John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

MEMORANDUM

DATE: September 21, 2017

TO: All Louisiana Medicaid Fee for Service (FFS) Providers

FROM: Jen Steele, Medicaid Director

SUBJECT: Clinical Pre-Authorization for Glecaprevir/Pibrentasvir (Mavyret™)

Effective September 29, 2017, the Fee for Service (FFS) Louisiana Medicaid Pharmacy Program in conjunction with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established clinical pre-authorization criteria for Glecaprevir/Pibrentasvir (Mavyret™).

Pharmacy claims for Glecaprevir/Pibrentasvir (Mavyret™) will be reimbursed at Point of Sale (POS) when the prescriber has obtained an approved clinical pre-authorization. Prescribers must complete the Pharmacy Clinical Pre-Authorization Form, the Direct-Acting Antiviral (DAA) Agents Medication Therapy Worksheet, and the DAA Agents Treatment Agreement Form in full and fax to 1-866-797-2329. See forms following this document or refer to www.lamedicaid.com.

When clinical pre-authorization has not been obtained, pharmacy claims for Glecaprevir/Pibrentasvir (Mavyret™) will deny at Point of Sale (POS) with:

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 066 (Clinical Pre-Authorization Required)

Override provisions should be addressed through the Clinical Pre-Authorization process.

See updated Direct-Acting Antiviral (DAA) Agents criteria:
http://www.lamedicaid.com/provweb1/Pharmacy/rxpa/PA_HepC_Agents.pdf

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

If you have questions about the contents of this memo, you may contact the Pharmacy Help Desk at (800) 437-9101 or refer to www.lamedicaid.com.

JS/MBW/BMW

c: Healthy Louisiana Plans
Melwyn B. Wendt
Molina

Louisiana Medicaid
Pharmacy Clinical Pre-Authorization Form

Fax or Mail this form to:
1-866-797-2329
La Medicaid RxPA Operations
ULM School of Pharmacy
1800 Bienville Drive
Monroe, LA 71201-3765

Revised Date: 2/12/2015

MEMBER INFORMATION

Patient Name: Last Name	First Name	MI	
Date of Birth:	**Sex:** ☐ Male ☐ Female	**Height:**	**Weight:**
Address:	City	State	Zip Code
Phone #:	**Medicaid Recipient ID#: (required)**	**Plan Policy ID#: (optional)**	

PRESCRIBING PRACTITIONER INFORMATION

Practice Name:	**Specialty:**	**NPI # (2):**	
Prescribing Practitioner Name:	**Medicaid Provider ID #: (required)**	**NPI # (1):**	**DEA/License #:**
Address:	City	State	Zip Code
Phone #:	**Fax #:**	**Office Contact:**	**EPSDT Support Coordinator (Name / Address): (optional)**

MEDICATION INFORMATION

Drug Name:		**Dosage Form:**	**Quantity:**
Strength:	**Directions:**		
Dispense as Written: ☐ Yes ☐ No	**Substitutes Permitted:** ☐ Yes ☐ No		**Number of Refills:**
Currently on This Medication: ☐ Yes ☐ No	**Other Medications Tried toTreat This Condition:**		**Dates:**
List Other Current Medications: ☐ *See attached list*			
Reasons for Discontinuation of Tried Therapies:			
Diagnosis/Indication:			**ICD Diagnosis Code:**
Rationale and/or Other Information Relevant (☐ *included* lab results) to the Review of This Authorization Request: **Drug Allergies:**			

PHARMACY INFORMATION (Optional)

Pharmacy Name:	**Phone #:**	**Fax #:**

Prescribing Practitioner Signature: _____ **Date:** _____

For more information, refer to www.lamedicaid.com and follow the "Pharmacy and Prescribing Providers" link.

Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV)
Medication Therapy Worksheet for Louisiana Fee for Service Medicaid Recipients

Note: This worksheet must be completed in full and submitted with supporting documentation where applicable. [See DAA Clinical Pre-Authorization Criteria]

Recipient Name:	Medicaid Recipient ID #:	Recipient DOB:	Recipient weight:
Prescriber Name:	Prescriber Specialty:	Medicaid Provider ID #:	Office Contact:

