Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Acting Secretary

MARYLAND MEDICAL ASSISTANCE PROGRAM
Managed Care Organization Transmittal No. 148
December 3, 2021

To: Managed Care Organizations (MCOs)

From: Athos Alexandrou, Director
Office of Pharmacy Services

Alex Shekhdar, Acting Director
Medical Benefits Management

Re: Hepatitis C Virus (HCV) Retrospective Review Process

Note: **Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.**

The purpose of this transmittal is to extend the retrospective review process and update the clinical criteria communicated in PT 33-21 Hepatitis C Virus (HCV) Retrospective Review Process, effective January 1, 2021. MCOs are required to review and approve all requests for prior authorization for HCV medications, without first submitting them to the Department for review and approval. To ensure that the MCOs are following the Department's HCV Clinical Criteria (**see attachment A**) when approving the requests, the Department implemented a monthly retrospective review process for HCV therapies approved by the MCOs. The review process policy is shown in **attachment B**.

During the retrospective review process, if after sufficient investigation, the Department determines that an MCO did not comply with the HCV Clinical Criteria 100% of the time, the Department will impose sanctions pursuant to COMAR 10.67.10.01.

Attachment A

Clinical Criteria for Hepatitis C (HCV) Therapy

Pre-Treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented*;
- Patients who have prior exposure to DAA therapy must have a pre-DAA genotype and post-DAA genotype documented (Appendix A);
- HCV RNA quantitative within 180 days of application for therapy, unless the patient is cirrhotic then the baseline lab values must be within 90 days of prior authorization request;
- Liver biopsy or other accepted fibrosis test (ex. fibrosure, hepascore/fibroscore, fibroscan, point shear wave elastography (PSWE) acoustic radiation force impulse imaging (AFRI)*;
- Previous HCV treatment history and outcome;
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- HBV status and, if active HBV disease, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy;
- Drug resistance testing as indicated; and

*Not required in the treatment of HCV-Uninfected Recipients of Non-liver Organs from HCV-Viremic Donors

Patient Treatment Plan

- It is required that the patient have a treatment plan developed by, or in collaboration with, a provider with expertise in Hepatitis C management. Sample treatment plan documents are available for use.
  If the patient or their partner is of childbearing age, at least two (2) forms of contraception must be used (by the patient or their partner) if a RBV-containing regimen is prescribed throughout the duration of therapy and for six (6) months after the regimen is completed.

Drug Therapy

- Must be in accordance with FDA approved indications.
- RBV= Ribavirin, IFN = Interferon, CTP = Child-Turcotte-Pugh

Treatment Naïve Patients			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
1a	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 8 wks* Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1a	***Alternative Regimens*** Zepatier + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Zepatier + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 8 wks* Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1b			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks (if no Y93 RAS) Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
3		***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks (if Y93 RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
4			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
5 or 6			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks

*if HCV RNA < 6 million

Treatment Experienced Patients arrange by treatment			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
IFN + RBV Experienced			
1a	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks
1a	***Alternative Regimens*** Zepatier (elbasvir/grazoprevir) + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks Zepatier (elbasvir/grazoprevir) + RBV x 16 (if NS5A RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks (if no NS5A RAS)	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1b		***Alternative Regimens*** Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks (if no Y93 RAS) Mavyret (glecaprevir/pibrentasvir) x 16 wks	Mavyret (glecaprevir/pibrentasvir) x 16 wks	*No currently FDA approved treatment regimens*
3	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks (if Y93 RAS present)	***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks	
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks Zepatier (elbasvir/grazoprevir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks Zepatier (elbasvir/grazoprevir) x 12 wks	*No currently FDA approved treatment regimens*
4		***Alternative Regimens*** Harvoni ledipasvir/sofosbuvir) + RBV x 12 wks	
5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	*No currently FDA approved treatment regimens*
NS3 PI Experienced			
1a or 1b	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBV x 12 wks
1a or 1b			***Alternative Regimens***

			Epclusa (sofosbuvir/velpatasvir) x 24 wks Harvoni (ledipasvir/sofosbuvir) x 24 wks
SOF Experienced and NS5A Naïve			
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x12 wks	*No currently FDA approved treatment regimens*
NS5A Experienced			
1a or 1b	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
1a or 1b	***Alternative Regimens*** Mavyret (glecaprevir/pibrentasvir) x 16 wks	***Alternative Regimens*** Mavyret (glecaprevir/pibrentasvir) x 16 wks	
2	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
DAA Experienced			
3	Mavyret (glecaprevir/pibrentasvir) x 16 wks Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Mavyret (glecaprevir/pibrentasvir) x 16 wks Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*
4,5 or 6	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 wks	*No currently FDA approved treatment regimens*

Post Liver and Kidney Transplant Patients			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis**	**Decompensated Cirrhosis (CTP B or C)**
1	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
1			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
2			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks*
3	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
3			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks*
4	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
4			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*
5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 12 wks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks Harvoni (ledipasvir/sofosbuvir) + RBVx 12 wks
5 or 6			***Alternative Regimens*** Epclusa (sofosbuvir/velpatasvir) x 24 wks* Harvoni (ledipasvir/sofosbuvir) x 24 wks*

