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.
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 infected with genotype 1a **AND** for which treatment with Zepatier is requested.
G. 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.
H. 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®.
    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

- Liver biopsy or other accepted test (Appendix A) demonstrating **liver fibrosis corresponding to Metavir score of greater than or equal to 2**;
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy;
- Drug resistance testing as indicated.
- 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.

Treatment Options[1]:

Genotype 1a:

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

- 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
- **Send to state for review and approval**

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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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. Individual has the following:
     i. Individual is post-liver allograft transplant recipient; OR
     ii. 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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).

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

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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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. Individual has the following:
     i. Individual is post-liver allograft transplant recipient; OR
     ii. 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 Zepatier ± ribavirin; 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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).

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

Genotype 2:

- **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

- **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**, documentation of the following:
    - Completion of a full course of Epclusa; OR
    - Rationale why Epclusa cannot be used

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

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

- **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

- **Daclatasvir (Dacklinza®) 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**, documentation of the following:
    - Completion of a full course of Epclusa; OR
    - Rationale why Epclusa cannot be used

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 **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 Zepatier ± ribavirin 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 post-liver allograft transplant recipient.

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 Zepatier ± ribavirin 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 the preferred regimen or regimens which is not also in the requested non-preferred regimen; 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 **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:

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.

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: 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)