MEDICATION POLICY: Technivie™

Generic Name: Ombitasvir/Paritaprevir/Ritonavir

Therapeutic Class or Brand Name: Technivie™

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1235990360

Preferred: N/A.

Non-preferred: N/A.

Date of Origin: 9/22/2015

Date Last Reviewed / Revised: 12/5/2018

PRIOR AUTHORIZATION CRITERIA
(May be considered medically necessary when criteria I to VI are met)

I. Documented diagnosis of chronic hepatitis C (CHC) genotype 4 infection.

II. Patient must have a documented contraindication to Mavyret™ and Zepatier™.

III. Documentation of patient’s Hepatitis C treatment history and baseline viral load.

IV. Documentation that patient’s hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section.

V. Minimum age requirement: 18 years old.

VI. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

EXCLUSION CRITERIA

- Moderate (Child-Pugh B) to severe (Child-Pugh C) hepatic impairment.
- Known hypersensitivity (i.e. toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome) to ritonavir.
- Coadministration of Technivie™ with drugs that are highly dependent on CYP3A for clearance, moderate or strong inducers of CYP3A, or any of the drugs listed in the table below:

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drugs within class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha1-adrenerceptor antagonist</td>
<td>Alfuzosin HCL</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>Carbamazepine, phenytoin, phenobarbital</td>
</tr>
<tr>
<td>Anti-anginal</td>
<td>Ranolazine</td>
</tr>
<tr>
<td>Antiarrhythmic</td>
<td>Dronedarone</td>
</tr>
<tr>
<td>Anti-gout</td>
<td>Colchicine</td>
</tr>
<tr>
<td>Antimycobacterial</td>
<td>Rifampin</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Lurasidone, pimozide</td>
</tr>
<tr>
<td>Ergot derivatives</td>
<td>Ergotamine, dihydroergotamine, ergonovine, methylergonovine</td>
</tr>
<tr>
<td>Ethinyl estradiol-containing products</td>
<td>Ethinyl estradiol-containing medications such as combined oral contraceptives</td>
</tr>
<tr>
<td>GI Motility Agent</td>
<td>Cisapride</td>
</tr>
</tbody>
</table>
**Technivie™**

**Drug Class** | **Drugs within class**
---|---
Herbal Product | St. John’s Wort (Hypericum perforatum)
HIV-Antiviral Agents | Atazanavir, atazanavir/ritonavir, darunavir/ritonavir, efavirenz, lopinavir/ritonavir, rilpivirine
HMG-CoA Reductase Inhibitors | Atorvastatin, lovastatin, pravastatin (if > 40mg/day), simvastatin
Immunosuppressants | Everolimus, sirolimus, tacrolimus
Long-acting beta-adrenoceptor agonist | Salmeterol
Non-nucleoside reverse transcriptase inhibitor | Efavirenz
Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection | Daklinza™ (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)
Phosphodiesterase-5 (PDE5) inhibitor | Sildenafil when dosed as Revatio® for the treatment of pulmonary arterial hypertension (PAH)
Sedatives/hypnotics | Triazolam, orally administered midazolam

**Other Criteria**

- Technivie™ should be discontinued in patients who develop evidence of hepatic decompensation or failure.

**Quantity / Days Supply Restrictions**

- 1 monthly carton (56 tablets) per 28 days.

**Approval Length**

- **Authorization:** See table directly below:

<table>
<thead>
<tr>
<th>Drug Therapy</th>
<th>Cirrhosis</th>
<th>Authorization Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>G4</td>
<td>TN</td>
<td>12w</td>
</tr>
<tr>
<td></td>
<td>TE</td>
<td>12w</td>
</tr>
<tr>
<td>No</td>
<td>12w</td>
<td>12w¹</td>
</tr>
</tbody>
</table>

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Technivie™ Drug Therapy for Cirrhosis

<table>
<thead>
<tr>
<th>Drug Therapy</th>
<th>Cirrhosis</th>
<th>Authorization Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technivie™+RBV</td>
<td>Comp</td>
<td>12w 12w¹</td>
</tr>
</tbody>
</table>

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

¹For patients who have failed pegIFN/RBV.

Re-Authorization: N/A.

APPENDIX

N/A.

REFERENCES

3. Medi-Span.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes/Changes</th>
</tr>
</thead>
</table>
| 12/5/2018| 1. **Deleted** under Prior Authorization Criteria:  
   II. Documentation that patient meets ONE of the following criteria A, B, or C:  
      a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis).  
      b. Is post-liver transplant.  
      c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2:  
         i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).  
         i. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis |
10/27/2017

2. Changed “III. Patient must have a documented contraindication to Zepatier™ and Epclusa®” to “III. Patient must have a documented contraindication to Mavyret™ and Zepatier™” under Prior Authorization Criteria.
3. Added “Mavyret™ (glecaprevir/pibrentasvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)” to list of drugs following the statement “As retreatment when there has been relapse after, or no response to, a prior treatment course with...” under Exclusion Criteria.
4. Added “Atorvastatin” under Exclusion Criteria to table under “Coadministration of Technivie™ with...”, line entitled “HMG-CoA Reductase Inhibitors”.
5. Added “Immunosuppressants: Everolimus, sirolimus, tacrolimus” under Exclusion Criteria to table under “Coadministration of Technivie™ with...”. 
6. Added “Mavyret™ (glecaprevir/pibrentasvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)” under Exclusion Criteria to table under “Coadministration of Technivie™ with...”, line entitled “Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”.

7/30/2016

1. Changed “Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir / dasabuvir)” to “Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)” in list of drugs following the statement “As retreatment when there has been relapse after, or no response to, a prior treatment course with...” under Exclusion Criteria.
2. Changed “Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir / dasabuvir)” to “Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)” under Exclusion Criteria to table under “Coadministration of Technivie™ with...”, line entitled “Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”.

7/21/2016

1. Changed “III. Patient must have a documented contraindication to Zepatier™” to “III. Patient must have a documented contraindication to Zepatier™” and Epclusa® under Prior Authorization Criteria.
2. Added “Epclusa® (sofosbuvir/velpatasvir)” under Exclusion Criteria to: 1) List of drugs following the statement “As retreatment when there has been relapse after, or no response to, a prior treatment course with...” under Exclusion Criteria. 2) Table under “Coadministration of Technivie™ with...”, line entitled “Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”.
4. Added “(elbasvir/grazoprevir)” following Zepatier™ to table under “Coadministration of Technivie™ with...”, line entitled “Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection” under Exclusion Criteria.
5. Unhighlighted authorization duration lengths on table below Authorization under Approval Length.
6. Added “pegIFN = peginterferon” beneath table below Authorization under Approval Length.
1. Changed “member” to “patient” throughout policy.
2. Changed “I. Documentation of member’s Hepatitis C treatment history” to “I. Patient must have a documented contraindication to Zepatier™”; IV. Documentation of member’s Hepatitis C treatment history and baseline viral load; V. Documentation that patient’s hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section under Prior Authorization Criteria.
3. Changed “As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)” to “As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir), or Zepatier™ (elbasvir/grazoprevir)” under Exclusion Criteria.
4. Added “Zepatier™” to “Other protease inhibitors, NS5A inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection” line on table underneath Exclusion Criteria.
5. Changed table following Authorization under Approval Length from:

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Treatment</th>
<th>Authorization Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 4 without cirrhosis</td>
<td>Technivie™ + ribavirin*</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

*Technivie™ administered without ribavirin for 12 weeks may be considered for treatment-naïve patients who cannot take or tolerate ribavirin.

to:

<table>
<thead>
<tr>
<th>Drug Therapy</th>
<th>Cimosis</th>
<th>Authorization Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>RBV</td>
<td>Comp</td>
<td>12w</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12w^1</td>
</tr>
</tbody>
</table>

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks

^1For patients who have failed pegIFN/RBV.

11/18/2015

2. Changed “A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis)” to “A. Has a Metavir score of F3 (advanced fibrosis)” under “II. Documentation that member meets ONE of the following criteria A, B, or C.” under Prior Authorization Criteria.
3. Added “Technivie™ should be discontinued in patients who develop evidence of hepatic decompensation or failure” under Other Criteria.
4. **Changed** “Genotype 4” to “Genotype 4 without cirrhosis” under Patient Characteristics on table under Approval Length.

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.