

**Generic Name:** Sofosbuvir/Velpatasvir

**Preferred:** N/A

**Therapeutic Class or Brand Name:** Epclusa®

**Non-preferred:** N/A

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

**Date of Origin:** 7/19/2016

**GPI Code:** 1235990265

**Date Last Reviewed / Revised:** 12/11/2018

## PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, 4, 5, or 6 infection.
- II. Documentation of patient's Hepatitis C treatment history and baseline viral load.
- III. Documentation that patient meets ONE of the following criteria A or B:
  - A. Patient has genotypes 1 or 4 AND meets ONE of criteria 1 or 2:
    1. Patient has a documented contraindication to Mavyret™ and Zepatier™.
    2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets one of criteria a or b:
      - a. Epclusa® is prescribed in combination with ribavirin.
      - b. Patient has a documented intolerance or contraindication to ribavirin.
  - B. Patient has genotypes 2, 3, 5, or 6 AND meets ONE of criteria 1 or 2:
    1. Patient has a documented contraindication to Mavyret™.
    2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets one of criteria a or b:
      - a. Epclusa® is prescribed in combination with ribavirin.
      - b. Patient has a documented intolerance or contraindication to ribavirin.
- IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the tables 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

- As retreatment when there has been relapse after, or no response to, a prior treatment course with Epclusa® (sofosbuvir/velpatasvir) or Vosevi® (sofosbuvir/velpatasvir/voxilaprevir).
- Coadministration of Epclusa® with drugs that are inducers of P-gp and/or moderate to potent inducers of CYP2B6, CYP2C8, or CYP3A4 or any of the drugs listed in the table below:

Drug Class	Drugs within class
Antiarrhythmics	Amiodarone
Anticancers	Topotecan
Anticonvulsants	Carbamazepine, oxcarbazepine, phenytoin, phenobarbital
Antimycobacterials	Rifabutin, rifampin, rifapentine
Herbal Products	St. John's Wort ( <i>Hypericum perforatum</i> )
HIV Antiretrovirals	Efavirenz-containing regimens, tipranavir/ritonavir
HMG-CoA Reductase Inhibitors	Rosuvastatin if dose exceeds 10 mg per day
Proton Pump Inhibitors	Omeprazole and others
Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection	Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)

**OTHER CRITERIA**

- N/A.

**QUANTITY / DAYS SUPPLY RESTRICTIONS**

- 28 tablets per 28 days.

**APPROVAL LENGTH**

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

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w <sup>5</sup>	12w	12w <sup>5,9</sup>	12w	12w <sup>2,5</sup>	12w	12w <sup>5~</sup>
	Comp	12w	12w <sup>5</sup>	12w	12w <sup>5,9</sup>	12w	12w <sup>2,5</sup>	12w <sup>~</sup>	12w <sup>5</sup>
	Decomp	24w		24w		24w		24w	
Epclusa® + RBV	No								12w <sup>1~</sup>
	Comp							12w <sup>~</sup>	12w <sup>1</sup>
	Comp & Post Transplant <sup>^</sup>					12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>
	Decomp	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>
	Decomp & Post Transplant <sup>^</sup>					12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>

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

~RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.

^For patients who develop HCV infection post-liver transplantation.

<sup>1</sup>For patients who have failed pegIFN/RBV.

<sup>2</sup>For patients who have failed sofosbuvir + RBV.

<sup>5</sup>For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

<sup>9</sup>For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.

<sup>10</sup>For patients who failed a sofosbuvir- or NS5A-containing regimen.

Drug Therapy	Cirrhosis	G4		G5		G6	
		TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>
	Comp	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>
	Decomp	24w		24w		24w	
Epclusa® + RBV	No						
	Comp						
	Comp & Post Transplant^						
	Decomp	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>
	Decomp & Post Transplant^						

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

^For patients who develop HCV infection post-liver transplantation.

<sup>5</sup>For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

<sup>10</sup>For patients who failed a sofosbuvir- or NS5A-containing regimen.

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

## APPENDIX

N/A.

## REFERENCES

1. [http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf) .
2. <http://hcvguidelines.org/full-report-view> .
3. Medi-Span®.

