IOWA Health and Human Services

Request for Prior Authorization

HEPATITIS C TREATMENTS, DIRECT ACTING ANTIVIRALS

(PLEASE PRINT – ACCURACY IS IMPORTANT)

FAX Completed Form To
1 (800) 574-2515
Provider Help Desk
1 (877) 776-1567

IA Medicaid Member ID #	Patient name	DOB
Patient address		
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). Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. 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 has had testing for hepatitis C virus (HCV) genotype; and 3) Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and 4) Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and 5) DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines and patient's weight is provided; and 6) Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. 7) 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). 8) 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) The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and 3) HCV retreatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; 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.

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.

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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)

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 patient have a limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions? ☐ Yes ☐ No

Pediatric patients:

Patient weight:_____ Date obtained: _____

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:** _____

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Treatment experienced (previous DAA)

In addition to criteria above:

Prescriber Information:

Provider Practice: Digestive Disease Liver Disease Infectious Disease Other: _____

If other, note consultation with Specialist: Consultation Date:_____

Physician Name, Phone & Specialty: _____

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 Health and Human Services, that the member continues to be eligible for Medicaid.*