STANDARDIZED ONE PAGE PHARMACY PRIOR AUTHORIZATION FORM

Mississippi Division of Medicaid, Pharmacy Prior Authorization Unit,
550 High St., Suite 1000, Jackson, MS 39201

☐ Medicaid Fee for Service/Change Healthcare
Fax to: 1-877-537-0720 Ph: 1-877-537-0722
https://medicaid.ms.gov/providers/pharmacy/pharmacy-prior-authorization/

☐ Magnolia Health/Envolve Pharmacy Solutions
Fax to: 1-866-399-0929 Ph: 1-866-399-0928
https://www.magnoliahealthplan.com/providers/pharmacy.html

☐ UnitedHealthcare/OptumRx
Fax to: 1-866-940-7328 Ph: 1-800-310-6826
http://www.uhccommunityplan.com/health-professionals/ms/pharmacy-program.html

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:_____

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PRIOR AUTHORIZATION DESCRIPTION

MISSISSIPPI DIVISION OF MEDICAID

Hepatitis C Therapy PA Request
Guidelines for Regimen Selection and Definitions

The Mississippi Division of Medicaid (DOM) will approve Hepatitis C treatment PA requests for members who meet the following criteria:

- Requested regimen is compliant with latest American Association for The Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (ISDA) Recommendations for Testing, Managing, and Treating Hepatitis C *(* http://www.hcvguidelines.org/full-report-view)
  AND
  The regimens listed under each genotype and clinical scenario below are the preferred regimens for MS Medicaid beneficiaries, based on clinical and cost considerations and are consistent with AASLD/IDSA guidelines.
- **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.

DEFINITIONS USED ON PA FORM:

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.
Patients with CrCl <30 ml/min should not be treated with sofosbuvir containing regimens (including Harvoni/Epclusa).

Preferred Direct Acting Antivirals

Harvoni (ledipasvir/sofosbuvir) 90/400 mg
Sovaldi (sofosbuvir) 400 mg
Technivie (ombitasvir/paritaprevir, ritonavir) 12.5/75/50 mg
Viekira Pak (ombitasvir/paritaprevir/ritonavir) 12.5/75/50mg + (dasabuvir) 250mg
Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir) 200/8.33/50/33.33 mg
Zepatier (elbasvir/grazoprevir) 50/100 mg
Epclusa (sofosbuvir/velpatasvir) 400/100 mg

Non-Preferred Direct Acting Antivirals

Daklinza (daclatasvir) 60 mg
Olysio (simeprevir) 150 mg

Preferred Regimens Listed Below

PRIOR AUTHORIZATION DESCRIPTION

MISSISSIPPI DIVISION OF MEDICAID

Genotype 1 (Note the subtype is only indicated when treatment is different for subtypes)

Treatment naïve, no cirrhosis

- ☐ 1a/1b Harvoni - one tablet daily for 8 weeks (viral load < 6 million copies AND HIV negative only)
- ☐ 1a/1b Harvoni- one tablet daily for 12 weeks
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 12 weeks
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks
- ☐ 1a: Zepatier- one tablet daily for 12 weeks in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks

Treatment naïve, compensated cirrhosis

- ☐ Harvoni- one tablet daily for 12 weeks
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)-two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 24 weeks (Child-Pugh (CP) Class A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (CP-A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1a: Zepatier- one tablet daily for 12 weeks in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks

Treatment experienced, no cirrhosis (drugs that patient has had experience with listed in parentheses)

- ☐ Harvoni- one tablet daily for 12 weeks (PEG-IFN/RBV OR PEG-IFN/RBV + PI)
- ☐ 1a: Viekira Pak- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg)-BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based ribavirin for 12 weeks (PEG-IFN/RBV)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (PEG-IFN/RBV)
- ☐ Harvoni- one tablet daily plus weight-based RBV for 12 weeks (Sovaldi plus ribavirin WITH or WITHOUT PEG-IFN)

Note: If prior treatment with NS5A such as daclatasvir with sofosbuvir, ledipasvir/sofosbuvir or ombitasvir, paritaprevir, ritonavir and dasabuvir or simeprevir with sofosbuvir), recommendation is to defer treatment pending more data

