GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health Care Finance

Subject: Prior Authorization of Sovaldi® (sofosbuvir) **Policy Number:** HCRA-DEP-01

Policy Scope: Department-wide	**Number of Pages:**
Responsible Office or Division: Clinician, Pharmacy and Acute Provider Services	**Number of Attachments:** 1. Sovaldi® Initial Prior Authorization Request Form 2. Clinical Criteria for Approving Sovaldi® Form 3. DC Medicaid Beneficiary Disclosure and Commitment Form
Supercedes Policy Dated: N/A	**Effective Date:** 6/15/2014
Cross References and Related Policies: State Plan for Medical Assistance, Section 4. 19B, Part 1	**Expiration Date, if Any:** N/A

1. PURPOSE

To establish policies and procedures governing the submission of Prior Authorization (PA) requests for Sovaldi® (sofosbuvir) for District of Columbia Medicaid Fee for Service (FFS) beneficiaries.

2. APPLICABILITY

This policy applies to all Medicaid providers and beneficiaries that participate in the DC Medicaid FFS Program for the period beginning June 15, 2014.

3. AUTHORITY

The Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109); 8 U.S.C. § 1611 (b) (1) (A), 42 U.S.C. § 1396b (v), and 42 C.F.R. § 440.225(c); the District of Columbia State Plan for Medical Assistance –Section 4, Attachment 4.19B Part 1; and Section 5112(c) of the Fiscal year 2013 Budget Support Emergency Act of 2012, PR 19-796, effective June 20, 2012.

4. DEFINITIONS

a. **Sovaldi® (sofosbuvir) -** A Hepatitis C virus nucleotide analog ND5B polymerase inhibitor indicated for the treatment of chronic Hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Sovaldi is available in 400 mg tablets taken once daily with or without food.

b. **Prior Authorization** – Approval from the Department of Health Care Finance that may be required before a service or prescription order will be reimbursed to a provider.

c. **Drug Utilization Review (DUR) Board** – An advisory group of licensed physicians, pharmacists and allied health professionals established by Section 4401, 1927 9g) of the Omnibus Reconciliation Act of 1990. The Drug Utilization Review Board reviews and approves drug use criteria and standards for both retrospective and prospective drug use reviews (DURs); applies these criteria and standards in the application of DUR activities; reviews and reports the results of DURs; and recommends and evaluates educational intervention programs for covered outpatient drugs under the Medicaid Fee for Service Program.

5. POLICY

Effective June 15, 2014, all PA requests for Sovaldi® must be submitted on the designated Sovaldi® Prior Authorization Request Form. The completed request submission will be evaluated for approval in accordance with Clinical Criteria for Approving Sovaldi® (attached and incorporated by reference as Attachment #2), developed by the District of Columbia Drug Utilization Review Board.

6. PROCEDURE FOR REQUESTING SOVALDI® PRIOR AUTHORIZATION

a. The requesting physician can obtain the following documents from http://www.dcpbm.com/forms.html:

i. Sovaldi® Initial Prior Authorization Request Form
ii. Clinical Criteria for Approving Sovaldi®
iii. DC Medicaid Beneficiary Disclosure and Commitment Form

b. **To initiate the PA request,** after review of the Clinical Criteria for Approving Sovaldi® (sofosbuvir) Form, the requesting physician submits a signed dated and completed Sovaldi® Prior Authorization Request Form via facsimile to **866-535-7622.**

c. Submission of the following supporting documentation is also required to complete the request:

   i. **A Letter of Medical Necessity** from Prescriber
   ii. **Lab Test Results** (including, *but not limited to)*
      1. Initial hematology evaluations
      2. White cell differential count
      3. HCV-RNA level
   iii. **DC Medicaid Beneficiary Disclosure and Commitment Form** (*that has been)*
      1. Signed and dated by Prescriber; AND
      2. Signed and dated by Beneficiary (patient)

NOTE: The requesting Prescriber must submit the required supporting documentation to the Xerox Clinical Pharmacy Unit at **866-653-1431.** (*This is a separate fax number from the one used to initiate the fax PA request).*

d. The initial review of the PA Forms and required clinical information will be performed by the Xerox Clinical Pharmacy Unit for completeness and to address any missing information.

e. The DUR Board members will participate in the review process and will make approval recommendations to DHCF on the initial PA request.

f. It is anticipated that the Sovaldi® treatment PA decisions will occur within ten (10) to fourteen (14) days after receipt of a completed PA request and **ALL** required supporting documentation.

g. The requesting Prescriber will be notified of the disposition of the request. In the event of a denial of a PA, the beneficiary will be notified of unmet criteria and will be advised of their right to appeal.

