



MEDICATION POLICY

Generic Name: Elbasvir/Grazoprevir

Therapeutic Class or Brand Name: Zepatier™

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/13/16

Date Last Reviewed/Revised: 10/17/17

GPI Code: 1235990230

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

- I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 3, or 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) 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 of patient's Hepatitis C treatment history and baseline viral load.
- IV. Documentation that patient has a contraindication to Mavyret™.
- V. Documentation that patient meets ONE of the following criteria A or B:
 - A. Patient has genotypes 1 or 4. If the patient has genotype 1a, then criterion 1 must also be met:
 1. Documentation that patient has been tested for the presence of virus with NS5A resistance-associated polymorphisms.
 - B. Patient has genotype 3 AND meets criterion 1:
 1. Patient has a documented contraindication to Epclusa® and Vosevi®.
- VI. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section
- VII. Minimum age requirement: 18 years old.
- VIII. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

Exclusion Criteria:

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- 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), Mavyret™ (glecaprevir/pibrentasvir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier™ (elbasvir/grazoprevir).
- Moderate or severe hepatic impairment (Child-Pugh B or C).
- Coadministration of Zepatier™ with any organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors, strong or moderate CYP3A inducers, efavirenz, or any of the drugs listed in the table below:

Drug Class	Drugs within class
Antibiotics	Nafcillin
Anticonvulsants	Carbamazepine, phenytoin
Antifungals	Ketoconazole
Antimycobacterials	Rifampin
Endothelin Antagonists	Bosentan
Herbal Products	St. John's Wort (<i>Hypericum perforatum</i>)
HIV Medications	Atazanavir, darunavir, efavirenz, elvitegravir/cobicistat/emtricitabine/tenofovir (disoproxil fumarate or alafenamide), etravirine, lopinavir, saquinavir, tipranavir
HMG-CoA Reductase Inhibitors	Atorvastatin (if > 20 mg/day), rosuvastatin (if > 10 mg/day)
Immunosuppressants	Cyclosporine
Other NS5A inhibitors, protease 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), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)
Wakefulness Promoting Agents	Modafinil

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 28 tablets per 28 days.

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Approval Length:

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

Drug Therapy	Cirrhosis	G1a		G1b		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™	No	12w ^t	12w ^{t1}	12w	12w ¹			12w	12w ^{1a}
	Comp	12w ^t	12w ^{t1}	12w	12w ¹			12w	12w ^{1a}
Zepatier™ + RBV	No	16w ^t	12-16w ^{p4} , 16w ^{t1}		12w ⁴				16w ^{1b}
	Comp	16w ^t	12-16w ^{p4} , 16w ^{t1}		12w ⁴				16w ^{1b}
Zepatier™ + Sovaldi®	No					12w			
	Comp					12w	12w ¹		

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

^tFor genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

^pPatients who have NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93 should have treatment extended to 16 weeks.

¹For patients who have failed pegIFN/RBV.

^{1a}For patients who experienced virologic relapse after prior pegIFN/RBV therapy.

^{1b}For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.

⁴For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.

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

Appendix:

N/A

References:

1. http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf.
2. https://pdf.hres.ca/dpd_pm/00039964.PDF.
3. <http://hcvguidelines.org/full-report-view>.
4. Medi-Span.

