Hepatitis C Agents
Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Pre - PA Allowance
None

Prior-Approval Requirements

Age  18 years of age or older

Diagnosis

Patient must have the following:
1. Chronic Hepatitis C
   a. Required documented viral load (HCV RNA) at least 6 months prior to request for treatment

Harvoni or Epclusa

1. Genotype 1 or 4 with ONE of the following:
   a. Treatment-naïve – without cirrhosis
      i. Harvoni Genotype 1 only – if the baseline viral load is < 6 million IU/ml, then HCV RNA will be drawn at week 4
   b. Treatment-naïve – with cirrhosis
   c. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
   d. Treatment-experienced – previously treated with Protease Inhibitor (NS3)
   e. Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)
      i. Genotype 1 - Harvoni must be combined with Ribavirin (RBV)
   f. Treatment-experienced – previously treated with Sovaldi and Olysio or NS5a inhibitor
      i. Genotype 1 - Sovaldi based dual therapy with a Direct-Acting Agent – must be combined with Ribavirin (RBV) unless RBV ineligible
   g. Decompensated cirrhosis
      i. Genotype 1 – must be combined with Ribavirin (RBV) unless RBV ineligible
      ii. Genotype 4 – must be combined with Ribavirin (RBV) unless
Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

RBV ineligible

h. Post-Transplant
   i. Harvoni only – it must be combined with Ribavirin (RBV) unless RBV ineligible
   i. Hepatocellular Carcinoma
      i. Must be combined with Ribavirin (RBV)

2. Genotype 2 or 3 – Epclusa only with ONE of the following:
   a. Treatment-naïve
   b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin
   c. Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)
      i. Genotype 3 – must be combined with Ribavirin (RBV)
   d. Decompensated cirrhosis
      i. Must be combined with Ribavirin (RBV)
   e. NOT Post-Transplant
   f. Hepatocellular Carcinoma
      i. Must be combined with Ribavirin (RBV)

3. Genotype 5 or 6 with ONE of the following:
   a. Treatment-naïve
   b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
   c. Decompensated cirrhosis
   d. Hepatocellular Carcinoma
      i. Must be combined with Ribavirin (RBV)
   e. NOT Post-Transplant

AND the following:
   a. Absence of severe renal impairment (eGFR less than 30 ml/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis

Zepatier or Viekira/Viekira XR

1. Genotype 1 or 4 with ONE of the following:
   a. Treatment-naïve
Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

i. **Zepatier** – Patient’s with genotype 1a must have been tested for the NS5A resistance-associated polymorphisms
ii. **Viekira/Viekira XR** – Genotype 1 and 4

b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
   i. **Zepatier** – Genotype 1 and 4
   ii. **Viekira/Viekira XR** – Genotype 1 and 4

c. Treatment-experienced – previously treated with Protease Inhibitor (NS3)
   i. **Zepatier** – Genotype 1 only

d. Post-Transplant
   i. **Viekira/Viekira XR** – Genotype 1 only

e. End-Stage Renal disease (eGFR less than 30 ml/min/1.73m²)
   i. **Zepatier** – Genotype 1 and 4
   ii. **Viekira/Viekira XR** – Genotype 1 only

2. Genotype 3 with **ONE** of the following:
   a. **Zepatier** – Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
      i. Compensated cirrhosis – must be combined with Sovaldi and (RBV) unless RBV ineligible
   b. **Zepatier** – Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)
      i. Must be combined with Sovaldi and (RBV) unless RBV ineligible

   AND the following:
   a. **NO** moderate or severe hepatic impairment (Child-Pugh Class B or C)

Daklinza/Sovaldi

1. Genotype 1 or 4 with
   a. Treatment-naïve – Genotype 1 only
      i. Compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible
   b. Treatment-experienced – previously treated with Peg-Interferon and

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*Hep_C FEP Clinical Criteria*
Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

Ribavirin (RBV) – Genotype 1 only
  i. Compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible

- Treatment-experienced – previously treated with Protease Inhibitor (NS3) – Genotype 1 only
  i. Compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible

- Decompensated cirrhosis
  i. Must be combined with Ribavirin (RBV) unless RBV ineligible

- Post-Transplant
  i. **NO** decompensated cirrhosis
  ii. Must be combined with Ribavirin (RBV) unless RBV ineligible

- Hepatocellular Carcinoma
  i. Must be combined with Ribavirin (RBV)

2. Genotype 2 or 3 with ONE of the following:
   a. Treatment-naïve
      ii. Genotype 3 compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible
   b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin
      i. Genotype 3 compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible
   c. Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)
      i. Genotype 2 or 3 – must be combined with Ribavirin (RBV)
   d. Decompensated cirrhosis
      i. Must be combined with Ribavirin (RBV)
   e. Post-Transplant
      i. Genotype 2 or 3
         1) **NO** cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible
         2) Compensated cirrhosis – must be combined with Ribavirin (RBV) unless RBV ineligible
   f. Hepatocellular Carcinoma
      i. Must be combined with Ribavirin (RBV)
Hepatitis C Agents
Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viębira Pak, Viękira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

AND the following:
  a. Absence of severe renal impairment (eGFR less than 30 ml/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis
  b. Daklinza must be used in combination with Sovaldi

Sovaldi/Ribavirin (RBV)

1. Genotype 2 Post-Transplant decompensated cirrhosis
   a. Treatment-naïve
   b. Treatment-experienced

Vosevi

1. Genotype 1, 2, 3, 4, 5, or 6
   a. Treatment-experienced – previously treated with NS5A inhibitor

2. Genotype 1a, or 3
   a. Treatment-experienced – previously treated with Sovaldi without an NS5A inhibitor

AND ALL of the following:
  a. Absence of severe renal impairment (eGFR less than 30 ml/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis
  b. NO decompensated cirrhosis
  c. NO moderate or severe hepatic impairment (Child-Pugh Class B or C)

Mavyret

1. Genotype 1, 2, 3, 4, 5, or 6
   a. Treatment-naïve
   b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin
   c. Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)

2. Genotype 1
   a. Treatment-experienced – previously treated with NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor
Hepatitis C Agents
Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)
b. Treatment-experienced – previously treated with NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor

AND ALL of the following:
   a. NO decompensated cirrhosis
   b. NO moderate or severe hepatic impairment (Child-Pugh Class B or C)

AND ALL of the following for the Hepatitis C medications:
   1. Presence of viral load (HCV RNA) in the serum prior to treatment
   2. NO history of alcohol and/or substance abuse in the past 6 months
   3. If the patient has a history of Hepatitis B (HBV) infection
      a. Prescriber agrees to monitor for HBV reactivation

Age 12 – 17 years of age

Diagnosis

Patient must have the following:
   1. Chronic Hepatitis C
      a. Required documented viral load (HCV RNA) at least 6 months prior to request for treatment

Harvoni

   1. Genotype 1, 4, 5 or 6
      a. 35 kg or more
      b. NO decompensated cirrhosis

Sovaldi/Ribavirin (RBV)

   1. Genotype 2 or 3
      a. 35 kg or more
      b. NO decompensated cirrhosis
      c. Must be combined with Ribavirin (RBV)

   AND ALL of the following for the Hepatitis C medications:
      1. Presence of viral load (HCV RNA) in the serum prior to treatment
      2. NO history of alcohol and/or substance abuse in the past 6 months
      3. If the patient has a history of Hepatitis B (HBV) infection
Hepatitis C Agents
Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

a. Prescriber agrees to monitor for HBV reactivation

AND ALL of the following for the Hepatitis C medications if combined with ribavirin therapy:

1. Absence of significant or unstable cardiac disease
2. Neither the patient nor the partner of the patient is pregnant
3. If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

