

# HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Correction  
Division Of Prisons

SECTION: Clinical Practice Guidelines

POLICY # CP-7

SUBJECT: Hepatitis C

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EFFECTIVE DATE: September 2009

SUPERCEDES DATE: None

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## 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.

## PROCEDURE

### 1) **Evaluation of elevated ALT/AST**

Unexplained persistent elevated ALT/AST on two tests at least one month apart then

- a) Perform hepatic focused history (use of alcohol, substance abuse, hepato-toxic drugs, hepatitis hx, etc.) and physical exam (looking for spider angiomas, palmar erythema, clubbing of fingers, lower leg edema, light colored stools, dark urine, jaundice, increased tiredness, loss of appetite, right upper abdominal pain, etc.).
  - i) If on hepatotoxic drugs (see Table 1), consider stopping and re-checking ALT/AST after 30 days.
  - ii) Evaluate further any differential diagnoses apparent from the above
- b) Check HBsAG & anti-HCV
  - i) If HBsAG positive refer to Hepatitis A & B Policy
  - ii) If anti-HCV positive refer to Hepatitis C Policy
  - iii) If both positive and the patient agrees refer to Hepatology clinic
- c) If patient jaundiced and/or acutely ill check IgM anti-HAV
- d) If above unrevealing then obtain an abdominal ultrasound
- e) If the above unrevealing and the elevations persist consider referral to Hepatology

### 2) **Hepatitis C**

For Patients who are anti-HCV positive or give a history of having Hepatitis C:

- a) 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
  - iii) Determine HIV: if positive and patient agrees, refer to Hepatology clinic
- b) Recommend hepatitis A and B vaccination if not previously infected
- c) Determine if patient meets **all** the following criteria for hepatology consult for treatment of HCV:
  - i) Age 18 – 65
  - ii) Absolute neutrophil count > 1500/mm<sup>3</sup>
  - iii) Platelets > 75,000/mm<sup>3</sup>
  - iv) Hemoglobin > 13g/dl for men and 12g/dl for women
  - v) INR < 1.5
  - vi) Creatinine < 1.5 mg/dl
  - vii) Albumin > 3.4
  - viii) Total bilirubin < 1.5 g/dl
  - ix) No evidence of hepatic decompensation ( hepatic encephalopathy or ascites)
  - x) Must have ≥ 24 months on sentence remaining

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- xi) Counsel the patient on Hepatitis C, the benefits and risks of treatment and the requirements for treatment
- xii) Review with the patient the Informed Consent for Hepatitis C treatment (DC\_\_\_\_, attachment 1) and determine the patient's desires
- xiii) If patient wants to consider treatment
  - (1) Have him/her sign the informed consent (attachment 1)
  - (2) Obtain mental health consultation
    - (a) The patient may have an active mental illness but must 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
- d) If criteria are not met
  - i) Continue to monitor clinically as indicated
  - ii) If labs or clinically, the patient appears to have cirrhosis contact Hepatology Clinic to help determine if the patient needs consultation
- e) If patient
  - i) Meets all criteria,
  - ii) Has signed informed consent,
  - iii) Has been cleared by mental healthSubmit a UR request for Hepatology Clinic consultation.
- f) Hepatologist to assess patients' appropriateness for Hepatitis C treatment
  - i) Hepatology will institute the current DOP approved treatment if indicated once the patient agrees to treatment and has signed an informed consent for HCV treatment.
  - ii) If patient is started on treatment for HCV, the outreach nurses will follow the patient while he is on treatment.
- 3) **Monitoring**
  - a) Patients receiving active therapy for hepatitis should generally be followed in the Chronic Disease and/or Hepatology Clinics
  - b) Patients with Hepatitis or other stable chronic liver disease that are not currently receiving treatment or having significant symptoms **do not need** to be followed in the Chronic Disease Clinics
  - c) Monitoring for evidence of hepatocellular carcinoma when indicated will be done by:
    - i) **Ultrasound**
    - ii) Interval will be at least **every 12 months**
- 4) **Relapse**
  - a) Inmates who were previously treated with combination therapy with pegylated interferon and ribavirin and failed therapy, will not be considered for retreatment
  - b) Those who **were not** previously treated with combination therapy with pegylated interferon and ribavirin, have persistently elevated viral DNA, and meet the above criteria may be considered for therapy with this combination.

**Table 1: Some drugs that may cause liver damage:**

Acetaminophen  
Antiretroviral Agents

Acebutolol  
ACE inhibitor

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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

**Table 2 . Characteristics of Persons for Whom Therapy Is Currently Contraindicated**

- a. Major uncontrolled depressive illness
- b. Solid organ transplant (renal, heart, or lung)
- c. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by peginterferon and ribavirin
- d. Untreated thyroid disease
- e. Pregnant or unwilling to comply with adequate contraception
- f. Severe concurrent medical disease such as severe hypertension, heart failure, significant coronary heart disease, poorly controlled diabetes, chronic obstructive pulmonary disease
- g. Known hypersensitivity to drugs used to treat HCV



9/29/09

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

SOR: Deputy Medical Director

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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 50 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            |               |

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:

☐ I want to be considered for treatment of my Hepatitis C.

☐ I 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.....

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## 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:
- 5 a 25 tendrán cirrosis
  - 2 a 10 tendrán insuficiencia hepática
  - 2 a 10 tendrán cáncer hepático
13. El tratamiento no cura a todas las personas con la enfermedad y de cada 100 personas tratadas:
- Aproximadamente 50 que tienen el genotipo 1 (el tipo más común en los Estados Unidos) serán curadas.
  - 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: \_\_\_\_\_

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#### English Version on Reverses Side

Inmate Number.....

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Unit.....