*24 week duration should be used in treatment experienced patients

Treatment of HCV-Uninfected Recipients of Non-liver Organs from HCV-Viremic Donors	
Genotype	**No need to evaluate for cirrhosis**
Genotype is not required for approval with pangenotypic regimens.	Epclusa (sofosbuvir/velpatasvir) x 12 weeks Mavyret (glecaprevir/pibrentasvir) x 8 weeks

Pediatric Patients Treatment Naïve or IFN Experienced	
Genotype	**No Cirrhosis or Compensated Cirrhosis**
1	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks
2	Epclusa (sofosbuvir/velpatasvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks
3	Mavyret (glecaprevir/pibrentasvir) x 8 wks
4,5 or 6	Epclusa (sofosbuvir/velpatasvir) x 12 wks Harvoni (ledipasvir/sofosbuvir) x 12 wks Mavyret (glecaprevir/pibrentasvir) x 8 wks

Pediatric Dosing				
Epclusa (sofosbuvir/velpatasir) For patients ≥ 6 years old OR at least 17 kg		**Harvoni (ledipasavir/sofobuvir) For patients ≥ 3 years old**		**Mavyret (glecaprevir/pibrentasvir) For patients ≥ 12 years old OR at least 45 kg**
Body Weight	Once Daily Dose	Body Weight	Once Daily Dose	
17 kg to < 30 kg	200 mg/ 50 mg	< 17 kg	33.75 mg/ 150 mg	
≥ 30 kg	400 mg/ 100 mg	17 kg to < 35 kg	45 mg/ 200 mg	
		≥ 35 kg	90 mg/ 400 mg	

No Genotype Determined or Multiple Genotypes	
No cirrhosis or Compensated Cirrhosis	**Decompensated Cirrhosis (CTP B or C)**
Epclusa (sofosbuvir/velpatasvir) x 12 weeks Mavyret (glecaprevir/pibrentasvir) x 8 weeks	Epclusa (sofosbuvir/velpatasvir) + RBV x 12 wks
	Alternative Regimens Epclusa (sofosbuvir/velpatasvir) x 24 wks

Appendix A: HCV Treatment Definitions

Retreatment: Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR and current need for an additional course of therapy to treat chronic HCV infection.

Conditions required:

- Detectable HCV RNA at 12 weeks post treatment.
- HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection: Exposure to an HCV treatment regimen, which results in achievement of SVR.

Conditions required:

- Detectable HCV RNA > 12 weeks post treatment
- HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- Current infection has been present ≥ 6 months.

Attachment B

Retrospective review process for HCV medications policy (Effective - January 1, 2021)

Review Process

1. The Office of Pharmacy Services (OPS) will provide Excel workbook to MCOs no later than the 14th of each month. The Excel workbook will contain 3 tabs.

    A. Tab 1 (HEPC Recipients):
        a. OPS will provide data in columns highlighted in Yellow (A-D).
        b. MCO will provide data in columns highlighted in blue (E-K).

    B. Tab 2 (Detailed Sample):
        a. OPS will provide data in columns highlighted in Yellow (A-C), which are randomly selected number of patients based on the tiers below.
            i. 1-5 all patients.
            ii. 6-50 5 patients.
            iii. >50 10%.
        b. The MCO shall submit ALL clinical documentation for randomly selected patients (see documentation section of policy below).

    C. Tab 3 (Denials):
        a. MCO shall provide all the data in columns highlighted in blue (A-G) for HCV denials in the month.

2. MCO shall provide the completed Excel workbook and all clinical documentation required in 1(B)(b) to OPS within 30 days of receipt.

This is a quality audit of HCV claims approvals given the update to the HCV medication approval process. In order for a claim to be considered appropriate in the audit the following points must be met:

1. Maryland HealthChoice's MCO is following Maryland Medicaid's Fee-For-Service HCV Clinical Criteria,
2. Receipt of the completed Excel workbook, and
3. Clinical documentation as outlined below.

If the reviewer believes the Excel workbook and/or documentation provided as part of 1(B) (b) is inaccurate/incomplete, it will be returned to the MCO to be corrected. MCOs will have 7 calendar days to complete the Excel workbook or provide accurate documentation and resubmit it.

The necessary documentation shall be submitted as listed below for review:

Documentation:

a. Completed Excel workbook.
b. Completed PA form.
c. Completed coversheet. (see appendix A)
d. Recent (within the last six (6) months) provider note, unless the patient is cirrhotic then the last provider note must be within 90 days of prior authorization request
e. Genotype.
f. HCV RNA (up to and including 180 days of application for therapy), unless the patient is cirrhotic then the baseline lab values must be within 90 days of prior authorization request
g. Baseline lab values.
    i. Total bilirubin.(only in cirrhotic patient)
    ii. Albumin. (only in cirrhotic patient)
    iii. INR. (only in cirrhotic patient)
h. Fibrosis score.
i. HIV viral load (ONLY if the patient is co-infected) within six (6) months of application for therapy.
j. HBV viral load (ONLY if the patient has active infection) within six (6) months of application for therapy.

All the documentation should be submitted OPS in secure format to:
Kim.Rogers@maryland.gov

Appendix A

HCV PA Coversheet:

Member Name: _____
Medicaid number: _____

Initial Review:

□ Completed PA form on page _____

□ Baseline lab values (within the last 180/90 days) on page(s) _____

□ HCV genotype on page _____

□ Fibrosis documentation on page _____

□ Recent (within the last 3 months) provider note on page(s) _____