended pre-treatment evaluations have been completed

- Laboratory tests:** See Appendix 1 for list of recommended pre-treatment tests and evaluations.
- Interferon**—The patient should have the following acceptable labs for treatment initiation: absolute neutrophil count >1500/cells/mm³; platelets >75,000/mm³.

Note: When starting treatment with platelet counts between 75–90,000, consult first with a physician with expertise in treatment of hepatitis C.

- Ribavirin**—The patient should have the following acceptable for treatment initiation: Hemoglobin >13 g/dL (men) or >12 g/dL (women); creatinine <1.5 mg/dL (or creatinine clearance >50 mL/min).

Note: Some experts recommend that an acceptable starting hemoglobin is >12 g/dL (men) or >11 g/dL (women).

- Assess for contraindications** to ribavirin and/or Peginterferon.
 - Thalassemias (sickle cell anemia) or other hemoglobinopathy.
 - Significant cardiac disease (arrhythmias, angina, CABG, MI) in the past 12 months.
 - Pregnancy or unwillingness to use contraception in both female patients and female partners of male patients.
 - Renal dialysis or creatinine clearance < 50 mL/min.
 - Hypersensitivity to ribavirin or peginterferon
 - Autoimmune hepatitis
 - Unstable Psychiatric Disorder

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- Pregnancy test:** Because ribavirin may cause fetal abnormalities, all female inmates of childbearing potential must have a pregnancy test immediately prior to initiating therapy, and monthly thereafter. Continue with monthly tests until 6 months after treatment is completed.
 - Cardiac risk assessment:** Prior to therapy, a cardiac risk assessment is critically important because hemolysis associated with ribavirin may precipitate angina pectoris. Also, obtain an ECG for inmates with preexisting cardiac disease. For patients over age 50 or with multiple cardiac risk factors, should consider a cardiac stress test.
 - Mental health evaluation** is critically important prior to initiating treatment due to the severe psychotropic effects of interferon.
Obtain mental health consultation
 - (a) The patient may have an active mental illness but must be under good control
 - (b) Patients receiving mental health treatment, with a history of prior mental illness, or who develop psychiatric symptoms during treatment must have a mental health evaluation at least every three months during treatment
 - Review** the pros and cons of initiating Hepatitis C treatment with the patient and determine if patient is willing to be treated and to adhere to treatment requirements.
 - Compensated cirrhosis: Obtain liver-spleen ultrasound (preferred), and measurements of alpha fetoprotein, prior to treatment initiation. A screening upper endoscopy is indicated if the ultrasound suggests portal hypertension.**

If Patient has evidence of Cirrhosis:

- Screen for Hepatocellular carcinoma (HCC): If cirrhosis has been diagnosed, regular surveillance with hepatic ultrasound and AFP approximately q6months should be initiated. (Reference AASLD guidelines)
- Screen for esophageal varices: Consider an upper endoscopy for any inmate with known cirrhosis and evidence of portal HTN

Step 4a.

Determine if Hepatitis C treatment is not recommended.

Hepatitis C treatment is not recommended if any of the following five conditions are present

(1) Contraindications to peginterferon/ribavirin:

- Severe uncontrolled psychiatric disease, particularly depression with current suicidal risk.
- History of solid organ transplant (renal, heart, or lung)
- Certain autoimmune disorders, e.g., autoimmune Hepatitis, rheumatoid arthritis, lupus, etc.
- Uncontrolled endocrine disorders, e.g., diabetes, thyroid disease
- Serious concurrent medical diseases, such as severe: hypertension, heart failure, coronary heart disease, COPD
- Decompensated cirrhosis (see Complicating Medical Conditions)
- Platelet count <75,000/mm³ or ANC <1,500 cells/mm³
- Documented nonadherence to prior therapy, or

- (2) Inmate will be incarcerated for an insufficient period of time to complete treatment. Usually a 12 month period would be required to complete assessment and treatment for Hepatitis C.
- (3) Inmate has an unstable medical or mental health condition which precludes antiviral therapy.

