

# MEMORANDUM

State of Alaska  
Department of Corrections  
Inmate Health Care Program  
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TO: Medical Personnel AK-DOC  
Discussed @ Teleconference 12-13-01

DATE: December 13, 2001

FROM: John M. Robertson, MD, MPH  
Medical Director



SUBJECT:  
HCV Evaluations for Treatment  
Restriction of Ordering of HCV-RNA

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Attached is the most updated version of the standard DOC evaluation for HCV treatment. Please note that the evaluation is in "STEPS". It is the site practitioner's responsibility to complete STEP 1 prior to contacting ACO to proceed to STEPS 2 - 4. It is important that you verify the projected date of release. Frequently, unsentenced or inmates with less than 18 months remaining in the system receive work-ups that include evaluation that is not appropriate because they will not be candidates for therapy.

Please note that effective with receipt of this memo, HCV-RNA by PCR testing is a STEP 2 test and will require a prior approval like all other procedures requiring an HCR that are of an elective nature. The other laboratory parameter that requires an HCR in STEP 2 is the HCV genotype. Recent laboratory utilization review reveals multiple ordering of HCV-RNA levels in persons not specifically under consideration for treatment of HCV and not necessarily meeting either NIH or DOC criteria for treatment. The cost to the DOC is approximately \$225/test. The ONLY indication in HCV viral load are those being considered for treatment (i.e meet all STEP 1 Criteria) as part of a baseline assessment and then 6 months and one year after treatment to assess clinical response. It is NOT part of a routine evaluation of an HCV infected person.

Please have a copy of the attached outline of the HCV treatment protocol in order to participate in the discussion.

Alaska Department of Corrections: Inmate Health  
Standardized patient review for consideration for HCV treatment  
Based on 1997 NIH Consensus recommendations concerning treatment

STEP 1 Review

Comments: Exclusions and Inclusions for Consideration

Note : Patient must be a candidate after STEP 1 review  
PRIOR to request for a liver biopsy and treatment

Demographics

Name/DOB/OBICIS # Identification of potential candidate  
HCV Diagnosis Positive HCV Antibody, in high-risk does NOT require RIBA to confirm.  
HBV Sero status Identify as high-risk, offer HBV vaccine as indicated  
Age 18-59, Recommended treatment range  
Sentence time remaining 24 months at time of initial review to assure Rx course completion  
18 months for those already in process of evaluation

Laboratory parameters-I

Elevated ALT, AST > 6 mo Normal values are contraindication to Rx  
CBC & Plt count Normal values or Plt Ct > 100K generally required pre-Rx  
TSH Normal value required pre-Rx

Clinical Parameters

Clinical liver disease NO HISTORY of: Ascites, persistent jaundice, varices, or encephalopathy  
*These are contraindications to Rx*  
*May benefit from interferon*  
Mixed cryoglobulinemia *Pregnancy is contraindication to Rx*  
Pregnancy Status *Contraindication to Rx*  
Autoimmune Disease *Contraindication to Rx*  
Immunosuppressive Rx *Contraindication to Rx*

Psychiatric History

No Dx that might cause non-compliance with course completion  
No Hx of severe depression or other major psychiatric dx (e.g.. Bipolar)  
*These are contraindications to Rx*  
Informed consent Inmate can give informed consent and agrees to comply with Rx regimen

Substance Abuse Hx

Baseline negative drug screen, with a 6 month history of drug free status  
*Positive drug screen is a contraindication to Rx*

*N.B. STEPS 2-4 Require ACO HCR-Approval prior to continuing*

**STEP 2 Review** if STEP 1 criteria for Rx are met, Proceed to:

Laboratory parameters-II

HCV-Genotype Genotype 1 has less favorable response rate  
HCV-Quantitative HCV-RNA viral load by PCR Pre-treatment

GI Specialist Evaluation & Liver Bx

Review of Results Liver biopsy reveals portal or bridging fibrosis with  
moderate degree of inflammation and necrosis

**\*\* Findings of Advanced Cirrhosis Rx is NOT indicated**

**STEP 3 Review** all findings and offer treatment if all criteria still met

**Note: Reviews are on a case-by-case basis. Those most likely to benefit medically and are capable of compliance with a full course of therapy are given priority. Non-compliance with treatment, excessive toxicity, and a positive drug screen are all reasons to discontinue therapy.**

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**STEP 4**

Treatment Plan Treat 6 months and reevaluate, STOP Rx for all non-responders  
 Complete treatment on those with favorable genotype and positive response  
 Continue treatment for 6 more months on responders with unfavorable genotype

**\*\* Protocol for Laboratory Monitoring of Treatment**

*N.B. These are guidelines for minimum requirements and are not designed to replace clinical judgement, they assume no specific indications for other studies*

Parameter	Baseline Start Rx	Week 2	Week 4	Monthly	6 months		Months 6-12 Monthly-End Rx
					End Rx Non-Reponders	Responders with Favorable Genotype	
Drug Screen	X			<i>{Random- As indicated during therapy}</i>			X
Hepatitis Profile	X			<i>{See below, Re: Vaccinations}</i>			
Pregnancy	X						
HCV-RNA	X					X	
Hgb/Hct	X	X	X	X	X	X	X
WBC	X	X	X	X	X	X	X
Platelet Count	X	X	X	X	X	X	X
Chem-20	X	X	X	X	X	X	X
TSH	X					X	

Initial treatment is for six months, failure to clear HCV-RNA after that time will be reason to discontinue further treatment, regardless of Genotype

*Any person developing an adverse reaction to treatment that is deemed medically significant by a physicians will have their treatment permanently discontinued.*

*Testing positive for drugs during treatment will result in permanent treatment discontinuation.*

**\*\* Immunizations:**

- 1 ~~X~~ **Hepatitis A & B vaccines offered dependent upon profile**  
*Dose one of HBV and HAV vaccine one month prior to starting Rx, Dose two of HBV immediately prior to starting Rx, Doses two (HAV) and three (HBV) at 6 mos.*
- 2 **Pneumococcal vaccine offered to all with HCV due to start Rx**  
*Dose on identification of HCV positively and at least one month prior to Rx commencement*

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