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Prior Authorization Criteria

Hepatitis C Medications

All requests for Hepatitis C Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Hepatitis C Medications Requiring Prior Authorization:

Direct-Acting Antivirals	
Formulary:	**Non-Formulary:**
Mavyret (glecaprevir/ pibrentasvir) Zepatier (elbasvir/grazoprevir) Sofosbuvir/Velpatasvir (Epclusa authorized generic) Sofosbuvir/Ledipasvir (Harvoni authorized generic)	Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) Sovaldi (sofosbuvir) Harvoni (ledipasvir/sofosbuvir) Epclusa (sofosbuvir/velpatasvir) Daklinza (daclatasvir) Technivie (paritaprevir, ritonavir, ombitasvir) Olysio (simeprevir)

NOTE: Requests for Non-Preferred medications must document trial and failure of or contraindication to preferred medications to be considered for approval unless it is for a pediatric patient.

- Coverage is provided for **adult and pediatric** members with chronic Hepatitis C Virus (HCV) Genotypes 1-6 in the following situations:
  - The member is at least 12 years of age and older **OR** weighing at least 35kg
  - The member has a documented diagnosis of chronic HCV with documentation of completed genotyping and meets the criteria for coverage based on HCV genotype as outlined in the chart below
  - The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
  - If the member has a history of failure with previous Hepatitis C treatment, documentation is provided that indicates the reason for failure, which may include (but is not limited to) non-compliance, safety, tolerability, or efficacy. In addition, documentation must be provided indicating that the reasons for the previous treatment failure have been addressed (e.g. re-education)
  - The member has a documented liver biopsy or comparable liver fibrosis panel results from an FDA approved liver fibrosis test with a fibrosis score corresponding to Metavir F0 – F4
  - If the member is actively abusing alcohol or IV drugs, or has a history of abuse, there is documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of referral for substance abuse disorder treatment and care management

- The member does not have a limited life expectancy of less than 12 months due to non-liver-related comorbid conditions
- The member has had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact)
- Has documentation of:
  - A complete hepatitis B immunization series OR
  - Hepatitis B screening (sAb, sAg, and cAb)
    - If positive for hepatitis B sAg, quantitative HBV DNA results
    - If there is detectable HBV DNA, a treatment plan for Hepatitis B consistent with AASLD recommendations
    - If negative for hepatitis sAb a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series.
- Documentation of a pretreatment hemoglobin of at least 10g/dL if the member is being prescribed ribavirin
- If genotype 1a, or had a previous treatment failure with a direct-acting antiretroviral (DAA) regimen, is prescribed an AASLD recommended drug regimen based on the documented results of a NS5A RAS screening.
- For regimens containing sofosbuvir, the member does not have renal impairment or end stage renal disease (eGFR <30 mL/min/1.73m^2)
- The member's HCV RNA levels prior to treatment (within the past 3 months), their treatment status (naïve or experienced), the planned treatment regimen, and the planned start date will be documented
- The member will be obtaining the medication from a qualified specialty pharmacy
- In situations where the member is co-infected with HCV and HIV:
  - Coverage will be provided as long as the member satisfies the criteria for HCV mono-infected patients (based on genotype); **AND**
  - Documentation of HIV screening (HIV Ag/Ab) and if results are a confirmed positive by HIV-1/HIV-2 differentiation immunoassay
    - The member is being treated for HIV; **OR**
    - Medical record documentation stating the rationale for the member not being treated for HIV
- In all situations where coverage is approved, authorizations will be provided for the approved duration of therapy.

- Follow the FDA approved labeling and AASLD guideline supported treatment regimen chart for **adult** HCV coverage of genotypes 1-6 and unique patient populations:

HCV Genotype	Specific Patient Population	Treatment Regimen	Treatment Duration
1,2,3,4,5 or 6	Treatment-naïve with no cirrhosis	Mavyret	8 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks
1,2,3,4,5 or 6	Treatment-naïve with compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks

1 and 2	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with no cirrhosis	Mavyret	8 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks
1 and 2	Non-NS5A inhibitor, sofosbuvir-containing regimen-experienced without cirrhosis	Mavyret	12 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic**) GT 1b and 2 only**	12 weeks
4,5 or 6	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin and/or sofosbuvir but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with no cirrhosis	Mavyret	8 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks
1,2,4,5 or 6	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin and/or sofosbuvir but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
1,2,4,5 or 6	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin treatment experienced with compensated cirrhosis (Child Pugh A)	Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks
1	Treatment-experienced with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor and without cirrhosis or with compensated cirrhosis (Child Pugh A)	Vosevi	12 weeks
1	Treatment-experienced with an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor without cirrhosis or with compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
		Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks
1	Treatment-naive without cirrhosis who are non-black, HIV-uninfected, and whose HCV RNA level is <6 million IU/mL	Ledipasvir/Sofosbuvir (Harvoni authorized generic)	8 weeks
1a	Treatment-naïve or PEG-IFN/RBV treatment experienced without cirrhosis or with compensated cirrhosis (Child Pugh A) and **without** baseline NS5A polymorphism*	Zepatier	12 weeks
1a	Treatment-naïve **with** baseline NS5A polymorphisms without cirrhosis or with compensated cirrhosis (Child Pugh A)	Zepatier + ribavirin	16 weeks
1b	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child Pugh A) or PEG-IFN/RBV treatment experienced	Zepatier	12 weeks
1a, 1b	PEG-IFN/RBV or PI treatment experienced**	Zepatier (+ ribavirin if NS5A RAVS present [1a only])	12 weeks or 16 weeks if NS5A RAVS are present (1a only)
3	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin but no prior treatment with an HCV	Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	12 weeks

