John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

MEMORANDUM

DATE: August 2, 2016

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

FROM: Jen Steele, Medicaid Director

SUBJECT: Updated Criteria for Direct-Acting Antiviral (DAA) Agents used to treat Hepatitis C Virus (HCV)

Effective August 15, 2016, the Fee for Service (FFS) Louisiana Medicaid Pharmacy Program has updated the clinical pre-authorization criteria for Direct-Acting Antiviral (DAA) Agents used to treat Hepatitis C Virus (HCV).

Pharmacy claims for these agents 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 in full and fax to 1-866-797-2329. See complete instructions following this document or refer to www.lamedicaid.com.

When pre-authorization has not been obtained, 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 or refer to www.lamedicaid.com.

JS/MBW/ESF

c: Healthy Louisiana Plans
Melwyn B. Wendt
Molina

Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV)
Clinical Pre-Authorization Criteria
for Louisiana Legacy Fee-For-Service Medicaid Recipients

All DAA agents require clinical pre-authorization. Maximum duration of treatment is agent and disease state specific (See Table 1), pending results of quantitative hepatitis c virus (HCV) RNA testing at treatment week 4 and, if applicable, treatment week 6.

All requests for DAA agents will be reviewed on a case-by-case basis.

Requests must meet general approval criteria for *all* DAA agents, and must meet applicable agent-specific criteria for the DAA agent requested.

General Approval Criteria for all DAA agents for Initial Requests:

- Clinical pre-authorization requests will be considered for approval for 8 weeks (56 days) if applicable criteria are met; AND
- For initial requests, a completed Clinical Pre-Authorization form must be submitted along with a completed Hepatitis C Worksheet and a completed Hepatitis C Therapy Treatment Agreement. Each form must be dated and signed by the prescribing physician. Signature stamps and proxy signatures are not acceptable. Each item on the Hepatitis C Therapy Treatment Agreement must be initialed by the patient, and the agreement must be dated and signed by the patient; AND
- The prescribing physician attests that all necessary labs to evaluate Hepatitis C therapy efficacy, including sustained virological response 12 weeks after completion of treatment (SVR12), will be provided; AND
- Patient age is ≥ 18 years; AND
- The patient has a diagnosis of chronic HCV confirmed and genotyped by lab documentation with quantitative baseline HCV RNA levels; AND
- The patient does not have a short life expectancy (less than 12 months) owing to comorbid conditions; AND
- The treatment regimen prescribed is NOT for an indication outside of the FDA approved labeling and is prescribed as part of an FDA approved treatment regimen; AND
- As verified by the prescribing physician's review of the patient's current medication list, patient's current medication regimen does NOT include any medication(s) which:
  - is / are contraindicated or not recommended for coadministration with the DAA agent or any other component of a combination antiviral treatment regimen which includes the DAA agent as specified in the product labeling;
  - may result in significant drug interaction(s) with the prescribed treatment regimen;
  - contain(s) the requested DAA agent or any component of a combination antiviral treatment regimen which includes the requested DAA agent; AND
- Patient has not had solid organ transplant, except liver; AND
- Confirmation is provided that the prescribing physician and/or the physician's agent has accessed the Louisiana Prescription Monitoring Program (PMP) to evaluate and review controlled substance use; AND
- Confirmation is provided that the patient has not been actively participating in substance abuse and/or alcohol abuse within the past 12 months as attested by the prescribing physician and substantiated by results of a negative urine drug screen and blood alcohol level within 30 days of beginning treatment; AND
- In the presence of prior substance abuse and/or alcohol abuse, urine drug screen and blood alcohol level are required not only at the beginning of treatment, but also on a random basis at some point during each 30-day HCV treatment interval while on a DAA agent; the specific date of the screening/level during each 30-day treatment interval is at the discretion of the prescribing physician; the results of these screenings/levels must remain negative during treatment with a DAA agent; AND
- The clinical pre-authorization for the DAA agent(s) is requested by a physician with a specialty/subspecialty of gastroenterology, hepatology, or infectious disease; AND

- The DAA agent(s) will be prescribed by a physician with a specialty/subspecialty of gastroenterology, hepatology, or infectious disease; AND
- Patient has not had previous exposure to HCV DAA agents.

