Clinical Criteria for Hepatitis C (HCV) Therapy

Diagnosis

- Must have chronic hepatitis C, genotype and sub-genotype specified to determine the length of therapy;
- Liver biopsy or other accepted test demonstrating liver fibrosis corresponding to Metavir score of greater than or equal to 2;
- Consult performed and medication prescribed by a provider specializing in infectious disease, gastroenterology, hepatology or Hepatitis C.

Patient Treatment Plan

- Patient must have a treatment plan developed by the specialist.
- If patient or their partner is of childbearing age, she must utilize 2 forms of contraception.

Drug Therapy

- Must be in accordance to FDA approved indications.

Sofosbuvir (Sovaldi™)

RECOMMENDED REGIMENS AND TREATMENT DURATION FOR SOFOSBUVIR COMBINATION THERAPY IN HCV[i,ii,iii,iv,v,vi]

HCV Genotype and Comorbidities	Treatment	Duration
Patients with genotype 1 or 4 HCV with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Patients with genotype 2 HCV with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	12 weeks
Patients with genotype 3 HCV with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	24 weeks
Patients with HCV/HIV-1 co-infection (genotype 1 or 4) with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Patients with genotype 1 HCV and interferon ineligible, with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	24 weeks
Patients with hepatocellular carcinoma awaiting liver transplantation	sofosbuvir + ribavirin	48 weeks (or until the time of liver transplantation; whichever occurs first)

Age Edit: Adult patients age ≥18 years old

Quantity Limit: One 400 mg tablet per day (28 tablets/28 days).

Length of Authorization:

Based on HCV subtype, Patient must be treatment naïve to sofosbuvir.

INITIAL: 8 weeks

REFILLS: Should be reauthorized for additional 8 week period at a time, depending on the treatment plan. The patient must receive refills within one week of completing the previous 28 day supply throughout treatment.

Monitoring of the Virological Response:**

- Rapid virologic response (RVR): ≥ 2 log reduction in HCV RNA from the baseline or undetectable after 4 weeks of therapy
- Early Virologic response (EVR): undetectable HCV RNA viral load at treatment week 12
- Sustained virologic response (SVR): HCV RNA negative 12 weeks after cessation of therapy

DISCONTINUATION OF DOSING

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR), therefore discontinuation of treatment is recommended in these patients.

Treatment Stopping Rules in Any Patient with Inadequate On-Treatment Virologic Response**

HCV RNA	Action
Treatment Week 4: < 2 log reduction in HCV RNA from baseline	Discontinue sofosbuvir, peginterferon alfa and ribavirin
Treatment Week 12: any detectable HCV RNA level	Discontinue peginterferon alfa, ribavirin, and sofosbuvir (if applicable)
Treatment Week 24: any detectable HCV RNA level	Discontinue peginterferon alfa, ribavirin, and sofosbuvir (if applicable)

**** A FDA or AASLD recommendation for the discontinuation of treatment has not been released to date. Prescribers are encouraged to monitor HCV RNA to validate adherence to therapy/efficacy of therapy**

Interferon Alfa Ineligible Defined

- *Intolerance to interferon alfa;*
- *Autoimmune hepatitis and other autoimmune disorders;*
- *Hypersensitivity to peginterferon alfa or any of its components;*
- *Decompensated hepatic disease;*
- *Documented history of depression or mood disorder, which are not stable on the current drug regimen;*

- *Platelet count <75,000/mm3;*
- *A history of preexisting cardiac disease*.

For documented diagnosis of HCV with *genotype 1 [Triple therapy]* Combination with peginterferon and ribavirin – Approval for 12 weeks

- *Approve; OR*
- *Approve for HCV/HIV-1 co-infection; OR*
- *Approve* for patients with compensated cirrhosis, including those with hepatocellular carcinoma
- Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting sofosbuvir for a 12 week duration

For documented diagnosis of HCV with *genotype 1 [Dual therapy]* Combination with ribavirin – Approval for 24 weeks

- Patients **MUST** be interferon ineligible (document reason that patient is interferon ineligible)
- Approve; **OR**
- *Approve* for HCV/HIV-1 co-infection; **OR**
- *Approve* for patients with cirrhosis, including those with hepatocellular carcinoma
- Must be used in combination with ribavirin therapy

For documented diagnosis of HCV with genotype 2 *[Dual therapy]* Combination with ribavirin – Approval for 12 weeks

- Approve; **OR**
- *Approve* for HCV/HIV-1 co-infection; **OR**
- *Approve* for patients with cirrhosis, including those with hepatocellular carcinoma
- Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 12 week duration

For documented diagnosis of HCV with genotype 3 *[Dual therapy]* Combination with ribavirin – Approval for 24 weeks

- Approve; **OR**
- *Approve* for HCV/HIV-1 co-infection; **OR**
- *Approve* for patients with cirrhosis, including those with hepatocellular carcinoma
- Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 24 week duration

For diagnosis of HCV with genotype 4 [Triple therapy] Combination with peginterferon and ribavirin – Approval for 12 weeks

- Approve; **OR**
- *Approve* for HCV/HIV-1 co-infection; **OR**
- *Approve* for patients with cirrhosis, including those with hepatocellular carcinoma

- Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting sofosbuvir for a 12 week duration

For diagnosis of hepatocellular carcinoma awaiting liver transplantation [Dual therapy] Combination with ribavirin – Approval for 48 weeks

- Sofosbuvir efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria **and** awaiting liver transplantation)
- Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 48 week duration or until the time of liver transplantation, whichever occurs first.

- Milan criteria defined as:
  - ❒ the presence of a tumor 5 cm or less in diameter in subjects with single hepatocellular carcinoma; **AND**
  - ❒ no more than three tumor nodules, each 3 cm or less in diameter, in subjects with multiple tumors; **AND**
  - ❒ no extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor

ADDITIONAL SOFOSBUVIR INFORMATION TO AID IN THE FINAL DECISION

- Remind all providers that HCV-RNA levels will need to be obtained between treatment weeks 2 and 4 for continuation of treatment
- Approve for 8 weeks of initial therapy to begin with in order to allow time for lab test results to be processed.
- Must have baseline HCV RNA level within 60 days of anticipated treatment start date
- Patient is not receiving concomitant therapy with a hepatitis protease inhibitor (e.g. boceprevir (Victrelis®).
- Sofosbuvir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
- Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis.
- Patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state
- There is insufficient data to recommend use in patients with HCV genotypes 5 or 6.
- For HIV-1 lab report documenting that patient has HIV-1; AND
  - ❒ CD4 count greater than 500 cells/mm^3, if patient is not taking antiretroviral therapy; **OR**
  - ❒ CD4 count greater than 200 cells/mm^3, if patient is virologically suppressed (e.g. HIV RNA< 200 copies/mL)

Sofosbuvir/Ledipasvir (Harvoni®)

RECOMMENDED TREATMENT DURATION FOR SOFOSBUVIR/LEDIPASVIR COMBINATION THERAPY IN HCV

HCV Genotype and Comorbidities	Treatment	Duration
Treatment naive patients with genotype 1 HCV with or without cirrhosis	sofosbuvir + ledipasvir	12 weeks*
Treatment experienced** patients with genotype 1 HCV without cirrhosis	sofosbuvir + ledipasvir	12 weeks
Treatment experienced** patients with genotype 1 HCV with cirrhosis	sofosbuvir + ledipasvir	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.

**Treatment experienced patients include patients who have failed treatment with either peginterferon alpha + ribavirin or an HCV protease inhibitor + peginterferon alpha + ribavirin

Age Edit: Adult patients age ≥18 years old

Quantity Limit: One 90 mg/400 mg tablet per day (28 tablets/28 days).

Length of Authorization:

Based on treatment experience and cirrhosis, Patient must be treatment naïve to sofosbuvir and ledipasvir

INITIAL: 8 weeks

REFILLS: Should be reauthorized for additional 8 week period at a time, depending on the treatment plan. The patient must receive refills within one week of completing the previous 28 day supply throughout treatment.

Monitoring of the Virological Response:**

- Rapid virologic response (RVR): ≥ 2 log reduction in HCV RNA from the baseline or undetectable after 4 weeks of therapy
- Early Virologic response (EVR): undetectable HCV RNA viral load at treatment week 12
- Sustained virologic response (SVR): HCV RNA negative 12 weeks after cessation of therapy

DISCONTINUATION OF DOSING

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR), therefore discontinuation of treatment is recommended in these patients.

Treatment Stopping Rules in Any Patient with Inadequate On-Treatment Virologic Response**

HCV RNA	Action
Treatment Week 4: < 2 log reduction in HCV RNA from baseline	Discontinue sofosbuvir/ledipasvir
Treatment Week 12: any detectable HCV RNA level	Discontinue sofosbuvir/ledipasvir
Treatment Week 24: any detectable HCV RNA level	Discontinue sofosbuvir/ledipasvir

**** A FDA or AASLD recommendation for the discontinuation of treatment has not been released to date. Prescribers are encouraged to monitor HCV RNA to validate adherence to therapy/efficacy of therapy**

ADDITIONAL SOFOSBUVIR/LEDIPASVIR INFORMATION TO AID IN THE FINAL DECISION

- Remind all providers that HCV-RNA levels will need to be obtained between treatment week 2 and 4 for continuation of treatment
- Approve for 8 weeks of initial therapy to begin with in order to allow time for lab test results to be processed.
- Must have baseline HCV RNA level within 60 days of anticipated treatment start date
- Patient is not receiving concomitant therapy with a hepatitis protease inhibitor (e.g. boceprevir (Victrelis®).
- The concomitant use of sofosbuvir/ledipasvir and P-gp inducers (e.g., rifampin, St. John's wort) may significantly decrease ledipasvir and sofosbuvir plasma concentrations and may reduce the therapeutic effect. Therefore, the use of sofosbuvir/ledipasvir with P-gp inducers (e.g., rifampin or St. John's wort) is not recommended.
- Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis.
- Patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state.
- There is insufficient data to recommend use in patients with HCV genotypes other than genotype 1.
- For HIV-1 lab report documenting that patient has HIV-1; AND
  - ❒ CD4 count greater than 500 cells/mm^3, if patient is not taking antiretroviral therapy; **OR**
  - ❒ CD4 count greater than 200 cells/mm^3, if patient is virologically suppressed (e.g. HIV RNA< 200 copies/mL

[i] Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
[ii] FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
[iii] Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
[iv] Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. N Engl J Med. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
[v] Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. N Engl J Med. 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
[vi][vi][vi] American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.

Simeprevir (Olysio™)[vi,vi]

Length of Authorization:

INITIAL: 8 weeks for all three agents

RENEWAL: Request week 4 labs for renewal (see below). If meet renewal criteria, then reauthorize an additional 4 weeks of therapy with all three agents for a total duration of 12 weeks.

Refills: The patient must receive refills within one week of completing the previous supply.

Quantity Limit: Simeprevir 150mg should have a quantity limit of 1 tablet per day for a total duration of 12 weeks.

Approval Criteria: Approve simeprevir initially for 8 weeks of therapy if ALL of the following are true:

- Prescriber must specialize in infectious disease or gastro-enterology/hepatology
- Diagnosis of hepatitis C virus (HCV) with genotype 1; **AND**
- Patient CANNOT have failed therapy with an oral protease inhibitor indicated for HCV (e.g., Victrelis®, or Olysio); **AND**
- Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting simeprevir; **AND**
- Must be an adult patient age 18 and over; **AND**
- Patient has NOT had liver transplant; **AND**
- Patient is NOT infected with HCV genotype 1a containing the Q80K polymorphism; **AND**
- Patient is NOT co-infected with HCV/HIV

RENEWAL

After 8 weeks of therapy, approve simeprevir, peginterferon alfa and ribavirin for an additional 4 weeks of therapy if HCV-RNA shows a minimum 2 log reduction from baseline between treatment week 2 and 4

After 8 weeks of therapy, discontinue simeprevir, peginterferon alfa, and ribavirin if HCV-RNA does not show a 2 log or greater reduction from baseline at treatment week 4.