Prior – Approval Renewal Requirements

Harvoni only

Age 18 years of age or older

Diagnosis
Patient must have the following:

1. Chronic Hepatitis C – Genotype 1
   a. Continuation of therapy for treatment-naïve patients, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:
      i. Evaluation of patient at 4 weeks to determine that the viral load was not met within the 8 weeks of treatment

Prior - Approval Limits
(see below)
## Hepatitis C Agents

**Daklinza** (daclatasvir), **Epclusa** (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Sovaldi** (sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Viekira Pak**, **Viekira XR** (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), **Zepatier** (elbasvir, grazoprevir)

**Duration** – 18 years of age and older

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Naïve / Experienced</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis</th>
<th>Decompensated Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1a</strong></td>
<td>Naïve:</td>
<td>Harvoni 8 weeks (if RNA &lt; 6M iU/ml)</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Daklinza/Sovaldi/RBV (unless RBV ineligible) 24 weeks Mavyret 12 weeks Viekira/ RBV 24 weeks Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Mavyret 24 weeks Viekira/ RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
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<tr>
<td></td>
<td></td>
<td>Harvoni 12 weeks (if RNA &gt;= 6M iU/ml) Epclusa 12 weeks Daklinza/Sovaldi 12 weeks Mavyret 8 weeks Viekira/ RBV 12 weeks Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Mavyret 24 weeks Viekira/ RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>1b</strong></td>
<td></td>
<td>Harvoni 8 weeks (if RNA &lt; 6M iU/ml)</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Daklinza/Sovaldi/RBV (unless RBV ineligible) 24 weeks Mavyret 12 weeks Viekira/RBV 24 weeks Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Mavyret 24 weeks Viekira/ RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
</tr>
<tr>
<td><strong>1a</strong></td>
<td>Experienced: Peg-INF and RBV</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Daklinza/Sovaldi 12 weeks Mavyret 8 weeks Viekira/ RBV 12 weeks Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa 12 weeks Daklinza/Sovaldi/RBV (unless RBV ineligible) 24 weeks Mavyret 12 weeks Viekira/ RBV 24 weeks Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Mavyret 24 weeks Viekira/ RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
</tr>
</tbody>
</table>

**Hep_C FEP Clinical Criteria**
<table>
<thead>
<tr>
<th>Experience Level</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1b</strong> Experienced: Peg-INF and RBV</td>
<td><strong>Harvoni 12 weeks</strong>&lt;br&gt;Epclusa 12 weeks&lt;br&gt;Daklinza/Sovaldi 12 weeks&lt;br&gt;Mavyret 8 weeks&lt;br&gt;Viekira 12 weeks&lt;br&gt;Zepatier 12 weeks</td>
</tr>
<tr>
<td><strong>1</strong> Experienced: Protease Inhibitor (NS3)</td>
<td><strong>Harvoni 12 weeks</strong>&lt;br&gt;Epclusa 12 weeks&lt;br&gt;Daklinza/Sovaldi 12 weeks&lt;br&gt;Mavyret 8 weeks&lt;br&gt;Vosevi 12 weeks (for 1a only)&lt;br&gt;Zepatier/ RBV 12 weeks (Extend to 16wk if GT1a with NS5a RAV present)</td>
</tr>
<tr>
<td><strong>1</strong> Experienced: Sovaldi/RBV or Sovaldi/SMV</td>
<td><strong>Harvoni/ RBV 12 weeks</strong>&lt;br&gt;Mavyret 8 weeks (for only SOF/RBV failure)&lt;br&gt;Vosevi 12 weeks (for 1a only)</td>
</tr>
<tr>
<td><strong>1</strong> Experienced: NS5A</td>
<td><strong>Harvoni/ RBV 24 weeks</strong>&lt;br&gt;Epclusa/ RBV 24 weeks&lt;br&gt;Daklinza/Sovaldi/ RBV 24 weeks&lt;br&gt;Mavyret 16 weeks&lt;br&gt;Vosevi 12 weeks</td>
</tr>
<tr>
<td><strong>1</strong> Post-Transplant Naive:</td>
<td><strong>Harvoni/ RBV 12 weeks</strong>&lt;br&gt;Harvoni 24 weeks&lt;br&gt;Daklinza/Sovaldi/ RBV 12 weeks&lt;br&gt;Daklinza/Sovaldi 24 weeks&lt;br&gt;Viekira/ RBV 24 weeks</td>
</tr>
<tr>
<td><strong>1</strong> Post-Transplant Experienced:</td>
<td><strong>Harvoni/ RBV 12 weeks</strong>&lt;br&gt;Daklinza/Sovaldi/ RBV 12 weeks&lt;br&gt;Viekira/ RBV 24 weeks</td>
</tr>
<tr>
<td><strong>1</strong> End-Stage Renal Disease</td>
<td>Mavyret 8 weeks&lt;br&gt;Zeptiar 12 weeks&lt;br&gt;Viekira 12 weeks (Genotype 1b)&lt;br&gt;Viekira/ RBV 12 weeks (Genotype 1a)</td>
</tr>
</tbody>
</table>

