MISSISSIPPI DIVISION OF MEDICAID

# STANDARDIZED ONE PAGE PHARMACY PRIOR AUTHORIZATION FORM

**Mississippi Division of Medicaid,** Pharmacy Prior Authorization Unit, Gainwell Technologies, PO Box 2480, Ridgeland, MS 39158

**Medicaid Fee for Service/MSCAN/MSCHIP Members**
Gainwell Technologies
**Fax to: 1-866-644-6147** Ph: 1-833-660-2402
Pharmacy Prior Authorization - Mississippi Division of Medicaid (ms.gov)

**Submit your PA requests via the MESA (Medicaid Enterprise System Assistance) provider portal for the most efficient processing**
Mississippi Medical Assistance Portal for Providers > Home (ms-medicaid-mesa.com)

| **BENEFICIARY INFORMATION** | |
|---|---|
| **Beneficiary ID: ____ ____ ____ - ____ ____ ____ - ____ ____ ____** | **DOB:____ ____ /____ ____ /____ ____ ____ ____** |
| **Beneficiary Full Name:** | |
| **PRESCRIBER INFORMATION** | |
| **Prescriber's NPI:** | |
| **Prescriber's Full Name:** | **Phone:** |
| **Prescriber's Address:** | **FAX:** |
| **PHARMACY INFORMATION** | |
| **Pharmacy NPI:** | |
| **Pharmacy Name:** | |
| **Pharmacy Phone:** | **Pharmacy FAX:** |

**CLINICAL INFORMATION**

**Requested PA Start Date:_____ Requested PA End Date:_____**

**Drug/Product Requested:_____ Strength:_____ Quantity:_____**

**Days Supply:_____ RX Refills:_____ Diagnosis or ICD-10 Code(s):_____**

☐ **Hospital Discharge** ☐ **Additional Medical Justification Attached**

Medications received through coupons and/or samples are not acceptable as justification.

**PLEASE COMPLETE AND FAX DRUG SPECIFIC CRITERIA/ADDITIONAL DOCUMENTATION FORM FOUND BELOW**

***Prescribing provider's signature (signature and date stamps, or the signature of anyone other than the provider, are not acceptable)***

I certify that all information provided is accurate and appropriately documented in the patient's medical chart.

**Signature required: _____ Date: _____**

**Printed name of prescribing provider:_____**

# FAX THIS PAGE

# PRIOR AUTHORIZATION DESCRIPTION

- ***Note annotations and respective definitions as described on "*Hepatitis C Therapy PA Request Guidelines for Regimen Selection and Definitions" page**

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## Hepatitis C Therapy PA Request
## Guidelines for Regimen Selection and Definitions

For beneficiaries meeting the criteria, the Mississippi Division of Medicaid (DOM) will approve Hepatitis C treatment PA requests as follows:

- The regimens listed for each clinical scenario below are the preferred regimens for MS Medicaid beneficiaries, based on clinical and cost considerations and are consistent with AASLD/IDSA guidelines. http://www.hcvguidelines.org/full-report-view

- **Most patients will qualify for the Simplified Treatment outlined as follows.** Information about simplified treatment at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment .

| **WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT*** | **WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT** |
|---|---|
| Adults (18+ years of age) with chronic hepatitis C (any genotype) who **(please check appropriate boxes)**:<br>☐ Do NOT have cirrhosis by lab or clinical exam<br>☐ Have NOT been treated in the past<br>☐ Are NOT pregnant<br>☐ Are Hepatitis B Surface Antigen negative<br>☐ NO known or suspected hepatocellular carcinoma<br>☐ NO prior liver transplantation<br><br>*N.B. While not required for authorization, additional labs are recommended in the HCV guideline (link above). If a member qualifies for a simplified treatment regimen, the only information required are the Standardized One Page Pharmacy Prior Authorization Form (the first page of this document) as well as this form attesting that the member meets the criteria above by checking the boxes. | • Prior hepatitis C treatment<br>• Cirrhosis<br>• Hepatitis B Surface Antigen positive<br>• Current pregnancy<br>• Known or suspected hepatocellular carcinoma<br>• Prior liver transplantation<br>**IF NOT ELIGIBLE, SEE OPTIONS ON FOLLOWING PAGES AND PLEASE SUBMIT THE REQUIRED ADDITIONAL DOCUMENTATION.** |

**Preferred Simplified Treatment Regimens (check one)**

☐ Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks)

☐ sofosbuvir/velpatasvir 400/100 mg daily for 84 days (12 weeks)

**OR**

- **Pediatric formulations of direct acting antivirals (DAA) with FDA approval will be approved for those patients under the age of eighteen when used according to the table below for treatment naïve children as well as in accordance with current AASLD guidelines including for indication and age - Prior authorization is still required prior to the first dose.**

