Clinical Criteria for Hepatitis C (HCV) Therapy

Diagnosis
- Must have chronic hepatitis C (HCV infection > 6 months), 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
- It is recommended that the patient have a treatment plan developed in collaboration with a physician with expertise in Hepatitis C management. Sample treatment plan documents are available for use.
- If the patient or their partner is of childbearing age, she must utilize 2 forms of contraception if a ribavirin-containing regimen is prescribed.

Drug Therapy
- Must be in accordance to FDA approved indications.

Sofosbuvir (Sovaldi™)

RECOMMENDED REGIMENS AND TREATMENT DURATION FOR SOFOSBUVIR COMBINATION THERAPY IN HCV

<table>
<thead>
<tr>
<th>HCV Genotype and Comorbidities</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with genotype 2 HCV with or without compensated cirrhosis (including those with hepatocellular carcinoma)</td>
<td>sofosbuvir + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Patients with genotype 3 HCV without compensated cirrhosis (including those with hepatocellular carcinoma)†</td>
<td>sofosbuvir + daclatasvir OR Sofosbuvir + ribavirin + peginterferon OR Sofosbuvir + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Patients with genotype 4 HCV with or without compensated cirrhosis (including those with hepatocellular carcinoma)</td>
<td>sofosbuvir + peginterferon alfa + ribavirin OR Sofosbuvir + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24 weeks</td>
</tr>
</tbody>
</table>
Patients infected with genotype 3 and who have cirrhosis should be sent to DHMH for review

**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 4 to 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.

**DISCONTINUATION OF DOSING**
- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR) defined as an undetectable HCV RNA 12 weeks post-cessation of therapy, therefore discontinuation of treatment is recommended in these patients.

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

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Week 4: &lt; 2 log reduction in HCV RNA from baseline</td>
<td>Discontinue all HCV therapy</td>
</tr>
<tr>
<td>Treatment Week 12: any detectable HCV RNA level</td>
<td>Discontinue all HCV therapy (if applicable)</td>
</tr>
<tr>
<td>Treatment Week 24: any detectable HCV RNA level</td>
<td>Discontinue all HCV therapy (if applicable)</td>
</tr>
</tbody>
</table>

** 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

**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 daclatasvir – Approval for 12 weeks
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
For diagnosis of HCV with genotype 4 [Dual or Triple therapy] Combination with peginterferon and ribavirin – Approval for 12 or 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 and peginterferon when starting sofosbuvir for a 12 or 24 week duration

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 90 days of anticipated treatment start date
- 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/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
- 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, patient should be virologically suppressed or provider should provide additional rationale for treatment initiation.
DACLATASVIR (DAKLINZA™)

RECOMMENDED REGIMEN AND TREATMENT DURATION FOR DACLATASVIR COMBINATION THERAPY IN HCV™

<table>
<thead>
<tr>
<th>HCV Genotype and Comorbidities</th>
<th>Treatment*</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 3, without cirrhosis*</td>
<td>daclatasvir +sofosbuvir</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*Patients infected with genotype 3 and who have cirrhosis should be sent to DHMH for review

Age Edit: Adult patients age ≥18 years old

Quantity Limit*:
- One 30 mg tablet per day (28 tablets/28 days), or
- One 60 mg tablet per day (28 tablets/28 days), or
- One 30 and one 60 mg tablet per day (56 tablets/28 days). Note, 60 mg is usual dose, however, if there is a significant drug-drug interaction a patient may be prescribed 30 mg or 90 mg. See below for additional details.

*Quantity limits/dose modifications are based on drug-drug interactions.
  - Reduced dose to 30 mg once daily with strong CYP3A inhibitors
  - Increase dose to 90 mg once daily with moderate CYP3A inducers
  - Strong CYP3A inducers, including; phenytoin, carbamazepine, rifampin and St. John’s wort are contraindicated

Length of Authorization:
12 weeks

INITIAL: 8 weeks

REFILLS: Should be reauthorized for additional 4 weeks. The patient must receive refills within one week of completing the previous 28 day supply throughout treatment.

DISCONTINUATION OF DOSING
- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR) defined as an undetectable HCV RNA 12 weeks post-cessation of therapy, therefore discontinuation of treatment is recommended in these patients.

