A Public Entity
Inland Empire Health Plan

Drug Class Prior Authorization Criteria
Hepatitis

Line of Business: Medicaid
P & T Approval (pending): August 26, 2020 **Effective Date:** June 12, 2020

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 the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: Daklinza (daclatasvir), **Harvoni** (ledipasvir, sofosbuvir), **Mavyret** (glecaprevir, pibrentasvir), Velpatasvir/sofosbuvir (generic **Epclusa**), **Viekira XR** (dasabuvir, ombitasivir, paritaprevir, ritonavir), **Vosevi** (sofosbuvir, velpatasvir, voxilaprevir), **Zepatier** (elbasvir, 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:	IEHP Hepatitis Center of Excellence specialist
Other Criteria:	Re-treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to 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). d. Failure, contraindication or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**). Requests will be reviewed by IEHP pharmacist.
Age Restrictions:	See Section I
Prescriber Restrictions:	IEHP Hepatitis Center of Excellence specialist
Other Criteria:	Re-treatment and 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**). Requests will be reviewed by IEHP pharmacist.

Age Restrictions: See Section I

Prescriber Restrictions: IEHP Hepatitis Center of Excellence specialist

Other Criteria: Re-treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

DAKLINZA (DACLATASVIR)

Covered Uses: *****Chronic hepatitis C- genotype 1, 2, 3
(*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. Failure, contraindication or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**). Requests will be reviewed by IEHP pharmacist.

Age Restrictions: See Section I

Prescriber Restrictions: IEHP Hepatitis Center of Excellence specialist

Other Criteria: Re-treatment or reauthorization request will be reviewed by IEHP pharmacist in accordance to the AASLD recommendations.

VIEKIRA XR (DASABUVIR/OMBITASVIR/PARITAPREVIR/RITONAVIR)

Covered Uses:	*****Chronic hepatitis C- genotype 1 (*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. Failure, contraindication or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**). Requests will be reviewed by IEHP pharmacist.
Age Restrictions:	See Section I
Prescriber Restrictions:	IEHP Hepatitis Center of Excellence specialist
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, 3, 4, 5 or 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. Failure, contraindication or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**). Requests will be reviewed by IEHP pharmacist.

Age Restrictions:	See Section I
Prescriber Restrictions:	IEHP Hepatitis Center of Excellence specialist
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, 3, 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 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. Failure, contraindication or clinically significant adverse effects to preferred agent: velpatasvir/sofosbuvir (generic **Epclusa**). Requests will be reviewed by IEHP pharmacist.
Age Restrictions:	See Section I
Prescriber Restrictions:	IEHP Hepatitis Center of Excellence specialist
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 regarding the potential risks and benefits of HCV therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.

c. Age requirements: Treatment candidate must be at least the minimum age approved by the FDA for use of the medication.

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. Documentation of HCV Genotype.
   iii. 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 limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment. Chronic HCV is associated with a wide range of comorbid conditions. 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." In patients with a life expectancy less than 12 months, treatment is not recommended.

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.
      1. Conventional therapy will not adequately treat the intended patient's condition.
      2. Conventional therapy will not prevent progressive disability or premature death.
      3. 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.
      4. 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.
      5. The service is not being performed as a part of a research study protocol.

6. 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.

ii. 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*** **= Non-Formulary Preferred Hepatitis C Drug Regimen**	**Regimen Duration**
Naïve GT 1a	Non-cirrhotic	**Mavyret** (Glecaprevir/pibrentasvir) 300/120mg	8 weeks
	Non-cirrhotic, non-black, HIV-uninfected, HCV RNA level <6 million IU/mL	**Harvoni** (Ledipasvir/sofosbuvir) 90/400mg	8 weeks
	Non-cirrhotic	*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**
	Non-cirrhotic	**Zepatier** (elbasvir/grazoprevir) 50/100mg + RBV (Baseline high fold-change NS5A RAVs for elbasvir are detected)	16 weeks
Naïve GT 1a	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (Glecaprevir/pibrentasvir) 300/120mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**

		(No baseline high fold-change NS5A RAVs for elbasvir are detected)	
		Zepatier (elbasvir/grazoprevir) 50/100mg + RBV (Baseline high fold-change NS5A RAVs for elbasvir are detected)	16 weeks
Naïve GT 1b	Non-cirrhotic	**Mavyret** (glecaprevir/pibrentasvir) 300/120mg	8 weeks
	Non-cirrhotic, non-black, HIV-uninfected, HCV RNA level <6 million IU/mL	**Harvoni** (ledipasvir/sofosbuvir)90/400mg	8 weeks
	Non-cirrhotic	*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* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	*12 weeks*
Experienced GT 1a (failed PEG-IFN and RBV treatment)	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
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **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
Experienced GT 1b (failed PEG-IFN and RBV treatment)	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	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Experienced GT 1a/1b (failed NS3 Protease Inhibitor {telaprevir, boceprevir or simeprevir} + PEG-IFN + RBV)	Non-cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**
	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg	**12 weeks**

Experienced GT 1a/1b (failed non-NS5A inhibitor, sofosbuvir containing regimen)	Non-cirrhotic and Compensated Cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg (for genotype 1a)	**12 weeks**
Experienced GT 1a/1b (failed NS5A inhibitor DAA)	Non-cirrhotic and Compensated Cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg	12 weeks
Naïve GT2	Non-cirrhotic	**Mavyret** (glecaprevir/pibrentasvir) 300/120mg	8 weeks
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg*	**12 weeks**
	Compensated Cirrhosis	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg	**12 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	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 GT3 (failed PEG-IFN and RBV)	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	**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**
	Compensated Cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Experienced GT4 (failed PEG-IFN and RBV)	Non-cirrhotic	**Mavyret** (glecaprevir/pibrentasvir) 300/120mg	8 weeks
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Zepatier** (elbasvir/grazoprevir) 50/100mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**

	Compensated cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Zepatier** (elbasvir/grazoprevir) 50/100mg	**12 weeks**
Experienced GT4 (failed DAA – experienced, including NS5A inhibitors)	Non-cirrhotic and Compensated Cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg	12 weeks
Naïve GT 5 or 6	Non-cirrhotic	**Mavyret** (glecaprevir/pibrentasvir) 300/120mg	8 weeks
		*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**
	Compensated Cirrhotic	*Sofosbuvir/velpatasvir (generic **Epclusa**) 400/100mg* **Mavyret** (glecaprevir/pibrentasvir) 300/120mg **Harvoni** (ledipasvir/sofosbuvir) 90/400mg	**12 weeks**
Experienced GT5 or GT 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, GT5 or GT 6 (DAA – experienced, including NS5A inhibitors)	Non-cirrhotic and Compensated Cirrhotic	**Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100mg	12 weeks

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 February 1, 2019.
2. Department of Health Care Services. Treatment Policy for the Management of Chronic Hepatitis C. https://www.dhcs.ca.gov/Documents/DHCS_Hep_C_Policy_7_1_18.pdf. Accessed February 1, 2019.

Change Control		
Date	**Change**	**RPH**
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
2/20/2019	• Updated the generic status of **Epclusa** • Generic **Epclusa** is now the preferred Hepatitis C agent	ND
9/19/2018	• Updated references section	ND
7/3/18	• 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 includes: 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
6/29/2018	• Changed Format	IK