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Generic Name: Dasabuvir, Ombitasvir, Paritaprevir, Ritonavir

Therapeutic Class or Brand Name: Viekira Pak™/XR™

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

Date of Origin: 1/8/15 **Date Last Reviewed/Revised:** 04/30/2018

GPI Code: 1235990460

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

I. Documented diagnosis of chronic hepatitis C (CHC) genotype 1 infection.

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:

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

III. Documentation that patient meets ONE of the following criteria A or B:

A. Patient has a documented contraindication to Mavyret™ and Zepatier™.

B. Patient is post-liver transplant and criterion 1 is met:

1. Patient has a documented contraindication to Mavyret™ and Harvoni® + ribavirin.

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

V. Documentation of patient's Hepatitis C treatment history and baseline viral load.

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),

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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 Viekira Pak™/XR™ with drugs that are highly dependent on CYP3A for clearance, moderate or strong inducers of CYP3A and strong inducers of CYP2C8, strong inhibitors of CYP2C8, or any of the drugs listed in the table below:

Drug Class	Drugs within class
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL
Anti-anginal	Ranolazine
Antiarrhythmic	Dronedarone
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital
Anti-gout	Colchicine
Antihyperlipidemic agent	Gemfibrozil
Antimycobacterial	Rifampin
Antipsychotic	Lurasidone, pimozide
Ergot derivatives	Ergotamine, dihydroergotamine, 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	Darunavir/ritonavir, efavirenz, lopinavir/ritonavir, rilpivirine
HMG-CoA Reductase Inhibitors	Atorvastatin, lovastatin, pravastatin (if > 40mg/day), rosuvastatin (if > 10mg/day), simvastatin
Immunosuppressants	Everolimus, sirolimus, tacrolimus
Long-acting beta-adrenoceptor agonist	Salmeterol
Other polymerase inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection	Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Victrelis® (boceprevir), 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

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Other Criteria:

- Viekira Pak™/XR™ should be discontinued in patients who develop evidence of hepatic decompensation or failure.

Quantity/Days Supply Restrictions:

- 1 monthly carton per 28 days.

Approval Length:

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

Drug Therapy	Cirrhosis	Authorization Duration			
		G1a		G1b	
		TN	TE	TN	TE
Viekira Pak™/XR™	No			12w	12w[1]
	Comp			12w	12w[1]
Viekira Pak™/XR™ + RBV	No	12w	12w[1]		
	No & Post Transplant[^]	24w[^]		24w[^]	
	Comp	24w	24w[1]		

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[^]For patients who develop HCV infection post-liver transplantation.
[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.bcbsnc.com/assets/services/public/pdfs/formulary/viekira_criteria.pdf.
3. https://securews.bcbswny.com/web/content/dam/COMMON/Drug%20Therapy%20Guidelines/T,U,V/Viekira.pdf.

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4. Medi-Span.
5. http://www.rxabbvie.com/pdf/viekirapak_pi.pdf.
6. http://www.rxabbvie.com/pdf/viekiraxr_pi.pdf.

Historical Tracking Of Changes Made To Policy	
4/30/2018	No Changes
10/28/2017	1. **Changed** "III. A. Patient has a documented contraindication to Zepatier™ and Epclusa®" **to** "III. A.

