DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Sofosbuvir tablet (Sovaldi®)

PRIOR AUTHORIZATION PROGRAM Request Form – Initial Request

CLIENT'S NAME: _____ ADAP ID:_____

CLIENT'S DATE OF BIRTH_____ ADAP Pharmacy_____

DC ADAP Policy: Sovaldi® (Sofosbuvir) is a nucleotide analog inhibitor of hepatitis C virus (HCV) NS5B polymerase. Sofosbuvir is available as a 400mg film-coated tablet for oral administration.

Sovaldi® requires prior approval for coverage. Allow up to 96 hours for completion of request.
Please fax (1) supportive medical letter of necessity of necessity (2) applicable diagnostic tests and (3) patient signed acknowledgement and commitment letter (4) Indicate Jurisdiction of ADAP Approval □DC □ MD □VA □WVA

Indication for Use:
Sofosbuvir is indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.
The effectiveness of sofosbuvir was established in patients with HCV genotype 1, 2, 3 or 4 infection, including patients with hepatocellular carcinoma meeting Milan criteria (those waiting for liver transplants) and those with hepatitis C virus/human immunodeficiency virus type 1 (HCV/HIV-1) co-infection.

Sovaldi® Treatment Regimen:

Drug	Dose	Route	Frequency

Criteria for use:
Please complete and check all that apply:

1. Medical Provider is experienced in the care of HIV/hepatitis C infection, or in consultation with an infectious disease specialist or gastroenterologist.
   YES □ NO □
2. Client does have adherence issues with antiretroviral or other medications.
   YES □ NO □
3. Client is not being treated with medications that are not recommended for use with or contraindicated with sofosbuvir (refer to product labeling).
   YES □ NO □
4. Client is currently receiving or recently received amiodarone.
   YES □ NO □
5. Client's has confirmed clinical diagnosis of Hepatitis C, genotype _____.
   YES □ NO□
6. Client is not pregnant or attempting to become pregnant and/or female partner of a male patient is not pregnant.
   YES □ NO □

7. Client does have decompensated liver disease.
   YES □ NO □
8. Client has cirrhosis
   YES □ NO □
9. Client has a FibroSure score of _____.
   Date of test_____ or biopsy proven score of _____ Date:_____
10. Client has had a positive hepatitis C viral load taken within the last 6 months.
    YES □ NO □
11. Client's anticipated start date of Sovaldi® is_____.
12. Client's anticipated duration of CHC treatment is _____ weeks.

Recommended dosage and administration: The recommended dose is one 400mg tablet orally once a day with or without food. Sofosbuvir should be administered in combination with ribavirin or in combination with peginterferon and ribavirin to treat chronic hepatitis C in adults. The following table describes the duration of therapy for adults with sofosbuvir combination therapy in patients infected with CHC or in patients co-infected with CHC/HIV-1:

Sofosbuvir Treatment Regimens and Durations based on Patient Characteristics *(Reference Only)*

Genotype	Treatment	Duration
Genotype 1 or 4 CHC	Sofosbuvir plus peginterferon alfa plus ribavirin	12 weeks
Genotype 2 CHC	Sofosbuvir plus ribavirin	12 weeks
Genotype 3 CHC	Sofosbuvir plus ribavirin	24 weeks

The dose of ribavirin is weight-based, as determined by the manufacturer's guidelines. For patients with genotype 1 CHC, an alternative for patients ineligible for interferon therapy is the administration of sofosbuvir plus ribavirin for 24 weeks.

The recommendation for the use of sofosbuvir in patients with hepatocellular carcinoma awaiting liver transplantation is combination therapy with ribavirin for up to 48 weeks or until the time of the transplant (whichever comes first).

Physician's signature:_____ Date:_____

Physician's Name (Print):_____Phone#:_____Fax#:_____

Fax Completed Form to Clinical Pharmacy Associates: Fax: 1 (888) 971-7229

Phone: 1 (800) 745-0434 ext 150 Attention: Prior Approval Program

Approval: YES □ NO□ Date_____ Initials_____ Office use only

Reason for denial_____