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

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Week 4: &lt; 2 log reduction in HCV RNA from baseline</td>
<td>Discontinue sofosbuvir and daclatasvir</td>
</tr>
</tbody>
</table>
** 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 DACLATASVIR 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 90 days of anticipated treatment start date
• No dosage adjustment is required for patients with any degree of renal impairment
• No dosage adjustment is required for patients with mild, moderate or severe hepatic impairment
• There is insufficient data to recommend use in patients with HCV genotypes other than genotype 3.
• For HIV-1 lab report documenting that patient has HIV-1, patient should be virologically suppressed or provider should provide additional rationale for treatment initiation.
**Ledipasvir/Sofosbuvir/ (Harvoni®)**

**RECOMMENDED REGIMEN AND TREATMENT DURATION FOR SOFOSBUVIR/LEDIPASVIR COMBINATION THERAPY IN HCV**

<table>
<thead>
<tr>
<th>HCV Genotype and Comorbidities</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment naïve patients with genotype 1 HCV with or without cirrhosis</td>
<td>sofosbuvir + ledipasvir</td>
<td>12 weeks*</td>
</tr>
<tr>
<td>Treatment naïve patients with genotype 4 HCV with or without cirrhosis</td>
<td>Sofosbuvir + ledipasvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment naïve patients with genotype 5 HCV with or without cirrhosis</td>
<td>Sofosbuvir + ledipasvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment naïve patients with genotype 6 HCV with or without cirrhosis</td>
<td>Sofosbuvir + ledipasvir</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*8 weeks of treatment can be considered in treatment naïve 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 peginterferon alfa + 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 4 to 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.

**DISCONTINUATION OF DOSING**

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR) defined as an undetectable HCV RNA 12 weeks post-cessation of therapy, therefore discontinuation of treatment is recommended in these patients.

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

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Week 4: &lt; 2 log reduction in HCV RNA from baseline</td>
<td>Discontinue sofosbuvir/ledipasvir</td>
</tr>
<tr>
<td>Treatment Week 12: any detectable HCV RNA level</td>
<td>Discontinue sofosbuvir/ledipasvir</td>
</tr>
<tr>
<td>Treatment Week 24: any detectable HCV RNA level</td>
<td>Discontinue sofosbuvir/ledipasvir</td>
</tr>
</tbody>
</table>

**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 90 days of anticipated treatment start date
- The concomitant use of ledipasvir/sofosbuvir 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 ledipasvir/sofosbuvir with P-gp inducers is not recommended.
- Patient does not have severe renal impairment (eGFR <30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
- 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 patient should be virologically suppressed or provider should provide additional rationale for treatment initiation.
SOFOSBUVIR (SOVALDI™) AND SIMEPREVIR (OLYSIO™)

- Any request for this therapy will be reviewed on a case-by-case basis by DHMH.
OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR (VIEKIRA PAK™)

RECOMMENDED REGIMENS AND TREATMENT DURATION FOR OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR COMBINATION THERAPY IN HCV

<table>
<thead>
<tr>
<th>HCV Genotype and Comorbidities</th>
<th>Treatment*</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1a, without cirrhosis</td>
<td>Viekira Pak™ + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 1a, with cirrhosis</td>
<td>Viekira Pak™ + ribavirin</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Genotype 1b, without or without cirrhosis</td>
<td>Viekira Pak™</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*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, sub-genotype 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.

**DISCONTINUATION OF DOSING**

- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR) defined as an undetectable HCV RNA 12 weeks post-cessation of therapy, therefore discontinuation of treatment is recommended in these patients.
**Treatment Stopping Rules in Any Patient with Inadequate On-Treatment Virologic Response**

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Week 4: &lt; 2 log reduction in HCV RNA from baseline</td>
<td>Discontinue Viekira Pak™ + ribavirin</td>
</tr>
<tr>
<td>Treatment Week 12: any detectable HCV RNA level</td>
<td>Discontinue Viekira Pak™ + ribavirin</td>
</tr>
<tr>
<td>Treatment Week 24: any detectable HCV RNA level</td>
<td>Discontinue Viekira Pak™ + ribavirin</td>
</tr>
</tbody>
</table>

** 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 90 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 moderate to severe hepatic impairment/Child-Pugh B or C secondary to risk of potential toxicity.
- 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.
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.
**OMBITASVIR/PARITAPREVIR/RITONAVIR (TECHNIVIE™)**

RECOMMENDED TREATMENT DURATION FOR
OMBITASVIR/PARITAPREVIR/RITONAVIR COMBINATION THERAPY IN HCV

<table>
<thead>
<tr>
<th>HCV Genotype and Comorbidities</th>
<th>Treatment*</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 4, with or without cirrhosis</td>
<td>Technivie™ + ribavirin</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

**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). NOTE THAT PRODUCT IS PACKAGED IN A MONTHLY CARTON WHICH CONTAINS A TOTAL OF 28 DAYS OF THERAPY.

