Inland Empire Health Plan

Drug Class Prior Authorization Criteria
Hepatitis

Line of Business: Medicaid
P & T Approval: August 6, 2021 **Effective Date:** September 17, 2021

This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by t he IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: *Velpatasvir/sofosbuvir (generic **Epclusa**), **Mavyret** (glecaprevir, pibrentasvir)*, **Harvoni** (ledipasvir, sofosbuvir), **Vosevi** (sofosbuvir, velpatasvir, voxilaprevir), **Zepatier** (elbasavir, grazoprevir)

CRITERIA:

VELPATASVIR/SOFOSBUVIR (Generic **EPCLUSA**)

Covered Uses:	*****Chronic hepatitis C- genotype 1 to 6 (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	See Section I
Required Medical Information:	Must meet all of the following requirements: a. Documented baseline quantitative HCV RNA level b. Treatment criteria in Section I: Identifying treatment candidates c. Requested drug must be used in an antiviral treatment regimen and duration recommended by the AASLD (please see Section III: HCV Treatment Regimen).
Age Restrictions:	See Section I
Prescriber Restrictions:	N/A
Other Criteria:	Re- treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance with the AASLD recommendations.

MAVYRET (GLECAPREVIR/PIBRENTASVIR)

Covered Uses:	*****Chronic hepatitis C- genotype 1 to 6 (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	See Section I
Required Medical Information:	Must meet all of the following requirements: a. Documented baseline quantitative HCV RNA level b. Treatment criteria in Section I: Identifying treatment candidates c. Requested drug must be used in an antiviral treatment regimen and duration recommended by the AASLD (please see Section III: HCV Treatment Regimen).
Age Restrictions:	See Section I
Prescriber Restrictions:	N/A
Other Criteria:	Re- treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

HARVONI (LEDIPASVIR/SOFOSBUVIR)

Covered Uses:	*****Chronic hepatitis C- genotype 1, 4 to 6 (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	See Section I
Required Medical Information:	Must meet all of the following requirements: a. Documented baseline quantitative HCV RNA level and genotype b. Treatment criteria in section I: Identifying treatment candidates c. Requested drug must be used in an antiviral treatment regimen and duration recommended by the AASLD (please see Section III: HCV Treatment Regimen). d. For genotype 1 naïve patients without cirrhosis, a treatment duration of 8 weeks is recommended for members who meet all of the following criteria: i. Non-black ii. HIV-uninfected iii. HCV RNA level is less than 6 million IU/mL

e. Failure, contraindication, or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**) or **Mavyret** (glecaprevir/pibrentasvir). Requests will be reviewed by IEHP pharmacist.

Age Restrictions:	See Section I
Prescriber Restrictions:	N/A
Other Criteria:	Re- treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

VOSEVI (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

Covered Uses:	*****Chronic hepatitis C- genotype 1 to 6 (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	See Section I
Required Medical Information:	Must meet all of the following requirements: a. Documented baseline quantitative HCV RNA level b. Treatment criteria in Section I: Identifying treatment candidates c. Requested drug must be used in an antiviral treatment regimen and duration recommended by the AASLD (please see Section III: HCV Treatment Regimen). d. Failure, contraindication, or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**) or **Mavyret** (glecaprevir/pibrentasvir). Requests will be reviewed by IEHP pharmacist.
Age Restrictions:	See Section I
Prescriber Restrictions:	N/A
Other Criteria:	Re- treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

ZEPATIER (ELBASVIR/GRAZOPREVIR)

Covered Uses:	*****Chronic hepatitis C- genotype 1 or 4 (*Subject to review by Clinical Pharmacist)

Exclusion Criteria:	See Section I
Required Medical Information:	Must meet all of the following requirements: a. Documented baseline quantitative HCV RNA level b. Treatment criteria in Section I: Identifying treatment candidates c. Requested drug must be used in an antiviral treatment regimen and duration recommended by the AASLD (please see Section III: HCV Treatment Regimen). d. Failure, contraindication, or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**) or **Mavyret** (glecaprevir/pibrentasvir). Requests will be reviewed by IEHP pharmacist.
Age Restrictions:	See Section I
Prescriber Restrictions:	N/A
Other Criteria:	Re- treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

Section I: Identifying Treatment Candidates

a. Treatment is recommended for all patients with chronic HCV infection, except those with a short life expectancy who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.

