MedStar Family Choice

PRIOR AUTHORIZATION FOR HEPATITIS C MEDICATION

Subject:	**Hepatitis C Medication PA Policy for District of Columbia Healthy Families and Alliance**	
Section:	**Pharmacy**	
Effective Date:	**7/2015**	
Revision Date(s):	**12/2/2015, 2/5/2016, 5/19/2016, 11/2016**	
Review Date(s):	**10/26/2016**	
Responsible Parties:	**Patryce Toye, Danielle Gerry**	
Responsible Department(s):	**P&T Committee, Case Management**	
Regulatory References:		
Approved:		
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Purpose: Epclusa® (sofosbuvir/vetpatasvir) and Harvoni® (sofosbuvir/ledipasvir) require Prior Authorization. While both medications are on the formulary, Epclusa is preferred over Harvoni. It is the purpose of this policy to define the conditions under which MedStar Family Choice will approve Harvoni® (sofosbuvir/ledipasvir) and and Epclusa® (sofosbuvir/vetpatasvir). These same criteria will apply to all Hepatitis C medications, formulary and non–formulary. Additionally, non-formulary medications will require clinical justification as to why a formulary medication cannot be used.

Scope: Applies to members of MedStar Family Choice, District of Columbia Healthy Families and DC Healthcare Alliance.

Policy: It is the policy of MedStar Family Choice to cover hepatitis C therapy for appropriate members.

Background: MedStar Family Choice will require Prior Authorization for Epclusa® (sofosbuvir/vetpatasvir) and Harvoni® (sofosbuvir/ledipasvir).

Procedure: Requests for Epclusa® (sofosbuvir/vetpatasvir) and Harvoni® (sofosbuvir/ledipasvir) should be submitted by the provider along with the

supporting clinical information in accordance with the MedStar Family Choice Prior Authorization Policy. The clinical information will be gathered and a Referral entered by pharmacy nurses. All requests for these medications will be reviewed and can only be approved or denied by a Physician Advisor.

GENERAL Inclusion Criteria:

For formulary medications Harvoni® (sofosbuvir/ledipasvir) and Epclusa® (sofosbuvir/vetpatasvir):

1. Members must have chronic hepatitis C (defined as the presence of detectable virus for at least 6 months).
2. Members must be ≥ 18 years of age.
3. Members must have a liver biopsy or other test of fibrosis (ex: Fibrosure®) Liver biopsy must demonstrate a Metavir score of 2 or greater. Fibrosure testing must demonstrate a score **greater than F1** wherein Fibrosure results of F1-F2 and higher are acceptable. If a member is co-infected with HIV or HBV, there is no fibrosis requirement and these members are qualified for treatment regardless of their Metavir score.
4. A **recent** baseline viral load must be obtained to ensure **no more than 90 days** between the date of the viral load and the initiation of therapy.
5. **Members and prescribers must agree to mandatory virologic testing at 2-4, 12, and 24 weeks** with the intent to discontinue treatment if there is inadequate viral response (see General Discontinuation Criteria below).
6. Prescribed drug therapy must be in accordance with FDA approved indications.

GENERAL Discontinuation Criteria:

If, at 4 weeks of therapy, a member has a detectable HCV RNA viral load, repeat viral load testing is recommended at week 6. If, at week 6, the viral load has increased by >1 $\log_{10}$ IU/mL (more than 10 fold), then additional medication refills will not be authorized.

SPECIAL CONSIDERATIONS:

For cases where any of the MedStar Family Choice criteria are not met, Physician Advisors may consult additional resources for the most current standards of care (ex: AASLD/IDSA guidelines). Physician Advisors may also contact the prescriber for additional information or to discuss concerns or extenuating circumstances.

MEDICATION SPECIFIC Criteria:

Epclusa® (sofosbuvir/vetpatasvir)

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1. Members must not have a history of severe renal impairment (eGFR < 30).
2. Epclusa is approved for **ALL** genotypes.
3. Prescribed therapy must be in accordance with the following algorithm:

No Cirrhosis or Compensated Cirrhosis (Child-Pugh A)	12 weeks
Decompensated cirrhosis (Child-Pugh B & C)	12 weeks (+ ribavirin)

Harvoni® (sofosbuvir/ledipasvir)

1. Members must have genotype 1, 4, 5 or 6 HCV.
2. Members must not have a history of severe renal impairment (eGFR < 30).
3. Prescribed therapy must be in accordance with the following algorithm as found in the Harvoni Prescribing Information:

Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks*
	Treatment-experienced** without cirrhosis	HARVONI 12 weeks
	Treatment-experienced** with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks†
	Treatment-naïve and treatment-experienced** with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin‡ 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment-experienced** liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin§ 12 weeks
Genotype 4, 5 or 6	Treatment-naïve and treatment-experienced**, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

* HARVONI for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pretreatment HCV RNA less than 6 million IU/mL *[see Clinical Studies (14.2)]*.
**Treatment-experienced patients include those who have failed a peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor.
† HARVONI + ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin *[see Clinical Studies (14.2)]*. See footnote § for ribavirin dosage recommendations.
‡ In patients with decompensated cirrhosis, the starting dosage of ribavirin is 600 mg and can be titrated up to 1000 mg for patients <75 kg and 1200 mg for those ≥75 kg in two divided doses with food. If the starting dosage of ribavirin is not well tolerated, the dosage should be reduced as clinically indicated based on hemoglobin levels.
§ The daily dosage of ribavirin is weight-based (1000 mg for patients <75 kg and 1200 mg for those ≥75 kg) administered orally in two divided doses with food.

References:

American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed Nov 22, 2016.

Department of Health Care Finance, District of Columbia Drug Utilization Review Board. (Dec 11, 2015). *Update on HCV Prior Authorization Approval Criteria).* District of Columbia.

Harvoni [package insert]. Foster City, CA; Gilead, November, 2015.

Epclusa [package insert]. Foster City, CA; Gilead, June, 2016

Summary of Changes:	• **12/2/2015 (new genotype indications for Harvoni)** • **2/5/2016 (DCHF 12/11/15 changes- altering fibrosis req.)** • **5/19/2016 (add Zepatier, update treatment regimen recommendations based on new AASLD guidance)** • **11/2016- addition of Epclusa, removal of medications removed for 1/1/2017 Formulary.**