PARTNERSHIP HEALTHPLAN of CALIFORNIA

4665 Business Center Drive
Fairfield, California 94534

March 1, 2019

Re: **Authorization for the use of Mavyret/Zepatier/Epclusa/Harvoni/Viekira/Sovaldi/Daklinza/ Technivie/Vosevi in the Treatment of Hepatitis C**

Dear Prescriber,

As of July 1, 2018, the State of California's Department of Health Care Services (DHCS) updated the Treatment Policy for the Management of Chronic Hepatitis C to give current guidance for the usage of Hepatitis C treatments.

Due to the extraordinary cost associated with these products, the State developed prior authorization criteria which reference the most recent guidelines and reports published by the American Association of the Study of Liver Diseases (AASLD) for approval of these medications. These guidelines set the treatment considerations and choice of regimen and duration of therapy for patients infected with Hepatitis C virus. Please refer to the AASLD website, www.hcvguidelines.org.

DHCS criteria for the identification of treatment candidates follow the AASLD recommendations, where evidence supports treatment for all chronically infected individuals with Hepatitis C Virus aged 12 years and above, except those with limited life expectancy (<12 months) who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.

1. If there is a high probability of cirrhosis (e.g. biopsy, imaging, APRI >1.5, FIB-4 >3.25, Fibrosure > .74), please provide a CTP score: http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/.

2. Clinical/abdominal findings "suggestive of" cirrhosis will require ALL OF THE FOLLOWING:
    a. Physical exam findings that suggest advanced liver disease (such as palpable left lobe, splenomegaly, palmar erythema)
    b. AND low platelet count (<100,000/mm^3)
    c. AND abdominal imaging findings that are consistent with cirrhosis including surface abnormalities, features of portal hypertension and ascites.

3. Pre and post liver transplantation treatment will be considered on a case-by-case basis (transplant specialist referral required).

4. Pediatric population (e.g. 12-17 years of age) HCV treatment regimen will be reviewed on a case-by-case basis and must meet minimum age approved by the FDA.

5. Populations Unlikely to Benefit from HCV Treatment:

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a. Patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment. Little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

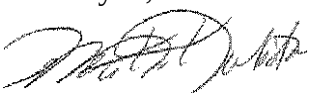
6. Note the PHC preferred treatment regimens and specialty pharmacy information, which are listed in the new TAR supplemental form for Hepatitis C Treatment.

Checklist to submit with new prescriptions, together with HCV TAR Supplemental information form:

- HCV Genotype
- HCV Viral Load
- Chemistry panel (Platelets, AST, ALT), CBC; if cirrhosis is present, also include INR, CTP score, total bilirubin, and albumin.
- If genotype is 1a, mixed 1a/b, or indeterminate 1, *and* requested regimen includes elbasvir (i.e., Zepatier): Hepatitis C Viral RNA Genotype 1 NS5A Drug Resistance assay is required.
- Request for Epclusa for genotype 3 may require submission of Genotype 3 NS5A Drug Resistance assay (please refer to PHC hepatitis C matrix for details)
- Documentation, as may be required, for: Ribavirin intolerance / ineligible, ascites, esophageal varices, hepatic encephalopathy.
- Letter of clinician experience in the treatment of HCV (once only per clinician)
    - *See the attached HCV TAR Supplemental Form for additional submission requirements.*

By working together with our hepatitis treating clinicians, patients eligible for HCV treatment can have the elements for authorization for medical treatment ready at the time of consultation- reducing delays in authorization.

Thank you,



Marshall Kubota, MD
Regional Medical Director
Partnership HealthPlan of California
mkubota@partnershiphp.org

Partnership HealthPlan of California Hepatitis C Treatment Regimens – Naïve to prior treatment and IFN experienced Effective: 3/1/2019

Member Name: _____ ID#: _____ DOB: _____

Physician: _____ Specialty: _____

Office Contact Person: _____ Title: _____

Email: _____ Phone: _____

PHC Preferred Hepatitis C Treatments:

- Treatments in DARK BOLD BLUE are PHC's exclusively preferred (PHC 1st line) regimens for the indicated genotype/stage. Zepatier and authorized generic of Epclusa (Sofosbuvir/Velpatasvir) are Partnership HealthPlan's exclusively preferred Hepatitis C regimens for the indicated genotype/stage as noted on the matrix.

