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:** 7/30/2016

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 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.

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

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), Olysio® (simeprevir) + Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), or Zepatier™ (elbasvir/grazoprevir).
- Child-Pugh C.
- 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), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Zepatier™ (elbasvir/grazoprevir)

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 28 tablets per 28 days.

Approval Length:

- **Authorization:** See tables directly below. Table 1 contains information for genotypes 1 through 2, and table 2 contains information for genotypes 3 through 6.

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	TE
Epclusa®	No	12w	12w[1]	12w	12w[1]	12w	12w[1]	12w	12w[1]
	Comp	12w		12w	12w[1]	12w	12w[1]	12w	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.

- **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.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
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".