



# **Alabama Medicaid Preferred Drug and Prior Authorization Program**

## **Hepatitis C Antiviral Agents Prior Authorization (PA) Criteria Instructions**

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This document contains detailed instructions on completing the Medicaid Prior Authorization Form, Form 415. When Hepatitis C Antiviral Agents are prescribed, the practitioner will be required to obtain prior authorization (PA). If approval is given to dispense the requested agent, an authorization number will be given. Hepatitis C Antiviral Agents included on this form are Daklinza™, Eplclusa®, Harvoni®, ledipasvir-sofosbuvir, Mavyret®, sofosbuvir-velpatasvir, Sovaldi®, Viekira Pak™, Vosevi®, and Zepatier®.

Preferred Hepatitis C Antiviral Agents will be considered “preferred with clinical criteria”. These agents will require a prior authorization request be submitted. Clinical criteria must be met in order to be approved. Non-preferred products will continue to require prior authorization. For a non-preferred product to be approved, contraindication to preferred agents must exist or the non-preferred agent must be prescribed for a genotype for which all preferred agents are non-FDA approved.

### **Table of Contents**

<b>Overview</b>	<a href="#"><u>Prior Authorization Request Submittal</u></a>
<b>Section 1</b>	<a href="#"><u>Hepatitis C Antiviral Agents PA Form: Patient Information</u></a>
<b>Section 2</b>	<a href="#"><u>Hepatitis C Antiviral Agents PA Form: Prescriber Information</u></a>
<b>Section 3</b>	<a href="#"><u>Hepatitis C Antiviral Agents PA Form: Drug/Clinical Information</u></a>
<b>Section 4</b>	<a href="#"><u>Hepatitis C Antiviral Agents PA Form: Dispensing Pharmacy Information</u></a>

## **Overview**

### **Hepatitis C Antiviral Agents PA Form: PA Request Submittal**

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#### **Prior Authorization Request Submittal**

##### **Electronic Prior Authorization (PA)**

Electronic Prior Authorization does not apply to Hepatitis C Antiviral Agents.

##### **Paper Requests**

Hepatitis C Antiviral Agents prior authorization requests should be submitted on PA Form 415. Once the form is completed, the paper request can be submitted via fax or mail.

##### **Online Form Submission**

Online form submission does not apply to Hepatitis C Antiviral Agents.

##### **Verbal PA Requests**

Verbal PA requests cannot be submitted for the Hepatitis C Antiviral Agents.

**Section One**  
**Hepatitis C Antiviral Agents PA Form: Patient Information**

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Below are fields to be completed on the PA Form.

<b>Form States</b>	<b>Your Response</b>
<b>Patient Name</b>	Record the patient's name as it appears on the Medicaid card.
<b>Patient Medicaid #</b>	Record patient's Medicaid number.
<b>Patient DOB</b>	Record patient's date of birth.
<b>Patient Phone # With Area Code</b>	Record the patient's phone number including area code.

## Section Two

### Hepatitis C Antiviral Agents Form: Prescriber Information

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Below are fields to be completed on the PA Form.

Form States	Your Response
<b>Prescriber Name</b>	Record the prescribing practitioner's name.
<b>NPI #</b>	Record the prescribing practitioner's NPI number.
<b>License #</b>	Record the prescribing practitioner's license number.
<b>Phone # With Area Code</b>	Record the prescribing practitioner's phone number with area code.
<b>Fax # With Area Code</b>	Record prescribing practitioner's fax number with area code.
<b>Address (optional)</b>	Prescribing practitioner's mailing address is optional
<b>Prescribing Practitioner Signature/Date</b>	The prescriber should sign and date in this section on the prescribing practitioner signature line.*

*\*By signing in the designated space, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.*

## Section Three

### Hepatitis C Antiviral Agents PA Form: Clinical Information

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Below are fields to be completed on the PA Form.