- Treatments in italics and followed by asterisk(*) indicate that the regimen is not yet approved by the FDA and is considered "unlabeled" or off-label usage, although usage is supported by AASLD guidelines.

- "Treatment Experienced" is defined as having had a prior null response, rebound or relapse after ETR (End Treatment Response) to HCV treatment. Listing only IFN/RBV experienced; all other regimen experienced will be reviewed on a case-by-case basis.

IFN = Interferon	RBV = Ribavirin	RBV WB = Ribavirin (wt based)	
Dac = Daclatasvir	RBV LD = Ribavirin (low initial dose of 600mg, increase as tolerated)		
Sof = Sofosbuvir	VL = Viral Load	Wks = Weeks	
RAVs = Resistance Associated Variants – Applicable to Zepatier		AASLD Alternative Regimens = *Italicized* (not all alternative regimens are included in the matrix)	

Partnership HealthPlan of California Hepatitis C Treatment Regimens for Adults - Naïve to prior treatment and IFN experienced, Effective 3/1/19

Genotype	Stage 0-4, unconfirmed cirrhosis		Cirrhosis -definitive (bx, US, FibroSure/Test ≥ 0.75, findings of portal HTN, ascites, varices, encephalopathy)			
			CTP A (Score 5-6)		CTP B (7-9) / C (10-15)	
	Naïve	IFN/RBV experienced	Naïve	IFN/RBV experienced	Naïve	IFN/RBV experienced
GT 1a, mixed a/b or indeterminate GT 1	**Zepatier (no baseline NS5A RAVs) x 12 weeks**				**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
	Sofosbuvir/Velpatasvir (Epclusa) x 12 wks				Ledipasvir/Sofosbuvir (Harvoni) + RBV LD x 12 wks	
	Ledipasvir/Sofosbuvir (Harvoni) x 8 wks (HCV VL <6 million, non-black, HIV-uninfected)	Mavyret x 8 wks	Ledipasvir/Sofosbuvir (Harvoni) x 12 weeks	Mavyret x 12 wks	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
	Mavyret x 8 wks	Ledipasvir/Sofosbuvir (Harvoni) x 12 wks	Mavyret x 12 wks		Ledipasvir/Sofosbuvir (Harvoni) x 24 wks if RBV intolerant	
GT 1b	**Zepatier x 12 weeks**				**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB x 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
	Sofosbuvir/Velpatasvir (Epclusa) x 12 wks				Ledipasvir/Sofosbuvir (Harvoni) + RBV LD x 12 wks	
	Ledipasvir/Sofosbuvir (Harvoni) x 8 wks (HCV VL <6 million, non-black, HIV-uninfected)	Mavyret x 8 weeks	Ledipasvir/Sofosbuvir (Harvoni) x 12 wks	Mavyret x 12 wks	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
	Mavyret x 8 wks	Ledipasvir/Sofosbuvir (Harvoni) x 12 wks	Mavyret x 12 wks		Ledipasvir/Sofosbuvir (Harvoni) x 24 wks if RBV intolerant	
GT 2	**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks**		**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks**		**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB x 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
	Mavyret x 8 wks		Mavyret x 12 wks		Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
					Dac / Sof / RBV LD x 12 wks	
GT 3	**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks (RAS testing for Y93H required)**	**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks (RAS testing for Y93H required)**	**Vosevi x 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB x 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
	Mayret x 8 wks	*Sofosbuvir/Velpatasvir (Epclusa) + RBV WB x 12 wks (when Y93H present)*	Mavyret x 12 wks	Zepatier / Sovaldi x 12 wks*	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	
		Mavyret x 16 wks	*Sofosbuvir/Velpatasvir (Epclusa) + RBV WB x 12 wks (when Y93H present)*	*Sofosbuvir/Velpatasvir (Epclusa) + RBV x 12 wks*	Dac / Sof / RBV LD x 12 wks	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
				Mavyret x 16 wks		
GT 4	**Zepatier x 12 weeks**	**Zepatier x 12 weeks* (virologic relapse after prior peginterferon/ribavirin)**	**Zepatier x 12 weeks**	**Zepatier x 12 weeks* (virologic relapse after prior peginterferon/ribavirin)**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
	Sofosbuvir/Velpatasvir (Epclusa) x 12 wks		Sofosbuvir/Velpatasvir (Epclusa) x 12 wks	Sofosbuvir/Velpatasvir (Epclusa) x 12 wks	Ledipasvir/Sofosbuvir (Harvoni) + RBV LD x 12 wks	
	Mavyret x 8 wks		Ledipasvir/Sofosbuvir (Harvoni) x 12 wks	Mavyret x 12 wks	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
	Ledipasvir/Sofosbuvir (Harvoni) x 12 wks		Mavyret x 12 wks		Ledipasvir/Sofosbuvir (Harvoni) x 24 wks* if RBV intolerant	
GT 5 & 6	**Sofosbuvir/Velpatasvir (Epclusa) x 12 weeks**				**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**	**Sofosbuvir/Velpatasvir (Epclusa) + RBV WB X 12 weeks**
					Ledipasvir/Sofosbuvir (Harvoni) + RBV LD x 12 wks	
	Mavyret x 8 wks		Ledipasvir/Sofosbuvir (Harvoni) x 12 wks		Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant	Sofosbuvir/Velpatasvir (Epclusa) x 24 wks* if RBV intolerant
	Ledipasvir/Sofosbuvir (Harvoni) x 12 wks		Mavyret x 12 wks		Ledipasvir/Sofosbuvir (Harvoni) x 24 wks* if RBV intolerant	
Pre/Post Liver Transplant	**Case by Case Review, Transplant Specialist Referral Required**					

