OHIO DEPARTMENT OF MEDICAID

PRIOR AUTHORIZATION HEPATITIS C TREATMENT

Request Date	Review Requested ☑ STANDARD ☐ URGENT	
Individual's Name	Prescriber's Name	
Individual's Medicaid ID Number	Prescriber's NPI Number	
Individual's Date of Birth	Prescriber's Address	
	Prescriber's Phone Number	Prescriber's Fax Number

Only Hepatitis C treatment PA requests for individuals who meet the following guidelines will be approved.
This PA form will cover up to the length authorized by the American Association for the Study of Liver Disease (AASLD) guidelines.

Please refer to the **APPENDIX** which lists the various regimens and the clinical situations for which they will be considered medically necessary according to the Ohio Department of Medicaid (ODM) criteria.

The PA must be approved prior to the 1st dose and include appropriate supporting documentation.

PREFERRED REGIMENS

INFECTIOUS DISEASE AGENTS: HEPATITIS C-DIRECT ACTING ANTIVIRAL

CLINICAL PA REQUIRED "PREFERRED"+	PA REQUIRED "NON-PREFERRED"
SOFOSBUVIR/VELPATASVIR (generic of EPCLUSA)	LEDIPASVIR/SOFOSBUVIR (generic of HARVONI)
MAVYRET (glecaprevir and pibrentasvir)	HARVONI (ledipasvir and sofosbuvir)
	SOVALDI (sofosbuvir)
	VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)
	ZEPATIER (elbasvir and grazoprevir tablet)

Selection of regimen to be based upon the APPENDIX below and in accordance with American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA) guidelines for those 18 years old and over (https://www.hcvguidelines.org/.) FDA approved pediatric formulations of direct acting antivirals (DAA) will be approved for those under the age of 18 years when used in accordance with current AASLD guidelines.

The following documentation must be submitted with initial request for consideration of approval:

☐ Active HCV infection verified by viral load within 180 days HCV RNA: million IU/mL Date	
☐ HCV Genotype verified by lab Genotype ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6	
Hepatitis fibrosis stage	Date
Method(s) used:	
☐ Individuals scheduled to receive an HCVNS3 protease inhibitor *(i.e. grazoprevir, voxilaprevir, glecaprevir)* should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score if cirrhosis is determined to be likely present *(as evidenced by clinical findings, radiology, Metavir fibrosis score of F4, pathology findings or other laboratory markers (FibroTest/FibroSure/FIB-4 index).*	
☐ Prescriber has discussed the importance of adherence to treatment plan, office visits, lab monitoring, imaging, procedures and to taking requested regimen as prescribed.	
☐ Individual does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.	

Ribavirin (RBV)-ineligible:

- CrCl<50mL/min (unless dose is adjusted)
- Hypersensitivity to ribavirin
- History of severe or unstable cardiac disease
- Pregnant women and men with pregnant partners
- Diagnosis of hemoglobinopathy (e.g. thalassemia major, sickle cell anemia)
- Baseline platelet count <70,000 cells/mm^3
- ANC<1,500 cells/mm^3
- Hb<12gm/dl in women or <13g/dL in men

Low dose Ribavirin = 600mg/day and increased as tolerated

For ANY regimen that includes ribavirin:

- For women of childbearing potential (and male individuals with female partners of childbearing potential):
    - Individual is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping
    - Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping
    - Verification that monthly pregnancy tests will be performed throughout treatment

FOR TREATMENT EXPERIENCED INDIVIDUALS, ANSWER THE FOLLOWING OR INCLUDE TREATMENT NOTES THAT DOCUMENT THIS INFORMATION:

Prior treatment regimens, dates & outcomes, including reason for failure, if known *(e.g. failed to complete prior therapy, failure of past therapy):*

APPENDIX

Treatment naïve

No cirrhosis

- ☐ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended)
- ☐ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

Compensated cirrhosis, HIV negative

- ☐ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks
- ☐ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Compensated cirrhosis, HIV positive

- ☐ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- ☐ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Treatment experienced

Previously failed a Sofosbuvir-based regimen

- ☐ Mavyret 100/40 mg, three (3) tablets daily for 16 weeks

Previously failed a NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)

- ☐ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

Previously failed Mavyret

- ☐ Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight-based RBV)

Previously failed Vosevi or sofosbuvir + Mavyret

- ☐ Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 24 weeks

Previously failed GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)

- ☐ Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 12 weeks

Re-infection of Allograft Liver after Transplant

DAA-treatment naïve, no decompensated cirrhosis

- ☐ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- ☐ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

DAA-treatment experienced, no decompensated cirrhosis

- ☐ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

IF multiple negative baseline characteristics, consider

- ☐ Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment naïve, decompensated cirrhosis

- ☐ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)

- ☐ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks

Decompensated Cirrhosis

No prior sofosbuvir or NS5A failure

- ☐ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)
- ☐ sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for individuals with documented ineligibility for RBV)

Prior sofosbuvir or NS5A failure

- ☐ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

Other Treatment Regimen
Genotype, treatment history, and extent of liver disease:
Drug names, doses and durations:
Clinical rationale for selecting regimens other than those outlined above:

☐ I attest that I am a member of the prescriber's staff in accordance with Ohio Administrative Code 5160-9-03, as applicable. Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization.

_____ _____

Prescriber's Signature (or staff of prescriber) Date

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IF a staff member is attesting, please print your name

Fax To: Ohio Department of Medicaid
Fax: (800) 396 – 4111 Helpdesk Phone Number: (877) 518 – 1546
Hours: Monday – Friday 8:00 am to 8:00 pm EST