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**Ombitasvir+paritaprevir+ritonavir + dasabuvir Agents**

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Based on Genotype, Treatment status, or Cirrhosis status</td>
</tr>
<tr>
<td>Quantity Limit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viekira Pak (ombitasvir + paritaprevir + ritonavir + dasabuvir)</td>
<td>4 tablets per day</td>
</tr>
<tr>
<td>Viekira XR (ombitasvir + paritaprevir + ritonavir + dasabuvir)</td>
<td>3 tablets per day</td>
</tr>
</tbody>
</table>

**APPROVAL DURATION**

<table>
<thead>
<tr>
<th>Genotype and Status (HCV mono-infected or HCV/HIV-1 co-infected)</th>
<th>Associated Treatment Regimens</th>
<th>Total Approval Duration of ombitasvir + paritaprevir + ritonavir + dasabuvir agents (Viekira Pak, Viekira XR)</th>
</tr>
</thead>
</table>
| Genotype 1b (treatment naïve or dual P/R<sup>2b</sup> treatment-experienced, with compensated cirrhosis or without cirrhosis) | Viekira Pak  
Viekira XR | 12 weeks |
| Genotype 1a, unknown Genotype 1 subtype, or mixed Genotype 1 subtypes (treatment naïve or dual P/R<sup>2b</sup> treatment-experienced, without cirrhosis) | Viekira Pak+ ribavirin  
Viekira XR + ribavirin | 12 weeks |

**APPROVAL CRITERIA**

Requests for ombitasvir + paritaprevir + ritonavir + dasabuvir (Viekira Pak, Viekira XR) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**  
II. Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection<sup>a</sup>, which includes genotype, a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013); **AND**  
III. Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy; **AND**
IV. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017); **AND**

V. Individuals who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program; **AND**

VI. Individual has Genotype 1 and compensated liver disease\(^1\) (with or without cirrhosis); **AND**

VII. Individual is using with one of the following antiviral treatment regimens (AASLD/IDSA 2017):

A. As monotherapy for individuals with Genotype 1b, treatment-naïve or dual P/R\(^{2b}\) treatment-experienced, with compensated\(^1\) cirrhosis or without cirrhosis; **AND**

B. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
   1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
   2. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Viekira Pak/Viekira XR; **OR**
   3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

**OR**

C. In combination with ribavirin for the following:
   1. Individual with Genotype 1a or mixed/unknown Genotype1, treatment-naïve or dual P/R\(^2\) treatment-experienced;
      **AND**
   2. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Mavyret; **OR**
      a. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
      b. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Mavyret which is not also in Viekira Pak/Viekira XR; **OR**
      c. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

Ombitasvir + paritaprevir + ritonavir + dasabuvir (Viekira Pak, Viekira XR) may **not** be approved for the following:

I. Individual has decompensated\(^1\) cirrhosis; **OR**

II. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to the following: Strong cytochrome (CYP) 2C8 inhibitors [such as but not limited to, gemfibrozil, ritonavir-boosted atazanavir], strong CYP 2C8

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inducers (such as but not limited to, carbamazepine, phenobarbital, rifampin, rifabutin, rifapentine), moderate or strong CYP 3A4 inducers (such as but not limited to, phenytoin, St. Johns’ Wort, efavirenz-based regimens, agents highly dependent on CYP3A clearance (substrates) [such as but not limited to, dronedarone, amiodarone, flecainide, propafenone, quinidine, ranolazine, lurasidone, cisapride, alfuzosin, colchicine, ergot derivatives, ethinyl estradiol-containing agents, lovastatin, simvastatin, pimozone, Revatio, triazolam, oral midazolam, darunavir, lopinavir/ritonavir, rilpivirine-based regimens, voriconazole, salmeterol], atorvastatin, everolimus, sirolimus, tacrolimus, tipranavir/ritonavir, etravirine, nevirapine or cobicistat-containing regimens; OR

III. Individual is using in combination with a regimen containing another NS3/4A\textsuperscript{2c} protease inhibitor; OR

IV. Individual is using in combination with a regimen containing another nucleotide NS5B polymerase inhibitor (such as sofosbuvir) or another non-nucleoside NS5B polymerase inhibitor (such as dasabuvir); OR

V. Individual is using in combination with a regimen containing another NS5A\textsuperscript{2a} inhibitor; OR

VI. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a NS3/4A\textsuperscript{2c} protease inhibitor, NS5A\textsuperscript{2a} inhibitor, or NS5B polymerase inhibitor (such as sofosbuvir or dasabuvir).

Notes:

\textsuperscript{a}Per label, ombitasvir/paritaprevir/ritonavir + dasabuvir agents (Viekira Pak, Viekira XR) may be used in individuals co-infected with HIV-1. Individuals co-infected with HCV/HIV-1 treated with Viekira Pak/Viekira XR should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

1. Compensated Liver Disease:

According to the American Association for the Study of Liver Diseases (AASLD/IDSA2017), the specific criteria for compensated liver disease include all of the following: a total bilirubin; serum albumin; prothrombin time/INR; presence of ascites; and presence of hepatic encephalopathy. However, these criteria do not establish a comprehensive definition of compensated liver disease. The AASLD guidance refers to compensated liver disease as Class A based on the Child Pugh-Turcotte (CPT) classification scoring system.

Moderate to Severe (Decompensated) Liver Disease:

The AASLD guidance refers to decompensated (moderate to severe) liver disease as Class B or C based on the Child-Pugh Turcotte (CPT) classification scoring system.

Child Pugh Classification (AASLD/IDSA 2017)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>1 point</th>
<th>2 points</th>
<th>3 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Bilirubin ((\mu\text{mol/L}))</td>
<td>&lt;34</td>
<td>34-50</td>
<td>&gt;50</td>
</tr>
<tr>
<td>Serum Albumin (g/L)</td>
<td>&gt;35</td>
<td>28-35</td>
<td>&lt;28</td>
</tr>
</tbody>
</table>
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