Prior Authorization (PA) Form for Epclusa® (Sofosbuvir and Velpatasvir) **Pharmacy Department (Fax)** ☐ First Medical 1-844-347-7807 ☐ MMM Holdings 1-844-997-9950 ☐ Plan de Salud Menonita 1-877-447-6488 ☐ Triple S 1-844-672-1515			
Physician Information	Name:		
	License #:	NPI#:	Medical Specialty:
	Telephone:		Fax:
Patient Information	Name		
	Date of Birth (m/d/y):		Telephone:
	Member ID:		
	Gender: ☐ Female ☐ Male		Weight:
Requested Drug	**Epclusa®(Sofosbuvir and velpatasvir)**	SIG:	
		Quantity:	
		Total weeks of therapy:	

Information to be provided by Prescriber *Please review and provide the following information:*

Exclusion Criteria		
	1. Age under 3	☐ YES ☐ NO
	2. Patient without cirrhosis and compensated cirrhosis (Child-Pugh A). Note: This indication will be covered with Mavyret.	☐ YES ☐ NO
	3. Severe disease states or medical conditions with short life expectancy. Note: Little evidence exists to support initiation of HCV treatment in patients with a limited life expectancy (<12 months) owing to non liver-related comorbid conditions	☐ YES ☐ NO
	4. Contraindications: Combination regimen of Epclusa and ribavirin is contraindicated in patients for whom ribavirin is contraindicated: pregnancy, men whose female partners are pregnant, patients with known hypersensitivity reactions such as Stevens-Johnson syndrome, toxic, epidermal necrolysis, and erythema multiforme to ribavirin or any component of the product, patients with autoimmune hepatitis, patients with hemoglobinopathies (e.g., thalassemia major, sickle-cell anemia), patients with creatinine clearance less than 50 mL/min and coadministration with didanosine, stavudine or zidovudine.	☐ YES ☐ NO
	5. Severe disease states or medical conditions which significantly impede compliance with treatment.	☐ YES ☐ NO
	6. Off label uses	☐ YES ☐ NO
Required Information for Initial Requests		
	7. Does the patient have a baseline quantitative HCV RNA level completed? ☐ YES ☐ NO Baseline quantitative HCV RNA: _____	

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Date completed:_____

8. Has the patient had hepatic laboratory testing completed at baseline (e.g, serum bilirubin)? ☐ YES ☐ NO

9. Has the documentation confirming been submitted? ☐ YES ☐ NO

10. Was screening for evidence of current or prior hepatitis B virus (HBV) infection completed? ☐ YES ☐ NO

11. Has the documentation confirming been submitted? ☐ YES ☐ NO

12. Does the patient has HIV coinfection? ☐ YES ☐ NO

13. Has the documentation confirming been submitted? ☐ YES ☐ NO

14. For female patients of child bearing potential, has a negative pregnancy test been collected prior to initiation of therapy? ☐ YES ☐ NO ☐ N/A

15. Will the patient receive treatment in Puerto Rico? ☐ YES ☐ NO

16. Does the patient currently have another health plan insurance which covers for HCV? ☐ YES ☐ NO

Treatment History and Readiness

17. Has the patient been treated previously for HCV? ☐ YES (treatment experienced) ☐ NO (treatment naïve)

a. If treatment experienced, provide previous treatment regimen/outcome:

Regimen:_____

Outcome:_____

b. What is the patient's HCV genotype (GT)? ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

18. Answer **ALL** of the following, documentation with recent evidence must be attached:

a. Does the patient have severe renal impairment (Stages 4)? ☐ YES ☐ NO

b. Does the patient have End Stage renal Disease (Stage 5)? ☐ YES ☐ NO

c. Has the patient received a transplant for any of the following organs:

i. ☐ Liver ☐ Kidney ☐ N/A

d. What is the patient's Model of End Liver Disease (MELD) score? _____

e. What is the patient's Child-Pugh (CPT) score? _____Cirrhosis? ☐ YES ☐ NO

f. Compensated Cirrhosis (Child-Pugh A)☐ YES ☐ NO

g. Decompensated Cirrhosis? (Child-Pugh B and C) ☐ YES ☐ NO

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i. Has ribavirin been prescribed to be given in combination with Epclusa for patients with decompensated cirrhosis? ☐ YES ☐ No

1. If no, is the patient ribavirin ineligible? ☐ YES ☐ No
2. If yes, document the cause of the contraindication or if there is intolerance to the use of Ribavirin:

_____

(Note: Epclusa monotherapy for these patients will be for 24 weeks of treatment according to AASLD/IDSA Guideline recommendations)

19. Provide at least **ONE** of the following criteria, documentation with recent evidence (within 30 days?) must be attached:

a. What is the patient's Metavir fibrosis score? ☐ F0 ☐ F1 ☐ F2 ☐ F3 ☐ F4
b. FibroTest (e.g., FibroSure) score equal? ☐ YES ☐ NO
c. Ultrasound images consistent with cirrhosis (e.g, Portal Hypertension)? ☐ YES ☐ NO
d. Clinical findings consistent with cirrhosis: portal hypertension, ascites, esophageal varices or other extrahepatic manifestations of HCV like cryoglobulinemia with organ lesions as proteinuria or nephrotic syndrome? ☐ YES ☐ NO

20. Has the documentation confirming any of the above been submitted with this request?
☐ YES ☐ NO

Coverage Duration Information	
	21. PA requests will be approved for the time prescribed, however dispensing of Epclusa must be **monthly**.
	22. Treatment with Epclusa varies depending on treatment history and cirrhosis status [i]
	23. No additional supply of the medication will be given when the patient claims that it was lost, stolen or missing.

Please provide any medical information which may support approval: (optional)

Physician signature:	
Date:	

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I attest that this is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis is available for review if requested by Administración de Seguros de Salud de Puerto Rico (ASES).
CONTAINS CONFIDENTIAL INFORMATION- The information contained in this document is CONFIDENTIAL and sensitive. We are sending this information considering the recipients authorization or for situations where we are allowed by law. You, as the recipient of this information, are responsible to keep this information in a safe place and handle in a confidential manner. The use or dissemination of this information without prior authorization of the recipient or for situations allowed by law is prohibited. The unauthorized use or dissemination of this information or the use without observing measures of handling the information in a safe and confidential manner is subject to fines and penalties as established by Federal and State Laws and Regulations. / **IMPORTANT NOTICE**- If the reader/recipient of this message is not the person to whom it was addressed to, or is not an employee or authorized agent of the entity to which this communication was addressed to, you are duly notified that any dissemination, distribution or copying of this information is STRICTLY PROHIBITED. If you receive this message by error, please notify us immediately and destroy all related documents to this message. Revised **September 16, 2021.**

[i] Epclusa Prescribing Information, June 2021. Recommended treatment regimen and duration in patients 3 years of age and older with genotypes 1, 2, 3, 4, 5, or 6 HCV in table below:

Patient Population	Regimen and Duration
Treatment-naïve and treatment-experienced[a], without cirrhosis and with compensated cirrhosis (Child-Pugh A)	EPCLUSA 12 weeks
Treatment-naïve and treatment-experienced[a], with decompensated cirrhosis (Child-Pugh B and C)	EPCLUSA + ribavirin 12 weeks

a. In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).