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## **Information Regarding Hepatitis C Virus (HCV) (December 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, 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. Since then, all HCV patients who want treatment are eligible to get it. However, while everyone is eligible, there are factors that can exclude patients from HCV treatment. Also, not everyone will be treated at the same time. There are three Priority Groups (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 treatment Groups are explained in a HCV Care Guide (updated November 2018, available in your law library) that prison doctors use. The page from the Care Guide that explains the exclusion factors and Priority Groups is attached. We also attach a May 2018 "Update" regarding the plan to treat HCV patients that CCHCS provided to all Men and Women Advisory Councils. Your doctor can look at a list of all HCV patients that includes every patient's HCV treatment Priority Group. We suggest you ask your prison doctor if you are eligible for HCV treatment, and which HCV Group you are in.

**[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.

Approximately 18,000 people in CDCR have HCV. CDCR plans to provide medication to 6,000 patients in each of the next three fiscal years. CDCR currently is offering medication to Group 1 and some Group 2 HCV patients, since they are most at risk. Medication will then be offered to the rest of Group 2, and finally to all Group 3 patients:

- Between July 2018 and June 2019: medication for 1,000 Group 1 and 5,000 Group 2 patients.
- Between July 2019 and June 2020: medication for 3,000 Group 2 and 3,000 Group 3 patients.
- Between July 2020 and June 2021: medication for 4,000 Group 3 patients.

Most HCV treatment is ordered by headquarters doctors who see patients by tele-medicine. Your prison doctor can also order medication, if you are in a HCV Group scheduled for treatment.

Prison Law Office monitors CDCR's HCV program. In first five months of the new program (since July 1, 2018), an average of about 600 new patients each month have started HCV medication. If this continues, CDCR will meet its goal of starting 6,000 patients on HCV medication by the end of June 2019.

## **Advice regarding HCV Treatment in CDCR**

HCV is a complicated medical condition. If you have a question or request about HCV or treatment for it – including which Priority Group you are under the HCV Care Guide and when you will be offered medication – 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 your question 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. If the appeal is not fully granted you should 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   |
|--------------------|---|
| <b>1 (Highest)</b> | <ul style="list-style-type: none"> <li>Any previous Fibroscan or liver biopsy demonstrating stage 3 or 4 fibrosis (<math>\geq 9.5</math> kPa)</li> <li>Cirrhosis otherwise diagnosed</li> <li>Diagnosis of decompensated cirrhosis (see page 4)</li> <li>Diagnosis of hepatocellular carcinoma (see exclusion criteria below)</li> <li>HIV co-infection and any previous Fibroscan or liver biopsy demonstrating greater than stage 1 fibrosis (<math>&gt; 7.0</math> kPa)</li> <li>Liver Transplantation (consult with transplant and HCV specialists required)</li> <li>Women of childbearing age who wish to get pregnant in the next 12 months</li> <li>Serious extra-hepatic manifestations of HCV (e.g., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia)</li> </ul> |
| <b>2 (Medium)</b>  | <ul style="list-style-type: none"> <li>Does not qualify for risk group 1 and:</li> <li>Any previous Fibroscan or liver biopsy demonstrating stage 2 fibrosis (<math>&gt; 7.0</math> kPa)</li> <li>Age <math>&gt; 50</math> years old</li> <li>HIV or HBV co-infection</li> <li>Patients with diabetes</li> <li>HCV genotype 3</li> <li>Body mass index <math>&gt; 30</math> kg/m<sup>2</sup></li> <li>GFR <math>&lt; 30</math></li> <li>Does not meet any priority group 1 criteria</li> </ul>  |
| <b>3 (Lowest)</b>  | <ul style="list-style-type: none"> <li>Any previous Fibroscan or liver biopsy demonstrating stage 0-1 fibrosis (<math>\leq 7.0</math> kPa)</li> <li>Does not meet any priority group 1 or 2 criteria</li> </ul>   |

**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)

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Dear Members of the MAC/WAC,

This is to update those persons living with Chronic Hepatitis C about the current treatment in CCHCS.

**BACKGROUND:**

- Currently, there are over 18,000 patients in CDCR that are infected with chronic hepatitis C (HCV).
- When persons are infected with HCV, the following things can happen:
  - At least 20% will cure the infection with their own immune system and these people will not develop a chronic HCV infection
  - 80% of the patients who develop chronic HCV infection will live with the disease for decades with no significant damage to the liver
  - 20% of the patients with a chronic HCV infection will develop scar tissue (fibrosis) in their liver and some of these patients can develop liver cirrhosis (severe scarring) or other serious kinds of liver disease that may result in their death.
- CCHCS offers HCV tests for every inmate and, if it is diagnosed, periodic evaluations are scheduled to identify whether liver damage has started.
- The disease has been closely studied and we know that the damage can occur more quickly in some patients. For example, patients that are also infected with HIV; have diabetes, are over 50 years old or are obese, may develop liver disease sooner than others.