**Hepatitis C Agents**

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)
## Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir)
Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

### Hepatocellular Carcinoma

<table>
<thead>
<tr>
<th></th>
<th>Harvoni/RBV 12 weeks</th>
<th>Epclusa/RBV 12 weeks</th>
<th>Daklinza/Sovaldi/ RBV 12 weeks</th>
</tr>
</thead>
</table>
| 1 | Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 8 weeks | Epclusa 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 2 | Naïve:  
Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 8 weeks | Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 2 | Experienced:  
Peg-INF and RBV  
Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 8 weeks | Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 2 | Experienced:  
NS5A  
Vosevi 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 2 | Experienced:  
Sovaldi and RBV  
Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 24 weeks  
Mavyret 8 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 24 weeks  
Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 2 | Post-Transplant  
Naïve:  
Daklinza/Sovaldi/ RBV 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 8 weeks | Daklinza/Sovaldi/ RBV 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 8 weeks | Sovaldi/RBV 24 weeks |
| 2 | Post-Transplant  
Experienced:  
Daklinza/Sovaldi/ RBV 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 8 weeks | Daklinza/Sovaldi/ RBV 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 8 weeks | Sovaldi/RBV 24 weeks |
| 2 | Hepatocellular Carcinoma  
Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |

### Hepatitis C FEP Clinical Criteria

#### Naïve:

<table>
<thead>
<tr>
<th></th>
<th>Harvoni/RBV 12 weeks</th>
<th>Epclusa/RBV 12 weeks</th>
<th>Daklinza/Sovaldi/RBV 12 weeks</th>
</tr>
</thead>
</table>
| 3 | Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 8 weeks | Epclusa 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 3 | Experienced:  
Peg-INF and RBV  
Epclusa 12 weeks  
Daklinza/Sovaldi 12 weeks  
Mavyret 16 weeks | Epclusa/ RBV 12 weeks  
Daklinza/Sovaldi/ RBV 24 weeks  
Mavyret 16 weeks  
Zepatier/RBV/Sovaldi 12 weeks  
Zepatier/Sovaldi 16 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |
| 3 | Experienced:  
Sovaldi and No Prior NS5A  
Epclusa/RBV 12 weeks  
Daklinza/Sovaldi 24 weeks  
Mavyret 16 weeks  
Vosevi 12 weeks  
Zepatier/RBV/Sovaldi 12 weeks  
Zepatier/Sovaldi 16 weeks | Epclusa/RBV 12 weeks  
Daklinza/Sovaldi/ RBV 12 weeks |

Hep_C FEP Clinical Criteria
### Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