DISCONTINUATION OF DOSING

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR), therefore discontinuation of treatment is recommended in these patients.

Treatment Stopping Rules in Any Patient with Inadequate On-Treatment Virologic Response

HCV RNA	Action
Treatment Week 4: < 2 log reduction in HCV RNA from baseline	Discontinue simeprevir, peginterferon alfa and ribavirin
Treatment Week 12: any detectable HCV RNA level	Discontinue peginterferon alfa and ribavirin (treatment with simeprevir is complete at week 12)

****A FDA or AASLD recommendation for the discontinuation of treatment has not been released to date. Prescribers are encouraged to monitor HCV RNA to validate adherence to therapy/efficacy of therapy**

ADDITIONAL OLYSIO INFORMATION TO AID IN THE FINAL DECISION

- Remind all providers that HCV-RNA viral levels will need to be obtained between treatment week 2 and 4 for continuation of treatment with simeprevir and week 12 for continuation of treatment with interferon and ribavirin.
- Approve for 8 weeks of initial therapy to begin with in order to allow time for lab test results to be processed.
- Patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state.

[vi] Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
[vi] FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
[vi] Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
[vi] Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. N Engl J Med. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
[vi] Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. N Engl J Med. 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
[vi] American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.
[vi] Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. November 2013.
[vi] American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.

Sofosbuvir (Sovaldi™) and Simeprevir (Olysio™)[vi,vi]

- **Any request for this therapy will be reviewed on a case-by-case basis by DHMH.**

Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira Pak™)

RECOMMENDED TREATMENT DURATION FOR Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir COMBINATION THERAPY IN HCV

HCV Genotype and Comorbidities	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira Pak™ + ribavirin	12 weeks
Genotype 1a, with cirrhosis	Viekira Pak™ + ribavirin	24 weeks
Genotype 1b, without cirrhosis	Viekira Pak™	12 weeks
Genotype 1b, with cirrhosis	Viekira Pak™ + ribavirin	12 weeks

*Follow genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.

Patients with HCV/HIV-1 co-infection: Follow the dosage recommendations in the table above.

Age Edit: Adult patients age ≥18 years old

Quantity Limit: Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablet per day (56 tablets/28 days) + two dasabuvir 250 mg tablets per day (56 tablets/ 28 days). Note that product is packaged in a monthly carton which contains a total of 28 days of therapy.

Length of Authorization:

Based on genotype, subgenotype and presence of cirrhosis.

INITIAL: 8 weeks

REFILLS: Should be reauthorized for additional 4 to 8 week period, depending on the treatment plan. The patient must receive refills within one week of completing the previous 28 day supply throughout treatment.

Monitoring of the Virological Response:**

- Rapid virologic response (RVR): ≥ 2 log reduction in HCV RNA from the baseline or undetectable after 4 weeks of therapy
- Early Virologic response (EVR): undetectable HCV RNA viral load at treatment week 12
- Sustained virologic response (SVR): HCV RNA negative 12 weeks after cessation of therapy

DISCONTINUATION OF DOSING

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR), therefore discontinuation of treatment is recommended in these patients.

Treatment Stopping Rules in Any Patient with Inadequate On-Treatment Virologic Response**

HCV RNA	Action
Treatment Week 4: < 2 log reduction in HCV RNA from baseline	Discontinue Viekira Pak™ + ribavirin
Treatment Week 12: any detectable HCV RNA level	Discontinue Viekira Pak™ + ribavirin
Treatment Week 24: any detectable HCV RNA level	Discontinue Viekira Pak™ + ribavirin

**** A FDA or AASLD recommendation for the discontinuation of treatment has not been released to date. Prescribers are encouraged to monitor HCV RNA to validate adherence to therapy/efficacy of therapy**

