PRIOR AUTHORIZATION PROTOCOL FOR HEPATITIS C TREATMENT FOR AHDC

MAVYRET (Glecaprevir/Pibrentasvir)-PREFERRED AGENT
SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA)-PREFERRED AGENT
LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI)-PREFERRED AGENT

VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir)
ZEPATIER (elbasvir/grazoprevir)
DAKLINZA (Daclatasvir)
TECHNIVIE (Ombitasvir, paritaprevir, ritonavir)
VIEKIRA PAK/VIEKIRA XR (Ombitasvir/paritaprevir/ritonavir/dasabuvir)
OLYSIO (simeprivir)
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 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 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 abuse disorder treatment has been made.
9. Provider attests that member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan.
10. The beneficiary has agreed to participate in Hepatitis C monitoring, educational and counseling program provided by the health plan, and the beneficiary clearly understands that only one course of therapy is allowed in DC Medicaid lifetime
11. The request includes the completed DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications Form
12. 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
13. All approvals are for 28 days supply (see treatment summary that follows), and 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 refer to bottom of the page for links to guideline specific treatment regimens****

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 8 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,	**Mavyret**	**12 weeks**	**12 weeks**

	Incivek or Victrelis	**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 weeks-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 (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)	
Decompensated Cirrhosis (Child-Pugh B or C)	Refer to current AASLD guidelines @ 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 @ 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 @ 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 @ 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.

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