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Information Regarding Hepatitis C Virus (HCV) (March 2018)

Hepatitis C Virus (HCV) is an infectious disease that can cause serious liver problems. HCV infection is usually slowly progressive and may not result in clinically apparent liver disease in many patients. Generally, approximately 5 to 30 percent of chronically infected individuals develop cirrhosis (a serious liver disease) over a 20- to 30-year period of time, although some patients develop serious liver disease more quickly. Various factors are thought to influence how quickly the disease develops. For example, alcohol use has a major negative impact on disease progression.

Any person in CDCR can ask to be tested for HCV. A blood test is used to determine if a patient is infected with HCV. There is no co-pay for any medical appointment regarding HCV, including being tested.

HCV is treated with medication (pills). The newest medications work for most but not all patients, must be taken for between two and six months, can have side effects and thus require careful monitoring, and cost tens of thousands of dollars for each patient. CDCR has treated some HCV patients since approximately 2002. Over the last four years, approximately 4,000 CDCR patients have received medication for HCV.

CDCR primary care providers (PCPs) currently evaluate and treat CDCR patients who have HCV by using the December 2017 HCV Care Guide written and approved by medical staff that work for the federal court-appointed Receiver in charge of CDCR medical care. A copy of the December 2017 Care Guide should be available at your prison law library.

The December 2017 HCV Care Guide states that all HCV patients who want treatment are eligible to get it. This is different from how HCV treatment was handled before December 2017. However, there are still factors that will exclude some patients from treatment. Also, the Care Guide establishes three Priority Groups for HCV treatment, and says that patients with the greatest risk of harm from HCV will be treated first. The page from the CDCR HCV Care Guide that explains the exclusion factors and Priority Groups is enclosed. Prison medical officials have said that in 2018 they will offer HCV medication to all of the approximately 2,300 Group 1 and 2 patients, and in 2019 will start offering it to the more than 16,000 Group 3 patients (it may take several years to treat all Group 3 patients). **- Please see other side of page -**

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Advice regarding HCV Treatment in CDCR

(March 2018)

HCV is a complicated medical condition. If you have a question, concern, or request about HCV or treatment for it – including which Priority Group you are under the December 2017 HCV Care Guide – you should put in a 7362 (“sick call”) form and ask your doctor or PCP. A medical appointment for HCV does not require a co-pay.

If you cannot resolve the concern or request after that, submit a medical appeal using Form 602-HC (the blue appeal form). Filing a 602-HC regarding HCV treatment should result in a written response from medical staff, and if the appeal is not fully granted you should then re-submit it to the Headquarters Level, which should then send you a response.

Prison Law Office will consider asking prison medical officials about your HCV concern if you send us a Headquarters Level response to a 602-HC about the issue (urgent cases are an exception). A Headquarters Level Response to a 602-HC is also usually required before you can file your own formal legal action about a medical issue.

SUMMARY

DECISION SUPPORT

PATIENT EDUCATION/SELF MANAGEMENT

HCV TREATMENT PRIORITIZATION

Due to the significant number of patients eligible for treatment, patients at highest risk for complication or death if they remain untreated will be prioritized to receive HCV treatment first. Priority groups are listed below.

Risk Group	Clinical Examples
1 (Highest)	<ul style="list-style-type: none"> Any previous Fibroscan or liver biopsy demonstrating stage 3 or 4 fibrosis (≥ 9.5 kPa) Cirrhosis otherwise diagnosed Diagnosis of decompensated cirrhosis (see page 4) Diagnosis of hepatocellular carcinoma (see exclusion criteria, below) HIV co-infection and any previous Fibroscan or liver biopsy demonstrating greater than stage 1 fibrosis (> 7.0 kPa) Liver Transplantation (consult with transplant and HCV specialists required) Women of childbearing age who wish to get pregnant in the next 12 months Serious extra-hepatic manifestations of HCV (e.g., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia)
2 (Medium)	<ul style="list-style-type: none"> Does not qualify for risk group 1 and: Any previous Fibroscan or liver biopsy demonstrating stage 2 fibrosis (> 7.0 kPa) Age > 50 years old HIV or HBV co-infection Patients with Diabetes HCV genotype 3 Body mass index > 30 kg/m² GFR < 30 Does not meet any priority group 1 criteria
3 (Lowest)	<ul style="list-style-type: none"> Any previous Fibroscan or liver biopsy demonstrating stage 0-1 fibrosis (≤ 7.0 kPa) Does not meet any priority group 1 or 2 criteria

HCV TREATMENT EXCLUSION CRITERIA**TREATMENT EXCLUSION CRITERIA****Release Date Exclusion**

Clinical History	Minimum # of Months*
Not cirrhotic	5
Decompensated cirrhotic and/or previous Direct Acting Agents (DAA) treatment failure	8

*Patients will be excluded from treatment consideration in CCHCS if they will be released before the evaluation and course of treatment can be completed. The minimum # of months noted above shows the minimum number of months of incarceration needed to complete HCV therapy based on patient factors.

More time may be required in some cases.

Exclusion Criteria: HCV Treatment (all)

- Life expectancy < 12 months that cannot be remediated by treating HCV, by transplantation, or by other directed therapy
- Inability to cooperate with treatment
- Inability to give informed consent
- Pregnancy or inability to practice contraception

Exclusion Criteria: DAA

- On a medication contraindicated for use with DAA and unable to substitute
- Allergy to DAA
- Allergy to Ribavirin (if regimen requires RBV)

Exclusion Criteria: Ribavirin

- Poorly controlled or unstable cardiopulmonary disease
- Anemia; hemoglobin < 11 g/dl or hematocrit $< 33\%$
- Allergy to Ribavirin
- Inability to practice contraception during and for 6 months after treatment completion (teratogen)