Medication regimen requested *[Choose one.]*

☐ Daclatasvir / Sofosbuvir (Daklinza™/ Sovaldi®)
☐ Elbasvir / Grazoprevir (Zepatier®)
☐ Ledipasvir / Sofosbuvir (Harvoni®)
☐ Simeprevir (Olysio®)
☐ Ombitasvir / Paritaprevir / Ritonavir (Technivie™)
☐ Simeprevir / Sofosbuvir (Olysio® / Sovaldi®)
☐ Ombitasvir / Paritaprevir / Ritonavir with Dasabuvir (Viekira Pak™)
☐ Sofosbuvir / Velpatasvir (Epclusa®)
☐ Ombitasvir / Paritaprevir / Ritonavir / Dasabuvir (Viekira XR™)
☐ Sofosbuvir (Sovaldi®)
☐ Glecaprevir / Pibrentasvir (Mavyret™)

Will patient's therapy include peginterferon? ☐ Yes ☐ No Will patient's therapy include ribavirin? ☐ Yes ☐ No

If the request is for a non-preferred regimen, is there clinical justification as to why one of the preferred products cannot be used?
☐ Yes ☐ No If yes, explain._____
(Use additional sheet as necessary)

Indicate reason for request (Choose all that apply) :
☐ Chronic Hepatitis C Virus (HCV) ☐ CHC with hepatocellular carcinoma awaiting transplant Co-infection ☐HCV/HIV and/or ☐HCV/HBV

Indicate HCV Genotype _____If Genotype 1, please indicate subtype. ☐ 1a ☐ 1b

If the patient has HCV Genotype 1a and request is for:
- simeprevir (Olysio®), does the patient have the Q80K polymorphism? ☐Yes ☐ No
- elbasvir/grazoprevir (Zepatier®), does the patient have NS5A resistance-associated polymorphisms? ☐Yes ☐ No

Is patient treatment-naïve? ☐ Yes ☐ No If no, provide previous HCV therapy:_____

Was previous therapy completed? ☐ Yes ☐ No If no, provide reason for discontinuation._____

What is the patient's baseline HCV RNA viral load? _____ IU/ml _____Date measured

What is the patient's estimated glomerular filtration rate (eGFR) or creatinine clearance (CrCl)? _____ ml/min_____ Date measured

Does the patient have end stage renal disease (ESRD) requiring dialysis? ☐Yes ☐ No

What are the patient's liver enzyme levels (ALT/AST)? ALT_____U/L _____Date measured
AST_____U/L _____Date measured

What is the patient's platelet count? _____µL _____ Date measured

Has the patient had a solid organ transplant, not including liver? ☐ Yes ☐ No

Does the patient have a short life expectancy (less than 12 months) owing to comorbid conditions? ☐ Yes ☐ No

Does the patient have a diagnosis of advanced fibrosis? ☐ Yes ☐ No

If yes, choose the following indicator(s) supporting this diagnosis: *[Choose all that apply and provide documentation of the results.]*
_____Liver biopsy or Fibrosure® results indicating Metavir score 3 or Ishak stage 4 or 5
_____AST to Platelet Ratio Index (APRI) >1.5 and ≤ 2
_____Fibroscan® value of ≥9.5 and < 12.5 kilopascals.

Does the patient have a diagnosis of cirrhosis? ☐ Yes ☐ No

If yes, choose the following indicator(s) supporting this diagnosis: *[Choose all that apply and provide documentation of the results.]*
_____Liver biopsy or Fibrosure® results indicating Metavir score 4 or Ishak stage 6
_____AST to Platelet Ratio Index (APRI) >2
_____Platelet count less than 140,000-150,000/mm^3 in the absence of other factors that affect platelet count
_____Fibroscan® value of ≥12.5 kilopascals
_____Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or* ascites.)

Does the patient have decompensated liver disease? ☐ Yes ☐ No

If cirrhotic, what is the patient's Child-Turcotte-Pugh (CTP) Class? ☐ Class A ☐ Class B ☐ Class C

Does the patient have significant extrahepatic disease manifestations caused by HCV? ☐ Yes ☐ No If yes, please list:_____

Does the patient have a history of any of the following: (check all that apply and provide supporting documentation)

☐	Platelet count <75000 / mm^3
☐	Decompensated liver cirrhosis
☐	Severe mental health conditions that may be exacerbated by interferon therapy or respond poorly to medical therapy
☐	Autoimmune diseases that may be exacerbated by interferon-mediated immune modulation (such as autoimmune hepatitis)
☐	Inability to complete a prior treatment course of interferon due to documented interferon-related adverse effects and/or hypersensitivities

☐	Pregnancy in female patients or pregnancy in female sexual partners of male patients
☐	Unwillingness to comply with two forms of effective contraception
☐	History of significant or unstable cardiac disease
☐	Creatinine clearance < 50ml/min
☐	Hemoglobinopathy (such as thalassemia major and sickle cell anemia)
☐	Current therapy with didanosine
☐	Inability to complete prior treatment course of ribavirin due to documented ribavirin-related adverse effects

Has the prescribing physician and/or the physician's agent accessed the Louisiana Prescription Monitoring Program (PMP) to evaluate and review controlled substance use? ☐ Yes ☐ No

Has the patient been free from alcohol and substance abuse during the past 12 months? ☐ Yes ☐ No

Please provide laboratory results of urine drug screen and blood alcohol level taken within 30 days of the beginning of treatment.