	NS3/4A PI or NS5A inhibitor without cirrhosis***		
3	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with compensated cirrhosis (Child Pugh A)	Vosevi	12 weeks
3	DAA (not including prior NS5A inhibitors) Treatment-experienced without cirrhosis or with compensated cirrhosis (Child Pugh A)	Vosevi	12 weeks
	DAA (including a NS5A inhibitor) Treatment-experienced without cirrhosis or with compensated cirrhosis (Child Pugh A)	Vosevi+ ribavirin	12 weeks
4	PEG-IFN/RBV treatment experienced without cirrhosis or with compensated cirrhosis (Child Pugh A) who had on-treatment virologic failure while on PEG-IFN/RBV	Zepatier + RBV	16 weeks
4	PEG-IFN/RBV experienced who had virologic relapse after prior PEG-IFN/RBV therapy without cirrhosis or with compensated cirrhosis (Child Pugh A)	Zepatier	12 weeks
1-6	Decompensated cirrhosis (Child Pugh B and C)	Sofosbuvir/Velpatasvir (Epclusa Authorized Generic) + ribavirin	12 weeks
1-6	Decompensated Cirrhosis (Child Pugh B and C) with a contraindication to ribavirin	Sofosbuvir/Velpatasvir (Epclusa Authorized Generic)	24 weeks
1- 6	Post-transplantation without cirrhosis	Mavyret	12 weeks
1, 4, 5 or 6	Post-transplantation with compensated cirrhosis or decompensated cirrhosis	Ledipasvir/Sofosbuvir (Harvoni authorized generic) + ribavirin	12 weeks
2 or 3	Post-transplantation for treatment-naïve or treatment experienced with compensated cirrhosis or decompensated cirrhosis	Daklinza + sofosbuvir + ribavirin	12 weeks

*For genotype 1a, testing for the presence of NS5A resistance-associated polymorphisms (RAVs) is recommended to determine appropriate regimen and treatment duration. In clinical trials, patients with one or more baseline NS5A RAVs at amino acid positions 28, 30, 31 or 93 had lower SVR12 rates.

** Peginterferon alfa in combination with ribavirin and a HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir)

*** For Sofosbuvir/Velpatasvir patients with GT3, testing is recommended to undergo resistance-associated substitutions (RAS) to detect the presence of Y93H. In the presence of Y93H substitution, 12 weeks of Vosevi is preferred.

- Follow the FDA approved labeling and guideline supported treatment regimen chart for **pediatric** patients who are at least 12 years of age **OR** who weigh **≥ 45 kg** who need HCV coverage of genotypes 1-6 and unique patient populations[10]:

HCV Genotype	Specific Patient Population	Treatment Regimen	Treatment Duration
1,2,3,4,5 or 6	Treatment-naïve with no cirrhosis	Mavyret	8 weeks
1,2,3,4,5 or 6	Treatment-naïve with compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
1	An NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor (PI), in patients with no cirrhosis or compensated cirrhosis (Child Pugh A)	Mavyret	16 weeks
1	An NS3/4A PI2 without prior treatment with an NS5A inhibitor, in patients with no cirrhosis or compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
1, 2, 4, 5, or 6	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with no cirrhosis	Mavyret	8 weeks
1, 2, 4, 5, or 6	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with compensated cirrhosis (Child Pugh A)	Mavyret	12 weeks
3	Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor, in patients with no cirrhosis or compensated cirrhosis (Child Pugh A)	Mavyret	16 weeks

- Follow the FDA approved labeling and guideline supported treatment regimen chart for **pediatric** patients who are at least 12 years of age **OR** who weigh from **35 to < 45 kg** who need HCV coverage of genotypes 1-6 and unique patient populations[2,3]:

HCV Genotype	Specific Patient Population	Treatment Regimen	Treatment Duration
1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Ledipasvir/Sofosbuvir (Harvoni authorized generic)	12 weeks
1	Treatment-experienced** without cirrhosis	Ledipasvir/Sofosbuvir (Harvoni authorized generic)	12 weeks
1	Treatment-experienced ** with compensated cirrhosis (Child-Pugh A)	Ledipasvir/Sofosbuvir (Harvoni authorized generic)	24 weeks

2	Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	12 weeks
3	Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	24 weeks
4,5 or 6	Treatment-naïve and treatment-experienced**, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Ledipasvir/Sofosbuvir (Harvoni authorized generic)	12 weeks

** Treatment-experienced patients have failed an interferon based regimen with or without ribavirin.

Recommended Dosing for Ribavirin in Combination Therapy with Sovaldi for Pediatric Patients 12 Years of Age and Older or Weighing at least 35kg[2,3]	
Body Weight (kg)	Ribavirin Daily dosage*
Less than 47	15mg/kg/day
47-49	600mg/day
50-65	800mg/day
66-80	1000mg/day
Greater than 80	1200mg/day

*The daily dosage of ribavirin is weight-based and is administered orally in two divided doses with food.