*All request for decompensated liver must be reviewed by IEHP Clinical Pharmacist for final decision

b. Patient readiness and adherence:
   i. Patients shall be evaluated for readiness to initiate treatment.
   ii. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
   iii. Caution shall be exercised with patients who have a history of treatment failure with prior HCV treatment due to non-adherence with treatment regimen and appointments.
   iv. Patients shall be educated to non-adherence with treatment regimen and appointments.

Section II: Other Considerations

a. Quantity limits:
   i. Prescription of HCV therapy will be dispensed in quantities up to 28 days at a time.

b. Criteria for reauthorization/continuation of therapy:
   i. Initial authorization criteria have been met.
   ii. Evidence of lack of adherence may result in denial of treatment reauthorization.

iii. Missed medical appointments related to HCV may result in the denial of treatment authorization.

c. Laboratory testing:
    i. Documentation of baseline HCV-RNA level.
    ii. Laboratory testing and monitoring should be consistent with current AASLD/IDSA guidelines.

d. Populations unlikely to benefit from HCV Treatment:
    i. According to AASLD/IDSA HCV guidelines, “Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation or another directed therapy do not require antiviral treatment. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.” Please refer to AASLD guidelines for more information on populations unlikely to benefit from HCV treatment (hcvguidelines.org).

e. Retreatment:
    i. Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).

f. Criteria for coverage of investigational services (Title 22 § 51303):
    i. Investigational services are not covered except when it is clearly documented that all of the following apply.
    ii. Conventional therapy will not adequately treat the intended patient's condition.
    iii. Conventional therapy will not prevent progressive disability or premature death.
    iv. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service.
    v. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives.
    vi. The service is not being performed as a part of a research study protocol.
    vii. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.
    viii. All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

g. Unlabeled use of medication: Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based upon:
    i. Reference to current medical literature.
    ii. Consultation with provider organizations and academic and professional specialists.

Section III: HCV Treatment Regimen (AASLD Recommendation)

Treatment History and HCV Genotype (GT)	Cirrhosis status	AASLD Recommended Regimen* *Italicized* = Formulary Preferred Hepatitis C Drug Regimen	Regimen Duration
Naïve GT 1a	Non-cirrhotic	***Mavyret*** *(Glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg (No baseline high fold-change NS5A RAVs for elbasvir are detected)	**12 weeks**
		Zepatier (elbasvir/grazoprevir) 50/100mg + RBV (Baseline high fold-change NS5A RAVs for elbasvir are detected)	**16 weeks**
	Non-cirrhotic, Non –black, HIV-uninfected, HCV RNA level 6 million IU/mL	**Harvoni** (Ledipasvir/sofosbuvir) 90/400mg	**8 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* ***Mavyret*** *(Glecaprevir/pibrentasvir) 300/120mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg (No baseline high fold-change NS5A RAVs for elbasvir are detected)	**12 weeks**
		Zepatier (elbasvir/grazoprevir) 50/100mg + RBV (Baseline high fold-change NS5A RAVs for elbasvir are detected)	**16 weeks**
	Non-cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**

Naïve GT 1b		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
	Non-cirrhotic, Non-black, HIV-uninfected, HCV RNA level 6 million IU/mL	**Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**8 weeks**
	Compensated cirrhotic	***Mavyret** (glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Experienced GT 1 a/1b (failed PEG-IFN and RBV treatment)	Non cirrhotic and compensated cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg	**12 weeks**
		***Mavyret** (glecaprevir/pibrentasvir) 300/120mg*	**16 weeks**
Sofosbuvir-Based Treatment Failures	With or without compensated cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg	**12 weeks**
		***Mavyret** (glecaprevir /pibrentasvir 300/120 mg*	**16 weeks**
Glecaprevir/ Pibrentasvir Treatment Failures	With or without compensated cirrhotic	***Mavyret** (glecaprevir/pibrentasvir 300/120 mg plus daily sofosbuvir (400 mg) and weight-based ribavirin*	**16 weeks**
		Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg *For patients with compensated cirrhosis, addition of weight-based ribavirin is recommended.*	**12 weeks**

