Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Prior Authorization Criteria for Louisiana Fee for Service and MCO Medicaid Recipients

Preferred Agents	Non-Preferred Agents
• Sofosbuvir/Velpatasvir (Epclusa®) Genotype 4 only • Elbasvir/Grazoprevir (Zepatier®) • Glecaprevir/pibrentasvir (Mavyret®)	• Simeprevir (Olysio®) • Sofosbuvir/Velpatasvir (Epclusa®) Genotypes 1, 2, 3, 5 and 6 • Daclatasvir (Daklinza®) • Ledipasvir/Sofosbuvir (Harvoni®) • Ombitasvir/Paritaprevir/Ritonavir (Technivie®) • Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira Pak®) • Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira XR®) • Sofosbuvir (Sovaldi®) Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

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:

I. The prescribing physician attests that all requested labs will be provided; **AND**
II. The patient is assessed for hepatitis B virus (HBV) coinfection prior to initiation of HCV treatment. If HBV/HCV coinfected, the patient is monitored for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up and appropriate patient management for HBV infection is initiated as clinically indicated; **AND**
III. The patient has a diagnosis of chronic HCV confirmed and genotyped by lab documentation with; **AND**
IV. The patient has a diagnosis of chronic HCV evidenced by detectable HCV RNA levels over a six-month period; **AND**
V. The patient does not have a short life expectancy (less than 12 months) owing to comorbid conditions; **AND**
VI. 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**
VII. 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:

A. 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;
B. May result in significant drug interaction(s) with the prescribed treatment regimen;
C. Contain(s) the requested DAA agent or any component of a combination antiviral treatment regimen which includes the requested DAA agent; **AND**

VIII. Patient has not had solid organ transplant, except liver; **AND**
IX. 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**
X. Prescriber and patient has attested that the patient is not actively participating in substance and/or alcohol abuse; **AND**
XI. Patient has not had previous exposure to HCV DAA agents (with exception of requests for Vosevi); **AND**
XII. Patient has one of the following:

A. A diagnosis of advanced fibrosis or cirrhosis, which is supported by at least one of the following diagnostic measures:
    1. Liver biopsy showing Metavir score $\geq$3 (See Table 3) or Ishak stage $\geq$4 (See Table 4); **OR**
    2. AST to Platelet Ratio Index (APRI) >1.5; **OR**
    3. Fibrosis 4 Index (FIB-4) > 3.25; **OR**
    4. Platelet count less than 140,000-150,000/mm^3 (cirrhosis) in the absence of other factors that affect platelet count; **OR**
    5. Fibroscan® value of $\geq$9.5 kilopascals (severe/significant fibrosis); **OR**
    6. FibroSure® results indicating Metavir score $\geq$ 3; **OR**
    7. Abdominal imaging that is strongly suggestive of cirrhosis. (*Examples include surface abnormalities, features of portal hypertension and/or ascites*); **OR**
B. Patient is HIV/HCV co-infected.

Specific Criteria for DAA Agents

Glecaprevir/pibrentasvir (Mavyret)

I. Patient has a diagnosis of chronic HCV genotype 1, 2, 3, 4, 5, or 6; **AND**
II. Patient age is ≥ 18 years; AND
III. Patient does not have moderate to severe hepatic impairment; **AND**
IV. Patient is not currently taking any medication(s) that are contraindicated or not recommended with glecaprevir/pibrentasvir. (See Table 13); **AND**
V. Glecaprevir/Pibrentasvir requests must adhere to the following applicable quantity limits: maximum 3 tablets per day, 84 tablets per rolling 28 days.

Sofosbuvir/velpatisvir/voxilaprevir (Vosevi)

I. NOTE: Sofosbuvir/ Velpatasvir/ Voxilaprevir (Vosevi™) is not indicated for initial treatment of patients with chronic HCV; **AND**
II. Patient has a diagnosis of chronic HCV genotype 1, 3, 4, 5 or 6; **AND**
III. Patient age is ≥ 18 years; **AND**
IV. Patient is using in the following antiviral treatment regimen:
    A. Monotherapy for one of the following:
        1. Individual is NS5A treatment-experienced, with compensated cirrhosis or without cirrhosis, and Genotype 1; **OR**
        2. Individual is treatment experienced with a sofosbuvir-containing regimen without an NS5A inhibitor, with compensated cirrhosis or without cirrhosis, and Genotype 1a (AASLD/IDSA 2017); **OR**
        3. Individual is direct acting antiviral (DAA) treatment-experienced, without cirrhosis, and Genotype 3; **OR**
        4. Individual is non-NS5A treatment-experienced with compensated cirrhosis, and Genotype 3 (AASLD/IDSA 2017); **OR**
        5. Individual is dual P/R treatment-experienced, with compensated cirrhosis, and Genotype 3 (AASLD/IDSA 2017); **OR**
        6. Individual is treatment-naïve, with compensated cirrhosis or dual P/R treatment-experienced without cirrhosis, polymorphism present at the Y93H amino acid position, and Genotype 3 (AASLD/IDSA 2017); **OR**
        7. Individual is DAA treatment-experienced, with compensated cirrhosis or without cirrhosis, and Genotypes 4, 5 or 6; **OR**
    B. In combination with ribavirin if patient is NS5A treatment-experienced, with compensated cirrhosis and Genotype 3; **AND**

Daklinza (Daclatasvir)

I. Patient has a diagnosis of chronic HCV genotype 1 or 3; **AND**
    A. For genotype 1
        1. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
        2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
        3. One of the following:
            a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
            b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret;
    B. For genotype 3
        1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
        2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**

3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret; **OR**
4. Daklinza (daclatasvir) + Sovaldi (sofosbuvir) ± ribavirin may be approved if the individual is a post-liver allograft transplant recipient; **AND**

II. Patient age is ≥ 18 years; **AND**

III. 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**

IV. 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**

V. Daclatasvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days.

Ledipasvir/sofosbuvir (Harvoni)

I. Patient has a diagnosis of chronic HCV:
    A. Genotype 1 **AND one of the following:**
        1. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
        2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
        3. One of the following:
            a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret or Zepatier which is not also in the requested non-preferred regimen; **OR**
            b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret or Zepatier; **OR**
        4. One of the following:
            a. Individual is a post-liver allograft transplant recipient; **OR**
            b. Individual has decompensated1 cirrhosis; **OR**
            c. Individual is aged 12 to 17 years old or at least 35 kg; **OR**
            d. Individual is a post-kidney transplant recipient with or without compensated cirrhosis; **OR**
    B. Genotype 4 **and one of the following**

1. Individual has had a prior trial and inadequate response to Mavyret, Epclusa or Zepatier; **OR**
2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret, Epclusa or Zepatier which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret, Epclusa or Zepatier; **OR**
4. One of the following:
    a. Individual is a post-liver allograft transplant recipient; **OR**
    b. Individual has decompensated cirrhosis; **OR**
    c. Individual is aged 12 to 17 years old or at least 35 kg; **OR**
    d. Individual is a post-kidney transplant recipient with or without compensated cirrhosis; **OR**

C. Genotype 5 **and one of the following**
1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret; **OR**
4. One of the following:
    a. Individual is a post-liver allograft transplant recipient; **OR**
    b. Individual has decompensated cirrhosis; **OR**
    c. Individual is aged 12 to 17 years old or at least 35 kg; **OR**

D. Genotype 6 **and one of the following**
1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is

contraindicated or not recommended for concomitant use with Mavyret; **OR**

4. One of the following:
    a. Individual is a post-liver allograft transplant recipient; **OR**
    b. Individual has decompensated cirrhosis; **OR**
    c. Individual is aged 12 to 17 years old or at least 35 kg; **AND**

II. Patient age is ≥ 12 years OR patient weighs at least 35 kg; **AND**
III. Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; **AND**
IV. Patient is not currently taking any medication(s) that are contraindicated or not recommended with ledipasvir/sofosbuvir. (See Table 5); **AND**
V. If administered with ribavirin, patient does not have CrCl < 50ml/min; **AND**
VI. 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 (Technivie)

I. Patient has a diagnosis of chronic HCV genotype 4 **and one of the following**
    A. Individual has had a prior trial and inadequate response to Mavyret, Epclusa or Zepatier; **OR**
    B. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
    C. One of the following:
        1. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret, Epclusa or Zepatier which is not also in the requested non-preferred regimen; **OR**
        2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret, Epclusa or Zepatier; **AND**

II. Patient age is ≥ 18 years; **AND**
III. Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); **AND**
IV. Patient is not currently taking any medication(s) that are contraindicated or not recommended with ombitasvir/paritaprevir/ritonavir. (See Table 7) These include, but are not limited to, the following:
    A. 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**
    B. Medications that are moderate or strong inducers of CYP3A and may lead to decreased efficacy; **OR**
    C. 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**
V. Patient has compensated liver disease; **AND**

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

Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Viekira Pak, Viekira XR) (Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir = Pak and Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir = XR formulation)

I. Patient has a diagnosis of chronic HCV genotype 1 **and one of the following**
   A. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
   B. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
   C. One of the following:
      1. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret or Zepatier which is not also in the requested non-preferred regimen; **OR**
      2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret or Zepatier; **AND**
II. Patient age is ≥ 18 years; **AND**
III. Patient is not currently taking any medication(s) that are contraindicated or not recommended with dasabuvir/ombitasvir/paritaprevir/ritonavir (Pak and XR). (See Table 8) These include, but are not limited to, the following:
   A. 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**
   B. medications that are moderate or strong inducers of CYP3A and strong inducers of CYP2C8 and may lead to reduced efficacy; **OR**
   C. medications that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation; **OR**
   D. 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**
IV. Patient has compensated liver disease; **AND**
V. Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); **AND**
VI. If administered with ribavirin, patient does not have CrCl < 50ml/min; **AND**
VII. Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Pak and XR) requests must adhere to the following applicable quantity limits:
   A. Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Pak): maximum 4 tablets per day, 112 tablets per rolling 28 days.
   B. Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (XR): maximum 3 tablets per day, 84 tablets per rolling 28 days.

Sofosbuvir (Sovaldi)

I. Patient has a diagnosis of chronic HCV:
   A. Genotype 1, 2, 3 or 4; **OR**
   B. Genotype 1, 2, 3 or 4 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**

II. Patient has had a prior trial and inadequate response to one of the following preferred HCV regimens:
   A. Genotype 1: Mavyret or Zepatir
   B. Genotype 2: Mavyret
   C. Genotype 3: Mavyret
   D. Genotype 4: Mavyret or Epclusa; **OR**
   E. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret, Zepatier or Epclusa which is not also in the requested non-preferred regimen; OR
   F. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret, Zepatier, or Epclusa; **AND**

III. Patient age is ≥ 18 years; **OR**

IV. Patient age is ≥ 12 years OR patient weighs at least 35kg AND patient has genotype 2 or 3; **AND**

V. Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; **AND**

VI. Patient is not currently taking any medication(s) that are contraindicated or not recommended with sofosbuvir. (See Table 9); **AND**

VII. Patient has compensated / decompensated liver disease, depending upon concurrent therapy; **AND**

VIII. Current HCV treatment regimen must include concurrent therapy with peginterferon alfa/ribavirin, ribavirin, simeprevir or daclatasvir; **AND**

IX. If administered with ribavirin, patient does not have CrCl < 50ml/min; **AND**

X. Sofosbuvir requests must adhere to the following applicable quantity limits: maximum 1 tablet per day, 28 tablets per rolling 28 days.

Elbasvir/Grazoprevir (Zepatier)

I. Patient has a diagnosis of chronic HCV:
   A. Genotype 1. Patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms if patient has genotype 1a**; OR**
   B. Genotype 4

II. Patient age is ≥ 18 years; **AND**

III. Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C)

(See Table 6); **AND**

IV. Patient is not currently taking any medication(s) that are contraindicated or not recommended with elbasvir/grazoprevir. (See Table 10) These include, but are not limited to, the following:
    A. Medications that are inhibitors of OATP1B1/3; **OR**
    B. Medications that are strong inducers of CYP3A and may lead to decreased efficacy. Refer to complete prescribing information for more information; **AND**

V. Patient has compensated liver disease; **AND**

VI. If administered with ribavirin, patient does not have CrCl < 50ml/min; **AND**

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

Simeprevir (Olysio)

I. Patient has a diagnosis of chronic HCV:
    A. Genotype 1 **and one of the following:**
        1. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
        2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
        3. One of the following:
            a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret or Zepatier which is not also in the requested non-preferred regimen; **OR**
            b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret or Zepatier; **OR**
    B. Genotype 4 **and one of the following:**
        1. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
        2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
        3. One of the following:
            a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret or Zepatier which is not also in the requested non-preferred regimen; **OR**
            b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret or Zepatier; **AND**

II. Patient is NOT infected with HCV genotype 1a with the Q80K polymorphism; **AND**

III. Patient age is ≥ 18 years; **AND**

IV. Patient is not taking any medication(s) that are contraindicated or not recommended with simeprevir. (See Table 11) 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 of simeprevir, respectively, which may result in reduced therapeutic effect or adverse reactions. Refer to the complete prescribing information for more information; **AND**

V. Patient does not have severe renal impairment (CrCl < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring dialysis; **AND**

VI. Patient has compensated liver disease; **AND**

VII. Patient does not have moderate to severe hepatic impairment (Child-Pugh B and C) (See Table 6); **AND**

VIII. If administered with ribavirin, patient does not have CrCl < 50ml/min; AND

IX. Current HCV treatment regimen must include concurrent therapy with peginterferon alfa/ribavirin or sofosbuvir; **AND**

X. Simeprevir requests must adhere to the following applicable quantity limits: maximum 1 capsule per day, 28 capsules per rolling 28 days.

Sofosbuvir/Velpatasvir (Epclusa)

I. Patient has a diagnosis of chronic HCV:
   A. Genotype 1 **and one of the following**;
      1. Individual has had a prior trial and inadequate response to Mavyret or Zepatier; **OR**
      2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
      3. One of the following:
         a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret or Zepatier which is not also in the requested non-preferred regimen; **OR**
         b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret or Zepatier; **OR**
         c. Individual has decompensated cirrhosis; **OR**
   B. Genotype 2 **and one of the following**
      1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
      2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
      3. One of the following:
         a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
         b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret; **OR**
         c. Individual is a post-liver allograft transplant recipient and has

decompensated cirrhosis; **OR**

d. Individual has decompensated cirrhosis; **OR**

C. Genotype 3 **and one of the following**

1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret; **OR**
    c. Individual is a post-liver allograft transplant recipient and has decompensated cirrhosis; **OR**
    d. Individual is dual P/R treatment-experienced without cirrhosis; **OR**
    e. Individual has decompensated cirrhosis; **OR**

D. Genotype 4; **OR**

E. Genotype 5 or 6 **and one of the following:**

1. Individual has had a prior trial and inadequate response to Mavyret; **OR**
2. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Mavyret; **OR**
    c. Individual has decompensated cirrhosis; **AND**

II. Patient age is ≥ 18 years; **AND**

III. Patient does not have severe renal impairment (eGFR < 30 ml/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; **AND**

IV. Patient is not currently taking any medication(s) that are contraindicated or not recommended with sofosbuvir/velpatasvir. (See Table 12)
These include, but are not limited to, the following:

A. medications that are inducers of P-gp; **OR**
B. medications that are moderate to potent inducers of CYP; **AND**

V. If administered with ribavirin, patient does not have CrCl < 50ml/min; **AND**

VI. 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 (Daklinza) + Sofosbuvir (Sovaldi)	12 weeks
Ledipasvir/Sofosbuvir (Harvoni)	12 – 24[b] weeks
Elbasvir/Grazoprevir (Zepatier)	12 – 16[c] weeks
Ombitasvir/Paritaprevir/Ritonavir (Technivie)	12 weeks
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira)	12 – 24[d] weeks
Simeprevir (Olysio)	12 weeks
Simeprevir (Olysio) + Sofosbuvir (Sovaldi)	12 – 24[e] weeks
Sofosbuvir (Sovaldi)	12 – 48 weeks
Sofosbuvir/Velpatasvir (Epclusa)	12 weeks
Glecaprevir/pibrentasvir (Mavyret)	8-16 weeks[g]
Sofosbuvir/velpatasvir/voxilaprevir (Vosevi)	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 compensated cirrhosis is 24 weeks
c. maximum duration of treatment with elbasvir/grazoprevir for genotype 1a treatment–naïve or peginterferon alfa/ribavirin-experienced patients with baseline NS5A polymorphisms or genotype 4 peginterferon/ribavirin-experienced patients is 16 weeks
d. maximum duration of treatment with ombitasvir/paritaprevir/ritonavir/dasabuvir for patients with genotype 1a, genotype 1 unknown subtype or mixed genotype 1 with compensated 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.
g. Maximum duration of treatment for genotype 1 (treatment-experienced with an NS5A2a inhibitor and without prior treatment with an NS3/4A2c protease inhibitor, with compensated cirrhosis or without cirrhosis) is 16 weeks

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. 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 4. 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 5. 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 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-anginal
Ranolazine
Antiarrhythmic
Dronedarone
Antidiabetic
Metformin (in patients with renal insufficiency or hepatic impairment)
Anti-gout
Colchicine
Anticonvulsants
Carbamazepine, phenytoin, phenobarbital
Antifungals
Voriconazole (unless an assessment of benefit-to-risk ratio justifies concomitant use)
Antimycobacterials
Rifampin
Antipsychotics
Lurasidone, pimozide
Ergot Derivatives
Ergotamine, dihydroergotamine, ergonovine, methylergonovine
Ethinyl estradiol-containing Products
Ethinyl estradiol-containing medications such as combined oral contraceptives
GI Motility Agents
Cisapride
Herbal Product
St. John's Wort (*Hypericum perforatum*)
HIV-Antiviral Agents
Atazanavir or atazanavir/ritonavir, lopinavir/ritonavir, rilpivirine
HMG-CoA Reductase Inhibitors
Lovastatin, simvastatin
Long acting Beta-adrenoceptor Agonist
Salmeterol
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 Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Pak and XR Formulations)[a]

Alpha1-adrenoreceptor antagonist
Alfuzosin HCl
Anti-anginal
Ranolazine
Antiarrhythmic
Dronedarone
Anti-gout
Colchicine
Anti-convulsants
Carbamazepine, phenytoin, phenobarbital
Antidiabetic
Metformin (in patients with renal insufficiency or hepatic impairment)
Antifungals
Voriconazole (unless an assessment of benefit-to-risk ratio justifies concomitant use)
Antimycobacterials
Rifampin
Antipsychotics
Lurasidone, pimozide
Ergot derivatives
Ergotamine, dihydroergotamine, methylergonovine
Ethinyl estradiol-containing products
Ethinyl estradiol-containing medications such as combined oral contraceptives
GI Motility Agent
Cisapride
Herbal product
St. John's Wort (*Hypericum perforatum*)
HIV-Antiviral Agents
Darunavir/ritonavir, lopinavir/ritonavir, rilpivirine
Long acting Beta-adrenoceptor Agonist
Salmeterol
Phosphodiesterase-5 (PDE5) inhibitors
Sildenafil when dosed as Revatio for the treatment of pulmonary arterial hypertension (PAH)
Sedatives/Hypnotics
Triazolam, orally administered midazolam

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 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 in 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 Elbasvir/Grazoprevir[a]

Antibiotics
Nafcillin
Anticonvulsants
Carbamazepine, phenytoin
Antifungals
Ketoconazole
Antimycobacterials
Rifampin
Endothelin Antagonists
Bosentan
Herbal Products
St. John's Wort (*Hypericum perforatum)*
HIV Medications
Atazanavir, cobicistat-containing regimens, darunavir, efavirenz, etravirine, lopinavir, saquinavir, tipranavir
Immunosuppressants
Cyclosporine
Wakefulness-Promoting Agents
Modafinil

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 11. 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
Cobicistat-containing regimens, 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 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.

Table 13. Medications Contraindicated or Not Recommended with Glecaprevir/Pibrentasvir (Mavyret™)

Anticonvulsants
Carbamazepine
Antimycobacterials
Rifampin
Ethinyl Estradiol-Containing Products
Ethinyl estradiol-containing medications such as combined oral contraceptives
Herbal Products
St. John's Wort (*Hypericum perforatum*)
HIV Antiretrovirals
Atazanavir, Darunavir, Efavirenz, Lopinavir, Ritonavir
HMG-CoA Reductase Inhibitors
Atorvastatin, Lovastatin, Simvastatin

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

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