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10/17/2017	<ol style="list-style-type: none"> 1. Added “Documentation that patient has a contraindication to Mavyret™” under Prior Authorization Criteria. 2. Changed “V. B. 1. Patient has a documented contraindication to Epclusa®” to “V. B. 1. Patient has a documented contraindication to Epclusa® and Vosevi®” 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 “Mavyret™ (glecaprevir/pibrentasvir)” and “Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)” and removed “Sovaldi® (sofosbuvir)” under Exclusion Criteria to table under “Coadministration of Zepatier™ with...”, line entitled “Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”. 5. Changed table below Authorization under Approval Length from (change made highlighted in yellow): <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th rowspan="2" style="background-color: #f08080;">Drug Therapy</th> <th rowspan="2" style="background-color: #90ee90;">Cirrhosis</th> <th colspan="2" style="background-color: #add8e6;">G1a</th> <th colspan="2" style="background-color: #add8e6;">G1b</th> <th colspan="2" style="background-color: #add8e6;">G3</th> <th colspan="2" style="background-color: #add8e6;">G4</th> </tr> <tr> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™</td> <td style="background-color: #90ee90;">No</td> <td>12w^t</td> <td>12w^{t1}</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td>12w^t</td> <td>12w^{t1}</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™ + RBV</td> <td style="background-color: #90ee90;">No</td> <td>16w^t</td> <td>12-16w^{p4}, 16w^{t1}</td> <td></td> <td>12w⁴</td> <td></td> <td></td> <td></td> <td>16w^{1b}</td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td>16w^t</td> <td>12-16w^{p4}, 16w^{t1}</td> <td></td> <td>12w⁴</td> <td></td> <td></td> <td></td> <td>16w^{1b}</td> </tr> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™ + Sovaldi®</td> <td style="background-color: #90ee90;">No</td> <td></td> <td></td> <td></td> <td></td> <td>12w</td> <td></td> <td></td> <td></td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td></td> <td></td> <td></td> <td></td> <td>12w</td> <td style="background-color: yellow;"></td> <td></td> <td></td> </tr> </tbody> </table> <p style="margin: 5px 0;">to:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th rowspan="2" style="background-color: #f08080;">Drug Therapy</th> <th rowspan="2" style="background-color: #90ee90;">Cirrhosis</th> <th colspan="2" style="background-color: #add8e6;">G1a</th> <th colspan="2" style="background-color: #add8e6;">G1b</th> <th colspan="2" style="background-color: #add8e6;">G3</th> <th colspan="2" style="background-color: #add8e6;">G4</th> </tr> <tr> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> <th>TN</th> <th>TE</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™</td> <td style="background-color: #90ee90;">No</td> <td>12w^t</td> <td>12w^{t1}</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td>12w^t</td> <td>12w^{t1}</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™ + RBV</td> <td style="background-color: #90ee90;">No</td> <td>16w^t</td> <td>12-16w^{p4}, 16w^{t1}</td> <td></td> <td>12w⁴</td> <td></td> <td></td> <td></td> <td>16w^{1b}</td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td>16w^t</td> <td>12-16w^{p4}, 16w^{t1}</td> <td></td> <td>12w⁴</td> <td></td> <td></td> <td></td> <td>16w^{1b}</td> </tr> <tr> <td rowspan="2" style="background-color: #f08080;">Zepatier™ + Sovaldi®</td> <td style="background-color: #90ee90;">No</td> <td></td> <td></td> <td></td> <td></td> <td>12w</td> <td></td> <td></td> <td></td> </tr> <tr> <td style="background-color: #90ee90;">Comp</td> <td></td> <td></td> <td></td> <td></td> <td>12w</td> <td style="background-color: yellow;">12w¹</td> <td></td> <td></td> </tr> </tbody> </table> 6. 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Added “Eplclusa® (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 Zepatier™ with...”, line entitled “Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”.</p> <p>3. 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TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks ¹For genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. ^{1a}For patients who have failed pegIFN/RBV. ^{1b}For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy. ⁴For patients who have failed a NS3 protease inhibitor + pegIFN/RBV. ⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.</p> <p>to:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th rowspan="3" style="background-color: #f8d7da;">Drug Therapy</th> <th rowspan="3" style="background-color: #d4edda;">Cirrhosis</th> <th colspan="2" style="background-color: #d9e1f2;">G1a</th> <th colspan="2" style="background-color: #d9e1f2;">G1b</th> <th colspan="2" style="background-color: #d9e1f2;">G3</th> <th colspan="2" style="background-color: #d9e1f2;">G4</th> </tr> <tr> <th style="background-color: #d9e1f2;">TN</th> <th style="background-color: #d9e1f2;">TE</th> <th style="background-color: #d9e1f2;">TN</th> <th style="background-color: #d9e1f2;">TE</th> <th style="background-color: #d9e1f2;">TN</th> <th style="background-color: #d9e1f2;">TE</th> <th style="background-color: #d9e1f2;">TN</th> <th style="background-color: #d9e1f2;">TE</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="background-color: #f8d7da;">Zepatier™</td> <td style="background-color: #d4edda;">No</td> <td>12w^t</td> <td>12w¹</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td style="background-color: #d4edda;">Comp</td> <td>12w^t</td> <td>12w¹</td> <td>12w</td> <td>12w¹</td> <td></td> <td></td> <td>12w</td> <td>12w^{1a}</td> </tr> <tr> <td style="background-color: #f8d7da;">Zepatier™ + RBV</td> <td style="background-color: #d4edda;">No</td> <td>16w^t</td> <td style="background-color: #fff3cd;">12-16w^{p4}, 16w¹</td> <td></td> <td style="background-color: #fff3cd;">12w⁴</td> <td></td> <td></td> <td></td> <td>16w^{1b}</td> </tr> </tbody> </table>									Drug Therapy	Cirrhosis	Authorization Duration								G1a		G1b		G3		G4		TN	TE	TN	TE	TN	TE	TN	TE	Zepatier™	No	12w ^t	12w ¹	12w	12w ¹			12w	12w ^{1a}	Comp	12w ^t	12w ¹	12w	12w ¹			12w	12w ^{1a}	Zepatier™ + RBV	No	16w ^t	12w ⁵ , 16w ⁵		12w ⁵				16w ^{1b}	Comp	16w ^t	12w ⁴ , 16w ⁵		12w ⁴				16w ^{1b}	Zepatier™ + Sovaldi®	No					12w				Comp					12w				Drug Therapy	Cirrhosis	G1a		G1b		G3		G4		TN	TE	TN	TE	TN	TE	TN	TE	Zepatier™	No	12w ^t	12w ¹	12w	12w ¹			12w	12w ^{1a}	Comp	12w ^t	12w ¹	12w	12w ¹			12w	12w ^{1a}	Zepatier™ + RBV	No	16w ^t	12-16w ^{p4} , 16w ¹		12w ⁴				16w ^{1b}
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MEDICATION POLICY