- ☐ 1a: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV) in patients without baseline NS5A polymorphisms
- ☐ 1a: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir) in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV)
- ☐ 1b: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir)

PRIOR AUTHORIZATION DESCRIPTION

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Continued-–Genotype 1 (Note the subtype is only indicated when treatment is different for subtypes)

Treatment experienced, cirrhosis (drugs that patient has had experience with listed in parentheses)

- ☐ Harvoni- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN/RBV OR PEG-IFN/RBV+PI – NOT FOR Olysio/Sovaldi experienced)
- ☐ Harvoni- one tablet daily for 24 weeks (PEG-IFN/RBV OR PEG-IFN/RBV+PI ONLY if documented ineligible for RBV)
- ☐ Harvoni- one tablet daily + weight based RBV for 24 weeks (Sovaldi/RBV +/-PEG-IFN)
- ☐ 1a: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets AM and dasabuvir (250 mg)- BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) plus weight-based RBV for 24 weeks (PEG-IFN/RBV) (CP-A ONLY, contraindicated for CP-B or CP-C)
- ☐ 1b: Viekira Pak-(ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM and dasabuvir (250 mg) BID or Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir 200/8.33/50/33.33 mg three tablets once daily) for 12 weeks (PEG-IFN/RBV) (CP-A ONLY, contraindicated for CP-B or CP-C)

Note: If prior treatment with daclatasvir with sofosbuvir, ledipasvir/sofosbuvir, simeprevir/sofosbuvir or ombitasvir, paritaprevir, ritonavir and dasabuvir and in urgent need of treatment, recommendation is to test for resistance associated variants and treat with RBV containing regimen for 24 weeks.

- ☐ 1a: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV) in patients without baseline NS5A polymorphisms
- ☐ 1a: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir) in patients without baseline NS5A polymorphisms
- ☐ 1b: Zepatier- one tablet daily for 12 weeks (PEG-IFN+RBV)
- ☐ 1b: Zepatier- one tablet daily plus weight-based RBV for 12 weeks (PEG-IFN + RBV + HCV NS3/4A PI: boceprevir, simeprevir, or telaprevir)

Genotype 2

Treatment naïve, no cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment naïve, compensated cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment experienced (PEG-IFN + ribavirin), with or without cirrhosis

- ☐ Epclusa-one tablet daily for 12 weeks

Treatment experienced (sofosbuvir + ribavirin)

- ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks
- ☐ Daklinza-one tablet daily + Sovaldi-one tablet daily for 24 weeks (ONLY if RBV ineligible: document on PA form)

Decompensated cirrhosis

- ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks

Re-infection of allograft liver after transplant, no or compensated cirrhosis

- ☐ Daklinza- one tablet daily plus Sovaldi- one tablet daily + low dose RBV for 12 weeks
- ☐ Daklinza- one tablet daily plus Sovaldi- one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form)

