HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

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)
      i. Genotype 1 only
      ii. Not indicated for treatment in Genotype 4
   e. Treatment-experienced – previously treated with Sovaldi containing regimen that does NOT include an NS5A inhibitor
      i. Genotype 1 -
         i. Harvoni must be combined with ribavirin
         ii. Epclusa is only recommended for genotype 1b
      ii. Genotype 4 – not indicated for treatment
   f. Decompensated cirrhosis
      i. Genotype 1 – must be combined with Ribavirin (RBV) unless RBV ineligible
HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

ii. Genotype 4 – must be combined with Ribavirin (RBV) unless RBV ineligible

g. Post-Transplant
   i. Harvoni only – it must be combined with Ribavirin (RBV)
   ii. Epclusa is not recommended in treatment post-transplant

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

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

3. Genotype 5 or 6 with ONE of the following:
   a. Treatment-naive
   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. Post-Transplant
      i. Harvoni only – must be combined with Ribavirin (RBV)

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
HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pivrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

Zepatier

1. Genotype 1 or 4 with **ONE** of the following:
   a. Treatment-naïve
      i. Genotype 1 and 4
         i. Patients with genotype 1a must have been tested for the NS5A resistance-associated polymorphisms
   b. Genotype 4: must be with Ribavirin (RBV)
      Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
      i. Genotype 1 and 4
         i. Patient’s with genotype 1a must have been tested for the NS5A resistance-associated polymorphisms
   c. Treatment-experienced – previously treated with Protease Inhibitor (NS3)
      i. Genotype 1 only
         i. Patients with genotype 1a must have been tested for the NS5a resistance-associated polymorphisms.
         ii. Must be combined with Ribavirin (RBV)
   d. **NO** Post-Transplant
   e. End-Stage Renal disease (eGFR less than 30 ml/min/1.73m²)
      i. Genotype 1 and 4

2. Genotype 3 with the following:
   a. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin (RBV)
      i. Compensated cirrhosis – must be combined with Sovaldi

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

Vosevi

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

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

Hep C FEP Clinical Criteria

a. Treatment Naïve
   i. Genotype 3 only
      1) Compensated cirrhosis - if Y93H mutation is present

b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin
   i. Genotype 3 only
      1) No cirrhosis - if Y93H mutation is present
      2) Compensated cirrhosis

c. Treatment-experienced
   i. Genotype 1a & 3
      1) 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)

AND ALL of the following for the Hepatitis C medications:
   1. Presence of viral load (HCV RNA) in the serum prior to treatment
   2. If the patient has a history of Hepatitis B (HBV) infection
      a. Prescriber agrees to monitor for HBV reactivation

Age 12 years of age or older OR patient weighs ≥ 45 kg

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

Mavyret

1. Genotype 1, 2, 3, 4, 5, or 6
   a. Treatment-naïve
HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

b. Treatment-experienced – previously treated with Peg-Interferon and Ribavirin
c. Treatment-experienced – previously treated with Sovaldi and Ribavirin (RBV)
d. Post-transplant (liver and/or kidney transplant)

2. Genotype 1
   a. Treatment-experienced – previously treated with NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor
   b. Treatment-experienced – previously treated with NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor

3. Unknown genotype
   a. Treatment-naïve

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. 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
HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

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. If the patient has a history of Hepatitis B (HBV) infection
   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 Limits