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| GT | Age (years) | Weight (kg) | Drug | Dose | Weeks |
|---|---|---|---|---|---|
| Any | ≥ 3 to 11 | < 20 | Mavyret Oral Pellets | Three 50 mg/20 mg packets daily | 8+ |
| | | 20 - <30 | Mavyret Oral Pellets | Four 50 mg/20 mg packets daily | 8+ |
| | | 30 - < 45 | Mavyret Oral Pellets | Five 50 mg/20 mg packets daily | 8+ |
| | | 45+ | Mavyret Tablets | Three 100/40 mg tablets daily | 8+ |
| | 12+ | | Mavyret Tablets | Three 100/40 mg tablets daily | 8+ |
| | ≥ 3 | < 17 | Epclusa pellets | One 150/37.5 mg packet daily | 12 |
| | | 17- < 30 | Epclusa pellets or tablets | One 200/50 mg packet or tablet daily | 12 |
| | | ≥ 30 | sofosbuvir/velpatasvir tablet | One 400/100 mg tablet daily | 12 |
| GT 1, 4, 5, or 6 | ≥ 3 | < 17 | Harvoni pellet pack | One 33.75 mg/150 mg pack daily | 12 |
| | | 17- < 35 | Harvoni pellet pack or tablet (both 45 mg/200 mg) | One 45 mg/200 mg pellet pack or tablet | 12 |

**+ A longer duration of therapy may be needed for GT 3 interferon experienced patients (i.e. 16 weeks)**

**Preferred Pediatric Treatment Regimens (check one)**

- ☐ Mavyret (glecaprevir/pibrentasvir) pellets or tablets
- ☐ sofosbuvir/velpatasvir 400/100 mg tablets

**OR**

- *Clinical rationale is provided for using a regimen that is beyond those within the current guidelines, or for selecting regimens using non-preferred drugs on the Mississippi Division of Medicaid Universal Preferred Drug List*

On the PA Request Form, which must be approved prior to the 1st dose, document the clinical condition supporting the requested regimen. Unless otherwise specified, you do not need to attach documentation to the form. You are attesting to the fact that documentation is available in the patient chart for all information you provide.

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**DEFINITIONS/ANNOTATIONS USED ON PA FORM:**

∇ **Low Dose Ribavirin = 600 mg/day and increase as tolerated**

◊ **Ribavirin-Ineligible** (documentation exists in the patient's chart for at least one of the following):

- Hypersensitivity to RBV
- History of severe or unstable cardiac disease
- Pregnant women and men with pregnant partners
- Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- Baseline platelet count < 70,000 cells/mm3
- ANC < 1500 cells/mm3
- Hb < 12 gm/ml in women or <13 g/dl in men

**RENAL DYSFUNCTION** Patients with CrCl <50 ml/mm should not be treated with ribavirin

**Preferred Direct Acting Antivirals**

Mavyret (glecaprevir/pibrentasvir) 300/120 mg
sofosbuvir/velpatasvir 400/100 mg

**Non-Preferred Direct Acting Antivirals**

Harvoni (ledipasvir/sofosbuvir) 90/400 mg
Sovaldi (sofosbuvir) 400 mg
ledipasvir/sofosbuvir 90/400 mg
Epclusa 200/50 mg tablet
Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)
Epclusa (sofosbuvir/velpatasvir) 400/100 mg
Harvoni (ledipasvir/sofosbuvir) 45/200 mg tablet
Harvoni (ledipasvir/sofosbuvir) 90/400 mg tablet
Harvoni 33.75/150 mg pellet pack
Harvoni 45/200 mg pellet pack
Sovaldi (sofosbuvir) 200 mg

**Preferred Pediatric Indicated Direct Acting Antiretrovirals (FDA approved age ranges indications ONLY)**

Mavyret (glecaprevir/pibrentasvir) 400/100 mg
Mavyret Oral Pellets (glecaprevir/pibrentasvir) 50/20mg
sofosbuvir/velpatasvir 400/100 mg

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**Preferred (most cost-effective) Regimens Listed Below. *Not all available regimens are listed.***

**NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted in red**

## PLEASE CHECK REQUESTED REGIMEN

**ADULT: Treatment naïve**

**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, GT 1, 2, 3, 5, 6 HIV negative or positive, GT 4 HIV negative only**

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks
- ❑ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

**Compensated cirrhosis, GT 4, HIV positive**

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- ❑ sofosbuvir/velpatasvir 400/100 mg, 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 (Epclusa, Sovaldi, Harvoni only) GT 1, 2, 4, 5, 6 only**

