

MAY 2014

U.S. DEPARTMENT OF JUSTICE

Federal Bureau of Prisons

*After discussing each item with the inmate, the health care provider should have the inmate initial numbers 1 through 4 for all patients being considered for hepatitis C treatment, numbers 5 through 9 if treatment includes peginterferon, numbers 10 through 13, if treatment includes ribavirin, numbers 14 through 20 if treatment includes sofosbuvir, and numbers 21 through 27 if treatment includes simeprevir.*

I, \_\_\_\_\_, Reg. No. \_\_\_\_\_, hereby authorize Dr. \_\_\_\_\_, or his/her relief (designee), to prescribe treatment of hepatitis C virus infection (HCV) with medication, if indicated, and to continue said medication as is recommended by BOP Clinical Practice Guidelines.

1. \_\_\_\_\_ Your health care provider will prescribe the regimen that is most appropriate for your condition. This regimen may consist of a combination of HCV antivirals that could include: pegylated interferon injections (PEG-Intron®, Pegasys®), oral ribavirin (Rebetol®, Copegus®), oral direct-acting agents sofosbuvir (Sovaldi™), simeprevir (Olysio™), or other direct acting antiviral therapy. I understand my medical condition and why this combination of medications is being recommended to treat my disease.

2. \_\_\_\_\_ This treatment requires frequent visits to the Health Services Unit for outpatient visits, blood tests, medication injections and pill line administration of some medications. Attending these appointments and adhering to the treatment regimens are essential to achieve a safe and successful treatment result and to reduce the likelihood of the virus becoming resistant to treatment. Prior to starting treatment, each patient must assess their ability and willingness to comply with the treatment regimen described by their health care provider. In some cases, postponing treatment may be acceptable or even preferred.

3. \_\_\_\_\_ **It is important to abstain from illicit drug or alcohol use, or from receiving tattoos which may interfere with medication treatments, worsen liver disease, or increase the risk for reinfection with HCV or other infections.**

4. \_\_\_\_\_ This treatment is associated with numerous adverse and potentially serious side effects. Your health care provider, along with pharmacy and laboratory, will carefully monitor you for side effects and your response to this therapy. **To ensure continuity of care and provide the best opportunity for a successful outcome, a medical hold status that prevents your transfer to another institution and/or defers your halfway house placement may be placed until the course of therapy is complete.**

**For patients treated with pegylated interferon, the following applies:**

5. \_\_\_\_\_ The most common side effects are "flu-like" symptoms, such as headache, fatigue, muscle aches, and fever. These symptoms may decrease in severity as treatment continues. Taking acetaminophen (Tylenol®) prior to interferon administration may help alleviate some of these adverse effects.

6. \_\_\_\_\_ Psychiatric problems, such as insomnia and depression, are frequently associated with this therapy. If you feel you are getting irritable or easily upset, feel hopeless or bad about yourself, or experience any other uncommon psychological problems, you should immediately contact your health care provider. More severe psychiatric problems also may occur, including psychosis, severe depression, suicidal thoughts, or completed suicide.

7. \_\_\_\_\_ Some patients will develop blood problems such as reduced red blood cells (anemia), or reduced white blood cells or platelets. You will receive a Complete Blood Count on a regular basis to determine if you are developing any of these adverse effects. If these levels drop below acceptable levels the medication may need to be dose adjusted or discontinued.

8. \_\_\_\_\_ Your thyroid function will be closely monitored because a small percentage of patients (approximately 4%) will develop thyroid dysfunction that may be irreversible, even if treatment is discontinued.

9. \_\_\_\_\_ Other common side effects include bruising, irritation, or itchiness at the injection site, nasal stuffiness, and reversible thinning of the hair.

**For patients treated with ribavirin, the following applies:**

10. \_\_\_\_\_ **Ribavirin can cause birth defects. Both women and men, particularly those awaiting release, must be counseled to use adequate birth control (2 forms of birth control) during treatment and 6 months after treatment is completed.**

11. \_\_\_\_\_ **Ribavirin should not be taken if you have severe kidney dysfunction.**

12. \_\_\_\_\_ Between 5%-10% of the patients taking ribavirin therapy develop anemia within 1 to 4 weeks of beginning treatment. You should immediately speak to your doctor if you experience any side effects described above, or you experience trouble breathing, chest pain, severe stomach or lower back pain, bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, decreased vision, weight loss, rashes, or other symptoms that concern you.