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TAR Supplemental Form for Hepatitis C Treatment: Effective 3-1-19

II. Patient readiness: Have the following been completed? Yes_____No _____

- **Patients shall be evaluated for readiness to initiate treatment.**
- **Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribe by their provider.**
- **Caution shall be exercised with patients who have a history of treatment failure with prior hepatitis C treatment due to non-adherence with treatment regimen and appointments.**
- **Patient shall be educated regarding the potential risks and benefits of hepatitis C virus therapy, as well at the potential for resistance and failed therapy if medication is not taken as prescribed.**

III. Requested regimen: _____

For Duration of: _____ weeks

IV. Status information; *complete the following*:

	YES	NO	N/A
Hepatic Information			
• HCV genotype 1a 1b 1-indeterminant 2 3 4 5 6 (circle genotype)			
• Has the patient been infected for more than 6 months or assumed so- *NOT required* but resolution of acute cases of HCV without treatment should be considered.			
• **REQUIRED: Limited Life Expectancy –** does patient have a limited life expectancy (< 12 months) which cannot be remediated by HCV therapy, liver transplantation, or another directed therapy?			
• If genotype 1a, 1b, or 1-indeterminant & viral load <6 million IU/mL: Patient is African American			
• Does patient have cirrhosis or suspected to have cirrhosis?			
o Abdominal ultrasound or liver biopsy included			
o APRI score of _____ calculator available at --- http://www.hepatitisc.uw.edu/page/clinical-calculators/apri			
o Fibro Sure / Fibro Test / FibroScan result of _____ which is consistent with F0-F3 or F4 (circle one)			
o **If proven cirrhosis** provide the numeric CTP score in the appropriate column at right. Calculator available at http://www.mdcalc.com/child-pugh-score-for-cirrhosis-mortality/ CTP A is score 5-6, CTP B is 7-9 and CTP C is 10-15	**A**	**B**	**C**
Indicate result of (or absence of) prior HCV treatment (Submit clinic notes and evaluation of nature of failure): Naïve ☐ Null responder ☐ Partial responder ☐ Relapse ☐ LTFU or Failed to Complete ☐			