- Coverage may be provided for regimens not listed above if it is determined that the use is a medically accepted indication supported by current product labeling, AASLD guidelines, nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

- When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

References:

1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C.www.hcvguidelines.org. Accessed: January 18, 2019.
2. Sofosbuvir [package insert]. Gilead Sciences, Inc. Foster City, CA, November 2017.
3. Harvoni (ledipasvir and sofosbuvir) [package insert]. Gilead Sciences Inc. Foster City, CA, November 2017.
4. Heimbach JK, Kulik LM, et al. AASLD Guidelines for the Treatment of Hepatocellular Carcinoma. *Hepatology*. 2018;67(1): 358-380
5. Zepatier (elbasvir and grazoprevir) [package insert]. Merck & Co., Inc. Whitehouse Station, NJ, June 2018.
6. Epclusa (sofosbuvir and velpatasvir) [package insert]. Gilead Sciences Inc. Foster City, CA, November 2017.
7. European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2015. www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf. Accessed November 21, 2018.

8. Daklinza (daclatasvir) [package insert]. Bristol-Myers Squibb Co. Princeton, NJ, November 2017.
9. US Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations. http://www.hepatitis.va.gov/pdf/treatment-considerations-2016-03-28.pdf. Accessed November 21, 2018
10. Mavyret (glecaprevir and pibrentasvir) [package insert]. AbbVie Inc. North Chicago, IL; April 2019.
11. Vosevi [prescribing information]. Foster City, CA. Gilead Sciences, Inc; November 2017.

Gateway Health

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HEPATITIS C MEDICATIONS
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:

Planned HCV Treatment Regimen:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Hepatitis C Virus ☐ Other: _____

HCV Genotype: _____

Hepatitis C Viral Load: _____ **Date collected:** _____

Please provide documented METAVIR (F0-F4) Score:

Does the member have hepatocellular carcinoma and awaiting liver transplant? ☐ Yes ☐ No

What is the member's HCV treatment status? ☐ Treatment-Naïve ☐ Treatment-experienced

If the member is treatment-experienced, please list the previous treatment regimens used and the reasons for failure below in the "current or previous therapy" box.

Is the member co-infected with HIV? ☐ Yes ☐ No
If yes, is the member being treated for HIV? ☐ Yes ☐ No
If no, please provide rationale for not treating the patient: _____

Does the member have active HBV infection? ☐ Yes; please provide planned treatment:_____ ☐ No
If no, does the member have document resistance to HBV? ☐ Yes ☐ No
If no, please provide planned date of HBV vaccination: _____

Does the member have a known substance or alcohol abuse diagnosis or is actively abusing alcohol or IV drugs?
☐ Yes ☐ No
If **YES**, has the member been counseled by the prescriber regarding the risks of alcohol or IV drug abuse and been offered a referral for substance use disorder treatment? ☐ Yes ☐ No

What treatment regimen is being requested for the member?
☐ Mavyret x 8 weeks
☐ Mavyret x 12 weeks
☐ Sofosbuvir/Velpatasvir (Epclusa authorized generic) x 12 weeks
☐ Sofosbuvir/Velpatasvir (Epclusa authorized generic) x 24 weeks

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HEPATITIS C MEDICATIONS
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

☐ Sofosbuvir/Velpatasvir (Epclusa authorized generic) x 24 weeks (if ribavirin ineligible)
☐ Sofosbuvir/Ledipasvir (Harvoni authorized generic) x 8 weeks
☐ Vosevi x 12 weeks
☐ Zepatier x 12 weeks
☐ Sofosbuvir/Ledipasvir (Harvoni authorized generic) + Ribavirin x 12 weeks (post-transplantation with compensated cirrhosis or decompensated cirrhosis only)
☐ Sofosbuvir/Ledipasvir (Harvoni authorized generic) x 12 weeks (pediatric members only)
☐ Sofosbuvir/Ledipasvir (Harvoni authorized generic) x 24 weeks (pediatric members only)
☐ Sovaldi + Ribavirin x 12 weeks (pediatric members only)
☐ Sovaldi + Ribavirin x 24 weeks (pediatric members only)
☐ Sovaldi + Daklinza + Ribavirin for 12 weeks
☐ Other: _____ for _____ weeks

What is the start date of the member's HCV Treatment Regimen? _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date