13. \_\_\_\_\_ To improve your comfort and the chances of successfully completing this course of treatment you should get plenty of rest, exercise lightly but regularly, drink plenty of water or clear fluids every day, eat regularly, and take acetaminophen for fevers and "flu-like" symptoms.

If oral direct-acting agents are not a treatment option for this patient, skip to the signature blocks at the bottom of page 2.

**For patients treated with the HCV polymerase inhibitor sofosbuvir, the following applies:**

14. \_\_\_\_\_ Sofosbuvir is indicated for the treatment of HCV genotype 1, 2, 3, or 4, and for HCV/HIV coinfection, and must be taken in combination with other HCV antiviral medications. It should never be taken by itself.

15. \_\_\_\_\_ Sofosbuvir must be taken by mouth once daily with or without food.

16. \_\_\_\_\_ If you forget to take a dose, you may take the dose later in the day and resume your normal dosing schedule thereafter. Do not take more than one tablet of sofosbuvir per calendar day.

17. \_\_\_\_\_ Sofosbuvir can be stored at room temperature up to 86°F.

18. \_\_\_\_\_ Common side effects include fatigue, headache, nausea, insomnia, and anemia.

19. \_\_\_\_\_ Sofosbuvir should not be taken or prescribed if you already are taking certain other medications. A comprehensive medication review is essential before initiation of Hepatitis C treatment. Your health care provider will discuss these medications in greater detail. If a new medication is prescribed for you while you are taking an HCV polymerase inhibitor, you should inform them that you are taking these medications.

20. \_\_\_\_\_ Due to the high potential for development of resistance, if sofosbuvir is discontinued, it shall not be restarted.

**For patients treated with the HCV protease inhibitor simeprevir, the following applies:**

21. \_\_\_\_\_ Simeprevir is indicated for the treatment of HCV genotype 1 only and must be taken in combination with other HCV antiviral medications. It should never be taken by itself.

22. \_\_\_\_\_ Simeprevir must be taken by mouth once daily with food. There is no specific requirement for type or amount of food. The capsule must be swallowed whole.

23. \_\_\_\_\_ If you forget to take a dose of simeprevir and it is less than 12 hours after the usual dosing time, you may take the missed dose with food as soon as possible. If it has been more than 12 hours since the usual dosing time, skip that dose and resume the dosing schedule at the next scheduled dosing time.

24. \_\_\_\_\_ Simeprevir can be stored at room temperature up to 86°F.

25. \_\_\_\_\_ Common side effects include photosensitivity and rash.

26. \_\_\_\_\_ Simeprevir should not be taken or prescribed if you already are taking certain other medications. A comprehensive medication review is essential before initiation of Hepatitis C treatment. Your health care provider will discuss these medications in greater detail. If a new medication is prescribed for you while you are taking an HCV protease inhibitor, you should inform them that you are taking these medications.

27. \_\_\_\_\_ Due to the high potential for development of resistance, if simeprevir is discontinued, it shall not be restarted.

Physician Signature \_\_\_\_\_

Based upon interview, assessment, and medical record review, it is my opinion that this patient understands the proposed treatment, the risks and benefits of the treatment, and **is competent** to give consent.

Physician Signature \_\_\_\_\_

Based upon interview, assessment, and medical record review, it is my opinion that this patient understands the proposed treatment, and **is not competent** to give consent.

Other issues discussed: \_\_\_\_\_

I certify that I have read the foregoing, or have had it explained to me in a language that I understand, and hereby consent to treatment and have no additional questions. I understand that I may stop taking this medication by contacting the physician. However, I understand that discontinuing the medication may result in failure to control progression of liver disease.

Inmate Signature: \_\_\_\_\_ Reg. No. \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Attending Physician: \_\_\_\_\_