Iowa Department of Human Services

Request for Prior Authorization
HEPATITIS C TREATMENTS

FAX Completed Form To
1 (800) 574-2515

Provider Help Desk
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		Patient phone
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

Prior authorization (PA) is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions: 1) Patient has a diagnosis of chronic hepatitis C; and 2) Patient's age and/or weight is within the FDA labeled age and/or weight; and 3) Patient has had testing for hepatitis C virus (HCV) genotype; and 4) Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and 5) Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and 6) Patient's prior treatment history is provided (treatment naïve or treatment experienced); and 7) If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and 8) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and 9) HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and 10) For patients on a regimen containing ribavirin, documentation of the following on the PA form: a) Patient is not a pregnant female or a male with a pregnant female partner; and b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and c) Monthly pregnancy tests will be performed during treatment; and 11) Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication; and 12) Documentation is provided for patients who are ineligible to receive ribavirin. 13) Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved. 14) Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. 15) If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below). 16) Lost or stolen medication replacement requests will not be authorized. 17) The 72-hour emergency supply rule does not apply to hepatitis C treatments. 18) Only one treatment attempt will be allowed per calendar year, regardless of compliance.

Preferred:
- ☐ Mavyret
- ☐ sofosbuvir/velpatasvir

Non-Preferred:
- ☐ Epclusa
- ☐ Harvoni
- ☐ ledipasvir/sofosbuvir
- ☐ Sovaldi
- ☐ Vosevi
- ☐ Zepatier

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Instructions for completing the Hepatitis C Treatments PA form:

Section 1 of the PA form lists the various regimens and clinical situations for which hepatitis C treatments will be considered medically necessary according to Iowa Medicaid PA criteria. Section 2 includes additional supporting documentation that is required on the PA form.

- Check ONE box in Section 1 – Treatment Regimen.
- Review and complete each numbered item in Section 2 – Supporting Documentation.
- Attach lab results, chart notes, and other documentation, sign, and fax the completed form to (800) 574-2515.

SECTION 1 – TREATMENT REGIMEN

Check ONE box below to indicate the requested treatment regimen based on the patient's genotype, treatment history, and extent of liver disease.

ADULT: Treatment naïve (includes those treated in the past with IFN/RBV or IFN + 1st generation protease inhibitors)

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)

ADULT: Treatment experienced (with or without compensated cirrhosis)

Sofosbuvir-based regimen

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

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

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

Mavyret

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

Vosevi or sofosbuvir + Mavyret

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

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

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

ADULT: 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

ADULT: 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 patients 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: _____

_____

_____

Pediatric Formulations of DAA

- Pediatric formulations of preferred DAAs with FDA approval will be approved for patients under the age of eighteen when used according to current AASLD guidelines, including indication and age.
- Prior authorization is required prior to the first dose

_____

Abbreviations: RBV=ribavirin; DAA=direct acting antiviral

 # low dose ribavirin = 600 mg/day and increase as tolerated

SECTION 2 – SUPPORTING DOCUMENTATION

Review and complete each numbered item below to provide the supporting documentation for the PA request.

Diagnosis:

1. Pretreatment viral load (**attach results**): _____ Date Obtained:_____

Patient History:

2. Does the patient have a history of non-compliance? ☐Yes ☐No
   If yes, submit chart notes documenting the steps taken to correct or address the non-compliance (**attach chart notes**)
3. Documentation in provider notes (**must be submitted**) showing that member has had no abuse of alcohol and drugs for the previous 3 months. **MUST submit** urine drug screen for members with history of abuse of drugs other than alcohol. Counseling MUST be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
4. Has patient been screened for Hepatitis B? □ No □ Yes Date:_____ Active Disease: □ No □ Yes If yes, has patient been treated or currently being treated? □ No □ Yes
5. Patient weight: _____ Date obtained: _____
6. Does patient have a limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions? ☐Yes ☐No

Prescriber Information:

7. Provider Practice: ☐Digestive Disease ☐Liver Disease ☐Infectious Disease ☐Other: _____

   If other, note consultation with Specialist:

   Consultation Date:_____ Physician Name, Phone & Specialty: _____

Regimens Containing Ribavirin:

8. If the patient is female and of childbearing potential, or the patient is male with a female partner of childbearing potential, the prescriber must acknowledge the following:

   - ❑ The patient is not pregnant (or a male patient with a pregnant female partner) and is not planning to become pregnant during treatment or within 6 months of stopping treatment.
   - ❑ Both partners will use two forms of effective contraception during treatment and for at least 6 months after stopping treatment.
   - ❑ Monthly pregnancy tests will be performed throughout treatment.

9. Complete blood count with differential (**attach results**)

10. If the patient is ineligible for ribavirin¶, select the appropriate reason from the list below:

- ❑ History of severe or unstable cardiac disease
- ❑ Pregnant women and men with pregnant partners
- ❑ Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- ❑ Hypersensitivity to ribavirin
- ❑ Baseline platelets <70,000 cells/µL
- ❑ Baseline absolute neutrophil count <1,500 cells/µL
- ❑ Baseline hemoglobin <12 g/dL in women or <13 g/dL in men
- ❑ Other: _____

Note: Laboratory values will be reviewed and requests will not be considered if labs are outside of a specific range. Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced.

Potentially Significant Drug Interactions:

11. By checking the following box, the prescriber attests that they have reviewed the patient's medications for potentially significant drug interactions with the Hepatitis C treatment on an electronic drug interaction website.

- ❑ **Website used: _____ Date completed: _____**

Attach lab results and other documentation

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.*