General Approval Criteria for all DAA agents for Renewal Requests:

Duration of the renewal approval is determined by agent-specific criteria. (See Table 1) Renewal requests for DAA agents will be considered for approval if ALL of the following criteria are met:

- A new completed Clinical Pre-Authorization form must be submitted along with the previously submitted Hepatitis C Worksheet, upon which applicable required information has been added; AND
- Patient must have had an HCV RNA viral load assessed at week 4 of treatment. If the HCV RNA viral load was quantifiable (> 25 IU/mL) at week 4, the HCV RNA viral load must have been reassessed after 2 additional weeks of treatment. If the repeated HCV RNA viral load increased by greater than tenfold (> 1 $\log_{10}$ IU/mL), the request will not be approved unless the physician submits medical justification and published clinical studies to support continuation of HCV therapy; AND
- Patient must be compliant with each component of the prescribed HCV antiviral treatment regimen. (Compliance will be assessed per pharmacy claim review); AND
- As verified by the prescribing physician's review of the patient's current medication list, patient's current medication regimen does NOT include any medication(s) which:
  - is / are contraindicated or not recommended for coadministration with the DAA agent or any other component of a combination antiviral treatment regimen which includes the DAA agent as specified in the product labeling;
  - may result in significant drug interaction(s) with the prescribed treatment regimen;
  - contain(s) the requested DAA agent or any component of a combination antiviral treatment regimen which includes the requested DAA agent; AND
- If applicable, confirmation is provided that the patient is not participating in illicit substance abuse or alcohol abuse as attested by the prescribing physician AND substantiated by documented results of negative urine drug screen and blood alcohol level.

Specific Criteria for DAA Agents

Daclatasvir

- Patient has a diagnosis of chronic HCV genotype 1 or 3; AND
- Patient's HCV treatment regimen must include sofosbuvir; therefore, patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND
- Patient is not currently taking strong inducers of cytochrome P450 3A (CYP3A). These medications are contraindicated with daclatasvir as they may lead to lower exposure and loss of efficacy. (See Table 2) Refer to complete prescribing information for more information; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5; OR
  - Fibrosis 4 Index (FIB-4) > 3.25; OR
  - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
  - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
  - FibroSure® results indicating Metavir score ≥ 3; OR

- Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND

- Daclatasvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day (30mg or 60mg dose), 28 tablets per rolling 28 days; as applicable, maximum 2 tablets per day (30mg + 60mg = 90mg dose), 56 tablets per rolling 28 days.

Ledipasvir/sofosbuvir

- Patient has a diagnosis of chronic HCV:
  - Genotype 1; OR
  - Genotype 4; OR
  - Genotype 5; OR
  - Genotype 6; AND
- Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND
- Patient is not currently taking any medication(s) that are not recommended with ledipasvir/sofosbuvir. (See Table 9); AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5; OR
  - Fibrosis 4 Index (FIB-4) > 3.25; OR
  - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
  - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
  - FibroSure® results indicating Metavir score ≥ 3; OR
  - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Ledipasvir / sofosbuvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days

Ombitasvir/Paritaprevir/Ritonavir

- Patient has a diagnosis of chronic HCV genotype 4; AND
- Patient does **not** have cirrhosis; AND
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); AND
- Patient is not currently taking any medication(s) that are contraindicated with ombitasvir/paritaprevir/ritonavir. (See Table 7) These include, but are not limited to, the following:
  - medications that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events; OR
  - medications that are moderate or strong inducers of CYP3A and may lead to decreased efficacy; OR
  - patients with known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis or Stevens-Johnson syndrome). Refer to the complete prescribing information for more information; AND
- Patient has compensated liver disease; AND
- Patient has a diagnosis of advanced fibrosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score 3 (See Table 4) or Ishak stage 4 or 5 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5 and ≤ 2; OR
  - Fibroscan® value of ≥9.5 and < 12.5 kilopascals; AND

- Patient is not currently on dialysis; AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Ombitasvir/Paritaprevir/Ritonavir requests must adhere to the following applicable quantity limits: maximum 2 tablets per day, 56 tablets per rolling 28 days.

Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir

- Patient has a diagnosis of chronic HCV genotype 1; AND
- Patient is not currently taking any medication(s) that are contraindicated with ombitasvir/paritaprevir/ritonavir with dasabuvir. (See Table 8) These include, but are not limited to, the following:
  - medications that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events; OR
  - medications that are moderate or strong inducers of CYP3A and strong inducers of CYP2C8 and may lead to reduced efficacy; OR
  - medications that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentration and the risk of QT prolongation; OR
  - patients with known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis or Stevens-Johnson syndrome). Refer to the complete prescribing information for more information; AND
- Patient has compensated liver disease; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score $\geq$3 (See Table 4) or Ishak stage $\geq$4 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5; OR
  - Fibrosis 4 Index (FIB-4) > 3.25; OR
  - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
  - Fibroscan® value of $\geq$9.5 kilopascals (severe/significant fibrosis); OR
  - FibroSure® results indicating Metavir score $\geq$ 3; OR
  - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); AND
- Patient is not currently on dialysis; AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir requests must adhere to the following applicable quantity limits: maximum 4 tablets per day, 112 tablets per rolling 28 days

Sofosbuvir

- Patient has a diagnosis of chronic HCV:
  - Genotype 1; OR
  - Genotype 2; OR
  - Genotype 3; OR
  - Genotype 4; OR
  - With hepatocellular carcinoma meeting MILAN criteria (defined as the presence of a tumor 5 cm or less in diameter in patients with a single hepatocellular carcinoma and no more than three tumor nodules, each 3 cm or less in diameter in patients with multiple tumors and no extrahepatic manifestations of the cancer or evidence of vascular invasion of the tumor) AND is currently awaiting liver transplantation; AND
- Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND

- Patient is not currently taking any medication(s) that are not recommended with sofosbuvir. (See Table 11); AND
- Patient has compensated / decompensated liver disease, depending upon concurrent therapy; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
    - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
    - AST to Platelet Ratio Index (APRI) >1.5; OR
    - Fibrosis 4 Index (FIB-4) > 3.25; OR
    - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
    - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
    - FibroSure® results indicating Metavir score ≥ 3; OR
    - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- Current HCV treatment regimen must include concurrent therapy with peginterferon alfa/ribavirin, ribavirin, simeprevir or daclatasvir; AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Sofosbuvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days.

Elbasvir/Grazoprevir

- Patient has a diagnosis of chronic HCV:
    - Genotype 1 with documented clinical justification as to why a preferred product or a regimen containing a preferred product indicated for genotype 1 cannot be used; OR
    - Genotype 4 with documented clinical justification as to why a preferred product or a regimen containing a preferred product indicated for genotype 4 cannot be used; AND
    - Patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms if patient has genotype 1a; AND
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); AND
- Patient is not currently taking any medication(s) that are contraindicated with elbasvir/grazoprevir. (See Table 3) These include, but are not limited to, the following:
    - medications that are inhibitors of OATP1B1/3; OR
    - medications that are strong inducers of CYP3A and may lead to decreased efficacy. Refer to complete prescribing information for more information; AND
- Patient has compensated liver disease; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
    - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
    - AST to Platelet Ratio Index (APRI) >1.5; OR
    - Fibrosis 4 Index (FIB-4) > 3.25; OR
    - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
    - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
    - FibroSure® results indicating Metavir score ≥ 3; OR
    - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND

- Elbasvir/Grazoprevir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days.

