2015 Hepatitis C Second Generation Antivirals (Harvoni [ledipasvir/sofosbuvir], and Viekira Pak [ombitasvir/paritaprevir/ritonavir + dasabuvir]) Prior Authorization – Through Preferred Oral Agent(s)

The Hepatitis C First Generation, Hepatitis C Second Generation and Sovaldi Prior Authorization Programs must be implemented together.

OBJECTIVE
The intent of the Hepatitis C second generation antiviral Prior Authorization (PA) program is to appropriately select patients for therapy according to the Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. The PA process will evaluate the use of these agents when there is supporting clinical evidence of Class IIa, Level C or better for their use. Patients requesting Harvoni that are treatment naïve, non-cirrhotic and with an initial viral load < 6 M IU/mL will be approved for 8 weeks assuming all other criteria are met. This criteria does not include the use of Sovaldi (sofosbuvir), and requests for Sovaldi (sofosbuvir) in combination with Olysio (simeprevir) which will not be approved. For the use of Olysio in combination with peginterferon and ribavirin, see Hepatitis C First Generation criteria. For hepatocellular carcinoma patients, see Sovaldi (sofosbuvir) specific criteria.

TARGET DRUGS
Preferred Agent(s)
Harvoni® (ledipasvir/sofosbuvir)

Nonpreferred Agent(s)
Viekira Pak (ombitasvir/paritaprevir/ritonavir + dasabuvir)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Harvoni (ledipasvir/sofosbuvir) will be approved when the following criteria are met:

1. The patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
2. The prescriber has provided a baseline HCV RNA value AND
3. This agent will not be used in combination with other protease inhibitors used to treat chronic hepatitis C (i.e. boceprevir, simeprevir, or telaprevir) AND
4. The patient does not have any FDA labeled contraindications to therapy with the requested agent
**AND**

<table>
<thead>
<tr>
<th>Agent(s)</th>
<th>Contraindication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvoni (ledipasvir/sofosbuvir)</td>
<td>None</td>
</tr>
<tr>
<td>Viekira Pak</td>
<td>Known hypersensitivity to ritonavir, severe hepatic impairment, co-administration with drugs that are highly dependent on CYP3A for clearance, strong inducers of CYP3A and CYP2C8, and strong inhibitors of CYP2C8. When co-administered with RBV: pregnancy, males whose female partners are pregnant, patients with hemoglobinopathies (e.g. thalassemia major or sickle-cell anemia) and in combination with didanosine.</td>
</tr>
</tbody>
</table>

5. The patient does not have hepatocellular carcinoma (see Sovaldi criteria for approval) **AND**
6. The patient is not co-infected with chronic hepatitis B **AND**
7. **ONE** of the following:
   a. The patient has a METAVIR score of $\geq 2$ **OR**
   b. The patient has an APRI score $> 2$ **OR**
   c. The patient has a Ishak score $\geq 3$ **OR**
   d. The patient has a Fibroscan score of $\geq 7.65$ kPa **OR**
   e. The patient has radiological imaging consistent with fibrosis and/or cirrhosis (e.g. portal hypertension) **OR**
   f. The patient has type 2 or 3 mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis) **OR**
   g. The patient has proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis **OR**
   h. The patient is currently awaiting liver transplant **OR**
   i. The patient is post-liver transplant **OR**
   j. The patient is co-infected with HIV-1 **AND**

8. If the request is for Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir) or any nonpreferred agent, the patient is currently being treated with the requested agent **OR**
9. If the request is for Harvoni, the following:
   a. The patient has genotype 1, 4, or 6 **AND**
   b. The patient has not been previously treated with Viekira (ombitasvir/paritaprevir/ritonavir + dasabuvir) or Harvoni **AND**
   c. **ONE** of:
      i. The patient has NOT failed a previous sofosbuvir containing regimen (not including Harvoni) **OR**
      ii. BOTH of the following:
         1. The patient has failed a previous sofosbuvir containing regimen (not including Harvoni) **AND**
         2. The patient has advanced fibrosis (Metavir F3 or F4) with compensated liver disease **AND**

10. The dose is within the FDA labeled dose (90 mg of ledipasvir/400 mg of sofosbuvir or 25 mg ombitasvir/150 mg of paritaprevir/100 mg ritonavir plus 250 mg twice daily of dasabuvir)

**Length of Approval:** Up to 24 weeks as determined in Tables 1 and 2 below.
### Table 1
#### Harvoni Treatment Duration Recommendations

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Patient Population</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Treatment naïve without cirrhosis and initial viral load &lt; 6 M IU/mL</td>
<td>8 weeks*</td>
</tr>
<tr>
<td></td>
<td>Treatment naïve with or without cirrhosis</td>
<td>12 weeks*</td>
</tr>
<tr>
<td></td>
<td>Treatment experienced** without cirrhosis</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Treatment experienced** with cirrhosis</td>
<td>24 weeks</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>12 weeks</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*8 weeks may be considered in treatment naïve patients without cirrhosis who have pre-treatment HCV RNA < 6 million IU/mL. **For this patient population, HCSC is requiring 8 weeks of therapy.**

**Treatment-experienced patients who have failed therapy with either peginterferon + ribavirin or an HCV protease inhibitor + peginterferon + ribavirin.

### Table 2
#### Viekira Treatment Duration Recommendations based on labeling

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1a, no cirrhosis</td>
<td>Viekira + RBV</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 1a, cirrhosis</td>
<td>Viekira + RBV</td>
<td>24 weeks**</td>
</tr>
<tr>
<td>Genotype 1b, no cirrhosis</td>
<td>Viekira</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 1b, cirrhosis</td>
<td>Viekira + RBV</td>
<td>12 weeks</td>
</tr>
<tr>
<td>4</td>
<td>Viekira + RBV</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

**Viekira with RBV for 12 weeks may be considered for some patients based on prior treatment history. The SVR12 rate difference between 24 and 12 weeks of treatment was +6% with differences varying by pretreatment history.**

^HCV/HIV-1 coinfection, follow recommendations above

^Liver transplant patients with normal hepatic function and mild fibrosis (Metavir ≤2), recommended duration with RBV is 24 weeks.