<table>
<thead>
<tr>
<th>3</th>
<th>Experienced: NS5A</th>
<th></th>
<th>Vosevi 12 weeks</th>
<th>Daklinza/Sovaldi/RBV 12 weeks</th>
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<tbody>
<tr>
<td>3</td>
<td>Post-Transplant Naive:</td>
<td>Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td>Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>3</td>
<td>Post-Transplant Experienced:</td>
<td>Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td>Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>3</td>
<td>Hepatocellular Carcinoma</td>
<td></td>
<td>Epclusa/RBV 12 weeks Daklinza/Sovaldi/RBV 12 weeks</td>
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</tr>
<tr>
<td>4</td>
<td>Naive:</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 8 weeks Viekira/RBV 12 weeks Zepatier 12 weeks</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 12 weeks Viekira/RBV 12 weeks Zepatier 12 weeks</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Epclusa 24 weeks Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
</tr>
<tr>
<td>4</td>
<td>Experienced: Peg-INF and RBV</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 8 weeks Viekira/RBV 12 weeks Zepatier 12 weeks (if Relapsed after tx) Zepatier/RBV 16 weeks (if Failure on prior tx)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa 12 weeks Mavyret 12 weeks Viekira/RBV 12 weeks Zepatier 12 weeks (if Relapsed after tx) Zepatier/RBV 16 weeks (if Failure on prior tx)</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Epclusa/RBV 12 weeks Epclusa 24 weeks Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
</tr>
<tr>
<td>4</td>
<td>Experienced: NS5A</td>
<td></td>
<td>Vosevi 12 weeks</td>
<td>Harvoni/RBV 24 weeks Epclusa/RBV 24 weeks</td>
</tr>
<tr>
<td>4</td>
<td>Post-Transplant Naive:</td>
<td>Harvoni/RBV 12 weeks Harvoni 24 weeks Daklinza/Sovaldi/RBV 12 weeks Daklinza/Sovaldi 24 weeks</td>
<td>Harvoni/RBV 12 weeks</td>
<td>Harvoni/RBV 12 weeks</td>
</tr>
<tr>
<td>4</td>
<td>Post-Transplant Experienced:</td>
<td>Harvoni/RBV 12 weeks Daklinza/Sovaldi/RBV 12 weeks</td>
<td>Harvoni/RBV 12 weeks</td>
<td>Harvoni/RBV 12 weeks</td>
</tr>
<tr>
<td>4</td>
<td>End-Stage Renal Disease</td>
<td>Zepatier 12 weeks Mavyret 12 weeks</td>
<td></td>
<td>NONE</td>
</tr>
</tbody>
</table>
### Hepatitis C Agents

**Daklinza** (daclatasvir), **Epclusa** (sofosbuvir & velpatasvir), **Harvoni** (ledipasvir & sofosbuvir), **Sovaldi** (sofosbuvir), **Mavyret** (glecaprevir and pibrentasvir), **Viekira Pak**, **Viekira XR** (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), **Vosevi** (sofosbuvir, velpatasvir, & voxilaprevir), **Zepatier** (elbasvir, grazoprevir)

<table>
<thead>
<tr>
<th>Year</th>
<th>Hepatocellular Carcinoma</th>
<th>Harvoni/RBV 12 weeks</th>
<th>Epclusa/RBV 12 weeks</th>
<th>Daklinza/Sovaldi/RBV 12 weeks</th>
<th>Harvoni/ RBV 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 &amp; 5</td>
<td>Naïve</td>
<td>Harvoni 12 weeks</td>
<td>Epclusa 12 weeks</td>
<td>Mavyret 8 weeks</td>
<td>Harvoni 12 weeks</td>
</tr>
<tr>
<td>5 &amp; 6</td>
<td>Experienced: Peg-INF and RBV</td>
<td>Harvoni 12 weeks</td>
<td>Epclusa 12 weeks</td>
<td>Mavyret 8 weeks</td>
<td>Harvoni 12 weeks</td>
</tr>
<tr>
<td>5 &amp; 6</td>
<td>Experienced: NS5A</td>
<td>Vosevi 12 weeks</td>
<td>Harvoni 12 weeks</td>
<td>Epclusa 12 weeks</td>
<td>Mavyret 12 weeks</td>
</tr>
<tr>
<td>5 &amp; 6</td>
<td>Hepatocellular Carcinoma</td>
<td>Harvoni/RBV 12 weeks</td>
<td>Epclusa/RBV 12 weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 12 to 17 years of age

