落叶医助

前授权标准

直接抗病毒药物治疗丙型肝炎（HCV）基因型1

VieKira Pak™（奥美替韦+泊拉特韦+利托那韦+达莎韦）

Sovaldi®（索非布韦），Olysio®（辛多伐他汀）

Harvoni®（索非布韦+利匹那韦）

标准审批

1. 成人患者年龄≥18岁；
2. HCV基因型、HCV亚型和HCV病毒载量的文献包括在授权请求中；
3. 符合诊断和疾病严重性为丙型肝炎，基因型1（GT 1），和Metavir纤维化分数F2-F4等效；
4. 已经试用过的HCV治疗方案、治疗日期、是否完成全疗程或提前终止，以及若提前终止的原因包括在授权请求中；
5. 同意完成整个疗程；
6. 患者正在戒除非法药物和酒精，且通过90天内的尿检确认（结果随授权请求提交）；任何阳性结果需由开处方医生解释。
7. 若HCV/HIV共感染
   • 必须提供CD4计数、HIV病毒载量、治疗方案的文献。
8. 若需辛多伐他汀含有的方案
   • 若为基因型1a，必须报告NS3 Q80K多态性；
   • 必须是辛多伐他汀初治。
9. 对于续授权
   • 对于持续时间超过8周的方案，HCV RNA必须在治疗周4和8时提交；
   • HCV RNA < 25 IU/mL在治疗周4；
   • 若HCV RNA在治疗周4可检测，HCV RNA在治疗周6应低于周4或不可检测。

用量限制

Harvoni – 一次400 mg/90 mg片剂/天（28片/28天）
Olysio – 一次150 mg片剂/天（28片/28天）
Sovaldi – 一次400 mg片剂/天（28片/28天）
VieKira剂量包 – 四次片剂/天（112片/28天）
Duration of Approval

1. Based on HCV genotype and prior treatment experience
   • Refer to Table 1 for regimen durations; authorization duration will be approved as follows:

<table>
<thead>
<tr>
<th>Regimen Duration</th>
<th>Authorization Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>12 weeks</td>
<td>8 weeks + 4 weeks</td>
</tr>
<tr>
<td>24 weeks</td>
<td>8 weeks + 8 weeks + 8 weeks</td>
</tr>
</tbody>
</table>

2. Limits
   • Retreatment not authorized within two (2) years

3. Lost or stolen medication
   • Lost or stolen medication replacement requests will not be authorized.

Criteria for Denial

1. Patient is not abstaining from the use of illicit drugs and alcohol as evidenced by submitted urine confirmation test results.
2. Diagnostic/disease severity evidence is not submitted with the request.
3. HCV RNA results not submitted with the request.
4. For regimens containing ribavirin, patient is pregnant or lactating.
5. For regimens containing simeprevir, patient is not simeprevir naïve.
6. For regimens containing sofosbuvir, patient has severe renal impairment (eGFR < 30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
7. Patient has a Child-Pugh score greater than 6 [class B or C] and treatment is not being managed by a liver disease specialist.
8. Patient is taking a concomitant medication that has a significant clinical interaction or is contraindicated with any of the agents.
9. HCV genotype is 2, 3, 4, 5, 6 or mixed (refer to respective criteria).
**Regimen**

### Table 1†

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Regimen</th>
<th>Duration</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Line Preferred – Treatment naïve or Treatment experienced</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GT 1a, without cirrhosis Metavir F2-3</td>
<td>VieKira Pak + ribavirin‡,§</td>
<td>12 weeks</td>
<td>Child-Pugh B or greater; ESRD; pregnancy</td>
</tr>
<tr>
<td>GT 1a, with cirrhosis Metavir F4</td>
<td>VieKira Pak + ribavirin‡,§</td>
<td>24 weeks</td>
<td>Child-Pugh B or greater; ESRD; pregnancy</td>
</tr>
<tr>
<td>GT 1b, without cirrhosis Metavir F2-3</td>
<td>VieKira Pak</td>
<td>12 weeks</td>
<td>Child-Pugh B or greater; ESRD</td>
</tr>
<tr>
<td>GT 1b, with cirrhosis Metavir F4</td>
<td>VieKira Pak + ribavirin‡,§</td>
<td>12 weeks</td>
<td>Child-Pugh B or greater; ESRD; pregnancy</td>
</tr>
<tr>
<td>GT 1, s/p liver transplant</td>
<td>VieKira Pak + ribavirin‡,§</td>
<td>24 weeks</td>
<td>Abnml liver function, Fibrosis &gt;F2; pregnancy</td>
</tr>
</tbody>
</table>

*If patient has documented exclusions to first line therapy, approval may be considered for second line therapy.*

| **Second Line – Treatment naïve** | | | |
| GT 1, without cirrhosis, HCV RNA ≤ 6 million IU/mL Metavir F2-3, treatment naïve | Harvoni | 8 weeks | Treatment experienced; severe renal impairment, ESRD; HIV |
| GT 1, without cirrhosis, HCV RNA > 6 million IU/mL Metavir F2-3, treatment naïve | Harvoni | 12 weeks | Treatment experienced; severe renal impairment, ESRD |
| GT 1, with cirrhosis, Metavir F4, treatment naïve | Harvoni | 12 weeks | Treatment experienced; severe renal impairment, ESRD; decompensation |

| **Second Line – Treatment experienced** | | | |
| GT 1ab, without cirrhosis, Metavir F2-3 treatment experienced | Harvoni | 12 weeks | Severe renal impairment, ESRD |
| GT 1, with cirrhosis, Metavir F4 treatment experienced | Harvoni + ribavirin‡,§ | 12 weeks | Severe renal impairment, ESRD; decompensation |

HCV GT1 DAA PA Criteria
Version: 3
Last updated: 01/16/2015
Approval: 01/16/2015
### ALASKA MEDICAID
Prior Authorization Criteria

#### Table 1†

<table>
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</thead>
<tbody>
<tr>
<td>GT 1, Metavir F2-4</td>
<td>Interferon-based regimens with HCV direct acting antiviral + ribavirin†‡§</td>
<td>12 weeks</td>
<td>Severe renal impairment, ESRD; decompensation; contraindication/intolerance to interferon</td>
</tr>
</tbody>
</table>

**If patient has documented exclusions to second line therapy,**
approval may be considered for third line therapy.

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>GT 1, Metavir F2-3</td>
<td>Sovaldi + Olysio ± ribavirin†‡§</td>
<td>12 weeks</td>
<td>Severe renal impairment, ESRD; decompensation; pregnancy</td>
</tr>
<tr>
<td>GT 1, Metavir F4</td>
<td>Sovaldi + Olysio ± ribavirin†‡§</td>
<td>12 weeks</td>
<td>Severe renal impairment, ESRD; decompensation; pregnancy</td>
</tr>
</tbody>
</table>

**If patient has documented exclusions to third line therapy,**
approval may be considered for fourth line therapy.

<table>
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<th>Duration</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT 1, Metavir F2-4</td>
<td>Harvoni + ribavirin†‡§</td>
<td>12 weeks</td>
<td>Restricted to Specialist</td>
</tr>
<tr>
<td>GT 1, Metavir F4</td>
<td>Harvoni</td>
<td>12 weeks</td>
<td>Restricted to Specialist</td>
</tr>
<tr>
<td>GT 1, Hepatocellular Carcinoma (HCC)</td>
<td>Sovaldi</td>
<td>12 weeks</td>
<td>Restricted to Specialist</td>
</tr>
</tbody>
</table>

**If patient has documented exclusions to first line therapy,**
the following regimens may be considered but shall be restricted to liver disease specialists.

**Additional Considerations**

- Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes.
- Therapy with regimens containing ritonavir requires the co-infected patient to be on a suppressive antiretroviral drug regimen to decrease the risk of selection of HIV-1 protease inhibitor resistant strains.
- Combination treatment with ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

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†Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration; ‡Weight based ribavirin; §Refer to FDA approved labeling for use in individuals with impaired renal function
References

5. FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).