Duration – 18 years of age and older

12 years of age and older OR patient weighs ≥ 45 kg for Mavyret

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<thead>
<tr>
<th>Genotype</th>
<th>Naïve / Experienced</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis</th>
<th>Decompensated Cirrhosis</th>
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<tbody>
<tr>
<td>1a</td>
<td>Naïve:</td>
<td>Harvoni 8 weeks (if RNA &lt; 6M iU/ml)</td>
<td>Harvoni 12 weeks (if RNA &gt;= 6M iU/ml)</td>
<td>Harvoni 12 weeks Eclusa 12 weeks Mavyret 12 weeks Zepatier 12 weeks (if no NS5a RAS) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
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Hep_C FEP Clinical Criteria
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<th>Hepatitis C Genotype</th>
<th>Treatment Duration</th>
<th>Side Treatment</th>
<th>Notes</th>
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<tbody>
<tr>
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<td>Harvoni 8 weeks (if RNA &lt; 6M iU/ml)</td>
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<td>Harvoni 12 weeks (if RNA &gt;= 6M iU/ml)</td>
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<td>1a</td>
<td>Experienced: Peg-Inf and RBV</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 8 weeks (not previously treated with NS3/4 or NS5A) Zepatier 12 weeks (if no NS5a RAV) Zepatier/RBV 16 weeks (if NS5a RAV present)</td>
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<td>1b</td>
<td>Experienced: Peg-Inf and RBV</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 8 weeks (not previously treated with NS3/4 or NS5A) Zepatier 12 weeks</td>
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<td>1</td>
<td>Experienced: Protease Inhibitor (NS3)</td>
<td>Harvoni 12 weeks Epclusa 12 weeks Mavyret 12 weeks (not previously treated with NS5A) Zepatier/RBV 12 weeks (Extend to 16wk if GT1a with NS5a RAS present)</td>
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<td>Experience Level</td>
<td>Treatment Options</td>
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</table>
| Experienced: Sovaldi containing regimen that does NOT include NS5A | Harvoni/RBV 12 weeks (for only SOF/RBV failure)  
Mavyret 12 weeks  
Vosevi 12 weeks (for 1a only)  
Epclusa 12 weeks (for 1b only) | Mavyret 12 weeks  
Vosevi 12 weeks (for 1a only)  
Epclusa 12 weeks (for 1b only) | Harvoni/RBV 24 weeks  
Epclusa/RBV 24 weeks |
| Experienced: NS5A | Vosevi 12 weeks | Harvoni/RBV 24 weeks  
Epclusa/RBV 24 weeks |
| Post-Transplant Naïve: | Harvoni/RBV 12 weeks  
Mavyret 12 weeks (liver and/or kidney transplant) | Harvoni/RBV 12 weeks  
Mavyret 12 weeks (liver and/or kidney transplant) | Harvoni/RBV 12 weeks |
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Mavyret 12 weeks (liver and/or kidney transplant) | Harvoni/RBV 12 weeks |
| CKD stage 4 – 5/End-Stage Renal Disease | Mavyret 8-16 weeks (treatment determined by liver disease stage/prior treatments)  
Zepatier 12 weeks | Mavyret 8-16 weeks (treatment determined by liver disease stage/prior treatments)  
Zepatier 12 weeks | NONE |
| Hepatocellular Carcinoma | Harvoni/RBV 12 weeks  
Epclusa/RBV 12 weeks | Epclusa/RBV 12 weeks |
| Naïve: | Epclusa 12 weeks  
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Mavyret 12 weeks | Epclusa/RBV 12 weeks  
Epclusa 24 weeks |
| Experienced: Peg-INF and RBV | Epclusa 12 weeks  
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*Preferred Product*
### HEPATITIS C AGENTS

**Epclusa*** (sofosbuvir & velpatasvir), **Harvoni*** (ledipasvir & sofosbuvir), **Sovaldi*** (sofosbuvir), **Mavyret*** (glecaprevir and pibrentasvir), **Vosevi*** (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

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<th>Category</th>
<th>Treatment Options</th>
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<tr>
<td><strong>2</strong> Post-Transplant Naïve:</td>
<td>Mavyret 12 weeks (liver and/or kidney transplant)</td>
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<tr>
<td><strong>2</strong> Post-Transplant Experienced:</td>
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<tr>
<td><strong>2</strong> CKD stage 4 – 5/End-Stage Renal Disease</td>
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<td><strong>2</strong> Hepatocellular Carcinoma</td>
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<tr>
<td><strong>3</strong> Naïve:</td>
<td>Epclusa 12 weeks Mavyret 8 weeks</td>
</tr>
<tr>
<td><strong>3</strong> Experienced: Peg-INF and RBV</td>
<td>Epclusa 12 weeks (if Y93H mutation is present add RBV 12 weeks) Mavyret 16 weeks (not previously treated with NS3/4 or NS5A) Vosevi 12 weeks (when Y93H mutation is present)</td>
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<td><strong>3</strong> Experienced: Sovaldi and RBV</td>
<td>Mavyret 16 weeks (not previously treated with NS3/4 or NS5A)</td>
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<td><strong>3</strong> Experienced: Sovaldi and No Prior NS5A</td>
<td>Vosevi 12 weeks</td>
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<td>Vosevi 12 weeks</td>
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<td><strong>3</strong> Post-Transplant Naïve:</td>
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HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

