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.
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:**

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.
    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).

Pre-treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented.
- 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.

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

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 Zepatier; 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 OR Zepatier 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 has concomitant moderate or severe (Child-Pugh Class B or C hepatic impairment); OR
e. Request is for an 8 week course of Harvoni and the individual is eligible for an 8 week treatment course (treatment-naïve, no cirrhosis, baseline HCV RNA level of less than 6 million IU/mL, not HCV-HIV co-infected).

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 Zepatier; 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 OR Zepatier 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 Zepatier; 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 OR Zepatier 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 Zepatier; 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 OR Zepatier 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**, individual must have had a prior trial and inadequate response to Mavyret OR Zepatier; 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 OR Zepatier which is not also in Epclusa; 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 regimens; OR
  d. Individual has concomitant moderate or severe (Child-Pugh Class B or C) hepatic impairment.

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 Zepatier; **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 OR Zepatier 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

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 Zepatier; 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 OR Zepatier 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 has concomitant moderate or severe (Child-Pugh Class B or C hepatic impairment); OR

e. Request is for an 8 week course of Harvoni and the individual is eligible for an 8 week treatment course (treatment-naïve, no cirrhosis, baseline HCV RNA level of less than 6 million IU/mL, not HCV-HIV co-infected).

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 Zepatier; 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 OR Zepatier 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 toMavyret or Zepatier; 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 or Zepatier 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 Zepatier; 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 OR Zepatier 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**, individual must have had a prior trial and inadequate response to Mavyret OR Zepatier; 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 OR Zepatier which is not also in Epclusa; 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 regimens; OR
  d. Individual has concomitant moderate or severe (Child-Pugh Class B or C) hepatic impairment.

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 Zepatier; **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 OR Zepatier 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.

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 Epclusa; 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 OR Epclusa 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.

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:
    i. 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**
    ii. Individual is currently on and completing a course of therapy with Vosevi; **OR**
    iii. The individual has one of the following:
        a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa OR Mavyret which is not also in Vosevi; **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 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.

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:
    i. 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**
    ii. Individual is currently on and completing a course of therapy with Vosevi; **OR**
    iii. The individual has one of the following:
        a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa OR Mavyret which is not also in Vosevi; **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 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 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 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.

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

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:
  i. 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 Zepatier; **OR**
  ii. Individual is currently on and completing a course of therapy with Vosevi; **OR**
  iii. The individual has one of the following:
    a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa OR Mavyret OR Zepatier which is not also in Vosevi; **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 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 Zepatier; 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 OR Zepatier 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.

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 Zepatier; 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 OR Zepatier 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

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

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

References:

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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

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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: 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)