**Length of Authorization:**
12 weeks

**INITIAL:** 8 weeks

**REFILLS:** Should be reauthorized for additional 4 weeks. The patient must receive refills within one week of completing the previous 28 day supply throughout treatment.

**DISCONTINUATION OF DOSING**
- It is unlikely that patients with inadequate on-treatment virologic response will achieve a sustained virologic response (SVR) defined as an undetectable HCV RNA 12 weeks post-cessation of therapy, therefore discontinuation of treatment is recommended in these patients.

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

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Week 4: &lt; 2 log reduction in HCV RNA from baseline</td>
<td>Discontinue Technivie™</td>
</tr>
</tbody>
</table>

**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 TECHNIVIE™ 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 90 days of anticipated treatment start date.
- Technivie™ 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.
- Technivie™ is contraindicated in patients with moderate to severe hepatic impairment/Child-Pugh B or C secondary to risk of potential toxicity. The concomitant use
of Technivie™ 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)

- Patient does not have end stage renal disease (ESRD) requiring hemodialysis.
- There is insufficient data to recommend use in patients with HCV genotypes other than genotype 4.
- Patients co-infected with HIV and treated with Technivie™ should also be on suppressive antiretroviral therapy for HIV to reduce the risk of HIV protease inhibitor drug resistance, as Technivie™ contains ritonavir.
## Retreatment Guidelines

### Degree of hepatic damage/treatment experience*

<table>
<thead>
<tr>
<th>Recommended Treatment genotype 1a</th>
<th>Treatment</th>
<th>Duration of Total Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who do NOT have cirrhosis</td>
<td>Ledipasvir/sofosbuvir OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir + Ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir + Ribavirin</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Patients who have compensated cirrhosis</td>
<td>Ledipasvir/sofosbuvir OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir + Ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir + Ribavirin</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>

### Recommended treatment genotype 1b

<p>| Patients who do NOT have cirrhosis | Ledipasvir/sofosbuvir OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir | 12 weeks |
|                                   | Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir | 24 weeks |
| Patients who have compensated cirrhosis | Ledipasvir/sofosbuvir OR Ledipasvir/sofosbuvir + ribavirin OR Paritaprevir/ritonavir/om bitasvir + Dasabuvir | 12 weeks |</p>
<table>
<thead>
<tr>
<th>Recommended Treatment genotype 2</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with or without compensated cirrhosis</td>
<td>sofosbuvir + ribavirin</td>
<td>12 weeks (patients with cirrhosis may benefit from an extension to 16 weeks of treatment)</td>
</tr>
<tr>
<td>(including those with hepatocellular carcinoma)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Alternative Regimen genotype 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients (interferon eligible) with or without compensated cirrhosis (including those with hepatocellular carcinoma)</td>
<td>sofosbuvir + peginterferon alfa + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Recommended Treatment genotype 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients without compensated cirrhosis*</td>
<td>Daclatasvir + sofosbuvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td>OR</td>
<td>sofosbuvir + ribavirin + peginterferon alfa</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Recommended treatment genotype 4</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with or without compensated cirrhosis</td>
<td>Ledipasvir + sofosbuvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Recommended treatment genotype 5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with or without compensated cirrhosis</td>
<td>Ledipasvir + sofosbuvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>NOT RECOMMENDED (ALL GENOTYPES)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended treatment genotype 6</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with or without compensated cirrhosis</td>
<td>Ledipasvir + sofosbuvir</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>
*Treatment experienced is defined as a patient who has failed therapy with a peginterferon + ribavirin based regimen with or without an HCV protease inhibitor

**Patients infected with genotype 3 who have cirrhosis should be sent to DHMH for review

**Note:** All requests for retreatment for patients with prior direct acting antiviral (including older protease inhibitors) experience should be sent to DHMH for approval.

---

1. Sovaldi [package insert], Foster City, CA; Gilead, initial December 2013, update March 2015.
2. FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
7. Daklinza [package insert], initial 2015
8. Technivie [package insert], initial 2015