New medications have been developed that work much better than older treatments. The older medicines needed to be taken for a long time, required close monitoring, had many side effects and they were successful only about 50% of the time.

The new treatments have very few side effects, don't have to be taken as long and cures the infection about 95% of the time.

**CCHCS TREATMENT PLAN:**

- CCHCS is planning to treat 6000 patients for their HCV in fiscal year 2018-2019 (July 1, 2018-June 30, 2019).
- While treatment of HCV with the new medications is easier for both the patient and the medical provider, it still takes extra training and experience to choose the exact medicine that gives each patient the best chance at cure.
- CCHCS created a Central HCV Treatment Team of providers experienced with treatment using the new medications and they have been identifying patients with HCV and treating them using telemedicine.
- This team is also educating all CCHCS healthcare staff on the use of the new HCV medications.





**SELECTING WHICH PATIENTS TO TREAT FIRST:**

- CCHCS has approved a Hepatitis C Care Guide that follows national guidelines by the American Association for the Study of Liver Disease (AASLD). The new CCHCS Care Guide is based on these recommendations. (The care guide is available in the institution library.)
- In order to find the patients who need HCV treatment first, the AASLD guidelines are followed. Patients are placed into HCV Risk Group 1, HCV Risk Group 2, or HCV Risk Group 3 based on factors that make them more or less likely to develop significant liver scar tissue/fibrosis/cirrhosis.
- Below are the descriptions of each HCV Risk Group. Patients in HCV Risk Group 1 already have liver damage or are at the highest risk to develop scar tissue/cirrhosis so they are treated first. Patients in HCV Risk Group 2 are treated next because they have factors that make them more likely to develop scar tissue more quickly.
- Patients in HCV Risk Group 3 do not have significant liver scarring and do not have factors that make them more likely to develop scar tissues fast. They are safely able to wait for treatment.

**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  |
|------------------------|--|
| <b>1<br/>(Highest)</b> | <ul style="list-style-type: none"> <li>• Any previous Fibroscan or liver biopsy demonstrating stage 3 or 4 fibrosis (<math>\geq 9.5</math> kPa)</li> <li>• Cirrhosis otherwise diagnosed</li> <li>• Diagnosis of decompensated cirrhosis (see page 4)</li> <li>• Diagnosis of hepatocellular carcinoma (see exclusion criteria, below)</li> <li>• HIV co-infection and any previous Fibroscan or liver biopsy demonstrating greater than stage 1 fibrosis (<math>&gt; 7.0</math> kPa)</li> <li>• Liver Transplantation (consult with transplant and HCV specialists required)</li> <li>• Women of childbearing age who wish to get pregnant in the next 12 months</li> <li>• Serious extra-hepatic manifestations of HCV (e.g., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia)</li> </ul> |
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**HCV RISK GROUPS:**

- In order to ensure that each patient with chronic HCV is placed in the appropriate HCV Risk Group additional testing is often needed.
- The following testing is done:
  - Initial tests, often done at Reception Center, show whether a patient has a positive HCV antibody. If a patient does have a positive HCV antibody a HCV viral load test is needed to see if the virus is still in the patient. If the viral load is positive this tells us the patient has a chronic HCV infection.
  - There are 6 different kinds (genotypes) of the HCV virus. A blood test is ordered to determine the genotype of the virus that each patient has because the type of medication needed is based on the HCV genotype.
  - Each patient's age, liver enzyme test, and blood platelet test is used to calculate a number called the FIB4. If the patient does not have a blood count and blood chemistry test in the last year one is needed to determine their FIB4. The FIB4 test gives an estimate of the amount of scar tissue/fibrosis in a person's liver.
    - If the FIB4 result is less than 1.45 that person is not likely to have much scar tissue/fibrosis and is usually in HCV Risk Group 3 (lowest risk).
    - If the FIB4 result is more than 3.25 that person is likely to have significant scar tissue/fibrosis and is placed in Risk Group 1 (highest risk), and offered treatment as soon as possible.
    - If the FIB4 result is between 1.45 and 3.25 the person requires additional testing with an ultrasound liver test called a Fibroscan.
- The Central HCV treatment team is ordering these tests on hundreds of patients in order to place them in the appropriate risk groups and to start treatment. The team has provided the institution with some patient education materials and does attempt to send a message to each person explaining why the tests are being ordered.
- Unfortunately, many patients have been refusing/declining blood tests that were ordered by the members of the central HCV treatment team. We believe this is because the patient may not have received the information explaining what the HCV team is doing.
- It would help us if you could let all patients know that this statewide testing is being done in order to be sure that we find every patient with HCV and have the information needed to start their treatment as soon as possible based on their risk group.
- If a patient is not sure why a blood test is being done they can ask the lab staff. Blood tests or Fibroscans that are ordered by the Central HCV treatment team will have a notation in the comment section that laboratory personnel can identify.
- Once the test results are available, the patients will receive a letter about the results.
- For some patients' blood tests will be done and treatment will be offered fairly soon after testing is done. For some patients the lab tests may just be getting beginning information and treatment will not be needed for several months.