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(4) Inmate refuses treatment.

(5) Inmate life expectancy estimated to be less than 10 years due to co-morbid conditions



If any one of the above five conditions are present, then **STOP** further treatment-related work-up. No further HCV testing—i.e., HCV RNA, genotype, liver biopsy—is indicated at this time. If conditions change, reconsider for hepatitis C treatment.

Step 4b.

Monitor HCV-infected inmates who are not on treatment.

- Have a plan for each inmate: Outline the plan clearly in the Progress Notes.
- Get baseline laboratory evaluations if not already done: Obtain baseline labs as specified in Appendix 1.
- Follow-up labs:
 - Every 6 months: ALT, AST, bilirubin, albumin, and INR
 - Every year: CBC (with differential & platelets).
 - Other labs as clinically indicated, e.g., A1C (diabetics); TSH and free T4 (if hyperthyroid).

Note: The following tests are generally NOT indicated for inmates not on treatment.

- **HCV RNA and HCV genotype:** These tests are not needed unless treatment is indicated. Do not periodically check HCV RNA values for inmates who are not currently candidates for treatment. There is no correlation between HCV RNA levels and the risk or rate of disease progression.
- **Alpha fetoprotein:** Unless cirrhosis is known or strongly suspected, alpha fetoprotein is unnecessary because the risk for hepatocellular carcinoma in HCV infection does not begin until the development of cirrhosis.
- **Liver ultrasound or CT examinations:** Similarly, do not perform periodic liver ultrasound or CT examinations unless cirrhosis is present or there is another definitive indication.
- **Serum ammonia levels:** In a patient with known liver disease, the serum ammonia level has no prognostic value; nor can it be used for monitoring the effectiveness of medications such as lactulose. Serum ammonia levels are only useful in a delirious patient whose diagnosis is uncertain.

For inmates who may be eligible for hepatitis C treatment, proceed as follows.

Step 5.

Obtain HCV RNA assay and HCV genotype.

Before initiating antiviral therapy, an HCV RNA (viral load) is required in order to confirm chronic infection and guide therapy. If the HCV RNA level is undetectable, the individual can be considered uninfected.

- b) Obtain HCV RNA by PCR Quantitative with reflex to genotype
 - i) If non-detectable, redraw in three months and at six months, if still undetectable then patient no longer has HCV.
 - ii) If positive, proceed with evaluation

The HCV genotype should be ordered in conjunction with the initial HCV RNA test. In general, the test for genotype is not repeated—unless re-infection is suspected.

Step 6.

Determine if treatment should be initiated and Obtain Informed consent.

- Counsel patient regarding the pros and cons of initiating Hepatitis C treatment

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- Determine if patient is willing to be treated and to adhere to treatment requirements.
- Document rationale for decisions about treatment in the medical record.

Review with the patient and complete the Informed consent form for Hepatitis C treatment (DC 475) and initiate further treatment if the patient agrees.

Step 7

Initiate the UR process for referral to Hepatology Clinic

A UR request indicating that all the steps 1 -6 have been completed should be entered. UR reviewers may request documentation for any of the above steps. Once the UR is approved, appointment should be scheduled for Hepatitis C Clinic.

Appendix 1—Baseline LABS

HIV
HBsAb, HBsAg, HBcAb*
Anti HAV(IgG)
CBC with diff
ALT, AST
Bilirubin, Alk Phos
Albumin
INR
Creatinine
Ferritin, Iron Saturation
ANA#

* HBsAg to determine current infection and HBcAb to determine if prior exposure. Anti-HBs to determine immunity..

