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)
PEG-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 member 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 member (e.g. age/weight).
2. Provider attests that member does not have limited life expectancy of less than 12 months due to non-liver related comorbid conditions.
3. Provider attests that they have documented completion of the following:
   • Hepatitis B immunization series
   OR
   • Hepatitis B screening (sAb/sAg and cAb/cAg)
   AND
   • Quantitative HBV DNA if positive for hepatitis BsAg or cAb or cAg
   AND
   • If there is detectable HBV DNA, will be treated for Hepatitis B
   OR
   • If negative for Hepatitis BsAb, is being vaccinated against Hepatitis B
4. Provider attests that they have documented HIV screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
   • Is being treated for HIV
   OR
   • Is not being treated for HIV and the medical record documents the rationale for not being treated
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 member of the risks associated with the use of both medications).

6. Provider attests that member does not have current issues with compliance.

7. Provider attests if member is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled member 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 member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan.

9. Member’s treatment history and response has been provided with request.

10. Member’s fibrosis level has been provided with request.

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 indicted in treatment guidelines
   - Detectable HCV RNA viral load
   - CBC (within 3 months only if regimen contains ribavirin and hemoglobin must be at least 10g/dL)
   - Pregnancy test (within 1 month for regimens that contain ribavirin and the member is a female of child bearing age)

12. If member is cirrhotic, documentation of Child Turcotte Pugh Class (Class A, Class B, Class C).

13. The member will be referred to participate in Hepatitis C education and counseling program provided by the health plan.

14. 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.

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**TREATMENT SUMMARY**

<table>
<thead>
<tr>
<th>Treatment Naïve</th>
<th>Genotype</th>
<th>Treatment Option</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1,2,3,4,5 or 6</td>
<td>Mavyret</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>1,2,3,4,5 or 6</td>
<td>Epclusa *&lt;sup&gt;1&lt;/sup&gt;</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

<sup>1</sup>ONLY if medical reason provided that member 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 Dependent on treatment history, GT-refer to package insert/AASLD guidelines</td>
<td>12 weeks-16 weeks Dependent on treatment history, GT-refer to package insert/AASLD guidelines</td>
</tr>
<tr>
<td>1 or 4</td>
<td>Zepatier*</td>
<td>12 weeks-16** Dependent on RAV testing and previous treatment history-refer to package insert/AASLD guidelines</td>
<td>12 weeks-16** Dependent on RAV testing and previous treatment history-refer to package insert/AASLD guidelines</td>
</tr>
</tbody>
</table>

*RAV testing required for GT1a
*ONLY if medical reason provided that member is unable to use Mavyret
## Unique patient populations (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Guidelines and Notes</th>
</tr>
</thead>
</table>
| Decompensated Cirrhosis (Child-Pugh B or C) | Refer to current AASLD guidelines @ http://www.hcvguidelines.org/  
**NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret |
| Post-Transplant                  | Refer to current AASLD guidelines @ http://www.hcvguidelines.org/  
**NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret |
| Hepatocellular Carcinoma         | **NOTE:** Refer to current AASLD guidelines @ http://www.hcvguidelines.org/  
*If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret |
| Pediatrics                       | Refer to current AASLD guidelines @ http://www.hcvguidelines.org/  
*If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret |

Review/Revision Date: 12/22/2017  
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Effective Date: 1/1/2018