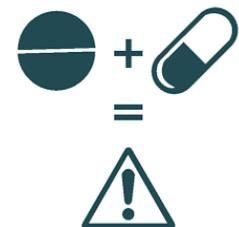
**HCV TREATMENT:**

- CCHCS plans to treat at least 6000 more patients for chronic HCV between July 2018 and the end of June 2019.
- In order to be sure that we first treat those patients who have the greatest medical need, the team will be focusing on the treatment of all patients in Risk Group 1 and will begin treating patients in Risk Group 2. There are over 9000 patients in HCV Risk Groups 1 and 2 so it will take over a year for them to all get treated.
- There are a number of very effective medications including those with trade names, Harvoni, Eplclusa, Mavyret and Zepatier. Which medication is used in each patient depends on a number of things including the patient's:
  - Genotype (1, 2, 3, 4, 5, or 6),
  - Amount of liver scarring,
  - Race, and
  - Previous HCV treatment the person may have had.
- In each case, the experienced Central HCV Team medical providers choose the medication that research says will give that patient the best chance at cure.



**WHAT TO DO DURING TREATMENT:**

- Once a medication has been selected, it is very important for the patient to follow instructions exactly.
- All HCV medications must be administered in the pill line by the nurse (NA/DOT), usually for a total of 12 weeks.
- It is crucial that every single dose is taken.
- If a patient on HCV treatment goes out to court, out to the emergency room, or hospital, that patient needs to be sure that every health care staff and custody staff is aware that they are taking HCV treatment and cannot miss any dose.
  - Hospitals do not always carry these medications and it is very important that everyone at the institution and the hospital be aware of the HCV treatment so medication can be provided without missing a dose.
- **Missing a dose can lead to the virus becoming stronger (viral resistance) and it can make it difficult or even impossible to cure.**
- Another important part of successful treatment is to be sure there are no other medications taken that can weaken the effect of the HCV medication. These are called drug-drug interactions.
- Many medications that are commonly taken such as ranitidine (Zantac), omeprazole (Prilosec), and Maalox or Mylanta interfere with the HCV medication and can cause the HCV treatment to fail. Some patients will need to stop one of their regular medications for the time they are on HCV treatment.
- For this reason, all of the patients prescribed medications are checked to be sure they are ok to take with the planned HCV medication.
- Because some medications cannot be taken at all when a person is taking HCV medication, some patients will need to stop one of their regular medications for the time they are on HCV treatment.





- Every time a nurse, PCP, dentist, mental health provider, or outside hospital or emergency room medical provider wants to give a new medication to a patient who is on HCV treatment, that patient must be sure that the person prescribing the new medicine knows that the HCV medicine is being given.
- HCV medication is relatively new and there are some providers who are not familiar with all of the possible drug-drug interactions that can cause the HCV medicine not to work.
- All patients on HCV treatment must also avoid taking medication from the canteen, vitamins or supplements from the outside or medication from friends unless they have confirmed that the medication will not interfere with the HCV treatment.

### **HOW LIKELY IS A CURE?**

- As mentioned above, the new treatments work about 95% of the time and patients can be considered cured.
- How will a patient know if they are cured? Each patient will need a HCV viral load blood test 12 weeks after they take their last dose of HCV medication.
- This test is called 12 week SVR and if it shows no virus in the blood, the patient is considered cured.



### **GETTING HCV AGAIN:**

- Treatment for HCV is far better and easier but the treatment is not permanent like a vaccine. It does NOT prevent a patient from getting HCV again.
- Every patient cured of HCV can easily get another infection with HCV if they do activities that are known to transmit HCV including:
  - IV drug use with needle sharing
  - Sharing straws to snort drugs
  - Receiving a tattoo (especially in prison)
  - Sharing razors
- Many of our patients with chronic HCV became infected through drug use. If a person needs help to stop abusing drugs they should ask their counselor about getting into Substance Abuse Treatment. Continuing to abuse drugs can easily lead to being re-infected with Hepatitis C, but it can also lead to serious or deadly infections of the heart, infection with HIV or Hepatitis B, or overdose and death. In the community overdose deaths are skyrocketing due to contaminated drugs from overseas. More than ever using illegal drugs can be deadly.
- Medical researchers are tracking patients who are successfully treated for HCV but then get another HCV infection. It is not clear how easy it will be for the patient who gets another infection to be treated again.
- Many patients have lived with HCV for years waiting for these improved medications to be developed so they can have a chance at being cured, we hope for a successful treatment for each patient, but do not risk getting infected again!

