

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: 12/4/2018

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 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.

¹For patients who have failed pegIFN/RBV.

⁶For patients who have failed direct-acting antiviral (including NS5A Inhibitor).

⁷For patients who have failed direct-acting antiviral (not including NS5A Inhibitor).

⁸For patients who have failed a NS5A inhibitor.

⁹For 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

⁶For 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
12/4/2018	<ol style="list-style-type: none"> 1. Deleted under Prior Authorization Criteria: <ol style="list-style-type: none"> II. Documentation that patient meets ONE of the following criteria A, B, or C: <ol style="list-style-type: none"> a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis). b. Is post-liver transplant.

	<ul style="list-style-type: none">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">i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).i. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephrit
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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.