Simeprevir

- Patient has a diagnosis of chronic HCV:
  - Genotype 1 with documented clinical justification as to why a preferred product or a regimen containing a preferred product indicated for genotype 1 cannot be used; OR
  - Genotype 4 with documented clinical justification as to why a preferred product or a regimen containing a preferred product indicated for genotype 4 cannot be used; AND
- Patient is NOT infected with HCV genotype 1a with the Q80K polymorphism; AND
- Patient is not taking any medication(s) that are not recommended with simeprevir. (See Table 10) These include, but are not limited to, the following: moderate or strong inducers or inhibitors of CYP3A as this may lead to significantly lower or higher exposure to simeprevir, respectively. Refer to the complete prescribing information for more information; AND
- Patient does not have severe renal impairment (CrCl < 30 ml/min/) or end stage renal disease (ESRD) requiring dialysis; AND
- Patient has compensated liver disease; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5; OR
  - Fibrosis 4 Index (FIB-4) > 3.25; OR
  - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
  - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
  - FibroSure® results indicating Metavir score ≥ 3; OR
  - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Current HCV treatment regimen must include concurrent therapy with peginterferon alfa/ribavirin or sofosbuvir; AND
- Simeprevir requests must adhere to the following applicable quantity limits: maximum 1 capsule per day, 28 capsules per rolling 28 days.

Sofosbuvir/Velpatasvir

- Patient has a diagnosis of chronic HCV:
  - Genotype 1; OR
  - Genotype 2; OR
  - Genotype 3; OR
  - Genotype 4; OR
  - Genotype 5; OR
  - Genotype 6; AND
- Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND

- Patient is not currently taking any medication(s) that are not recommended with sofosbuvir/velpatasvir. (See Table 12)

  These include, but are not limited to, the following:
  - medications that are inducers of P-gp; OR
  - medications that are moderate to potent inducers of CYP; AND
- Patient has a diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
  - Liver biopsy showing Metavir score ≥3 (See Table 4) or Ishak stage ≥4 (See Table 5); OR
  - AST to Platelet Ratio Index (APRI) >1.5; OR
  - Fibrosis 4 Index (FIB-4) > 3.25; OR
  - Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; OR
  - Fibroscan® value of ≥9.5 kilopascals (severe/significant fibrosis); OR
  - FibroSure® results indicating Metavir score ≥ 3; OR
  - Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites.*); AND
- If administered with ribavirin, patient does not have CrCl < 50ml/min; AND
- Sofosbuvir/Velpatasvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days.

Table 1. Duration of Treatment

Treatment	Duration[a]
Daclatasvir + Sofosbuvir	12 weeks
Ledipasvir/Sofosbuvir	12 – 24[b] weeks
Elbasvir/Grazoprevir	12 – 16[c] weeks
Ombitasvir/Paritaprevir/Ritonavir	12 weeks
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir	12 – 24[d] weeks
Simeprevir	12 weeks
Simeprevir + Sofosbuvir	12 – 24[e] weeks
Sofosbuvir	12 – 48[f] weeks
Sofosbuvir/Velpatasvir	12 weeks

a. maximum duration of DAA agent therapy over patient lifetime
b. maximum duration of treatment with ledipasvir/sofosbuvir for genotype 1 treatment-experienced patients with cirrhosis is 24 weeks
c. maximum duration of treatment with elbasvir/grazoprevir for genotype 1a treatment–naïve or treatment-experienced patients with baseline NS5A polymorphisms or genotype 4 treatment-experienced patients is 16 weeks
d. maximum duration of treatment with ombitasvir/paritaprevir/ritonavir with dasabuvir for patients with genotype 1a, genotype 1 unknown subtype or mixed genotype 1 with cirrhosis is 24 weeks
e. maximum duration of treatment with simeprevir + sofosbuvir for patients with genotype 1 with cirrhosis is 24 weeks
f. maximum duration of treatment with sofosbuvir for genotypes 1, 2 or 4 is 12 weeks, maximum duration for genotype 3 is 24 weeks, and maximum duration for HCV in patients with hepatocellular carcinoma awaiting liver transplantation is up to 48 weeks or until liver transplantation, whichever occurs first.