Multiple DAA Treatment Failures	With or without compensated cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir 300/120 mg plus daily sofosbuvir (400 mg) and weight-based ribavirin*	**16 weeks**
		Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg plus weight-based ribavirin	**24 weeks**
Naïve GT2	Non-cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		Sofosbuvir/velpatasvir (generic ***Epclusa****) 400/100mg*	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic* ***Epclusa****) 400/100mg*	**12 weeks**
		Mavyret *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
Experienced GT2 (failed PEG-IFN and RBV)	Non-cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		Sofosbuvir/velpatasvir (generic ***Epclusa****) 400/100mg*	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic* ***Epclusa****) 400/100mg* ***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**12 weeks**
Experienced GT2 (failed Sofosbuvir + RBV)	Non cirrhotic and compensated cirrhotic	*Sofosbuvir/velpatasvir (generic* ***Epclusa****) 400/100mg* ***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**12 weeks**
Experienced GT2 (failed sofosbuvir and NS5A)	Non cirrhotic and compensated cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400mg/100mg/100mg	**12 weeks**

Naïve GT3 *baseline RAS testing required for Epclusa. See footnote for details.	Non-cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg*	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* ***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg* *Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100 mg with weight-based ribavirin for* patients *with baseline NS5A RAS Y93H for velpatasvir* **Vosevi** (Sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg for patients with baseline NS5A RAS Y93H for velpatasvir	**12 weeks**
Experienced GT3 (failed PEG-IFN and RBV) *baseline RAS testing required for Epclusa. See footnote for details.	Non-cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg*	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Zepatier** (elbasvir/grazoprevir) 50/100mg + Sofosbuvir 400mg	**12 weeks**
Experienced GT3 (failed DAA – experienced, including NS5A inhibitors)	Non-cirrhotic and Compensated Cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg + RBV (for prior NS5S inhibitor failure and cirrhosis)	**12 weeks**
Naïve GT4	Non-cirrhotic and Compensated cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Experienced GT4	Non-cirrhotic	***Mavyret*** *(glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**

(failed PEG-IFN and RBV)		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Naïve GT 5 or 6	Non-cirrhotic and Compensated cirrhotic	***Mavyret** (glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**
Experienced GT 5 or 6 (failed PEG-IFN and RBV)	Non-cirrhotic	***Mavyret** (glecaprevir/pibrentasvir) 300/120mg*	**8 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* ***Mavyret** (glecaprevir/pibrentasvir) 300/120mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**
Experienced GT4, 5or 6 (DAA–experienced, including NS5A inhibitors)	Non-cirrhotic and Compensated Cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg	**12 weeks**

*Patients with Genotype 3 require baseline NS5A resistance-associated substitution (RAS) testing. Patients without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir. If Y93H is present, see HCV guidance for treatment recommendations.

Clinical Justification:

Please refer to the American Association for the Study of Liver Diseases (AASLD) HCV Clinical Practice Guideline.

References:

1. American Association for the Study of Liver Diseases. Recommendation for Testing, Managing and Treating Hepatitis C. Available at: http://www.hcvguidelines.org/full-report-view. Assessed July 19, 2021.

2. Department of Health Care Services. Treatment Policy for the Management of Chronic Hepatits C. https://www.dhcs.ca.gov/Documents/Chronic-Hep-C.pdf Accessed July 19, 2021.

Change Control		
Date	**Change**	**RPH**
07/21/2021	• Updated PA Criteria based on new DHCS Management Policies: https://www.dhcs.ca.gov/Documents/Chronic-Hep-C.pdf • Updated drugs requiring PA review (removed Daklinza and Viekira XR) • Removed age requirement from Section 1	APPE: NL, HL, TP
12/18/2020	• Removed prescriber restriction due to IEHP COE Program termination	RR
08/06/2020	• P&T email approval	ND
06/11/2020	• Removed criteria requirement for genotype testing for pan-genotypic first line agents: generic Epclusa and Mavyret	ND
11/20/2019	• Renewed with no changes	CN
02/20/2019	• Updated the generic status of **Epclusa** • Generic **Epclusa** is now the preferred Hepatitis C agent	ND
09/19/2018	• Updated references section	ND
07/3/2018	• Updated PA Criteria based on new DHCS Management Policies: http://www.dhcs.ca.gov/Documents/DHCS_Hep_C_Policy_7_1_18.pdf • Added Sections I and II based on "identifying treatment candidates" and "Other considerations", respectively. • Removed previous criteria identifying candidates through required clinical states. New DHCS policy states all patients with chronic HCV are recommended to receive HCV treatment. Age limit is no longer limited to 18 years and above. Treatment candidates are now restricted to the minimum age approved by the FDA for use of the medication. Other considerations now include: Quantity limits, Criteria for reauthorization, Lab testing, Retreatment, Criteria for coverage of investigational services, and Unlabeled use of medication. Populations unlikely to benefit from Hep C treatment remained from the previous version.	IK
06/29/2018	• Changed Format	IK