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Historical Tracking Of Changes Made To Policy	
	Patient has a documented contraindication to Mavyret™ and Zepatier™" **under Prior Authorization Criteria**. 2. **Changed** "III. B. 1. Patient has a documented contraindication to Harvoni® + ribavirin" **to** "III. B. 1. Patient has a documented contraindication to Mavyret™ and Harvoni® + ribavirin" **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. **Removed** "ergonovine" **under Exclusion Criteria on table under** "Coadministration of Viekira Pak™/XR™ with …", line entitled "Ergot derivatives". 5. **Added** "Atorvastatin" **under Exclusion Criteria to table under** "Coadministration of Viekira Pak™/XR™ with …", line entitled "HMG-CoA Reductase Inhibitors". 6. **Added** "Immunosuppressants: Everolimus, sirolimus, tacrolimus" **under Exclusion Criteria to table under** "Coadministration of Viekira Pak™/XR™ with…". 7. **Added** "Mavyret™ (glecaprevir/pibrentasvir)" **and** "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" **under Exclusion Criteria to table under** "Coadministration of Viekira Pak™/XR™ with…", line entitled "Other polymerase inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection".
8/5/2016	1. **Changed Generic Name from** "Ombitasvir, Paritaprevir, and Ritonavir/Dasabuvir" **to** "Dasabuvir, Ombitasvir, Paritaprevir, Ritonavir". 2. **Changed Brand Name from** "Viekira Pak™" **to** "Viekira Pak™/XR™". 3. **Changed** "III. A. Patient has a documented contraindication to Zepatier™" **to** "III. A. Patient has a documented contraindication to Zepatier™ and Epclusa®" **under Prior Authorization Criteria**. 4. **Changed** "III. B. Patient is post-liver transplant" **to** "Patient is post-liver transplant and criterion 1 is met: 1. Patient has a documented contraindication to Harvoni® + ribavirin' **under Prior Authorization Criteria**. 5. **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 Viekira Pak™/XR™ with…", line entitled "Other polymerase inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection". 6. **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**. 7. **Changed** "Coadministration of Viekira Pak™ with any of drugs listed in the table below:" **to** "Coadministration of Viekira Pak™/XR™ with drugs that are highly dependent on CYP3A for clearance, moderate or strong inducers of CYP3A and strong inducers of CYP2C8, strong inhibitors of CYP2C8, or any of the drugs listed in the table below:" **under Exclusion Criteria**. 8. **Added** "Anti-anginal: Ranolazine"**;** "Antiarrhythmic: Dronedarone"**;** "Anti-gout: Colchicine"**;** "Antipsychotic: Lurasidone, pimozide"**; and** "GI Motility Agent: Cisapride" on table under "Coadministration of Viekira Pak™/XR™ with…" **under Exclusion Criteria**. 9. **Added** "(elbasvir/grazoprevir)" following Zepatier™ **under Exclusion Criteria** to table under "Coadministration of Viekira Pak™/XR™ with…", line entitled "Other polymerase inhibitors or protease inhibitors used to treat chronic hepatitis C virus infection". 10. **Changed** "Viekira Pak™ should be discontinued…" **to** "Viekira Pak™/XR™ should be discontinued…" **under Other Criteria**. 11. **Changed** "Viekira Pak™" **to** "Viekira Pak™/XR™" **on table below Authorization under Approval Length.**

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>12. Added “http://www.rxabbvie.com/pdf/viekiraxr_pi.pdf” under References.</td></tr>
<tr><td>3/21/2016</td><td>1. Changed “member” to “patient” throughout policy.
2. Added “III. Documentation that patient meets ONE of the following criteria A or B: A. Patient has a documented contraindication to Zepatier™; B. Patient is post-liver transplant; IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section” to 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 polymerase inhibitors or protease 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 1a, without cirrhosis</td><td>Viekira Pak™ + ribavirin</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a, with cirrhosis</td><td>Viekira Pak™ + ribavirin</td><td>24 weeks</td></tr>
<tr><td>Genotype 1b, without cirrhosis</td><td>Viekira Pak™</td><td>12 weeks</td></tr>
<tr><td>Genotype 1b, with cirrhosis</td><td>Viekira Pak™</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a or 1b, Liver Transplant Recipients</td><td>Viekira Pak™ + ribavirin</td><td>24 weeks</td></tr>
</table>
*Genotype 1a lines apply to members with an unknown genotype 1 subtype or with mixed genotype 1 infection.
to:
<table>
<tr><th rowspan="2">Drug Therapy</th><th rowspan="2">Cirrhosis</th><th colspan="4">Authorization Duration</th></tr>
<tr><th colspan="2">G1a</th><th colspan="2">G1b</th></tr>
<tr><td></td><td></td><td>TN</td><td>TE</td><td>TN</td><td>TE</td></tr>
<tr><td rowspan="2">Viekira Pak™</td><td>No</td><td></td><td></td><td>12w</td><td>12w[1]</td></tr>
<tr><td>Comp</td><td></td><td></td><td>12w</td><td>12w[1]</td></tr>
<tr><td rowspan="3">Viekira Pak™ + RBV</td><td>No</td><td>12w</td><td>12w[1]</td><td></td><td></td></tr>
<tr><td>No & Post Transplant[^]</td><td>24w[^]</td><td></td><td>24w[^]</td><td></td></tr>
<tr><td>Comp</td><td>24w</td><td>24w[1]</td><td></td><td></td></tr>
</table>
TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[^]For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.</td></tr>
<tr><td>12/4/2015</td><td>1. Changed “III. Documentation of member’s Hepatitis C treatment history” to “III. Documentation of member’s Hepatitis C treatment history and baseline viral load” under Prior Authorization Criteria.</td></tr>
<tr><td>11/18/2015</td><td>1. Added “Viekira Pak™ should be discontinued in patients who develop evidence of hepatic decompensation or failure” under Other Criteria.</td></tr>
<tr><td>11/9/2015</td><td>1. Changed “Documented diagnosis of chronic hepatitis C (CHC) genotypes 1 or 4 infection” to</td></tr>
</table>

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Historical Tracking Of Changes Made To Policy	
	""Documented diagnosis of chronic hepatitis C (CHC) genotype 1 infection" **under Prior Authorization Policy**. 2. **Changed** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), 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), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)" **under Exclusions**. 3. **Changed** "Genotype 1b, with cirrhosis: Viekira Pak™ + ribavirin: 12 weeks" **to** "Genotype 1b, with cirrhosis: Viekira Pak™: 12 weeks" **on table under Approval Length**. 4. **Removed** "Genotype 4: Viekira Pak™ + ribavirin: 12 weeks" **from table under Approval Length**. 5. **Updated** "http://www.hcvguidelines.org/fullreport" **to** "http://hcvguidelines.org/full-report-view" **under References**.
5/20/2015	1. **Changed** "II. Documentation that member meets ONE of the following criteria A through I: A. Has a Metavir score of F2 (fibrosis), 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: 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; D. Is coinfected with HIV-1; E. Is coinfected with Hepatitis B virus (HBV); F. Has other coexistent liver disease [i.e. nonalcoholic steatohepatitis (NASH)]; G. Has debilitating fatigue as evidenced by the documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores, etc.); H. Has Type 2 diabetes mellitus (insulin resistant); I. Has porphyria cutanea tarda" **to** "II. Documentation that member 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: 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis" **under Prior Authorization Criteria**.
4/1/2015	1. **Changed** "I. Documented diagnosis of genotype 1 chronic hepatitis C virus (HCV) infection" **to** "I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1 or 4 infection" **under Prior Authorization Criteria**. 2. **Changed** "II. Documentation that member 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: 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis" **to** "II. Documentation that member meets ONE of the following criteria A through I: A. Has a Metavir score of F2 (fibrosis), 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: 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; D. Is coinfected with HIV-1; E. Is coinfected with Hepatitis B virus (HBV); F. Has other coexistent liver disease [i.e. nonalcoholic steatohepatitis (NASH)]; G. Has debilitating fatigue as evidenced by the documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores, etc.); H. Has Type 2 diabetes mellitus (insulin resistant); I. Has porphyria cutanea tarda" **under Prior Authorization Criteria**. 3. **Changed** "Liver Transplant Recipients" **to** "Genotype 1a or 1b, Liver Transplant Recipients" for Patient

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Historical Tracking Of Changes Made To Policy	
	Characteristics **on table under Approval Length**. 1. **Added** "Genotype 4: Viekira Pak™ + ribavirin: 12 weeks" for Patient Characteristics, Treatment, and Authorization Duration **on table under Approval Length**.
1/26/2015	1. **Added** "Documentation of member's Hepatitis C treatment history" **under Prior Authorization Criteria**. 2. **Consolidated** "HIV-Antiviral Agents: Darunavir/ritonavir, lopinavir/ritonavir, rilpivirine; Non-nucleoside reverse transcriptase inhibitor: Efavirenz" **to** "HIV-Antiviral Agents: Darunavir/ritonavir, efavirenz, lopinavir/ritonavir, rilpivirine" **on table for "Coadministered of Viekira Pak™ with any of drugs listed in the table below" under Exclusion Criteria**.