Table 2. Medications Contraindicated or Not Recommended with Daclatasvir or Sofosbuvir[a]

Antiarrhythmics
Amiodarone
Anticonvulsants
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antimycobacterials
Rifampin, rifabutin, rifapentine
Herbal Products
St. John's Wort (*Hypericum perforatum)*
HIV Protease Inhibitors
Tipranavir/ritonavir

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 3. Medications Contraindicated with Elbasvir/Grazoprevir

Anticonvulsants
Carbamazepine, phenytoin
Antimycobacterials
Rifampin
Herbal Products
St. John's Wort (*Hypericum perforatum)*
HIV Medications
Efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir
Immunosuppressants
Cyclosporine

a. This list in not all inclusive; refer to prescribing information for complete list of potential drug Interactions and dosage adjustment for concomitantly prescribed medications

Table 4. Metavir Histologic Scoring System

	Metavir Fibrosis Classification
Stage 0	No Fibrosis
Stage 1	Periportal fibrotic expansion
Stage 2	Periportal septae 1 (septum)
Stage 3	Porto-central septae
Stage 4	Cirrhosis

Table 5. Ishak Histologic Scoring System

Stage	Histologic Description
0	No fibrosis
1	Fibrous expansion of some portal areas with or without short fibrous septa
2	Fibrous expansion of most portal areas with or without short fibrous septa
3	Fibrous expansion of most portal areas with occasional portal-to-portal bridging
4	Fibrous expansion of most portal areas with marked bridging (portal-to-portal and portal-to-central)
5	Marked bridging (portal-to-portal and portal-to-central) with occasional nodules (incomplete cirrhosis)
6	Cirrhosis

Table 6. Child-Turcotte-Pugh (CTP) System

Parameters	**Points***		
	1 Point	**2 Points**	**3 Points**
Total Bilirubin (µmol/L)	< 34	34 – 50	> 50
Serum Albumin (g/L)	> 35	28 – 35	< 28
Prothrombin time/INR	< 1.7	1.71 – 2.30	> 2.30
Ascites	None	Mild	Moderate to Severe
Hepatic encephalopathy	None	Grade I or II (or suppressed with medication)	Grade III or IV (or refractory)

***CTP Score is obtained by adding the score for each Parameter**

CTP Class:

A = 5-6 Points (Mild)

B = 7-9 Points (Moderate)

C = 10-15 Points (Severe

Table 7. Medications Contraindicated or Not Recommended with Ombitasvir/Paritaprevir/Ritonavir[a]

Alpha1-adrenoreceptor antagonist
Alfuzosin HCl
Anti-gout
Colchicine
Anti-convulsants
Carbamazepine, phenytoin, phenobarbital
Antimycobacterials
Rifampin
Ergot derivatives
Ergotamine, dihydroergotamine, ergonovine, methylergonovine
Ethinyl estradiol-containing products
Ethinyl estradiol-containing medications such as combined oral contraceptives
Herbal product
St. John's Wort (*Hypericum perforatum*)
HMG-CoA Reductase Inhibitors
Lovastatin, simvastatin
Neuroleptics
Pimozide
Non-nucleoside reverse transcriptase inhibitor
Efavirenz
Phosphodiesterase-5 (PDE5) inhibitors
Sildenafil when dosed as Revatio for the treatment of pulmonary arterial hypertension (PAH)
Sedatives/Hypnotics
Triazolam, orally administered midazolam

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 8. Medications Contraindicated or Not Recommended with Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir

Alpha1-adrenoreceptor antagonist
Alfuzosin HCl
Anti-gout
Colchicine
Anti-convulsants
Carbamazepine, phenytoin, phenobarbital
Antihyperlipidemic Agents
Gemfibrozil
Antimycobacterials
Rifampin
Ergot derivatives
Ergotamine, dihydroergotamine, ergonovine, methylergonovine
Ethinyl estradiol-containing products
Ethinyl estradiol-containing medications such as combined oral contraceptives
Herbal product
St. John's Wort (*Hypericum perforatum*)
HMG-CoA Reductase Inhibitors
Lovastatin, simvastatin
Neuroleptics
Pimozide
Non-nucleoside reverse transcriptase inhibitor
Efavirenz
Phosphodiesterase-5 (PDE5) inhibitors
Sildenafil when dosed as Revatio for the treatment of pulmonary arterial hypertension (PAH)
Sedatives/Hypnotics
Triazolam, orally administered midazolam

