Generic Name: Sofosbuvir/Velpatasvir

Therapeutic Class or Brand Name: Epclusa®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1235990265

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/19/2016

Date Last Reviewed / Revised: 5/31/2019

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 (*Hypericum perforatum*)
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[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.
[1]For patients who have failed pegIFN/RBV.
[2]For patients who have failed sofosbuvir + RBV.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.
[10]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[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.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[10]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 .
2. http://hcvguidelines.org/full-report-view .
3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes

5/31/2019	1. Policy reviewed – no changes.
12/11/2018	1. **Deleted under Prior Authorization Criteria:** 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
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
[1]For patients who have failed pegIFN/RBV.
[2]For patients who have failed sofosbuvir + RBV.
[5]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	T
Epclusa®	No	12w	12w[1]	12w	12w[1]	12w	12w[1]	12w	1
	Comp	12w		12w	12w[1]	12w	12w[1]	12w	1
	Decomp			24w	24w				
Epclusa® + RBV	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
[1]For patients who have failed pegIFN/RBV.
[2]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[5]	12w	12w[5,9]	12w	12w[2,5]	12w
	Comp	12w	12w[5]	12w	12w[5,9]	12w	12w[2,5]	12w~
	Decomp	24w		24w		24w		24w
Epclusa® + RBV	No							
	Comp							12w~
	Comp & Post Transplant^					12w^	12w^	12w^
	Decomp	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w
	Decomp & Post Transplant^					12w^	12w^	12w^

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; R
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. [1]For patients who have failed pegIFN/RBV. [2]For patients who have failed sofosbuvir + RBV. [5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor. [9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen. [10]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[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.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[10]For patients who failed a sofosbuvir- or NS5A-containing regimen.

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 Epclusa® with…", line entitled "Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection".