Alabama Medicaid
Preferred Drug and Prior Authorization Program

Hepatitis C Antiviral Agents Prior Authorization (PA) Criteria Instructions

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™, Epclusa®, 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.

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Overview
Hepatitis C Antiviral Agents PA Form: PA Request Submittal

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

Below are fields to be completed on the PA Form.

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

Section Two
Hepatitis C Antiviral Agents Form: Prescriber Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Prescriber Name	Record the prescribing practitioner's name.
NPI #	Record the prescribing practitioner's NPI number.
License #	Record the prescribing practitioner's license number.
Phone # With Area Code	Record the prescribing practitioner's phone number with area code.
Fax # With Area Code	Record prescribing practitioner's fax number with area code.
Address (optional)	Prescribing practitioner's mailing address is optional
Prescribing Practitioner Signature/Date	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

Below are fields to be completed on the PA Form.

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

Specific Clinical Information

For all agents, please include the following information:

- Indicate if the patient previously competed 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.
- 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.
- Include the patients Glomerular Filtration Rate (GFR).

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

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

Below are fields to be completed on the PA Form.

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