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3/21/2016	<ol style="list-style-type: none"> 1. Changed “member” to “patient” throughout policy. 2. Changed “V. If the member has genotype 3, then both of criteria A AND B must also be met: A. Member is treatment-naïve; B. Member has documented intolerance or contraindication to peginterferon” to “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 table following Authorization under Approval Length from: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th colspan="2" style="text-align: left;">Patient Characteristics</th> <th colspan="2" style="text-align: left;">Authorization Information</th> </tr> <tr> <th style="text-align: left;">Genotype, Other Features</th> <th style="text-align: left;">Hepatitis Treatment History</th> <th style="text-align: left;">Treatment</th> <th style="text-align: left;">Authorization Duration</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">1a, without baseline NS5A polymorphisms*, with or without cirrhosis</td> <td style="padding: 2px;">Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)</td> <td style="padding: 2px;">Zepatier™</td> <td style="padding: 2px;">12 weeks</td> </tr> <tr> <td style="padding: 2px;">1a, without baseline NS5A polymorphisms*, with or without cirrhosis</td> <td style="padding: 2px;">Treatment-experienced (failed peginterferon + ribavirin + HCV NS3/4A protease inhibitor⁵)</td> <td style="padding: 2px;">Zepatier™ + ribavirin</td> <td style="padding: 2px;">12 weeks</td> </tr> <tr> <td style="padding: 2px;">1a, with baseline NS5A polymorphisms*, with or without cirrhosis</td> <td style="padding: 2px;">Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)</td> <td style="padding: 2px;">Zepatier™ + ribavirin</td> <td style="padding: 2px;">16 weeks</td> </tr> <tr> <td style="padding: 2px;">1b, with or without cirrhosis</td> <td style="padding: 2px;">Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)</td> <td style="padding: 2px;">Zepatier™</td> <td style="padding: 2px;">12 weeks</td> </tr> <tr> <td style="padding: 2px;">1b, with or without cirrhosis</td> <td style="padding: 2px;">Treatment-experienced (failed peginterferon + ribavirin + HCV NS3/4A protease inhibitor⁵)</td> <td style="padding: 2px;">Zepatier™ + ribavirin</td> <td style="padding: 2px;">12 weeks</td> </tr> </tbody> </table> 										Patient Characteristics		Authorization Information		Genotype, Other Features	Hepatitis Treatment History	Treatment	Authorization Duration	1a, without baseline NS5A polymorphisms*, with or without cirrhosis	Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)	Zepatier™	12 weeks	1a, without baseline NS5A polymorphisms*, with or without cirrhosis	Treatment-experienced (failed peginterferon + ribavirin + HCV NS3/4A protease inhibitor ⁵)	Zepatier™ + ribavirin	12 weeks	1a, with baseline NS5A polymorphisms*, with or without cirrhosis	Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)	Zepatier™ + ribavirin	16 weeks	1b, with or without cirrhosis	Treatment-naïve/ Treatment-experienced (failed peginterferon + ribavirin)	Zepatier™	12 weeks	1b, with or without cirrhosis	Treatment-experienced (failed peginterferon + ribavirin + HCV NS3/4A protease inhibitor ⁵)	Zepatier™ + ribavirin	12 weeks
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		4, with or without cirrhosis	Treatment-naïve	Zepatier™	12 weeks				
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<p>*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. ^Boceprevir, simeprevir, or telaprevir.</p>									
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Zepatier™ + RBV	No	16w ^t	12w ^{t5} , 16w ^{t5}		12w ⁵				16w ^{1b}
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	Comp					12w			
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