Washington State Health Care Authority

Antivirals - Hepatitis C Treatment

Medical policy no. 12.35.30.99-4 Effective August 1, 2019

Medical necessity

Drug	Medical Necessity
Preferred **Glecaprevir/pibrentasvir (MAVYRET)** *Non-preferred* Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	**MAVYRET is preferred and covered without authorization.** All non-preferred antiviral products for the treatment of Hepatitis C virus (HCV) will be considered on a case-by-case basis. Non-preferred HCV antivirals may be considered medically necessary for the treatment of chronic HCV infection when Mavyret is not indicated and the clinical criteria listed below are met. Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the **Brands with Generic Equivalents** policy (Non-Clinical Policy No. 0001).

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	1. Patient has confirmed diagnosis of Hepatitis C and a quantifiable HCV RNA test >15 IU/mL within the last 12 months. 2. Required documentation and lab tests: a. HCV Genotype. b. Current HCV RNA Viral Load less than 12 months old. c. Fibrosis staging test (e.g. FibroScan®, FibroSURE®, AST-to platelet ratio index (APRI), or FIB-4 index score) to determine liver fibrosis level required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis and/or decompensation may require longer treatment and/or ribavirin). Fibrosis staging test results must be less than 2 years old. d. Documentation of decompensation (or previous episodes of decompensation) if fibrosis level is F4 or cirrhosis.

	e. Documentation of treatment-experienced status including prior treatment regimen, length of treatment, response, and dates of treatment. f. Lab reports, if available, documenting presence or absence of resistant mutations in treatment-experienced patients. 3. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who: a. Are taking medications that are contraindicated with or that have a severe drug interaction with the prescribed HCV treatment. b. Are pregnant or planning on becoming pregnant. c. Have severe end organ disease and are not eligible for transplantation (e.g. heart, lung, kidney) d. Have a clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment. e. In the professional judgment of the primary treating clinician, would not achieve a long-term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure, receiving palliative care, with significant pulmonary or cardiac disease, or with malignancy outside of the liver not meeting oncologic criteria for cure). f. Have a MELD score <20 and one of the following: i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery ii. Malignancy outside the liver not meeting oncologic criteria for cure iii. Hepatocellular carcinoma with metastatic spread iv. Intrahepatic cholangiocarcinoma v. Hemangiosarcoma vi. Uncontrolled sepsis
	Criteria (Reauthorization)
	See treatment experienced dosing guidelines below.

Preferred therapies:

Drug Name	Preferred For:
Glecaprevir/pibrentasvir (MAVYRET)	**Patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) that are:** • treatment naïve patients with genotypes 1, 2, 3, 4, 5, and 6; or • patients with genotypes 1, 2, 3, 4, 5, and 6 with prior treatment with peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor; or • patients with genotype 1 with prior treatment with an NS5A inhibitor but not an NS3/4A protease inhibitor; or

	• patients with genotype 1 with prior treatment with an NS3/4A protease inhibitor but not an NS5A inhibitor.
Sofosbuvir/velpatasvir (EPCLUSA) **Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)**	Will be considered on a case-by-case basis when treatment with Mavyret is not indicated.

Dosage and quantity limits

Drug Name	Dose and Quantity Limits

Glecaprevir/pibrentasvir (MAVYRET)	**Treatment Naïve Genotypes 1, 2, 3, 4, 5, 6**
	• 8 weeks without cirrhosis or with compensated cirrhosis
	• 12 weeks for liver or kidney transplant recipients
	
	Treatment Experienced
	• With peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor
	  ○ Genotypes 1, 2, 4, 5, 6
	  ▪ 8 weeks without cirrhosis
	  ▪ 12 weeks with compensated cirrhosis
	  ▪ 12 weeks for liver or kidney transplant recipients
	  ○ Genotype 3
	  ▪ 16 weeks without cirrhosis or with compensated cirrhosis
	  ▪ 16 weeks for liver or kidney transplant recipients
	• With an NS5A inhibitor without an NS3/4A protease inhibitor
	  ○ 16 weeks for Genotype 1 without cirrhosis or with compensated cirrhosis
	  ○ 16 weeks for liver or kidney transplant recipients
	• With an NS3/4A protease inhibitor without an NS5A inhibitor
	  ○ 12 weeks for Genotype 1 without cirrhosis or with compensated cirrhosis
	  ○ 12 weeks for Genotype 1 liver or kidney transplant recipients

Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	Will be determined on a case-by-case basis when treatment with Mavyret is not indicated.

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History

Date	Action and Summary of Changes
06-07-2019	• Updated policy for preferred therapies and formatting.
07-08-2019	• Placed in updated policy format • Removed prescriber specialty requirement • Removed proof of chronic HCV infection • Added all drugs to the policy • Mavyret only preferred agent • Added treatment regimens
07-23-2019	Updated policy to reflect Mavyret covered without authorization
08-14-2019	Removed Mavyret from initial approval criteria
10-07-2020	Updated dosing for treatment naïve compensated cirrhosis
11-17-2020	Added dosing for liver or kidney transplant recipients
01-20-2023	Version 4 Updates: • Added version number to policy • Added APRI and FIB-4 for fibrosis staging