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 16 weeks

**NS3/4 protease inhibitor inclusive regimen - 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 with compensated cirrhosis: sofosbuvir/NS5A (e.g. Harvoni, Epclusa)**

- ❑ 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 and experienced, with or without compensated cirrhosis**

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

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| **ADULT: Decompensated Cirrhosis** |
|---|
| **No prior sofosbuvir or NS5A failure**<br>❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)<br>❑ 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**<br>❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C) |
| **Other Treatment Regimen requested** |
| **Genotype, treatment history, and extent of liver disease:**<br>_____<br>_____<br>**Drug names, doses and durations:**_____<br>_____<br>**Clinical rationale for selecting regimens other than those outlined above:**<br>_____<br>_____ |

**For unique patient populations with renal impairment:** please refer to the current AASLD Guidelines for recommended treatments. http://www.hcvguidelines.org/full-report-view

**If HIV positive:** Please refer to the current AASLD Guidelines for potential drug interactions and recommended dosing adjustments.

**DRUG INTERACTIONS**

Reference: http://hep-druginteractions.org/ provides clinically useful, reliable, and current evidence-based information on relevant drug interactions with hepatitis medications.

# CRITERIA/ADDITIONAL DOCUMENTATION

# HEPATITIS C *FAX THIS PAGE*

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| BENEFICIARY INFORMATION | |
|---|---|
| **Beneficiary ID:**____ ____ ____ - ____ ____ ____ - ____ ____ ____ | **DOB:**____ ____ /____ ____ /____ ____ ____ ____ |
| **Beneficiary Full Name:** | |

**Hepatitis C Therapy PA Request** ****Documentation listed below required for patients not eligible for simplified treatment regimen.**

**Diagnosis / Treatment Status** ***(check all that apply)*** ***See Hepatitis-C PA description sheet for approval criteria and intolerance definitions.**

□ For regimens other than Simplified Treatment, prescriber is, or has consulted with a gastroenterologist, hepatologist, ID specialist or other hepatic specialist. Requires consult within the past year with documentation of recommended regimen.

□ Active HCV infection verified by viral load within the last year: HCV RNA: _____ million IU/mL Date:_____

Genotype verified by lab: □ 1a □ 1b □ 2 □ 3 □ 4 □ 5 □ 6

HIV status: □ positive □ negative (required)

□ If HIV positive, drug interactions have been checked http://hep-druginteractions.org/ provides current evidence-based information on relevant drug interactions with hepatitis medications.

□ Patient has not taken amiodarone within 535 days (required if regimen includes Harvoni or Sovaldi)

□ RBV-Ineligible reason◊: _____

_____

Hepatic fibrosis stage _____

Last stage evaluation date: _____

Method of cirrhosis/fibrosis stage:_____

□ Decompensated cirrhosis

□ Compensated cirrhosis Child-Pugh Score and Date: _____

□ Post-liver transplant Date:

□ Hepatocellular carcinoma and awaiting a liver transplant:

Transplant date: _____

□ Not yet scheduled

□ Dialysis __Yes/____No

□ CrCl ____ mL/min Lab Date w/n last year:_____

□ Screened for HEP-B and HIV prior to HEP-C treatment start

- Date of last test: Hep B:____/__/____ HIV:___/__/____
  - Timing of the screening for Hep-B/HIV should be based on patient specific risk factors but lab result date must be provided and if > 1 year ago, it should be documented in the record as to why repeat testing is not clinically warranted**. If the patient has had ongoing risk factors of any type, consider retesting in the month prior to HCV therapy. If positive, treatment must be considered per AASLD/IDSA and current NIH HIV guidelines.**
  - Repeat screening should be patient specific.

Patient is: □ Treatment naïve □ Relapser

If Relapser, then prior HCV Treatment: last two regimens, if any

Regimen 1: _____ Dates/duration of use: _____ Response: _____

Regimen 2: _____ Dates/duration of use: _____ Response: _____

□ Stopped prior therapy for other reason: _____

Regimen: _____ Dates/duration of use: _____ Response: _____

**Social History** ***(check all that apply)***

□ Patient is ≥ **18** years of age **OR** meets current AASLD guidelines for treatment

**Documentation (available if requested) of:**

□ Counseling regarding abstinence from alcohol, IV drug use and education on how to prevent HCV transmission.

**For women of childbearing potential and male patients with female partners of childbearing potential** ***(for RBV regimens only)*****:**

□ Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping treatment.

□ Agreement that partners will use 2 forms of effective contraception during treatment and for at least 6 months after stopping tx.

□ Verification that monthly pregnancy tests will be performed throughout treatment.

**Other Medications (OTC, Herbal and Prescription) Information**

| Drug name / strength | Frequency / instructions | Quantity | Refills |
|---|---|---|---|
| | | | |
| | | | |