Further w/u of other liver diseases such as Wilson disease, hemochromatosis, etc may be considered if clinically warranted



6/28/13

Paula Y. Smith, MD, Director of Health Services Date

SOR: Deputy Medical Director

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Table 1: Some drugs that may cause liver damage:

Acetaminaphen
Antiretroviral Agents
Acebutolol
ACE inhibitor
Allopurinol
Amoxicillin-clavulanate
Amiodarone
Carbamazepine
Calcium channel blockers
Diclofenac
Isoniazid
Ketoconazole
Labetalol
Methotrexate
Methyldopa
Nicotinic acid
Nitrofurantoin
Phenytoin
Propoxyphene
Propylthiouracil
Rifampin
Sulfonamides
Sulfasalazine
Tacrine
Tetracyclines
Terbinafine
Tricyclic antidepressants
Trimethoprim-sulfamethoxazole
Valproic acid

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**North Carolina Division of Prisons Health Services
Hepatitis C Therapy Informed Consent**

1. Chronic Hepatitis C is a slowly progressive disease that usually takes 10 to 20 or more years to cause serious problems. Current medical knowledge says that out of every 100 persons with hepatitis C who have had it for 20 to 30 years, approximately:
 - a. 5 to 25 will get cirrhosis
 - b. 2 to 10 will have liver failure
 - c. 2 to 10 will get liver cancer
2. Treatment does not cure everyone with the disease, out of 100 persons treated:
 - a. Approximately 70 who have Genotype 1 (the most common type in the United States) will be cured.
 - b. Approximately 80 to 85 with genotypes 2 or 3 will be cured.
3. There appears to be benefit from the current treatment even if you are not "cured". Studies have shown that by having received treatment, you may have less risk of cirrhosis and cancer.
4. Treatment has many side effects. Most patients will experience some unpleasant side effects. A very small number of patients may have very serious even life threatening side effects.
5. **Common side effects** are usually mild and can be treated. They are usually worse when treatment is first started and get better with continued treatment. They include:

Flulike symptoms	Anemia (low blood)	Headaches
Loss of appetite	Muscle aches	Dizziness
Trouble thinking	Fatigue	Hair loss
Trouble breathing	Heartburn/indigestion	Nausea/vomiting
Trouble sleeping	Rash/Itching	Depression
Changes in taste	Irritability	Chest pain

6. **Serious and life-threatening side effects** can occur but are rare, they usually occur in less than 5% of patients and include:

Allergic reactions	Serious infections	Heart failure
Severe anemia	Kidney failure	Hearing loss
ringing in ears	Blindness	Lung disease
Autoimmune disease	Suicide	Severe skin rash

7. Depression and feelings of suicide are one of the common side effects. If treatment for Hepatitis C is recommended, a **mental health evaluation** may be required to assure that there is no preexisting depression, and if present it is properly controlled prior to starting treatment.
8. On-going drug and/or alcohol abuse will disqualify you from treatment. If you have a history of either, you must be **free from all drugs and alcohol** for at least six months and cooperate with any treatment programs.
9. You may be subject to **random drug and alcohol testing**, and if you have a positive drug/alcohol test during treatment, **your treatment may be stopped**.
10. While on treatment you may be required to be housed at a **designated treatment unit**.
11. You will be required to have blood work on a regular basis during treatment. This is needed to determine if the treatment is successful and to look for serious side effects. **Refusal to have the required blood work will result in your treatment being stopped.**

I have read (or have had it read to me) the above and had all my questions answered by a DOP Health Services provider and I:

want to be considered for treatment of my Hepatitis C.

do not want to consider treatment of my Hepatitis C at this time, but understand that I may change my mind in the future and request consideration for treatment as long as I still meet the criteria for treatment.

Inmate Signature: _____ Date: _____

Provider Name/Signature: _____ Date: _____

This form is not to be amended, revised or altered without the approval of the Medical Records Committee.

PRINT
 Inmate Name.....
 Inmate Number.....
 Unit.....

