

PRIOR AUTHORIZATION PROTOCOL FOR HEPATITIS C TREATMENT for AHDC

MAVYRET™ (Glecaprevir/Pibrentasvir)-PREFERRED AGENT

VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir)

EPCLUSA® (sofosbuvir/velpatasvir)

ZEPATIER® (elbasvir/grazoprevir)

HARVONI™ (ledipasvir/sofosbuvir)

DAKLINZA™ (Daclatasvir)

TECHNIVIE™ (Ombitasvir, paritaprevir, ritonavir)

VIEKIRA PAK™/VIEKIRA XR™ (Ombitasvir/paritaprevir/ritonavir/dasabuvir)

OLYSIO™ (simeprevir)

SOVALDI™ (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) is the PREFERRED AGENT 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.

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. Provider attests that member does not have limited life expectancy of less than 12 months
4. Provider attests that member has been screened for Hepatitis B (HBV) and human immunodeficiency virus (HIV)
5. 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)
6. Provider attests that member does not have current issues with compliance
7. Provider attests that they have counseled member on barriers to HCV therapy, alcohol and illicit drug use
8. Provider attests that member is committed to treatment plan, including lab monitoring at weeks 4, 8 and 12, and SVR12 lab testing will be completed and submitted to health plan
9. Member's treatment history and response has been provided with request
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. Member has **ONE** of the following:
 - History of liver transplant (include date, **NOTE: does not require a certain level of fibrosis**)
 - Is HIV or HBV co-infected
 - Serious extrahepatic manifestations of Hepatitis C such as leukocytoclastic vasculitis,

membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia

- A Metavir fibrosis score of F2-F4 documented by liver biopsy, Fibroscan, or a blood test
- Physical findings consistent with substantial or advanced fibrosis or cirrhosis
 - Hospitalization within the past 12 months for a condition attributed to hepatic cirrhosis, OR
 - History of hepatic encephalopathy requiring medication management and/or hospitalization within the past 12 months, OR
 - History of portal hypertension as demonstrated by variceal bleeding or radiographic evidence or Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure

13. The following lab testing is required before treatment (copies of labs required)

- Genotype (and subtype if provided)
- RASs (resistance-associated substitutions, previously called RAVs) testing for Zepatier 1a requests or as indicated in treatment guidelines

The following lab testing is required within **3 months** of starting therapy:

- Detectable HCV RNA viral load
- ALT/AST
- GFR
- INR
- CBC (only if regimen contains ribavirin and hemoglobin must be at least 10g/dL)
- TSH (only if regimen contains interferon)
- Pregnancy test (**within 1 month** for regimens that contain ribavirin and the member is of child bearing age)

14. If member is cirrhotic, documentation of Child Turcotte Pugh Class (Class A, Class B, Class C)

15. If member has hepatocellular carcinoma, documentation was provided confirming the diagnosis (image testing by ultrasound, tomography, MRI, laparoscopy or biopsy)

16. 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.

<u>Treatment Naive</u>			
Genotype	Treatment Option	Duration	
		No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1,2,3,4,5 or 6	Mavyret	8 weeks	12 weeks
1,2,3,4,5 or 6	Epclusa * *ONLY if medical reason provided that member is unable to use Mavyret	12 weeks	12 weeks

TREATMENT SUMMARY

<u>Treatment Experienced</u>			Duration	
<i>Mavyret can NOT be used if previously treated with Zepatier/Technivie/Viekira or Viekira XR</i>				
Genotype	Failed Regimen	Treatment Option	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
Genotype 1	Harvoni OR Epclusa OR Sovaldi/Daklinza	Mavyret	16 weeks	16 weeks
Genotype 1	Peg/Ribavirin with Olysio, Incivek or Victrelis OR Sovaldi/Olysio	Mavyret	12 weeks	12 weeks
Genotype 1, 2, 4, 5 or 6	Peg/Riba OR Sovaldi/Peg/Ribavirin OR Sovaldi/Ribavirin	Mavyret	8 weeks	12 weeks
Genotype 3	Peg/Riba OR Sovaldi/Peg/Ribavirin OR Sovaldi/Ribavirin	Mavyret	16 weeks	16 weeks
Genotype 1, 2,3,4,5 or 6	A regimen containing Daklinza* OR Zepatier OR Viekira/Viekira XR/Technivie OR Harvoni * OR Epclusa*	Vosevi* <i>*Must have documented reason why unable to use Mavyret for Genotype 1</i>	12 weeks	12 weeks
Genotype 1a or 3	Sovaldi/Peg/Riba* OR Sovaldi/Olysio* OR Sovaldi/Ribavirin*	Vosevi * <i>*Must have documented reason why unable to use Mavyret</i>	12 weeks	12 weeks
<u>Patients with mild, moderate or severe renal impairment, including those requiring hemodialysis</u>				
Genotype	Treatment Option	Duration		
		No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	
1,2,3,4,5 or 6	Mavyret	8 weeks-16 weeks Dependent on treatment history, GT-refer to package insert/guidelines	12 weeks-16 weeks Dependent on treatment history, GT-refer to package insert/guidelines	
1 or 4	Zepatier* RAV testing required for GT1a *ONLY if medical reason provided that member is unable to use Mavyret	12 weeks-16** **Dependent on RAV testing and previous treatment history-refer to package insert/guidelines	12 weeks-16** **Dependent on RAV testing and previous treatment history-refer to package insert/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 is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Post-Transplant	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ NOTE: If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Hepatocellular Carcinoma	NOTE: Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ *If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Pediatrics	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ *If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret

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