Re-infection of allograft liver after transplant, decompensated cirrhosis

- ☐ Sovaldi-one tablet daily + low initial dose RBV for 24 weeks

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Genotype 3
Treatment naïve, with or without cirrhosis ☐ Epclusa-one tablet daily 12 weeks
Treatment experienced (PEG-IFN + ribavirin), no cirrhosis ☐ Epclusa- one tablet daily for 12 weeks
Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis ☐ Epclusa-one tablet daily plus weight-based RBV for 12 weeks
Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis ☐ Epclusa-one tablet daily plus weight-based RBV for 12 weeks
Decompensated cirrhosis ☐ Epclusa-one tablet daily + weight-based ribavirin for 12 weeks
Re-infection of allograft liver after transplant, no or compensated cirrhosis ☐ Daklinza-one tablet daily plus Sovaldi- one tablet daily + low dose RBV for 12 weeks ☐ Daklinza-one tablet daily plus Sovaldi- one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form)
Genotype 4
Treatment naïve, no cirrhosis ☐ Harvoni-one tablet daily for 12 weeks ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks ☐ Zepatier- one tablet daily for 12 weeks
Treatment naïve, compensated cirrhosis ☐ Harvoni- one tablet daily for 12 weeks ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks ☐ Zepatier -one tablet daily for 12 weeks
Treatment experienced (PEG-IFN + ribavirin), no cirrhosis ☐ Harvoni- one tablet daily for 12 weeks ☐ Technivie- (ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg)- two tablets q AM, plus weight-based RBV for 12 weeks ☐ Zepatier -one tablet daily for 12 weeks (virologic relapse after PEG-IFN + RBV) ☐ Zepatier -one tablet daily plus weight-based RBV for 16 weeks (PEG-IFN+RBV on treatment virologic failure (failure to suppress or breakthrough)
Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis ☐ Harvoni one tablet daily + weight-based ribavirin for 12 weeks ☐ Technivie- two tablets q AM, plus weight-based RBV for 12 weeks ☐ Zepatier- one tablet daily for 12 weeks (virologic relapse after PEG-IFN + RBV) ☐ Zepatier- one tablet daily plus weight-based RBV for 16 weeks [(PEG-IFN + RBV on treatment virologic failure (failure to suppress or breakthrough)]
Decompensated cirrhosis ☐ Harvoni - one tablet daily + low initial dose ribavirin for 12 weeks ☐ Harvoni - one tablet daily for 24 weeks (ONLY if RBV ineligible – document on PA form) ☐ Harvoni – one tablet daily plus low initial dose ribavirin for 24 weeks (prior treatment with sofosbuvir only)

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MISSISSIPPI DIVISION OF MEDICAID

Genotype 5 and 6
Regardless of prior treatment or cirrhosis ☐ Harvoni - one tablet for 12 weeks (PEG-IFN/RBV failure)
Other treatment regimen
Genotype _____ Treatment history, and extent of liver disease: _____ _____ _____ Drug name, dose and duration: _____ _____ Clinical rationale for selecting regimens other than those outlined above: _____ _____ _____
Abbreviations: ***PEG-IFN*** *= peginterferon;* ***RBV*** *= ribavirin;* ***PI*** *= protease inhibitor*

For unique patient populations with decompensated cirrhosis, post-liver transplant, renal impairment, or HIV: 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, current, evidence-based information on relevant drug interactions with hepatitis medications

CRITERIA/ADDITIONAL DOCUMENTATION
HEPATITIS C

MISSISSIPPI DIVISION OF MEDICAID

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

Hepatitis C Therapy PA Request

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

□ 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

Patient is:
- □ Treatment naïve □ Relapser
- □ Prior partial responder □ Prior null responder
- □ Stopped prior therapy for other reason: _____

HIV status: □ positive □ negative □ unknown

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

□ RBV-Ineligible* *Ineligibility reason: _____

Hepatic fibrosis stage ___ Last stage evaluation date: _____Method of cirrhosis/fibrosis stage:_____

□ Decompensated cirrhosis

□ Compensated cirrhosis Child-Pugh Score: _____

□ Post-liver transplant

□ 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
- ➢ Repeat screening should be patient specific

Treatment considered per AASLD/IDSA guidelines

Prior HCV Treatment: last two regimens, if any

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

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

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

□ Patient is **18** years old or older **OR** Patient is **12** years old or older on Harvoni or Sovaldi

Documentation (available if requested) of:

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

□ Abstinence from drugs and alcohol for at least 6 months; negative urine drug screen required if there is IV drug use history.

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 two forms of effective contraception during treatment and for at least 6 months after stopping treatment.

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

Regimen Requested* ***See Hepatitis-C PA instruction sheet below for drug regimens and intolerance definitions.**

Regimens using preferred drugs:

□ Harvoni	for _____ weeks	□ Viekira Pak + RBV or Viekira XR + RBV	for _____weeks
□ Harvoni + RBV	for _____ weeks	□ Viekira Pak or Viekira XR	for _____weeks
□ Sovaldi + RBV	for _____ weeks	□ Technivie + RBV	for _____ weeks
□ Epclusa	for _____ weeks	□ Zepatier	for _____ weeks
□ Epclusa + RBV	for _____ weeks	□ Zepatier + RBV	for _____ weeks

□ OTHER drugs/treatment duration: _____

Please provide clinical rationale for choosing a regimen beyond current guidelines guidance, or for selecting regimens using non-preferred drugs.

Prescription Information

Drug name / strength	Frequency / instructions	Quantity	Refills

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