



**Request for Prior Authorization  
 HEPATITIS C TREATMENTS, DIRECT ACTING ANTIVIRALS**

(PLEASE PRINT – ACCURACY IS IMPORTANT)

**Preferred:**  Mavyret

 sofosbuvir/velpatasvir

**Non-Preferred:**  Epclusa

 Harvoni

 ledipasvir/sofosbuvir

 Sovaldi

 Vosevi

 Zepatier

**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 I – 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.

<b>ADULT: Treatment naïve (includes those treated in the past with IFN/RBV or IFN + 1<sup>st</sup> generation protease inhibitors)</b>
<b>No cirrhosis</b> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
<b>Compensated cirrhosis,</b> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (GT4 AND HIV/HCV co-infected patients, IDSA/AASLD guidelines recommend 12 weeks of treatment) <input type="checkbox"/> sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
<b>ADULT: Treatment experienced (with or without compensated cirrhosis)</b>
<b>Sofosbuvir-based regimen</b> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 16 weeks
<b>NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks
<b>Mavyret</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight-based RBV)
<b>Vosevi or sofosbuvir + Mavyret</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 24 weeks
<b>GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + weight-based RBV for 12 weeks
<b>ADULT: Re-infection of Allograft Liver after Transplant</b>
<b>DAA-treatment naïve, no decompensated cirrhosis</b> <input type="checkbox"/> Mavyret 100/40 mg, three (3) tablets daily for 12 weeks <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
<b>DAA-treatment experienced, no decompensated cirrhosis</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily for 12 weeks
<b>IF multiple negative baseline characteristics, consider</b> <input type="checkbox"/> Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks
<b>Treatment naïve, decompensated cirrhosis</b> <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks
<b>Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)</b> <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks
<b>ADULT: Decompensated Cirrhosis</b>
<b>No prior sofosbuvir or NS5A failure</b> <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis) <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)
<b>Prior sofosbuvir or NS5A failure</b> <input type="checkbox"/> sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

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**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

GT	Age (years)	Weight (kg)	Drug/Dose	Weeks
Any	≥3	<20	Mavyret 50/20mg Pellet Pack (3 packets once daily)	8
		≥20 to <30	Mavyret 50/20mg Pellet Pack (4 packets once daily)	8
		≥ 30 to <45	Mavyret 50/20mg Pellet Pack (5 packets once daily) -OR- sofosbuvir/velpatasvir 400/100 mg tablet	8 12
Any	≥12	≥45	Mavyret 100/40 mg tablets -OR- sofosbuvir/velpatasvir 400/100 mg tablet	8 12

**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:**

Pretreatment viral load (**attach results**): \_\_\_\_\_ Date Obtained: \_\_\_\_\_

**Patient History:**

- 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**)
- Has patient been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools?  
 Yes Document tool used: \_\_\_\_\_  No
- Has patient been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission?  Yes  No
- If patient is currently using IV drugs and/or alcohol, has participation in alcohol and/or substance abuse counseling been recommended?  Yes  No
- 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
- Patient weight: \_\_\_\_\_ Date obtained: \_\_\_\_\_
- Does patient have a limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions?  Yes  No

## Request for Prior Authorization HEPATITIS C TREATMENTS, DIRECT ACTING ANTIVIRALS

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**Prescriber Information:**

 Provider Practice:  Digestive Disease     Liver Disease     Infectious Disease     Other: \_\_\_\_\_

If other, note consultation with Specialist: Consultation Date: \_\_\_\_\_

Physician Name, Phone &amp; Specialty: \_\_\_\_\_

**Regimens Containing Ribavirin:**

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.

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

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/ $\mu$ L
- Baseline absolute neutrophil count <1,500 cells/ $\mu$ L
- 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:**

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:** \_\_\_\_\_

**Treatment experienced (previous DAA)**

In addition to criteria above:

If patient previously achieved SVR and has HCV recurrence due to IV drug use document the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment : \_\_\_\_\_

 Has patient been previously treated with and failed the requested DAA therapy?  Yes     No

Does patient have documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment?

 Yes    Date previous treatment completed? \_\_\_\_\_    Date of recent labs detecting HCV RNA: \_\_\_\_\_

 No

**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.