



MEDICATION POLICY

Generic Name: Sofosbuvir/Velpatasvir

Therapeutic Class or Brand Name: Epclusa®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 7/19/16

Date Last Reviewed/Revised: 10/30/2017

GPI Code: 1235990265

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

- I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, 4, 5, or 6 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 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.
- V. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the tables under Authorization in the Approval Length section.

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- 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 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.

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Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w ⁵	12w	12w ^{5,9}	12w	12w ^{2,5}	12w	12w ^{5~}
	Comp	12w	12w ⁵	12w	12w ^{5,9}	12w	12w ^{2,5}	12w [~]	12w ⁵
	Decomp	24w		24w		24w		24w	
Epclusa® + RBV	No								12w ^{1~}
	Comp							12w [~]	12w ¹
	Comp & Post Transplant [^]					12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰
	Decomp & Post Transplant [^]					12w [^]	12w [^]	12w [^]	12w [^]

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.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

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

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

¹⁰For 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 ⁵	12w	12w ⁵	12w	12w ⁵
	Comp	12w	12w ⁵	12w	12w ⁵	12w	12w ⁵
	Decomp	24w		24w		24w	
Epclusa® + RBV	No						
	Comp						
	Comp & Post Transplant [^]						
	Decomp	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰
	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.

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

¹⁰For patients who failed a sofosbuvir- or NS5A-containing regimen.

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

Appendix:

N/A

References:

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

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Historical Tracking Of Changes Made To Policy

10/30/2017

1. **Changed** “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” to “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;” **under Prior Authorization Criteria.**
2. **Removed** “Child-Pugh C” from Exclusion Criteria.
3. **Added** “Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)” and **removed** “Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Olysio® (simeprevir) + Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)” and “Zepatier™ (elbasvir/grazoprevir)” from 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)” **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”.
5. **Changed** “See tables directly below. Table 1 contains information for genotypes 1 through 2, and table 2 contains information for genotypes 3 through 6” to “See table directly below” **following Authorization below Approval Length.**
6. **Changed table below Authorization under Approval Length from (changes made highlighted in yellow):**

Table 1. Authorization information for Genotypes 1 through 2.

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

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

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

⁵For 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	TE
Epclusa®	No	12w	12w ¹	12w	12w ¹	12w	12w ¹	12w	12w ¹

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Epclusa® + RBV	Comp	12w		12w	12w ¹	12w	12w ¹	12w	12w ¹
	Decomp			24w	24w				
	No		12w ²						
	Comp		12w ^{1,2}						
	Decomp	12w	12w	12w	12w				

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

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

to:

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Epclusa®	No	12w	12w ⁵	12w	12w ^{5,9}	12w	12w ^{2,5}	12w	12w ^{5~}
	Comp	12w	12w ⁵	12w	12w ^{5,9}	12w	12w ^{2,5}	12w [~]	12w ⁵
	Decomp	24w		24w		24w		24w	
Epclusa® + RBV	No								12w ^{1~}
	Comp							12w [~]	12w ¹
	Comp & Post Transplant [^]					12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰
	Decomp & Post Transplant [^]					12w [^]	12w [^]	12w [^]	12w [^]

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.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

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

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

¹⁰For 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 ⁵	12w	12w ⁵	12w	12w ⁵
	Comp	12w	12w ⁵	12w	12w ⁵	12w	12w ⁵
	Decomp	24w		24w		24w	
Epclusa® + RBV	No						
	Comp						

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<i>Historical Tracking Of Changes Made To Policy</i>									
			Comp & Post Transplant [^]						
			Decomp	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰	12w	12w ⁵ , 24w ¹⁰
			Decomp & Post Transplant [^]						
<p>TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks</p> <p>[^]For patients who develop HCV infection post-liver transplantation.</p> <p>⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.</p> <p>¹⁰For patients who failed a sofosbuvir- or NS5A-containing regimen.</p>									
7/30/2016	<ol style="list-style-type: none"> 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 Eplclusa® with...”, line entitled “Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection”. 								

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