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<th>3</th>
<th>Post-Transplant Experienced:</th>
<th>Mavyret 12 weeks (liver and/or kidney transplant)</th>
<th>Epclusa/RBV 12 weeks Mavyret 12 weeks (liver and/or kidney transplant)</th>
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<tr>
<td>3</td>
<td>CKD stage 4 – 5/End-Stage Renal Disease</td>
<td>Mavyret 8 – 16 weeks (treatment determined by liver disease stage/prior treatments)</td>
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<td>CKD stage 4 – 5/End-Stage Renal Disease</td>
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**HEPATITIS C AGENTS**

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

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<td>5 &amp; 6</td>
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<th>Experienced: Sovaldi and RBV</th>
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<th>Experienced: NS5A</th>
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<tr>
<th>CKD stage 4 – 5/End Stage Renal Disease</th>
<th>Mavyret 8 - 16 weeks (treatment determined by liver disease stage/prior treatments)</th>
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</table>

<table>
<thead>
<tr>
<th>Unknown Genotype</th>
<th>Naïve</th>
<th>Mavyret 8 weeks</th>
<th>Mavyret 12 weeks</th>
<th>NONE</th>
</tr>
</thead>
</table>

**Bolded items are preferred products**

**Duration – 12 to 17 years of age for Harvoni and Sovaldi**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Naïve / Experienced</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis</th>
<th>Decompensated Cirrhosis</th>
</tr>
</thead>
</table>

Hep_C FEP Clinical Criteria
HEPATITIS C AGENTS

Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi* (sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, & voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

<table>
<thead>
<tr>
<th>Hepatitis C FEP Clinical Criteria</th>
<th>1 Naive</th>
<th>1 Experienced</th>
<th>2 Naive/Experience</th>
<th>3 Naive/Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvoni 12 weeks</td>
<td>Harvoni 12 weeks</td>
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<td>Harvoni 12 weeks</td>
<td>Harvoni 12 weeks</td>
</tr>
<tr>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
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<tr>
<td>Harvoni 24 weeks</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Sovaldi/RBV 12 weeks</td>
<td>Sovaldi/RBV 12 weeks</td>
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<td>NONE</td>
<td>NONE</td>
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<tr>
<td>Sovaldi/RBV 24 weeks</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
</tbody>
</table>

**Bolded items are preferred products

Harvoni 8 weeks = (56 tablets per 56 days)
Epclusa, Harvoni, Sovaldi, & Vosevi 12 weeks = (84 tablets per 84 days)
Epclusa, Harvoni, & Sovaldi 24 weeks = (168 tablets per 168 days)
Mavyret 8 weeks = (168 tablets per 56 days)
Mavyret 12 weeks = (252 tablets per 84 days)
Mavyret 16 weeks = (336 tablets per 112 days)
Zepatier 12 weeks = (84 tablets per 84 days)
Zepatier 16 weeks = (112 tablets per 112 days)

<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>
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</tr>
<tr>
<td>Paritaprevir</td>
<td>Elbasvir</td>
<td></td>
</tr>
<tr>
<td>Grazoprevir</td>
<td>Velpatasvir</td>
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</tr>
<tr>
<td>Voxilaprevir</td>
<td>Pibrentasvir</td>
<td></td>
</tr>
<tr>
<td>Glecaprevir</td>
<td></td>
<td></td>
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</tbody>
</table>
HEPATITIS C AGENTS
Epclusa* (sofosbuvir & velpatasvir), Harvoni* (ledipasvir & sofosbuvir), Sovaldi*
(sofosbuvir), Mavyret* (glecaprevir and pibrentasvir), Vosevi* (sofosbuvir, velpatasvir, &
voxilaprevir), Zepatier (elbasvir, grazoprevir)

*Preferred Product

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 Renewal Limits

Harvoni only

Treatment-Naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml
4 weeks Harvoni (28 tablets per 28 days)