Spanish Version on Revers Side

File: Outpatient Record, Section II / Inpatient

**División de Servicios de Salud Carcelarios de North Carolina
Consentimiento Informado de la Terapia contra Hepatitis C**

12. La Hepatitis C Crónica es una enfermedad que avanza lentamente y por lo general toma de 10 a 20 años, o más, para ocasionar problemas graves. El conocimiento médico actual indica que de cada 100 personas que han tenido hepatitis C durante 20 a 30 años, aproximadamente:
 - a. 5 a 25 tendrán cirrosis
 - b. 2 a 10 tendrán insuficiencia hepática
 - c. 2 a 10 tendrán cáncer hepático
13. El tratamiento no cura a todas las personas con la enfermedad y de cada 100 personas tratadas:
 - a. Aproximadamente 70 que tienen el genotipo 1 (el tipo más común en los Estados Unidos) serán curadas.
 - b. Aproximadamente 80 a 85 con los genotipos 2 ó 3 serán curadas.
14. Al parecer, el tratamiento actual es beneficioso aun si usted no es “curado”. Los estudios han demostrado que al haber recibido tratamiento, usted puede tener menos riesgos de padecer cirrosis y cáncer.
15. El tratamiento tiene muchos efectos secundarios. La mayoría de pacientes experimentarán algunos efectos secundarios desagradables y un número muy pequeño de pacientes puede tener efectos secundarios muy graves incluso mortales.
16. Por lo general, **los efectos secundarios comunes** son leves y se pueden tratar; normalmente, empeoran al principio cuando se inicia el tratamiento y mejoran al continuar el tratamiento. Entre los efectos secundarios se incluyen:

Síntomas parecidos a los de la gripe	Anemia (bajo nivel de hemoglobina)	Dolores de cabeza
Pérdida de apetito	Dolores musculares	Mareos
Problemas para pensar	Fatiga	Pérdida de cabello
Problemas para respirar	Acidez/indigestión	Náusea/vómito
Problemas para dormir	Sarpullido/comezón	Depresión
Cambios en el sabor	Irritabilidad	Dolor en el pecho

17. Pueden ocurrir **efectos secundarios graves y mortales** pero son raros, y por lo general suceden en menos del 5% de los pacientes e incluyen:

Reacciones alérgicas	Infecciones graves	Insuficiencia cardíaca
Anemia grave	Insuficiencia renal	Pérdida de audición
Zumbidos en los oídos	Ceguera	Enfermedad pulmonar
Enfermedades autoinmunes	Suicidio	

18. La depresión y los sentimientos de suicidio son uno de los efectos secundarios comunes. Si se recomienda tratamiento para la Hepatitis C, puede ser necesaria una **evaluación de salud mental** para asegurarse de que no existe depresión previa y si es así, se controle debidamente antes de empezar el tratamiento.
19. El uso continuo de drogas y/o el abuso de alcohol le descalificarán del tratamiento. Si tiene un historial de alguno de éstos, debe **estar libre de drogas y alcohol** durante seis meses como mínimo y cooperar con los programas de tratamiento.
20. Puede estar sujeto a una **prueba aleatoria de detección de drogas y alcohol**, y si los resultados de una prueba son positivos durante el tratamiento, **éste puede suspenderse**.
21. Mientras está en tratamiento, puede pedírsele que se aloje en una **unidad designada de tratamiento**.
22. Será necesario que le hagan pruebas sanguíneas con regularidad durante el tratamiento, lo cual es necesario para determinar si el tratamiento es exitoso y para observar si existen efectos secundarios graves. **Negarse a las pruebas sanguíneas requeridas dará como resultado la suspensión del tratamiento.**

He leído (o me han leído) lo anterior y todas mis preguntas han sido contestadas por un proveedor de Servicios de Salud de DOP y:

- deseo ser considerado para tratamiento de mi Hepatitis C.
- no deseo considerar el tratamiento de mi Hepatitis C en este momento, pero entiendo que puedo cambiar de opinión en el futuro y solicitar ser considerado para tratamiento siempre que cumpla los criterios para el tratamiento.

Firma del recluso: _____ Fecha: _____

Nombre/Firma del Proveedor: _____ Fecha: _____

This form is not to be amended, revised or altered without the approval of the Medical Records Committee.

PRINT
 Inmate Name.....
 Inmate Number.....
 Unit.....

English Version on Reverses Side

File: Outpatient Record, Section II / Inpatient