



PRISON LAW OFFICE

General Delivery, San Quentin CA 94964
Telephone (510) 280-2621 • Fax (510) 280-2704
www.prisonlaw.com

Director:
Donald Specter

Managing Attorney:
Sara Norman

Staff Attorneys:
Rana Anabtawi
Steven Fama
Alison Hardy
Corene Kendrick
Rita Lomio
Margot Mendelson
Thomas Nosewicz
Camille Woods
Lynn Wu

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

Hepatitis C Virus (HCV) is an infectious disease than 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, drinking alcohol will or can make the disease get worse much faster.

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 Direct Acting Anti-viral (DAA) medication (pills). The newest DAA medications work for most but not all patients, must be taken for between two and six months, and require careful monitoring to make sure there are no serious side effects. The medication costs tens of thousands of dollars for each patient. CDCR in 2002 began treating small numbers of HCV patients. Between 2013 and 2017, an average of approximately 1,000 CDCR patients per year received HCV treatment.

In December 2017, CDCR changed its medical treatment criteria for HCV. Now – and as stated in the most recent California Correctional Health Care Services' HCV Care Guide (dated June 2018, and which should be available at your prison law library) all HCV patients who want treatment are eligible to get it.

However, while everyone is eligible, there are still factors that can exclude patients from HCV treatment. Also, the Care Guide establishes three Priority Groups (Group 1, 2, and 3) for HCV treatment, based on the risk of harm from the disease (Group 1 patients are most at risk, Group 3 the least at risk from HCV). The page from the CDCR HCV Care Guide that explains the exclusion factors and Priority Groups is enclosed.

[see other side for information about when HCV patients will be offered treatment]

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CDCR's Plan to Treat People with HCV

CDCR plans to offer medication treatment to all eligible HCV patients over the over the next three fiscal years: July 1, 2018 to June 30, 2019, July 1, 2019 to June 30, 2020, and July 1, 2020 to June 30, 2021. CDCR and the State of California have authorized additional money to do this. There will be at least \$165 million available in each of the next three fiscal years for HCV treatment.

There are approximately 18,000 people with HCV in prison. CDCR plans to provide medication to 6,000 patients in each of the next three fiscal years. CDCR will offer treatment to Group 1 and some Group 2 patients first, since they are most at risk. Then treatment will be offered to the rest of the Group 2 and finally to all Group 3 patients.

Prison medical officials say there are approximately 1,000 patients in HCV Group 1 who need treatment, 8,000 in Group 2 (approximately 2,000 of whom are more at risk), and 7,000 Group 3 patients.

So, between July 2018 and June 2019, CDCR plans to treat 1,000 Group 1 patients, 2,000 Group 2 patients who are more at risk, and 3,000 other Group 2 patients. Between July 2019 and June 2020, CDCR plans to treat the 3,000 remaining Group 2 patients and approximately 3,000 Group 3 patients. Between July 2020 and July 2021, CDCR plans to treat the remaining 4,000 Group 3 patients. Prison Law Office will monitor whether CDCR does what it says it will do.

CDCR Headquarters has a list of all HCV patients that is available to all CDCR doctors. That list includes every patient's HCV treatment priority group. You can ask your prison doctor which HCV Group you are in.

Most HCV treatment will be ordered by headquarters doctors who will see patients by tele-medicine. The headquarters tele-medicine doctors will focus on approximately 10 prisons per month. We do not know the schedule. HCV treatment can also be requested by your doctor at the prison, so long as you are in an HCV Group that is scheduled for treatment.

Advice regarding HCV Treatment in CDCR

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
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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							
<u>Release Date Exclusion</u>							
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d9d9d9;"> <th style="width:60%;">Clinical History</th> <th style="width:40%;">Minimum # of Months*</th> </tr> </thead> <tbody> <tr> <td>Not cirrhotic</td> <td style="text-align: center;">5</td> </tr> <tr> <td>Decompensated cirrhotic and/or previous Direct Acting Agents (DAA) treatment failure</td> <td style="text-align: center;">8</td> </tr> </tbody> </table>	Clinical History	Minimum # of Months*	Not cirrhotic	5	Decompensated cirrhotic and/or previous Direct Acting Agents (DAA) treatment failure	8	
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Not cirrhotic	5						
Decompensated cirrhotic and/or previous Direct Acting Agents (DAA) treatment failure	8						
<p>*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.</p> <p>More time may be required in some cases.</p>							
<u>Exclusion Criteria: HCV Treatment (all)</u>							
<ul style="list-style-type: none"> • 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 							
<u>Exclusion Criteria: DAA</u>	<u>Exclusion Criteria: Ribavirin</u>						
<ul style="list-style-type: none"> • On a medication contraindicated for use with DAA and unable to substitute • Allergy to DAA • Allergy to Ribavirin (if regimen requires RBV) 	<ul style="list-style-type: none"> • 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) 						