ADDITIONAL OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR INFORMATION TO AID IN THE FINAL DECISION

- Remind all providers that HCV-RNA levels will need to be obtained between treatment weeks 2 and 4 for continuation of treatment
- Approve for 8 weeks of initial therapy to begin with in order to allow time for lab test results to be processed.
- Must have baseline HCV RNA level within 60 days of anticipated treatment start date
- Patient is not receiving concomitant therapy with a hepatitis protease inhibitor, HCV polymerase inhibitor or NS5A inhibitor (e.g. boceprevir, simeprevir, ledipasvir or sofosbuvir).
- Viekira Pak™ combination treatment with ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
- Viekira Pak™ is contraindicated in patients with severe hepatic impairment/Child-Pugh C secondary to risk of potential toxicity. Viekira Pak™ is not recommended in patients with moderate hepatic impairment/Child-Pugh B.
- The concomitant use of Viekira Pak™ is contraindicated with medications that are highly dependent on CYP3A for clearance (e.g. alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergot derivatives, ethinyl estradiol containing products, St. John's wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil when dosed for PAH, triazolam and oral forms of midazolam)
- Viekira Pak™ is contraindicated in patients with known hypersensitivity to ritonavir
- Patient does *not* have end stage renal disease (ESRD) requiring hemodialysis.
- Patient must be 6 months free of substance/alcohol/opioid dependence, unless a patient has significant progression of disease state.
- There is insufficient data to recommend use in patients with HCV genotypes other than genotype 1.
- Patients co-infected with HIV and treated with Viekira Pak™ should also be on suppressive antiretroviral therapy for HIV to reduce the risk of HIV protease inhibitor drug resistance, as Viekira Pak™ contains ritonavir.

Retreatment Guidelines

Degree of hepatic damage/treatment experience	Treatment	Duration of Total Therapy
Recommended Treatment genotype 1a		
Patients **(previous PEG-IFN and RBV))** who do NOT have cirrhosis	Ledipasvir/sofosbuvir OR Paritaprevir/ritonavir/ombitasvir + Dasabuvir + Ribavirin	12 weeks
Patients **(previous PEG-IFN and RBV))** who have compensated cirrhosis	Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/ombitasvir + Dasabuvir + Ribavirin	24 weeks 12 weeks 24 weeks
Patients **(previous PEG-IFN + RBV + HCV protease inhibitor)** who do NOT have cirrhosis	Ledipasvir/sofosbuvir	12 weeks
Patients **(previous PEG-IFN + RBV + HCV protease inhibitor)** who have cirrhosis	Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin	24 weeks 12 weeks
Patients **(sofosbuvir-containing regimen)** who have advanced fibrosis/ cirrhosis	Ledipasfivr/sofosbuvir +/- ribavirin	24 weeks
Recommended treatment genotype 1b		
Patients **(PEG-IFN and RBV))** who do NOT have cirrhosis	Ledipasvir/sofosbuvir OR Paritaprevir/ritonavir/ombitasvir + Dasabuvir	12 weeks
Patients **(previous PEG-IFN and RBV))** who have compensated cirrhosis	Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/ombitasvir + Dasabuvir + Ribavirin	24 weeks 12 weeks 12 weeks
Recommended Treatment genotype 2		

Patients with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	12 weeks (patients with cirrhosis may benefit from an extension to 16 weeks of treatment)
Alternative Regimen genotype 2		
Patients **(interferon eligible)** with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Recommended Treatment genotype 3		
Patients with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	24 weeks
Alternative Regimen genotype 3		
Patients **(interferon eligible)** with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Recommended treatment genotype 4		
Patients **(interferon eligible)** with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + peginterferon alfa + ribavirin	12 weeks
Alternative Regimen genotype 4		
Patients with or without compensated cirrhosis (including those with hepatocellular carcinoma)	sofosbuvir + ribavirin	24 weeks
NOT RECOMMENDED (ALL GENOTYPES)		
Telaprevir, boceprevir, or any monotherapy with any agent		