7. RESPONSIBILITY

Questions regarding this policy should be directed to Charlene Fairfax, Senior Pharmacist, Health Care Delivery Management Administration, Division of Clinician, Pharmacy and Acute Provider Services at (202) 442-9076 or email charlene.fairfax@dc.gov or to Gidey Amare, RPh, Pharmacist, Health Care Delivery Management Administration, Office of Clinician, Pharmacy and Acute Provider Services at (202) 442-5952 or email gidey.amare@dc.gov.

Questions regarding Prior Authorization forms access or submission should be directed to the Xerox PA Helpdesk at (800) 273-4962.

Claudia Schlosberg
Acting, Senior Deputy Director

6/20/14
Date

Government of District of Columbia
Department of Health Care Finance
SOVALDI (sofosbuvir) 400mg Tablet
Initial Prior Authorization Request

61010

Request Date ___/___/_____

PATIENT INFORMATION

Patient's Medicaid ID Number

Patient's Date of Birth ___/___/_____

Patient's Full Name

PRESCRIBER INFORMATION

Prescriber's Full Name

Prescriber's Phone: ___-___-____

Prescriber's Fax: ___-___-____

Prescriber's NPI # ___-_____

Prescriber's Speciality_____

Summary of FDA approved Prescribing Information

Sovaldi is used in combination with Peginterferon and Ribavirin or Ribavirin. If the other agents used in combination with SOVALDI are permanently discontinued, SOVALDI should also be discontinued.The dose for Sovaldi is 400mg once daily with or without food. Sovaldi is not used as a monotherapy. Please, refer to FDA approved product information for prescribing details and approved indications.

Information Required for Prior Authorization Approval

1. Is the patient at least 18 years old? ___ Yes ___ No
2. Patient supervised by: ___Gastroenterologist ___Infectious disease specialist ___A physician specialized in hepatitis treatment and management ___ A physician working in consultation with gastroenterologist or infectious disease specialist.
3. Patient has a diagnosis of (please attach a letter of medical necessity with documentation): ___Chronic Hepatitis C (CHC) monoinfection ___CHC/HIV-1 co-infection ___Hepatocellular carcinoma meeting Milan Criteria (Awaiting Liver Transplant) ___Other_____
4. Patient has compensated liver disease: ___Yes ___ No
5. Patient has identified HCV genotype: ___1a ___1b ___2 ___3 ___4 ___Other genotype _____
6. Is Sovaldi to be used in combination with: ___ Peginterferon and Ribavirin ___ Ribavirin ___ Other _____
7. Does the patient have a history of adherence problem to any prior therapy? ___Yes ___No. If Yes,
   a. Please, briefly describe the nature of the problem (attach additional sheet if necessary)

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   b. Please describe any educational efforts undertaken to improve patient's adherence (attach additional sheet if necessary)

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8. Is the patient on any one of the following medications: Carbamazepine, Phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort, or tipranavir/ritonavir? ___Yes ___No
9. Has the patient tested pregnancy negative and is not planning to become pregnant? ___Yes ___ No
10. Do both the patient and patient's partner plan to use two forms of effective contraception during treatment: ___Yes ___No ___N/A.
11. Has the patient agreed to abstain from illicit drug or alcohol use for at least three months and been counseled on potential barriers to adherence to HCV therapy. ___Yes ___No. If No, please give the reason(s) why?

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12. The beneficiary has agreed to participate in the Hepatitis C monitoring program provided by the District's Pharmacy Benefit Manager; clearly understands that only one course of therapy is allowed in his/her DC Medicaid lifetime; and, unless there is legitimate documented evidence, a request for loss/stolen medication replacement will not be authorized? ___Yes ___ No

FAX COMPLETED LETTER OF MEDICAL NECESSITY, LAB TEST RESULTS (Initial hematology evaluations (including white cell differential count) (HCV-RNA level)), AND PATIENT EDUCATION & COMMITMENT TO TREATMENT FORM TO 866-653-1431

I certify that, to the best of my knowledge, all information I have provided on this request is complete and factual.

Signature of Prescriber_____ Date ___/___/_____

61010

FAX TO: District of Columbia Pharmacy Program
Fax: 866-535-7622
PA HELPDESK: 800-273-4962

May 2014

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

Clinical Criteria for Approving Sovaldi™ (sofosbuvir)

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.