Form States	Your Response
<b>Drug Code (NDC)</b>	Enter the NDC.
<b>Quantity</b>	Enter the quantity of the drug being requested.
<b>Day's Supply</b>	Enter the day's supply for the quantity requested.
<b>Diagnosis or ICD-10 Code</b>	Record diagnosis(es) that justifies the requested drug. Diagnosis(es) <u>or</u> ICD-10 code(s) may be used. Use of ICD-10 codes provides specificity and legibility and will usually expedite review.
<b>Scheduled Start Date of Therapy</b>	Enter the date the patient will begin therapy.

#### Specific Clinical Information

**For all agents, please include the following information:**

- Indicate if the patient previously completed or started and discontinued one of the regimens for hepatitis C that is included on the form.
- Indicate if the patient is infected with HIV.
  - If yes, indicate whether the patient has been on a stable regimen of HIV medication for at least 8 weeks.
  - Include the patient's viral load and CD4 count.
- For recipients > 12 years of age, indicate if the patient has used alcohol or illicit drugs in the past 6 months. Include a copy of the patient's drug and alcohol screening laboratory report (performed at the time the requested medication is prescribed) with the PA request.
- Indicate whether the patient has been counseled on the proposed regimen to include possible side effects that may occur.
- Indicate whether the patient has been informed of Alabama Medicaid's policy to only approve 1 treatment regimen with one of the hepatitis C products included on this form per lifetime.
- Indicate if the patient has been informed that re-approvals or extensions of existing approvals will not be allowed due to patient non-compliance.
- Indicate if the patient is the recipient of an organ from a hepatitis C infected donor.

**Please include drug specific information as indicated below:**

**Daklinza™**

- Indicate the specific genotype and which treatment regimen is being requested.

**Epclusa® or sofosbuvir-velpatasvir**

- Indicate the specific genotype and which treatment regimen is being requested.

**Harvoni® or ledipasvir-sofosbuvir**

- Indicate the specific genotype and which treatment regimen is being requested.
- For patients that are treatment-naïve without cirrhosis, indicate pre-treatment HCV RNA level.

**Mavyret™**

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the patient has cirrhosis or moderate to severe hepatic impairment (Child-Pugh B-C).
- Indicate if the patient is a previous interferon/ribavirin non-responder.
- Indicate if the patient has previously been treated with an HCV protease inhibitor.

**Sovaldi®**

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the medication is indicated as monotherapy.
- Include the patients Glomerular Filtration Rate (GFR).
- Indicate if the patient is ineligible for peg-interferon therapy. If yes, include reason.
- Indicate if the patient is a previous interferon/ribavirin non-responder.
- Indicate if the patient has previously been treated with an HCV protease inhibitor.

**Viekira Pak™**

- Indicate the specific genotype and which treatment regimen is being requested.
- Indicate if the patient has decompensated liver disease or moderate to severe hepatic impairment (Child-Pugh B-C).
- Indicate if the patient has received a liver transplant and has normal hepatic function with a Metavir fibrosis score of 2 or lower.

**Vosevi®**

- Indicate the specific genotype and which treatment regimen is being requested.

- Indicate if the patient has previously been treated with an HCV protease inhibitor.

**Zepatier®**

- Indicate the specific genotype and which treatment regimen is being requested.
- For patients with NS5A polymorphism, include documentation supporting NS5A polymorphism.

**Section Four**  
**Hepatitis C Antiviral Agents PA Form: Dispensing Pharmacy**  
**Information**

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*(Information in this area may be completed by the pharmacy).*

Below are fields to be completed on the PA Form.

<b>Form States</b>	<b>Your Response</b>
<b>Dispensing Pharmacy</b>	Enter the pharmacy name.
<b>NPI #</b>	Enter the pharmacy NPI number.
<b>Phone # With Area Code</b>	Enter the pharmacy phone number with area code.
<b>Fax # With Area Code</b>	Enter the pharmacy fax number with area code.