

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

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 currently receiving or recently received amiodarone.
YES NO
4. Client is currently receiving drugs that induce P-gp transporter, e.g. rifampin, St John's wort
YES NO
5. 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?

6. Client has decompensated liver disease.
YES NO
7. Client has cirrhosis.
YES NO
8. Client has had a positive hepatitis C viral load taken within the last 6 months.
YES NO

9. Client has a FibroSure score of _____. Date of test _____ or biopsy proven fibrosis score of _____, Date _____.
10. Has client been previously treated with sofosbuvir?
YES NO
11. Client's anticipated start date of Harvoni® is _____.
12. 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 _____

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