Department of Health Care Finance

Clinical Criteria for Approving Sovaldi™ (sofosbuvir)

NOTE TO PRESCRIBERS: *PLEASE REFER TO THE CRITERIA BELOW WHEN COMPLETING A REQUEST FOR PRIOR AUTHORIZATION FOR SOLVADI. BE SURE TO INCLUDE ALL SUPPORTING DOCUMENTATION WITH THE REQUEST.* A District of Columbia Fee for Service Medicaid beneficiary **may** qualify to receive Sovaldi (Sofosbuvir) coverage if the following criteria are met:
1. A diagnosis of genotype 1, 2, 3 or 4 chronic hepatitis C (CHC) infection with compensated liver supported by clinical assessment to demonstrate liver fibrosis;
OR
2. A diagnosis of genotype 1,2, 3 or 4 chronic hepatitis (CHC) infection in addition to hepatocellular carcinoma and meets Milan criteria (Awaiting Liver Transplantation;
OR
3. A diagnosis of HCV/HIV-1 co-infection with documented HIV-1 diagnosis and are on Antiretroviral (ARV) Therapy (ARV) or meeting criteria for ARV therapy excluding those with cirrhotic chronic HCV/HIV1 co-infected and have decompensated cirrhosis (Child-Pugh score greater than 6 i.e. class B and C) before or during treatment.
OR
4. Beneficiary is interferon ineligible due to reasons that include but not limited to documented intolerance to interferon, hypersensitivity to peginterferon or any of its components; history of depression, or clinical features consistent with depression; baseline neutrophil count < 1,500 cells/μL; baseline platelet count < 90,000 cells/μL; baseline hemoglobin < 10 g/dL or preexisting cardiac disease;
AND
5. The beneficiary is 18 years of age or older;
AND
6. Sovaldi is prescribed by DC Medicaid Enrolled gastroenterologist, an infectious disease specialist, a physician specialized in hepatitis treatment and management or a physician working in consultation with gastroenterologist or infectious disease specialist; AND 7. Sovaldi is not prescribed as a monotherapy or not for a concurrent use with Victrelis (boceprevir) or Incivek (telaprevir) but for use only in combination with ribavirin or in combination with peglyated interferon and ribavirin;
AND
8. The prescribing provider has a documented plan to monitor HCV-RNA levels at weeks 4 and 12 to determine treatment duration and assess conditions that warrant discontinuation of

Approved by District of Columbia Drug Utilization Review Board
Date of Approval: April 25, 2014

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therapy; and a plan to undertake hematology evaluations (including white cell differential count) prior to initiating therapy and at weeks 2, 4, 8 and 12 or as clinically appropriate thereafter;
AND
9. The beneficiary agrees to participate in Hepatitis C educational and counseling program provided by the districts Pharmacy Benefit Manager; and beneficiary clearly understands that only one course of therapy is allowed in DC Medicaid lifetime; and unless there is a legitimate documented evidence, request for loss/stolen medication replacement will not be authorized;
AND
10. Beneficiary is not taking a concomitant medication that has a significant clinical interaction with Sovaldi including Carbamazepine, Phenytoin, Phenobarbital, Oxcarbazepine, Rifampin, Rifabutin, Rifapentine, Tipranavir/ritonavir, and St. John's wort;
AND
11. Sovaldi will NOT be used in conditions that include hemoglobinopathies (e.g. thalassemia major, sickle-cell anemia); in pregnant women or in men whose female partners are pregnant; autoimmune hepatitis; Cirrhotic chronic HCV mono-infected or co-infected with HIV patients with decompensated cirrhosis (Child-Pugh score greater than 6 i.e. class B and C) before or during treatment.
AND
12. Beneficiary should abstain from the use of illicit drugs and alcohol for at least three (3) months as evidenced by urine confirmation tests (submitted with prior authorization request);
AND
13. The duration of treatment depends on HCV genotype and patient's conditions. Initial prior authorization is approved for 6 weeks with one (1) renewal for genotype 1, 2, and 4 (including HCV-HIV-1 co-infection); three (3) renewals for genotype 3 (including HCV-HIV-1 co-infection) and for dual therapy in genotype 1 patients who are interferon ineligible; and with seven (7) renewals for hepatocellular carcinoma awaiting liver transplant patients.
AND
14. Clinical documentation of Hepatitis C Liver Disease (Metavir score of F2 or greater) is included with supporting information.

DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications

Please initial each statement that you have read and discussed the "Disclosure and Commitment to Take Hepatitis C Medications" form with your healthcare provider.

____ I understand that I will be taking the following combination of medications: Sovaldi plus Ribavirin, with or without Interferon (Pegasys, Peg-Intron, or Infergen), a very potent and expensive regimen. After discussion of the nature, alternatives risks and benefits of these medications with my physician, I agree to take them as instructed. I understand that this combination of medication is to manage my Hepatitis C and has shown a high chance of a good response in the treatment Hepatitis C when taken appropriately.

____ I understand that there are risks to not treating chronic Hepatitis C, including disease progression, developing cirrhosis, liver cancer, and liver failure. I also understand there are risks and hazards related to the use of these medications. The risks and benefits have been reviewed and discussed with me by my prescriber.

____ I will commit to the following processes to help make this treatment successful:
□ Daily adherence to medication unless told by prescriber/pharmacy to stop medication
□ Timely laboratory monitoring per prescriber's request
□ Medication Counseling, Education and Training regarding administration and side effects
□ Telephone follow-ups with prescriber, pharmacy and insurance
□ No missed follow-up appointments with prescriber during this treatment

____ I understand that if I am not committed to this regimen that I put myself in jeopardy with treatment failure and denial of medication coverage for this particular regimen by DC Medicaid, the insurance. I understand that only one course of therapy is allowed in his/her DC Medicaid lifetime.

____ I have been given an opportunity to ask questions about my condition, alternative treatment options and risk of treatment and I believe that I have sufficient information to understand the content of this disclosure and commitment to this treatment option.

____ I understand that no warranty of guarantee has been made to me as a result of using this drug or the possibility of curing my condition. I acknowledge that I have been given a copy of this completed commitment form. I willingly give commitment to the following regimen:

□ **Sovaldi** 400mg by mouth once daily for _____ weeks.
□ **Ribavirin Pill**
Daily Dose: _____ mg (_____ pills/day) for _____ weeks.
Take _____ pills every morning and _____ pills every evening.
□ **Pegylated Interferon Injection**
Dose: _____ injected in fat under skin once weekly for _____ weeks.

- Usually at bedtime
- Choose the same day each week
- Injection training will be provided

□ **Projected start date if regimen is approved by insurance**: _____ **Duration**: _____ weeks.

Patient Signature: _____ Date: _____

Prescriber Signature: _____ Date: _____

DHCF STATEMENT on SOVALDI®

The Department of Health Care Finance (DHCF) has published the prior authorization clinical criteria for Sovaldi® (sofosbuvir). Sovaldi® is a new oral treatment option for patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplant) and those with HCV/human immunodeficiency virus (HIV)-1 co-infection. Approved by the Food and Drug Administration (FDA) in December 2013, sofosbuvir is the first direct-acting antiviral (DAA) agent in the nucleoside/ nucleotide polymerase inhibitor class.

The Initial Prior Authorization Request Form for Sovaldi® is available on the following websites:

www.dc-medicaid.com

www.dcpbm.com

Prescribers may refer to the Clinical Criteria for Approving Sovaldi® Form for additional required information to be submitted with prior authorization requests.