Generic Name:
Sofosbuvir/Velpatasvir/Voxilaprevir

Therapeutic Class or Brand Name: Vosevi®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1235990380

Preferred: N/A.

Non-preferred: N/A.

Date of Origin: 10/23/2017

Date Last Reviewed / Revised: 12/2/2019

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 through D:

A. Patient has genotype 1 and meets ONE of criteria 1 or 2:

1. Patient has a documented contraindication to Mavyret™.
2. Patient has failed prior treatment with a NS3/4 protease inhibitor inclusive direct-acting antiviral combination regimen.

B. Patient has genotype 2 and meets criterion 1:

1. Patient has failed prior treatment with a NS5A Inhibitor.

C. Patient has genotype 3 and meets ONE of the following criteria 1 or 2:

1. Patient has a documented contraindication to Mavyret™.
2. Patient has failed prior treatment with a direct-acting antiviral.

D. Patient has genotypes 4, 5, or 6 and meets criterion 1:

1. Patient has failed prior treatment with a direct-acting antiviral.

IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table 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 Vosevi® (sofosbuvir/velpatasvir/ voxilaprevir).
- Moderate or severe hepatic impairment (Child-Pugh B or C).
- Coadministration of Vosevi® 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
Anticonvulsants	Carbamazepine, oxcarbazepine, phenytoin, phenobarbital
Antimycobacterials	Rifabutin, rifampin, rifapentine
Herbal Products	St. John's Wort (Hypericum perforatum)
HIV Antiretrovirals	Atazanavir, efavirenz, lopinavir, tipranavir/ritonavir
HMG-CoA Reductase Inhibitors	Pitavastatin, Pravastatin (if > 40 mg/day), rosuvastatin
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), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Zepatier™ (elbasvir/grazoprevir)
Drug Class	Drugs within class
Antiarrhythmics	Amiodarone
Anticonvulsants	Carbamazepine, oxcarbazepine, phenytoin, phenobarbital

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**
Vosevi®	No		12w8,9		12w8			12w	12w[1a]
	Comp		12w8,9		12w8			12w	12w[1a]
Vosevi® + RBV	No								16w[1b]
	Comp								16w[1b]

Drug Therapy	Cirrhosis	G1a	G1b	G2	G3	12w			
		TN	TE	TN	TE	12w	12w[1]		

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
#An alternative regimen for patients when Y93H is present.
[1]For patients who have failed pegIFN/RBV.
[6]For patients who have failed direct-acting antiviral (including NS5A Inhibitor).
[7]For patients who have failed direct-acting antiviral (not including NS5A Inhibitor).
[8]For patients who have failed a NS5A inhibitor.
[9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.

Drug Therapy	**Cirrhosis**	**G4**		**G5**		**G6**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**
Vosevi®	No		12w[6]		12w[6]		12w[6]
	Comp		12w[6]		12w[6]		12w[6]
Vosevi® + RBV	No						
	Comp						

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks
[6]For patients who have failed direct-acting antiviral (including NS5A Inhibitor).

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

APPENDIX

N/A.

REFERENCES

1. http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf.
2. http://hcvguidelines.org/full-report-view .
3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/2/2019	1. Policy reviewed - no changes.
12/4/2018	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: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis). i. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephrit