HEPATITIS C TREATMENT
PRIOR AUTHORIZATION (PA) POLICY

PROSPECTIVE APPROVAL OF HCV MEDICATIONS

The following is a list of **ALL** circumstances which **MUST** come to DHMH for initial approval. Patients who meet the specifications below must be sent to Gina Homer for review. If there is any question about whether or not the patient should come to DHMH for review, the MCO MUST send an inquiry to Gina. Clinical documentation (as described below in this policy*) for the following patients MUST be sent to **DHMH** for review:

A. Any patient who has received previous treatment with a direct acting antiviral (DAA) - equals treatment experienced. This includes patients who may have been reinfected (Appendix B).
B. Any patient infected with genotype 3 **AND** has cirrhosis (metavir score of F4).
C. Any patient co-infected with HIV **AND** their HIV is **NOT** virologically suppressed. Virologic suppression is defined as HIV RNA < 200 copies/mL.
D. Any patient who has received a liver transplant.
E. Any patient for whom therapy with the combination of sofosbuvir and simeprevir is requested.
F. Any patient for whom therapy with Vosevi ™ is requested.
G. Any patient infected with genotype 1a **AND** for which treatment with Zepatier is requested.
H. Any patient whose therapy was initially denied by the MCO and for which the provider is now requesting reconsideration **AND**
    - Requires therapy with an immunosuppressant **OR**
    - Has extrahepatic manifestations of HCV **OR**
    - Provider relates to the MCO that there are extenuation circumstances which require urgent treatment of HCV.
I. Any patient for whom a therapy is requested which is not included in the most recent version of DHMH's clinical criteria.

***CLINICAL DOCUMENTATION REQUIREMENTS:**

1. New Request (approve initial 8 weeks)

A. Completed PA form.
B. Recent (within the last 3 months) provider note.
    i. Prior HCV treatment history (i.e. treatment naïve or treatment experienced).
    ii. If treatment experienced, prior therapies and responses and genotype (pre and post) DAA therapy.
    iii. Planned HCV treatment regimen.
C. Genotype.
D. Baseline lab values up to and including 90 days of prior authorization request.
    i. HCV Viral load.
    ii. Serum creatinine **OR** eGFR for regimens containing Sovaldi®, Harvoni®, or Epclusa® or Vosevi ™.
    iii. Total bilirubin.
    iv. Albumin.
    v. AST.
    vi. ALT.
    vii. Hemoglobin, hematocrit and platelet count for RBV containing regimens.
E. Fibrosis score.

F. HIV viral load (**ONLY** if the patient is co-infected).
G. Polymorphism test (when required – See Clinical Criteria).
H. Detail assessment plan (required when individual has an active diagnosis of a substance use disorder, but is not actively engaged in treatment)

2. Refill Request (after the initial 8 weeks)

A. Total treatment duration of 12 weeks (approve additional 4 weeks)
   i. Viral load (VL) completed **AT OR BETWEEN** weeks 2 and 6 of therapy (note: this is 1st VL. VLs are **NOT** required to be done at multiple time points during this time period)
B. Total treatment duration of 16 weeks (approve additional 8 weeks)
   i. Viral load (VL) completed **AT OR BETWEEN** weeks 2 and 6 of therapy (note: this is 1st VL. VLs are **NOT** required to be done at multiple time points during this time period)
C. Total treatment duration of greater than 16 weeks (approve additional 8 weeks)
   i. Viral load (VL) completed **AT OR BETWEEN** weeks 2 and 6 of therapy (note: this is 1st VL. VLs are **NOT** required to be done at multiple time points during this time period)
   ii. VL completed **AT OR BETWEEN** weeks 8 and 14 of therapy is required (note: this is 2nd VL)

Pre-treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented.
- Patients who have prior exposure to DAA therapy must have a pre-DAA genotype and post-DAA genotype documented (Appendix B)
- HCV RNA quantitative within 90 days of application for therapy.
- Liver biopsy or other accepted test (Appendix A) demonstrating liver fibrosis corresponding to Metavir score of greater than or equal to 2.
- Previous HCV treatment history and outcome.
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression.
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy.
- Drug resistance testing as indicated.

Patient Treatment Plan

- It is required that the patient have a treatment plan developed by, or in collaboration with, a provider with expertise in Hepatitis C management. Sample Treatment plan documents are available for use.
- If the patient or their partner is of childbearing age, at least two (2) forms of contraception must be used (by the patient or their partner) if a RBV -containing regimen is prescribed throughout the duration of therapy and for 6 months after the regimen is completed.

Drug Therapy

- Must be in accordance with FDA approved indications.

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

Treatment Options[1]:

Genotype 1a:

o **Elbasvir/grazoprevir (Zepatier™)[3]** **Send to state for review and approval**

- Prior to requesting/initiating therapy with this agent, genotype testing for baseline **NS5A polymorphisms is REQUIRED**, in order to determine treatment length
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 1**, Individual has had a prior trial (medication samples/coupons/discount card are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
  a. Individual is currently on and completing a course of therapy with Zepatier; **OR**
  b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Zepatier; **OR**
  c. 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 the preferred regimen or regimens; **OR**
  d. Zepatier (elbasvir/grazoprevir) ± ribavirin may be approved if the individual has concomitant severe or end-stage CKD or requires dialysis.

Patient characteristics	Treatment	Treatment length
Treatment naïve, without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment naïve, with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks
Treatment experienced (PegIFN/RBV), without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV), with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks

o **Ledipasvir/sofosbuvir (Harvoni®)[4]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:

a. Individual is currently on or completing a course of therapy with the requested regimen; OR
b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Harvoni OR
c. 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 the preferred regimen or regimens; OR
d. Individual is a post-liver allograft transplant recipient; OR
e. Individual has decompensated[1] cirrhosis; OR
f. Individual is aged 12 to 17 years old or at least 35 kg; OR
g. Individual is a post-kidney transplant recipient with or without compensated[1] cirrhosis;

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naive patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.
**A 12 week regimen with weight-based ribavirin may be considered.

o **Daclatasvir (Daklinza®) and Sofosbuvir (Sovaldi®)[2]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; OR
  c. 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 the preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

o **Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak/Viekira XR®) with Weight Based Ribavirin[5]**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Viekira Pak/Viekira XR; OR
  c. 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 the

preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis	24 weeks

o Simeprevir (Olysio®) and Sofosbuvir (Sovaldi®)[5]

- Negative Q80K polymorphism test REQUIRED
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- Any request for concomitant use with sofosbuvir/simeprevir: **Send to state for review and approval**
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Olysio or Sovaldi; OR
  c. 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 the preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

o Sofosbuvir/velpatasvir (Epclusa®)[7]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval
- For **Genotype 1**
  a. Individual is currently on and completing a course of therapy with the requested regimen; OR
  b. Individual has had a prior trial and inadequate response to Mavyret; OR
  c. One of the following:
    i. 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
    ii. 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
    iii. Individual has decompensated cirrhosis.

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

oSofosbuvir/velpatasvir/voxilaprevir (Vosevi ™) Send to state for review and approval

- Prior DAA experience with an NS5A inhibitor or sofosbuvir

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**
- One of the following:
  a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
  b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
  c. The individual has one of the following:
     i. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Vosevi; **OR**
     ii. 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 the preferred regimen or regimens.

o **Glecaprevir/pibrentasvir (Mavyret ™)**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	**Treatment length**
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

Genotype 1b:

o **Elbasvir/grazoprevir (Zepatier™)**[3]

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 1**, Individual has had a prior trial (medication samples/coupons/discount card are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
  a. Individual is currently on and completing a course of therapy with Zepatier; **OR**
  b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Zepatier; **OR**
  c. 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 the preferred regimen or regimens; **OR**
  d. Zepatier (elbasvir/grazoprevir) ± ribavirin may be approved if the individual has concomitant severe or end-stage CKD or requires dialysis.

Patient characteristics	**Treatment length**
Treatment naïve	12 weeks
Treatment experienced (PegIFN/RBV)	12 weeks

o **Ledipasvir/sofosbuvir (Harvoni®)**[4]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any

ingredient in Mavyret which is not also in Harvoni; OR

c. 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 the preferred regimen or regimens; OR
d. Individual is a post-liver allograft transplant recipient; OR
e. Individual has decompensated1 cirrhosis; OR
f. Individual is aged 12 to 17 years old or at least 35 kg; OR
g. Individual is a post-kidney transplant recipient with or without compensated cirrhosis.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naive patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.
**A 12 week regimen with weight-based ribavirin may be considered.

o **Daclatasvir (Daklinza®) and Sofosbuvir (Sovaldi®)[2]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; OR
  c. 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 the preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

o **Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak/Viekira XR®)[5]**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Viekira Pak/Viekira XR; OR
  c. 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 the preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks

Treatment experienced, with or without cirrhosis*	12 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

o Simeprevir (Olysio®) and Sofosbuvir (Sovaldi®)[6]

- Negative Q80K polymorphism test REQUIRED
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- Any request for concomitant use with sofosbuvir/simeprevir: **Send to state for review and approval**
- For **Genotype 1**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Olysio or Sovaldi; OR
  c. 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 the preferred regimen or regimens.

Patient characteristics	**Treatment length**
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen for the same treatment length.

o Sofosbuvir/velpatasvir (Epclusa®)[7]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval
- For **Genotype 1**
  a. Individual is currently on and completing a course of therapy with the requested regimen; OR
  b. Individual has had a prior trial and inadequate response to Mavyret; OR
  c. One of the following:
    i. 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
    ii. 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
    iii. Individual has decompensated cirrhosis.

Patient characteristics	**Treatment**	**Treatment length**
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

o Sofosbuvir/velpatasvir/voxilaprevir (Vosevi ™) **Send to state for review and approval**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**
- One of the following:

a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
c. The individual has one of the following:
    i. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Vosevi; **OR**
    ii. 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 the preferred regimen or regimens.

o **Glecaprevir/pibrentasvir (Mavyret ™)**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	**Treatment length**
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

Genotype 2:

o **Sofosbuvir/velpatasvir (Epclusa®)[7]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval.
- For **Genotype 2**:
    a. Individual is currently on and completing a course of therapy with the requested regimen; OR
    b. Individual has had a prior trial and inadequate response Mavyret; OR
    c. One of the following:
        i. 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
        ii. 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
        iii. Individual is a post-liver allograft transplant recipient and has decompensated[1] cirrhosis; OR
        iv. Individual has decompensated[1] cirrhosis.

Patient characteristics	**Treatment**	**Treatment length**
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

o **Sofosbuvir (Sovaldi®) and weight based ribavirin[8]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 2**, Individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
    a. Individual is currently on or completing a course of therapy with the requested regimen; OR
    b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Sovaldi; OR
    c. 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 the preferred regimen or regimens; **OR**

d. Individual is aged 12 to 17 years old or at least 35 kg.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis	16 weeks
Treatment experienced, without cirrhosis*	16 weeks
Treatment experienced, with cirrhosis**	16 weeks

***Providers may add PegIFN to this regimen to shorten treatment length to 12 weeks.
**Providers may request and extension to 24 weeks if medically necessary

o **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi ™)** **Send to state for review and approval**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**
- As monotherapy:
  a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
  b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
  c. The individual has one of the following:
     i. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Vosevi; **OR**
     ii. 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 the preferred regimen or regimens; **OR**

o **Glecaprevir/pibrentasvir (Mavyret ™)**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

Genotype 3: Send these requests to the state for review in cases with cirrhosis (metavir score of F4)

o **Sofosbuvir/velpatasvir (Epclusa®)[7]**

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval.
- For **Genotype 3**
  a. Individual is currently on and completing a course of therapy with the requested regimen; OR
  b. Individual has had a prior trial and inadequate response to Mavyret; OR
  c. One of the following:
     i. 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

ii. 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;
iii. Individual is a post-liver allograft transplant recipient and has decompensated cirrhosis; OR
iv. Individual is dual P/R treatment-experienced without cirrhosis; OR
v. Individual has decompensated cirrhosis.

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

o **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi ™)** **Send to state for review and approval**

- Prior DAA experience with an NS5A inhibitor or sofosbuvir
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**
- One of the following:
  a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
  b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
  c. The individual has one of the following:
    i. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Vosevi; **OR**
    ii. 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 the preferred regimen or regimens; **OR**

o **Glecaprevir/pibrentasvir (Mavyret ™)**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	16 weeks
Treatment experienced, with compensated cirrhosis	16 weeks

o **Daclatasvir (Daklinza®) and Sofosbuvir (Sovaldi®)**[2]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 3**, individual must have had a prior trial and inadequate response to Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Mavyret which is not also in Daklinza or Sovaldi; OR
  c. 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 the preferred regimen or regimens; **OR**

d. Individual is a post-liver allograft transplant recipient.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

Genotype 4:

o **Elbasvir/grazoprevir (Zepatier™)**[3]

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 4**, Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa OR Mavyret; **OR**
  a. Individual is currently on and completing a course of therapy with Zepatier; **OR**
  b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa OR Mavyret which is not also in Zepatier; **OR**
  c. 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 the preferred regimen or regimens; **OR**
  d. Zepatier (elbasvir/grazoprevir) ± ribavirin may be approved if the individual has concomitant severe or end-stage CKD or requires dialysis.

Patient characteristics	Treatment	Treatment length
Treatment naïve	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV)	Zepatier + weight based ribavirin	16 weeks

o **Sofosbuvir/velpatasvir (Epclusa®)**[7]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

o **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi ™)** **Send to state for review and approval**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**
- One of the following:
  a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa OR Mavyret; **OR**
  b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
  c. The individual has one of the following:

i. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa OR Mavyret which is not also in Vosevi; **OR**
ii. 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 the preferred regimen or regimens; **OR**

o **Glecaprevir/pibrentasvir (Mavyret ™)**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	**Treatment length**
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

o **Ledipasvir/sofosbuvir (Harvoni®)**[4]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 4**, individual must have had a prior trial and inadequate response to Epclusa OR Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Epclusa OR Mavyret which is not also in Harvoni; OR
  c. 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 the preferred regimen or regimens; **OR**
  d. Individual is a post-liver allograft transplant recipient; OR
  e. Individual is aged 12 to 17 years old or at least 35 kg; OR
  f. Individual has decompensated1 cirrhosis; OR
  g. Individual is a post-kidney transplant recipient with or without compensated cirrhosis.

Patient characteristics	**Treatment length**
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

o **Ombitasvir/paritaprevir/ritonavir (Technivie®) and weight based ribavirin**[9]

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required
- For **Genotype 4**, individual must have had a prior trial and inadequate response to Epclusa OR Mavyret; OR
- One of the following:
  a. Individual is currently on or completing a course of therapy with the requested regimen; OR
  b. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Epclusa OR Mavyret which is not also in Technivie; OR
  c. 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 the

preferred regimen or regimens.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

Genotype 5 and 6:

o **Sofosbuvir/velpatasvir (Epclusa®)**[7]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval
- For **Genotype 5 and 6**
  a. Individual is currently on and completing a course of therapy with the requested regimen; OR
  b. Individual has had a prior trial and inadequate response to Mavyret; OR
  c. One of the following:
    i. 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
    ii. 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**
    iii. Individual has decompensated[1] cirrhosis.

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

o **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi ™)** **Send to state for review and approval**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.
- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥ 30 mL/min is required for approval**.**

o **Glecaprevir/pibrentasvir (Mavyret ™)**

ii. Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	12 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

o **Ledipasvir/sofosbuvir (Harvoni®)**[4]

- Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval
- For **Genotype 5 and 6**
  a. Individual is currently on and completing a course of therapy with the requested regimen; OR
  b. Individual has had a prior trial and inadequate response to Mavyret; OR
  c. One of the following:

i. 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
ii. 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**
iii. Individual is aged 12 to 17 years old or at least 35 kg; OR
iv. Individual is a post-liver allograft transplant recipient; OR
v. Individual has decompensated1 cirrhosis.

▪

Patient characteristics	**Treatment length**
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

References:

1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. July 13, 2016 accessed.
2. Daklinza [package insert]. Princeton, NJ: Bristol-Myers Squibb Company, February 2016.
3. Zepatier [package insert]. Whitehouse Station, NJ: Merck and Co., Inc., January 2016.
4. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2015.
5. Viekira pak [package insert]. North Chicago, IL: AbbVie Inc., January 2016.
6. Olysio [package insert]. NJ: Janssen Therapeutics, October 2015.
7. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc., June 2016.
8. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc., August 2015.
9. Technivie [package insert]. North Chicago, IL: AbbVie Inc., January 2016.
10. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc., August 2017.
11. Mavyret [package insert]. North Chicago, IL: AbbVie Inc., August 2017.

Appendix A: Acceptable tests for determination of fibrosis in HCV

Noninvasive methods for determination of liver disease

Numerous noninvasive methodologies have been developed to determine the degree of fibrosis in patients infected with chronic HCV. These methodologies employ either the use of biomarkers or evaluation of liver stiffness to make a determination regarding the degree of liver fibrosis.[1] Below is a table of acceptable noninvasive testing and the score which is equivalent to metavir stage F2.

Noninvasive test	**Score equivalent to metavir stage F2**
FibroScan (transient elastography)	7.9 kPa[2]
Point shear wave elastography (pSWE) Acoustic radiation force impulse imaging (AFRI)	1.34 m/s[3]
MR elastography	3.66 kPa[4]
Hepascore ®/Fibroscore ®	0.2
Fibrosure®	0.48

1. Castera L. Noninvasive methods to assess liver disease in patients with hepatitis B or C. Gastroenterology 2012;142:1293-1302.
2. Foucher J, Chanteloup E, Vergniol J, et al. Diagnosis of cirrhosis by transient elastography (Fibroscan): a prospective study. Gut 2006;55:403-8.
3. Ferraioli G, Tinelli C, Dal Bello B, et al. Accuracy of real-time shear wave elastography for assessing

liver fibrosis in chronic hepatitis C: a pilot study. Hepatology 2012;56:2125.
4. Singh S, Venkatesh SK, Wang Z, et al. Diagnostic performance of magnetic resonance elastography in staging liver fibrosis: a systematic review and meta-analysis of individual participant data. Clin Gastroenterol Hepatol 2015;13:440.

Appendix B: HCV Treatment Definitions

Retreatment: Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR and current need for an additional course of therapy to treat chronic HCV infection.
Conditions required:

- •Detectable HCV RNA at 12 weeks post treatment.
- •HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection: Exposure to an HCV treatment regimen, which results in achievement of SVR.
Conditions required:

- •Detectable HCV RNA > 12 weeks post treatment
- •HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- •Current infection has been present ≥ 6 months.

Appendix C: Child Pugh Score Interpretation (AASLD/IDSA 2009, 2016)

Class A	5-6 points	Well compensated liver disease
Class B	7-9 points	Significant functional compromise (moderate hepatic impairment)
Class C	10-15 points	Uncompensated liver disease (severe hepatic impairment)

Appendix D: Chronic Kidney Disease (CKD) Definitions (AASLD/IDSA 2017):

Severe CKD (Stage 4): eGFR 15-29 mL/min
End-Stage CKD (Stage 5): eGFR < 15 mL/min