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Naïve / Experienced</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis</th>
<th>Decompensated Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Naive</td>
<td>Harvoni 12 weeks</td>
<td>Harvoni 12 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>1</td>
<td>Experienced</td>
<td>Harvoni 12 weeks</td>
<td>Harvoni 24 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>4, 5, 6</td>
<td>Naïve / Experienced</td>
<td>Harvoni 12 weeks</td>
<td>Harvoni 12 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>2</td>
<td>Naïve / Experienced</td>
<td>Sovaldi/Ribavirin 12 weeks</td>
<td>Sovaldi/Ribavirin 12 weeks</td>
<td>NONE</td>
</tr>
<tr>
<td>3</td>
<td>Naïve / Experienced</td>
<td>Sovaldi/Ribavirin 24 weeks</td>
<td>Sovaldi/Ribavirin 24 weeks</td>
<td>NONE</td>
</tr>
</tbody>
</table>

**Bolded items are preferred products**

- Daklinza, Epclusa, Harvoni, Sovaldi, & Vosevi 12 weeks = (84 tablets per 84 days)
- Daklinza, Epclusa, Harvoni, & Sovaldi 24 weeks = (168 tablets per 168 days)
- Viekira Pak 12 weeks = (336 tablets per 84 days)
- Viekira Pak 24 weeks = (672 tablets per 168 days)
- Viekira XR 12 weeks = (252 tablets per 84 days)
- Viekira XR 24 weeks = (504 tablets per 168 days)
- Mavyret 8 weeks = (168 tablets per 56 days)
Hepatitis C Agents

Daklinza (daclatasvir), Epclusa (sofosbuvir & velpatasvir), Harvoni (ledipasvir & sofosbuvir), Sovaldi (sofosbuvir), Mavyret (glecaprevir and pibrentasvir) Viekira Pak, Viekira XR (ombitasvir, paritaprevir, ritonavir) and (dasabuvir), Vosevi (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

<table>
<thead>
<tr>
<th>Mavyret</th>
<th>12 weeks = (252 tablets per 84 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mavyret</td>
<td>16 weeks = (336 tablets per 112 days)</td>
</tr>
<tr>
<td>Zepatier</td>
<td>12 weeks = (84 tablets per 84 days)</td>
</tr>
<tr>
<td>Zepatier</td>
<td>16 weeks = (112 tablets per 112 days)</td>
</tr>
</tbody>
</table>

### NS3/4a Protease Inhibitors:

<table>
<thead>
<tr>
<th>NS3/4a Protease Inhibitors:</th>
<th>NS5a Inhibitors</th>
<th>NS5B Polymerase Inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telaprevir</td>
<td>Daclatasvir</td>
<td>Sofosbuvir (nuclear analog)</td>
</tr>
<tr>
<td>Boceprevir</td>
<td>Ledipasvir</td>
<td>Dasabuvir (non-nuclear analog)</td>
</tr>
<tr>
<td>Simeprevir</td>
<td>Ombitasvir</td>
<td></td>
</tr>
<tr>
<td>Paritaprevir</td>
<td>Elbasvir</td>
<td></td>
</tr>
<tr>
<td>Grazoprevir</td>
<td>Velpatasvir</td>
<td></td>
</tr>
</tbody>
</table>

### Prior – Approval Renewal Limits

**Harvoni only**

Treatment-Naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml

4 weeks Harvoni (28 tablets per 28 days)