Hepatitis C
Prior Authorization Criteria

Select Health of South Carolina
Healthy Connections

MAVYRET (glecaprevir/pibrentasvir) — preferred agent
SOFOSBUVIR/VELPATASVIR (GENERIC for EPCLUSA) — preferred agent
LEDIPASVIR/SOFOSBUVIR (GENERIC for HARVONI) — preferred agent
VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir)
ZEPATIER (elbasvir/grazoprevir)
VIEKIRA PAK
SOVALDI (sofosbuvir)
HARVONI (ledipasvir/sofosbuvir)
PEG-INTRON/ PEGASYS (peginterferon alfa-2a)
RIBAVIRIN tablets or capsules
(or any other newly marketed agent for treatment of hepatitis C)

Where applicable and appropriate: MAVYRET (Glecaprevir/Pibrentasvir), SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA), or LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI) are the PREFERRED AGENTS for hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni).

Initial requests must meet **all** of the following requirements:

1. Request must be for an appropriate FDA-approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate member (e.g., age/weight).
2. The drug is being prescribed by a specialist in hepatology/gastroenterology/infectious disease/HIV/or liver transplant.
3. Member is 3 years of age or older.
4. Provider attests that the member does not have limited life expectancy of less than 12 months due to non-liver-related comorbid conditions.
5. Provider attests that they have documentation of the following:
   - A complete hepatitis B immunization series
     or
   - Hepatitis B screening (sAb, sAg and cAb)
     and
   - Quantitative HBV DNA results if positive for hepatitis B sAg
     and
   - If there is detectable HBV DNA, a treatment plan for hepatitis B consistent with AASLD recommendations
     and
   - If negative for hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series

6. Provider attests that they have documented HIV screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
   - Is being treated for HIV
     or
   - Is not being treated for HIV and the medical record documents the rationale for not being treated
7. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications).
8. Provider attests if the member is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled member regarding the risks of alcohol or IV drug abuse, and an offer of referral for substance use disorder treatment has been made.
9. Provider attests that the member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan.
10. The following lab testing is required before treatment (copies of labs required)
    - Genotype (and subtype if provided) must be provided for:
      - Patients who are not going to receive Mavyret or generic Epclusa.
      - Generic Epclusa in treatment naive patients with compensated cirrhosis.
      - Patients who do not qualify for simplified treatment (treatment-experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant).
    - Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing and is prescribed a drug regimen in accordance with AASLD guidance.
11. All approvals are for 28 days' supply (see treatment summarybelow), will be consistent with labeling or current guidelines, and are subject to change as guidelines are updated.

Treatment Summary

For unique patient populations such as pediatric patients, please see page four for links to guideline specific treatment regimens

Please note, for all charts, Epclusa, and Harvoni refer to their generic formulations

Treatment Naïve			
Genotype	Treatment option	Duration	
		No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	Mavyret	8 weeks	8 weeks
1, 2, 3, 4, 5, or 6	Epclusa	12 weeks	12 weeks
1, 4, 5, or 6	Harvoni	8 – 12 weeks^	12 weeks

Treatment-naive patients without cirrhosis who have HCV RNA <6 million units/mL and are HIV-uninfected may be considered for therapy of eight weeks' duration with Harvoni for patients with genotype 1.

Treatment Experienced			Duration	
Genotype	**Failed regimen**	**Treatment options**	**No cirrhosis**	**Compensated cirrhosis (Child-Pugh A)**
Genotype 1, 4	Peg/Riba	Mavyret	8 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
		Harvoni (alternative)	12 weeks	12 weeks+RBV (alternate)
Genotype 2	Peg/Riba	Mavyret	8 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
Genotype 3	Peg/Riba	Epclusa	12 weeks	12 weeks
		Mavyret (alternative)	16 weeks	16 weeks
Genotype 5 or 6	Peg/Riba	Mavyret	8 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
		Harvoni	12 weeks	12 weeks
Genotype 1	Any NS5A (Daklinza, Zepatier, Harvoni, Viekira Pak/XR, Mavyret, Epclusa)	Vosevi	12 weeks	12 weeks
		Mavyret (alternative)	16 weeks	16 weeks
Genotype 1	Peg/Ribavirin with Olysio, Incivek or Victrelis	Mavyret	12 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
		Harvoni	12 weeks	12 weeks + RBV (alternative)
Genotype 1a	Sovaldi/Daklinza	Mavyret	12 weeks	12 weeks
		Vosevi	12 weeks	12 weeks
Genotype 1b	Sovaldi/Daklinza	Mavyret	12 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
Genotype 1 or 2	Sovaldi/Peg/Ribavirin **or** Sovaldi/Ribavirin	Mavyret	12 weeks	12 weeks
		Epclusa	12 weeks	12 weeks
All genotypes	Any other DAA regimen other than those specifically listed above	Vosevi	12 weeks	12 weeks

*Do not use if Mavyret has previously failed treatment or in NS3/4 protease inhibitor (Olysio, Incivek, or Victrelis) inclusive DAA combination regimens.

Alternate regimen only if previously failed treatment with NS3/4 (Olysio, Incivek, or Victrelis) plus Peg/Ribavirin.

Patients With Mild, Moderate or Severe Renal Impairment — Including Those Requiring Hemodialysis			
Genotype	Treatment option	Duration	
		No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1,2,3,4,5 or 6	Mavyret	**8 – 16 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines	**12 – 16 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines
1, 2, 3, 4, 5, or 6	Epclusa	**12 – 24 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines	**12 – 24 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines
1, 4, 5, or 6	Harvoni	**12 – 24 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines	**12 – 24 weeks** Dependent on treatment history, GT-refer to package insert/AASLD guidelines

Unique Patient Populations (Such As Decompensated Cirrhosis, Post-Transplant, etc. — Not Addressed in Previous Tables)	
Decompensated cirrhosis (Child-Pugh B or C)	Refer to current AASLD guidelines at **http://www.hcvguidelines.org/** **Note:** If Mavyret, Epclusa, or Harvoni are recommended treatment options, they are preferred unless medical reason provided that member is unable to use Mavyret, Epclusa, or Harvoni.
Post-transplant	Refer to current AASLD guidelines at **http://www.hcvguidelines.org/** **Note:** If Mavyret, Epclusa, or Harvoni are recommended treatment options, they are preferred unless medical reason provided that member is unable to use Mavyret, Epclusa, or Harvoni.
Hepatocellular carcinoma	**Note:** Refer to current AASLD guidelines at **http://www.hcvguidelines.org/** *If Mavyret, Epclusa, or Harvoni are recommended treatment options, they are preferred unless medical reason provided that member is unable to use Mavyret, Epclusa, or Harvoni.
Pediatrics	Refer to current AASLD guidelines at **http://www.hcvguidelines.org/** **Note:** If Mavyret, Epclusa, or Harvoni are a recommended treatment options, they are preferred unless medical reason provided that member is unable to use Mavyret, Epclusa, or Harvoni. *If patient is at least 35 kg and the request is for Harvoni or Sovaldi, the medication is being prescribed no more than one tablet daily. *If patient is at least 35 kg and the request is for Harvoni or Sovaldi oral pellets, medical reasoning is required as to why member is unable to use oral tablets at a one tablet daily dosage.

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