**PRIOR AUTHORIZATION PROTOCOL FOR HEPATITIS C TREATMENT**

**MAVYRET™ (Glecaprevir/Pibrentasvir)-PREFERRED AGENT**

VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir)  
EPCLUSA® (sofosbuvir/velpatasvir)  
ZEPATIER® (elbasvir/grazoprevir)  
HARVONI™ (ledipasvir/sofosbuvir)  
DAKLINZA™ (Daclatasvir)  
TECHNIVIE™ (Ombitasvir, paritaprevir, ritonavir)  
VIEKIRA PAK™/VIEKIRA XR™ (Ombitasvir/paritaprevir/ritonavir/dasabuvir)  
OLYSIO™ (simeprevir)  
SOVALDI™ (sofosbuvir)  
PENG-INTRON™/ PEGASYS™ (peginterferon alfa-2a)  
RIBAVIRIN tablets or capsules  
OR ANY OTHER NEWLY MARKETED AGENT for treatment of Hepatitis C

Where applicable and appropriate: **MAVYRET (Glecaprevir/Pibrentasvir) is the PREFERRED AGENT** for Hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the Participant is not able to use Mavyret.

Initial requests must meet ALL of the following requirements:

1. Request must be for an appropriate FDA approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate Participant (e.g. age/weight)  
2. The drug is being prescribed by a specialist in hepatology/gastroenterology/infectious disease/HIV or liver transplant  
3. Provider attests that Participant does not have limited life expectancy of less than 12 months due to non-liver related comorbid conditions  
4. Provider attests that Participant has been screened for Hepatitis B (HBV) and human immunodeficiency virus (HIV)  
5. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the Participant of the risks associated with the use of both medications)  
6. Provider attests that Participant does not have current issues with compliance  
7. Provider attests if Participant is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled Participant regarding the risks of alcohol or IV drug abuse, and an offer of referral for substance abuse disorder treatment has been made  
8. Provider attests that Participant is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan  
9. Participant’s treatment history and response has been provided with request  
10. Participant has **ONE** of the following:  
    - History of liver transplant (include date **NOTE: does not require a certain level of fibrosis**)  
    - Is HIV or HBV co-infected
- Serious extrahepatic manifestations of Hepatitis C such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia
- A Metavir fibrosis score of F1-F4 documented by liver biopsy, Fibroscan, or a blood test
- Physical findings consistent with substantial or advanced fibrosis or cirrhosis
  - Hospitalization within the past 12 months for a condition attributed to hepatic cirrhosis, OR
  - History of hepatic encephalopathy requiring medication management and/or hospitalization within the past 12 months, OR
  - History of portal hypertension as demonstrated by variceal bleeding or radiographic evidence or Transjugular Intrahepatic Portsystemic Shunt (TIPS) procedure

11. The following lab testing is required before treatment (copies of labs required)
   - Genotype (and subtype if provided)
   - RASs (resistance-associated substitutions, previously called RAVs) testing for Zepatier 1a requests or as indicated in treatment guidelines

The following lab testing is required within 3 months of starting therapy:
   - Detectable HCV RNA viral load
   - CBC (only if regimen contains ribavirin and hemoglobin must be at least 10g/dL)
   - TSH (only if regimen contains interferon)
   - Pregnancy test (within 1 month for regimens that contain ribavirin and the Participant is a female of child bearing age)

12. If Participant is cirrhotic, documentation of Child Turcotte Pugh Class (Class A, Class B, Class C)
13. The Participant will be referred to participate in Hepatitis C education and counseling program provided by the health plan
14. If Participant has hepatocellular carcinoma, documentation was provided confirming the diagnosis (image testing by ultrasound, tomography, MRI, laparoscopy or biopsy)
15. All approvals are for 28 days supply (see treatment summary that follows), and will be consistent with labeling or current guidelines, and are subject to change as guidelines are updated.

**TREATMENT SUMMARY**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Option</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No Cirrhosis</td>
</tr>
<tr>
<td>1,2,3,4,5 or 6</td>
<td>Mavyret</td>
<td>8 weeks</td>
</tr>
<tr>
<td>1,2,3,4,5 or 6</td>
<td>Epclusa *</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*ONLY if medical reason provided that Participant is unable to use Mavyret
## Treatment Experienced

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Failed Regimen</th>
<th>Treatment Option</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis (Child-Pugh A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1, 2, 4, 5 or 6</td>
<td>Peg/Riba</td>
<td>Mavyret</td>
<td>8 weeks</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Peg/Riba</td>
<td>Mavyret OR Vosevi</td>
<td>16 weeks</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Genotype 1</td>
<td>Peg/Ribavirin with Olysio, Incivek or Victrelis OR Sovaldi/Olysio</td>
<td>Mavyret</td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 1 or 2</td>
<td>Sovaldi/Peg/Ribavirin OR Sovaldi/Ribavirin</td>
<td>Mavyret</td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
<tr>
<td>ALL GENOTYPES</td>
<td>Any other DAA regimen other than those specifically listed above</td>
<td>Vosevi</td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

## Patients with mild, moderate or severe renal impairment, including those requiring hemodialysis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Option</th>
<th>No Cirrhosis</th>
<th>Compensated Cirrhosis (Child-Pugh A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3,4,5 or 6</td>
<td>Mavyret</td>
<td>8 weeks-16 weeks</td>
<td>12 weeks-16 weeks</td>
</tr>
</tbody>
</table>
| 1 or 4 | Zepatier*  
RAV testing required for GT1a  
*ONLY if medical reason provided that Participant is unable to use Mavyret | 12 weeks-16**  
**Dependent on RAV testing and previous treatment history-refer to package insert/AASLD guidelines | 12 weeks-16**  
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**Unique patient populations (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)**

| Compensated Cirrhosis (Child-Pugh B or C) | Refer to current AASLD guidelines @ [http://www.hcvguidelines.org/](http://www.hcvguidelines.org/)  
**NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that Participant is unable to use Mavyret |
| Post-Transplant | Refer to current AASLD guidelines @ [http://www.hcvguidelines.org/](http://www.hcvguidelines.org/)  
**NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that Participant is unable to use Mavyret |
| Hepatocellular Carcinoma | **NOTE:** Refer to current AASLD guidelines @ [http://www.hcvguidelines.org/](http://www.hcvguidelines.org/)  
*If Mavyret is a recommended treatment option it is preferred unless medical reason provided that Participant is unable to use Mavyret |
| Pediatrics | Refer to current AASLD guidelines @ [http://www.hcvguidelines.org/](http://www.hcvguidelines.org/)  
*If Mavyret is a recommended treatment option it is preferred unless medical reason provided that Participant is unable to use Mavyret |

Review/Revision Date: 9-20-2017