CURRENT MEDICATION LIST (Attach additional sheet as necessary)

Drug	Dosage form	Strength	Directions	Start Date/End Date

By signing below, the prescribing physician attests that he/she will provide all necessary labs, including but not limited to genotype and blood alcohol/urine drug screen, and will review medication therapy for medication-related issues.

Physician Signature:* _____ **Date:**_____

**(Signature stamps and proxy signatures are not acceptable.)*

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Louisiana Medicaid Direct-Acting Antiviral (DAA) Agents for Hepatitis C Virus (HCV) Treatment Agreement

Prescriber Instructions: Please submit the completed treatment agreement with the initial clinical pre-authorization request for the Direct-Acting Antiviral Agent(s) (DAA) for Hepatitis C.

Patient Information	Prescriber Information	
Recipient Name:	Prescriber Name:	
Medicaid Recipient ID #:	Medicaid Provider ID # or NPI:	
Date of Birth:	Office Contact:	
Hepatitis C Medication Regimen:	Provider Phone Number:	Provider Fax Number:

	Patient Instructions: Please read this treatment agreement carefully. Please initial each item to show you have read and understand it. Be sure to ask any questions you have before you sign it. Sign and date at the bottom of the form.	Patient's Initials
1.	I have been told how to take my hepatitis C medicines. I understand how to take them. I am aware of possible side effects. I understand why it is important to finish all the therapy.	
2.	I will take my hepatitis C medicines like my doctor said. I will not miss doses.	
3.	I understand that if I miss doses, Medicaid may no longer pay for my hepatitis C medicines.	
4.	I will tell my doctor and pharmacist the medicines I take. I understand there may be some medicines I cannot take with my heptatitis C medicines.	
5.	I understand that Medicaid may only pay for hepatitis C medicines for a certain number of weeks over my lifetime. For example:	

Medicines	How many weeks will Medicaid pay?	Treatment weeks based on one or more of the following:
Daklinza® / Sovaldi®	No more than 12 straight weeks (84 straight days)	• the amount of hepatitis C virus in my blood while on my hepatitis C medicine; AND/OR • the hepatitis genotype that I have; AND/OR • if I have cirrhosis or not; AND/OR • if I have taken a hepatitis c medication in the past; AND/OR • if I have liver cancer and I'm waiting on a liver transplant
Harvoni®	No more than 24 straight weeks (168 straight days)	
Zepatier®	No more than 16 straight weeks (112 straight days)	
Technivie®	No more than 12 straight weeks (84 straight days)	
Viekira Pak® OR Viekira XR®	No more than 24 straight weeks (168 straight days)	
Olysio®	No more than 12 straight weeks (84 straight days)	
Olysio® / Sovaldi®	No more than 24 straight weeks (168 straight days)	
Sovaldi®	No more than 48 straight weeks (336 straight days)	
Epclusa®	No more than 12 straight weeks (84 straight days)	
Mavret™	No more than 12 straight weeks (84 straight days)	

6.	I understand that past use of certain hepatitis C medicines may keep me from using medicines like them again.	
7.	I have not abused alcohol or other drugs within the past 12 months.	
8.	I understand that blood alcohol and urine drug screens are required before I start taking my hepatitis C medicines.	
9.	I understand that if I test positive for drugs and/or alcohol, Medicaid may not pay for my Hepatitis C medicines.	
10.	If I am taking ribavirin, I am (OR my female partner is) not pregnant.	
11.	If I am taking ribavirin, I am (OR my female partner is) not planning on getting pregnant while I am on my hepatitis C medicines and for at least 6 months after I finish them.	
12.	If I am taking ribavirin, I (OR my female partner) will use two forms of effective contraception while I am taking my hepatitis C medicines and for at least 6 months after I finish them.	
13.	If I am taking ribavirin, I (OR my female partner) will have monthly pregnancy testing while I am taking my hepatitis C medicines.	

I have read the above statements and understand the agreement.

Patient Signature:_____ **Date:**_____

Physician Signature:_____ **Date:**_____