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
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<p>12/11/2018</p>	<p>1. <b>Deleted under Prior Authorization Criteria:</b></p> <p>II. Documentation that patient meets ONE of the following criteria A, B, or C:</p> <ul style="list-style-type: none"> <li>A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis).</li> <li>B. Is post-liver transplant.</li> <li>C. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2:             <ul style="list-style-type: none"> <li>1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).</li> <li>2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis</li> </ul> </li> </ul>
<p>10/30/2017</p>	<p>1. <b>Changed</b> "IV. Documentation that patient meets ONE of the following criteria A or B: A. Patient has genotypes 1 or 4 AND meets ONE of criteria 1 or 2: 1. Patient has a documented contraindication to Zepatier™; 2. Patient has decompensated cirrhosis (Child-Pugh B) and meets one of criteria a or b: a. Epclusa® is prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin; B. Patient has genotypes 2, 3, 5, or 6" <b>to</b> "IV. Documentation that patient meets ONE of the following criteria A or B: A. Patient has genotypes 1 or 4 AND meets ONE of criteria 1 or 2: 1. Patient has a documented contraindication to Mavyret™ and Zepatier™; 2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets one of criteria a or b: a. Epclusa® is prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin; B. Patient has genotypes 2, 3, 5, or 6 AND meets ONE of criteria 1 or 2: 1. Patient has a documented contraindication to Mavyret™; 2. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets one of criteria a or b: a. Epclusa® is prescribed in combination with ribavirin; b. Patient has a documented intolerance or contraindication to ribavirin;" <b>under Prior Authorization Criteria.</b></p> <p>2. <b>Removed</b> "Child-Pugh C" <b>from Exclusion Criteria.</b></p> <p>3. <b>Added</b> "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" <b>and removed</b> "Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Olysio® (simeprevir) + Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" <b>and</b> "Zepatier™ (elbasvir/grazoprevir)" <b>from</b> list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..." <b>under Exclusion Criteria.</b></p> <p>4. <b>Added</b> "Mavyret™ (glecaprevir/pibrentasvir)" <b>and</b> "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" <b>under Exclusion Criteria</b> to table under "Coadministration of Epclusa® with...", line entitled "Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection".</p> <p>5. <b>Changed</b> "See tables directly below. Table 1 contains information for genotypes 1 through 2, and table 2 contains information for genotypes 3 through 6" <b>to</b> "See table directly below" <b>following Authorization below Approval Length.</b></p> <p>6. <b>Changed table below Authorization under Approval Length from (changes made highlighted in yellow):</b>  <b>Table 1. Authorization information for Genotypes 1 through 2.</b></p>

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>1</sup>
	Comp	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>1</sup>
	Decomp	24w	24w	24w	24w		
Epclusa® + RBV	No						12w <sup>2</sup>
	Comp						12w <sup>2</sup>
	Decomp	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; w = weeks

<sup>1</sup>For patients who have failed pegIFN/RBV.

<sup>2</sup>For patients who have failed sofosbuvir + RBV.

<sup>5</sup>For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

**Table 2. Authorization information for Genotypes 3 through 6.**

Drug Therapy	Cirrhosis	G3		G4		G5		G6
		TN	TE	TN	TE	TN	TE	TN
Epclusa®	No	12w	12w <sup>1</sup>	12w	12w <sup>1</sup>	12w	12w <sup>1</sup>	12w
	Comp	12w		12w	12w <sup>1</sup>	12w	12w <sup>1</sup>	12w
	Decomp			24w	24w			
Epclusa® + RBV	No		12w <sup>2</sup>					
	Comp		12w <sup>1,2</sup>					
	Decomp	12w	12w	12w	12w			

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; w = weeks

<sup>1</sup>For patients who have failed pegIFN/RBV.

<sup>2</sup>For patients who have failed sofosbuvir + RBV.

to:

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3
		TN	TE	TN	TE	TN	TE	TN
Epclusa®	No	12w	12w <sup>5</sup>	12w	12w <sup>5,9</sup>	12w	12w <sup>2,5</sup>	12w
	Comp	12w	12w <sup>5</sup>	12w	12w <sup>5,9</sup>	12w	12w <sup>2,5</sup>	12w
	Decomp	24w		24w		24w		24w
Epclusa® + RBV	No							
	Comp							12w <sup>~</sup>
	Comp & Post Transplant <sup>^</sup>					12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>
	Decomp	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w
	Decomp & Post Transplant <sup>^</sup>					12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; R = ribavirin; pegIFN = peginterferon; w = weeks

<sup>7</sup>RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.

<sup>^</sup>For patients who develop HCV infection post-liver transplantation.

<sup>1</sup>For patients who have failed pegIFN/RBV.

<sup>2</sup>For patients who have failed sofosbuvir + RBV.

<sup>5</sup>For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

<sup>9</sup>For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.

<sup>10</sup>For patients who failed a sofosbuvir- or NS5A-containing regimen.

Drug Therapy	Cirrhosis	G4		G5		G6	
		TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>
	Comp	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>	12w	12w <sup>5</sup>
	Decomp	24w		24w		24w	
Epclusa® + RBV	No						
	Comp						
	Comp & Post Transplant <sup>^</sup>						
	Decomp	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>	12w	12w <sup>5</sup> , 24w <sup>10</sup>
	Decomp & Post Transplant <sup>^</sup>						

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

<sup>^</sup>For patients who develop HCV infection post-liver transplantation.

<sup>5</sup>For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

<sup>10</sup>For patients who failed a sofosbuvir- or NS5A-containing regimen.

7/30/2016

- 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.**
- Changed** "Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/ dasabuvir)" to "Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" **under Exclusion Criteria** to table under "Coadministration of Epclusa® with...", line entitled "Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection".

**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.