DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Ledipasvir and Sofosbuvir (Harvoni®) tablets

PRIOR AUTHORIZATION PROGRAM Request Form- Initial Request (12 weeks maximum)

CLIENT'S NAME: _____ ADAP ID: _____

CLIENT'S DATE OF BIRTH_____ ADAP Pharmacy: _____

DC ADAP Policy: Harvoni® (ledipasvir and sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor and a HCV NS5B polymerase inhibitor (sofosbuvir). Harvoni® is a film-coated tablet for oral administration that contains ledipasvir 90 mg and sofosbuvir 400mg in a single tablet.

Harvoni® requires prior approval for coverage. Allow up to 96 hours for completion of request.

Please Fax (1) Supportive medical letter of necessity (2) Applicable diagnostic test results and (3) Patient signed acknowledgement and Commitment letter (4) Indicate Jurisdiction of ADAP Approval □DC □ MD □VA □WVA

Indication for Use:

HARVONI® is a fixed- dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1, 4 5 or 6 infections in adults.

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. Does client have adherence issues with antiretrovirals or other medications?
   YES □ NO □
3. Client is not being treated with medications that are not recommended for use with or contraindicated with sofosbuvir or ledipasvir (refer to product labeling).
   YES □ NO □
4. Client is currently receiving or recently received amiodarone.
   YES □ NO □
5. Client is currently receiving drugs that induce P-gp transporter, e.g. rifampin, St John's wort
   YES □ NO □
6. Client has confirmed clinical diagnosis of HIV co-infection with chronic Hepatitis C, genotype 1a or 1b. YES □ NO□
   - Why not use Viekera Pak for treatment?_____
7. Client has decompensated liver disease.
   YES □ NO □
8. Client has cirrhosis.
   YES □ NO □
9. Client has had a positive hepatitis C viral load taken within the last 6 months.
   YES □ NO □

10. Client has a FibroSure score of _____. Date of test_____ or biopsy proven fibrosis score of _____, Date _____.
11. Has client been previously treated with sofosbuvir?
    YES □ NO □
12. Client's anticipated start date of Harvoni® is_____.
13. Client's anticipated duration of CHC treatment is _____ weeks.

Recommended dosage and administration: The recommended dosage* of Harvoni® (ledipasvir 90 mg and sofosbuvir 400 mg) is one tablet taken orally once daily with or without food. Treatment duration is based on patient characteristics as described in the following table.

*There is no dose recommendation for patients with severe renal impairment or end stage renal disease

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

Patient Population: Genotype 1	Treatment Regimen	Treatment Duration
Treatment-naïve with or without cirrhosis	Ledipasvir and Sofosbuvir	12 weeks
Treatment-experienced without cirrhosis	Ledipasvir and Sofosbuvir	12 weeks
Treatment-experience with cirrhosis	Ledipasvir and Sofosbuvir	24 weeks

Physician's signature: _____ Date: _____

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

Fax Completed Form to Clinical Pharmacy Associates, Inc: 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_____