Iowa Department of Human Services

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

**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 direct-acting antivirals (DAA). 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 HCV DAA 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 been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the *SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools* and the *Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C)*; and 9) Patient has 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. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and 10) HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and 11) DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and 12) 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 13) Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the DAA; and 14) Documentation is provided for patients who are ineligible to receive ribavirin; and 15) Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and 16) Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. 17) 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). 18) Lost or stolen medication replacement requests will not be authorized. 19) The 72-hour emergency supply rule does not apply to DAAs. Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions: 1) Patient must meet all criteria for treatment approval above; and 2) Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that 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, and can be managed as an initial infections; and 3) The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and 4) Patient has not been previously treated with and failed the requested DAA therapy: 5) Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.**

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**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 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 sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

**Compensated cirrhosis,**

- ❑ 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)
- ❑ sofosbuvir/velpatasvir 400/100, 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)

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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- | 8 |
| | | | sofosbuvir/velpatasvir 400/100 mg tablet | 12 |
| Any | ≥12 | ≥45 | Mavyret 100/40 mg tablets -OR- | 8 |
| | | | sofosbuvir/velpatasvir 400/100 mg tablet | 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

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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 & 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/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:**

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.*