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	YES	NO	N/A
Renal function – Is the GFR or eGFR ≥ 30 ml/min			
Transplantation			
• Is the patient a transplant recipient (any type)			
• Is this 1. Pre-liver transplant -or- 2. Post liver transplant treatment (circle one)			
Pregnancy prevention – if ribavirin is used			
• Patient has been counseled on the risks to the fetus if pregnancy occurs during treatment or within 6 months of completion of treatment **(Pregnancy Category X)**			
• Patient is infertile or not sexually active			
• Will the patient (female) use effective contraception during treatment and continue for 6 months afterwards?			
• Male –Will the female partner(s) of treated men use effective contraception during treatment and continue for 6 months afterwards?			
Clinician Experience and Attestation			
• Is the treating clinician a specialist? *Check one or more:* ☐ Gastroenterologist ☐ Hepatologist ☐ ID ☐ HIV clinician ☐ None of the above (this selection requires submission of a letter detailing the clinician's experience in the treatment of HCV) ☞ ***To the best of my knowledge, the information provided in this form is (1) true, accurate and complete and (2) the requested services are medically indicated and necessary to the health of the patient.*** **Signature of the prescriber:**_____ **Date:**_____			

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TAR Supplemental Form for Hepatitis C Treatment: Effective 3-1-19

V. Additional required documentation:

Please submit the following data in original form:

- **If Genotype is 1a, mixed 1a/b, or indeterminate 1, *and* requested regimen includes elbasvir (i.e. Zepatier): Hepatitis C Viral RNA Genotype 1 NS5A Drug Resistance assay is required.**
- **HCV genotype**
- **HCV Viral Load (VL)**
- **Chem panel (AST with reference range, ALT, Platelet, total bilirubin, albumin), CBC, - If cirrhosis: INR and CTP score**
- **Documentation, as may be required, for Ribavirin intolerance / ineligible, ascites, esophageal varices, hepatic encephalopathy**
- **Letter of clinician experience in the treatment of HCV (once only per clinician)**
- **Request for Ecplusa for genotype 3 may require submission of genotype 3 NS5A resistance test result (please refer to matrix)**

In-therapy lab requirements:

- **All regimens: baseline; start of treatment HCV VL; 12 week SVR VL (to detect relapse vs reinfection)**
- **All regimens: 4 week HCV VL – if detectable then 6 week VL**
- **Regimens lasting more than 12 weeks: 12 week HCV VL**

VI. Case Management

- **Please describe the HCV case management plans for this patient to assure adherence to the treatment protocol and responsibility for medications.**
  - **Visit frequency should include initiation, and at least monthly until end of treatment. End of treatment visit. 12 week SVR Measurement.**
  - **Case management: in lieu of clinical visits, weekly phone call contacts will be required for continued refill of medications – chart documentation will be requested through the Treatment Authorization Request (TAR).**

VII. Patient responsibility

- **Lost medications might not be replaced and treatment authorization may be revoked**
- **Evidence of lack of adherence may result in treatment authorization revocation**
- **Missed appointments and lab data points may result in treatment authorization revocation**
- **Lack of compliance with case management may result in treatment authorization revocation**

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TAR Supplemental Form for Hepatitis C Treatment: Effective 3-1-19

VIII. DHCS Policy: Unlabeled Use of Medication (aka, Off-label use of an FDA approved drug):

- Authorization for off-label uses of drugs shall not be granted unless the requested use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:
  - Reference to current medical literature
  - Consultation with provider organizations, academic and professional specialists.

IX. Specialty Pharmacy Requirement:

- **HCV Rx and ALL the required documentation should be submitted to our specialty pharmacy:**

WALGREENS SPECIALTY PHARMACY #15987
Phone number: 916-738-3300
Fax number: 916-738-3302