Bobby Jindal
GOVERNOR

Kathy H. Kliebert
SECRETARY

State of Louisiana

Department of Health and Hospitals

Bureau of Health Services Financing

MEMORANDUM

DATE: June 26, 2014

TO: All Louisiana Medicaid Providers

FROM: J. Ruth Kennedy, Medicaid Director

SUBJECT: Clinical Pre-authorization for Incivek® (telaprevir), Sovaldi® (sofosbuvir), and Olysio® (simeprevir) for Louisiana Legacy Medicaid and Shared Health Plans

Effective July 1, 2014, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established clinical pre-authorization criteria for the following non-preferred direct-acting Hepatitis C agents: Incivek® (telaprevir), Sovaldi® (sofosbuvir), and Olysio® (simeprevir).

Claims for Incivek® (telaprevir), Sovaldi® (sofosbuvir), and Olysio® (simeprevir) 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 and the Hepatitis C Virus (HCV) Medication Therapy Worksheet in full and fax to 1-866-797-2329. See complete instructions following this document or refer to www.lamedicaid.com.

Pharmacy claims for these medications will deny at Point of Sale (POS) with:

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

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

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, send a fax to (225) 342-1980, or refer to www.lamedicaid.com.

MCJ/MBW/ESF

c: Bayou Health Plans
Dr. James Hussey
Dr. Rebekah Gee
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Magellan of Louisiana (Managed Care)
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LA Legacy Medicaid and Shared Health Plans
Pharmacy Clinical Pre-Authorization Form

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

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:**	

MEDICATION INFORMATION

Drug Name:	**Dosage Form:**	**Quantity:**	**Projected Duration of Treatment:**
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.

Louisiana Legacy Medicaid and Shared Health Plans

Hepatitis C Virus (HCV) Medication Therapy Worksheet

[Simeprevir (Olysio®), Sofosbuvir (Sovaldi®), and Telaprevir (Incivek®)]

Note: This worksheet must be completed in full and submitted with the Pharmacy Clinical Pre-Authorization Form. Provide supporting documentation where applicable.

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

HCV treatment strategies are rapidly evolving. Conservative treatment approaches have been suggested for selected patients diagnosed with HCV. Some of the factors which may have influenced these approaches include the:

1) slow course of HCV disease, with most patients showing few signs or symptoms during the first 20 years of infection;
2) rapid development of a variety of new HCV treatment options and combinations which may optimize the chance of treatment success;
3) absence of long-term clinical outcomes data for newly approved agents; and
4) periodic release of results of HCV clinical trials and outcomes studies which may influence treatment decisions.

Adherence to the prescribed HCV regimen is one condition considered when processing requests for continuation of therapy. Adherence will be assessed by a review of the recipient's Medicaid medication history. Additionally, factors such as abstinence from alcohol and illicit substances and on-treatment HCV RNA viral levels will be considered when processing continuation requests.

What medication is being requested? [One medication per request.]

☐ Simeprevir (Olysio®) ☐ Sofosbuvir (Sovaldi®) ☐ Telaprevir (Incivek®)

Will patient's therapy include peginterferon? ☐ Yes ☐ No If no, please explain_____

Will patient's therapy include ribavirin? ☐ Yes ☐ No If no, please explain_____

INITIAL REQUEST

Indicate reason for request:

☐ Chronic Hepatitis C (CHC) ☐ CHC with hepatocellular carcinoma awaiting transplant ☐ Co-infection (HCV/HIV)

Indicate HCV Genotype? _____ If Genotype 1, please indicate subtype. ☐ 1a ☐ 1b

If the patient HCV Genotype is 1a and request is for Simeprevir (Olysio®), does the patient have the Q80K polymorphism? ☐ Yes ☐ No

Check the box that best describes the patient:

☐ Treatment-naïve ☐ Prior relapser ☐ Prior partial responder ☐ Prior null responder

If not treatment-naïve, please provide previous HCV therapy:

Drug	Dosage form	Strength	Directions	Start Date/End Date	Duration (wks)

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 creatinine clearance (CrCl)? _____ ml/min_____ Date measured

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

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

Has a liver biopsy been performed? ☐ Yes (If yes, provide biopsy results.) ☐ No

(Liver biopsy required for Simeprevir (Olysio®) and Sofosbuvir (Sovaldi®).)

Metavir Stage (circle one) 0 1 2 3 4 Ishak Stage (circle one) 0 1 2 3 4 5 6

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 (If yes, please list_____) ☐ No

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

☐	Platelet count <75000 / mm^3	☐	Pregnancy in female patients or pregnancy in female sexual partners of male patients
☐	Decompensated liver cirrhosis (CTP score ≥ 7 HCV monoinfection; CTP score ≥ 6 in HCV/HIV coinfection)	☐	Unwillingness to comply with two forms of contraception
☐	Severe mental health conditions that may be exacerbated by interferon therapy or respond poorly to medical therapy	☐	History of significant or unstable cardiac disease
☐	Autoimmune diseases that may be exacerbated by interferon-mediated immune modulation (such as autoimmune hepatitis)	☐	Creatinine clearance < 50ml/min
☐	Inability to complete a prior treatment course of interferon due to documented interferon-related adverse effects and/or hypersensitivities	☐	Hemoglobinopathy (such as thalassemia major and sickle cell anemia)
		☐	Current therapy with didanosine
		☐	Inability to complete a prior treatment course of ribavirin due to documented ribavirin-related adverse effects

Has the patient been free from alcohol and substance abuse during the past year? ☐ Yes ☐ No
Please provide laboratory results of urine drug screen and blood alcohol level taken (1) 30 days prior to treatment start AND (2) at start of treatment.

Does the patient have a past history of alcohol and/or substance abuse? ☐ Yes ☐ No
If yes, laboratory results of urine drug screen and blood alcohol level required every 30 days during treatment. (See Continuation Section)

CURRENT MEDICATION LIST (Attach additional sheet as necessary)

Drug	Dosage form	Strength	Directions	Start Date/End Date	Duration (wks)

CONTINUATION REQUEST

Urine Drugs Screens / Blood Alcohol Levels

For patients with past history of alcohol and/or substance abuse, please include results of urine drug screen and blood alcohol level measured every 30 days during treatment.

Days of Treatment	Date measured		Results (+/-)	
	Urine Drug Screen	Blood Alcohol Level	Urine Drug Screen	Blood Alcohol Level
30				
60				
90				
120				
150				
180				
210				
240				

HCV RNA Viral Loads

Frequency requested depends on futility rules and/or response-guided therapy.

HCV RNA Viral Load (IU/ml)	Date measured	Simeprevir (Olysio®)	Sofosbuvir (Sovaldi®)	Telaprevir (Incivek®)
Week 4				
Week 8				
Week 12				
Week 20				
Week 28				
Week 36				

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

(If a signature stamp is used, then the physician must initial the signature.)