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 9. Medications Contraindicated or Not Recommended with Ledipasvir/Sofosbuvir[a]

Antiarrhythmics
Amiodarone
Anticonvulsants
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antimycobacterials
Rifampin, rifabutin, rifapentine
Herbal Products
St. John's Wort (*Hypericum perforatum*)
HIV Antiretrovirals
Tipranavir/ritonavir, elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate
HCV Products
Simeprevir
HMG-CoA Reductase Inhibitors
Rosuvastatin

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 10. Medications Contraindicated or Not Recommended with Simeprevir[a]

Antiarrhythmics
Amiodarone
Anticonvulsants
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Anti-infectives
Erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, rifampin, rifabutin, rifapentine
Corticosteroids
Dexamethasone
GI Products
Cisapride
Herbal Products
Milk thistle (*Silybum marianum*), St. John's Wort (*Hypericum perforatum*)
HIV Products
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, efavirenz, delavirdine, etravirine, nevirapine, darunavir/ritonavir, ritonavir, atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir
Immunosuppressants
Cyclosporine

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 11. Medications Contraindicated or Not Recommended with Sofosbuvir[a]

Antiarrhythmics
Amiodarone (when used with Sofosbuvir in combination with another DAA agent)
Anticonvulsants
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antimycobacterials
Rifampin, rifabutin, rifapentine
Herbal Products
St. John's Wort (*Hypericum perforatum*)
HIV Protease Inhibitors
Tipranavir/ritonavir

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

Table 12. Medications Contraindicated or Not Recommended with Sofosbuvir/Velpatasvir[a]

Antiarrhythmics
Amiodarone
Anticancers
Topotecan
Anticonvulsants
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antimycobacterials
Rifampin, rifabutin, rifapentine
Herbal Products
St. John's Wort (*Hypericum perforatum*)
HIV Antiretrovirals
Efavirenz, tipranavir/ritonavir

a. This list is not all inclusive; refer to prescribing information for complete list of potential drug interactions and dosage adjustment for concomitantly prescribed medications

ADDITIONAL INFORMATION

Criteria to Determine Peginterferon Intolerance / Ineligibility

- 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 (Mental health evaluation may be requested to assess eligibility)
- Autoimmune diseases that may be exacerbated by interferon-mediated immune modulation (such as autoimmune hepatitis)
- Inability to complete a prior treatment course due to documented interferon-related adverse effects and/or hypersensitivities

Criteria to Determine Ribavirin Intolerance / Ineligibility

- Pregnancy in female patients or pregnancy in female sexual partners of male patients – prescribing information recommends women have pregnancy tests before therapy, monthly during therapy, and for 6 months after therapy
- Unwillingness to comply with **two** forms of effective contraception
- History of significant or unstable cardiac disease
- Creatinine clearance < 50 ml/min
- Hemoglobinopathy (such as thalassemia major and sickle cell anemia)
- Coadministration with didanosine
- Inability to complete a prior treatment course due to documented ribavirin-related adverse effects

REFERENCES

American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of American (IDSA). (2015). *Recommendations for testing, managing, and treating hepatitis C.* Retrieved from http://www.hcvguidelines.org/full-report-view

Daklinza [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2015. Retrieved from http://packageinserts.bms.com/pi/pi_daklinza.pdf

Ghany MC, Strader DB, Thomas DL, Seeff LB. Diagnosis, management, and treatment of hepatitis C: an update. *Hepatology*. 2009;49(4):1335-1374.

Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2015. Retrieved from http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf

Olysio [package insert]. Titusville, NJ: Janssen Therapeutics, Division of Janssen Products, LP; 2015. Retrieved from http://www.olysio.com/shared/product/olysio/prescribing-information.pdf

Oregon Health & Sciences University Center for Evidence-based Policy, Medicaid Evidence Based Decisions Project (MED). (2014). *Sofosbuvir for the treatment of hepatitis C and evaluation of the 2014 American Association for the Study of Liver Diseases treatment guidelines*. Retrieved from http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir_for_HepatitisC_FINALDRAFT_6_12_2014.pdf

Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2015. Retrieved from http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf

Technivie [package insert]. North Chicago, IL: AbbVie Inc.; 2015. Retrieved from http://www.rxabbvie.com/pdf/technivie_pi.pdf

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). (2003). *Guidance for Industry: Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.* Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072123.pdf

Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. (2015). *Chronic Hepatitis C Virus (HCV) Infection:Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health*. Retrieved from http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-07.pdf

Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; 2015. Retrieved from http://www.rxabbvie.com/pdf/viekirapak_pi.pdf

Zepatier [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; 2016. Retrieved from https://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf

Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2016. Retrieved from http://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf?la=en

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

MEMBER INFORMATION

Revised Date: 2/12/2015

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.

Louisiana Legacy Fee-For-Service Medicaid
Direct-Acting Antiviral Agents (DAA) for Chronic Hepatitis C Virus (HCV)
Medication Therapy Worksheet

Note: This worksheet must be completed in full and submitted with the Pharmacy Clinical Pre-Authorization Form. Provide supporting documentation where applicable. Original form submitted for initiation of therapy should be re-submitted for continuation requests. [See DAA Clinical Pre-Authorization Criteria]

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

Medication regimen requested *[Choose one.]*

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

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)

INITIAL REQUEST

Indicate reason for request:
☐ Chronic Hepatitis C Virus (HCV) ☐ CHC with hepatocellular carcinoma awaiting transplant ☐ Co-infection (HCV/HIV)

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

If request is for simeprevir (Olysio®) and patient has HCV Genotype 1a, does the patient have the Q80K polymorphism? ☐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	☐	Pregnancy in female patients or pregnancy in female sexual partners of male patients
☐	Decompensated liver cirrhosis	☐	Unwillingness to comply with two forms of effective 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 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.

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 are required at some point during each 30-day treatment interval. (See Continuation Request Section)

CURRENT MEDICATION LIST (Attach additional sheet as necessary)

Drug	Dosage form	Strength	Directions	Start Date/End Date

CONTINUATION REQUEST

Urine Drug Screens / Blood Alcohol Levels

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

Interval (Days)	Date (UDS)	UDS (+/-)	Date (BAL)	BAL (+/-)
1 - 30				
31 - 60				
61 - 90				
91 - 120				
121 - 150				
151 - 180				

EXTENDED UDS / BAL TESTING PERIOD FOR PATIENTS AWAITING LIVER TRANSPLANT

Interval (Days)	Date (UDS)	UDS (+/-)	Date (BAL)	BAL (+/-)
181 - 210				
211 - 240				
241 - 270				
271 - 300				
301 - 330				

HCV RNA Viral Loads

Frequency requested depends on response-guided therapy.

HCV RNA Viral Load (IU/ml)	Date measured
Week	
4	
6	
_____	
_____	
SVR12*	

*SVR12 = sustained virological response 12 weeks after completion of treatment

By signing below, the prescribing physician attests that he/she will provide all necessary labs, including but not limited to genotype, blood alcohol/urine drug screens, and those used to evaluate efficacy of Hepatitis C treatment regimen, such as SVR12, and will review medication therapy for medication-related issues.

Initial Request: Physician Signature:* _____ **Date:**_____

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

Continuation Request: Physician Signature:* _____ **Date:**_____

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

Louisiana Legacy Fee-For-Service Medicaid
Direct-Acting Antiviral Agents (DAA) 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 pharmacists 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®	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)	

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 random drug and alcohol testing may be required while I am taking my hepatitis C medicines.	
10.	I understand that if I test positive for drugs and/or alcohol, Medicaid may not pay or may stop paying for my Hepatitis C medicines.	
11.	If I am taking ribavirin, I am (OR my female partner is) not pregnant.	
12.	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.	
13.	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.	
14.	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:**_____