MEDICATION POLICY

Generic Name: Ombitasvir, Paritaprevir, and Ritonavir

Therapeutic Class or Brand Name: Technivie™

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 9/22/15 **Date Last Reviewed/Revised:** 4/13/2018

GPI Code: 1235990360

Prior Authorization Criteria (may be considered medically necessary when criteria I through VII are met):

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

II. Documentation that patient meets ONE of the following criteria A, B, or C:

A. Has a Metavir score of F3 (advanced fibrosis).

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:

1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).
2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

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

IV. Documentation of patient'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.

VI. Minimum age requirement: 18 years old.

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

Exclusion Criteria:

- As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier™ (elbasvir/grazoprevir).

- 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:

Drug Class	Drugs within class
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital
Anti-anginal	Ranolazine
Antiarrhythmic	Dronedarone
Anti-gout	Colchicine
Antimycobacterial	Rifampin
Antipsychotic	Lurasidone, pimozide
Ergot derivatives	Ergotamine, dihydroergotamine, ergonovine, methylergonovine
Ethinyl estradiol-containing products	Ethinyl estradiol-containing medications such as combined oral contraceptives
GI Motility Agent	Cisapride
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.

Drug Therapy	Cirrhosis	Authorization Duration	
		G4	
		TN	TE
Technivie™+ RBV	No	12w	12w[1]
	Comp	12w	12w[1]

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

[1]For patients who have failed pegIFN/RBV.

- **Re-Authorization:** N/A

Appendix:

N/A

References:

1. http://hcvguidelines.org/full-report-view.
2. http://www.rxabbvie.com/pdf/technivie_pi.pdf.
3. Medi-Span.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
4/13/2018	No changes
10/27/2017	1. **Changed** "I. Documented diagnosis of chronic hepatitis C (CHC) genotype 4 infection without cirrhosis" **to** "I. Documented diagnosis of chronic hepatitis C (CHC) genotype 4 infection" **under Prior Authorization Criteria**. 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…; 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". 3. **Added** "Anti-anginal: Ranolazine"**;** "Antiarrhythmic: Dronedarone"**;** "Anti-gout: Colchicine"**;** "Antipsychotic: Lurasidone, pimozide"**; and** "GI Motility Agent: Cisapride" on table under "Coadministration of Technivie™ with…" **under Exclusion Criteria**. 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**.
3/21/2016	1. **Changed** "member" **to** "patient" **throughout policy**. 2. **Changed** "III. Documentation of member's Hepatitis C treatment history" **to** "III. 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

MEDICATION POLICY

<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>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>
<tr><th>Patient Characteristics</th><th>Treatment</th><th>Authorization Duration</th></tr>
<tr><td>Genotype 4 without cirrhosis</td><td>Technivie™ + ribavirin*</td><td>12 weeks</td></tr>
</table>
*Technivie™ administered without ribavirin for 12 weeks may be considered for treatment-naïve patients who cannot take or tolerate ribavirin.
to:
<table>
<tr><th rowspan="2">Drug Therapy</th><th rowspan="2">Cirrhosis</th><th colspan="2">Authorization Duration</th></tr>
<tr><th colspan="2">G4</th></tr>
<tr><td></td><td></td><td>TN</td><td>TE</td></tr>
<tr><td rowspan="2">Technivie™+ RBV</td><td>No</td><td>12w</td><td>12w[1]</td></tr>
<tr><td>Comp</td><td>12w</td><td>12w[1]</td></tr>
</table>
TN = treatment naïve; TE = treatment experienced;
Comp = compensated; RBV = ribavirin; w = weeks
[1]For patients who have failed pegIFN/RBV.</td></tr>
<tr><td>11/18/2015</td><td>1. Changed “I. Documented diagnosis of chronic hepatitis C (CHC) genotype 4 infection” to “I. Documented diagnosis of chronic hepatitis C (CHC) genotype 4 infection without cirrhosis” under Prior Authorization Criteria.
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.</td></tr>
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