



## MEDICATION POLICY

**Generic Name:** Sofosbuvir/Velpatasvir/Voxilaprevir

**Therapeutic Class or Brand Name:** Vosevi®

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 10/23/17

**Date Last Reviewed/Revised:** \_\_\_\_\_

**GPI Code:** 1235990380

### **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 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.

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- V. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table 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 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 ( <i>Hypericum perforatum</i> )
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)

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- 28 tablets per 28 days.

### Approval Length:

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- **Authorization:** See table directly below.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Vosevi®	No		12w <sup>8,9</sup>		12w <sup>8</sup>		12w <sup>8</sup>		12w <sup>1#,6,9</sup>
	Comp		12w <sup>8,9</sup>		12w <sup>8</sup>		12w <sup>8</sup>	12w <sup>#</sup>	12w <sup>1,7,9</sup>
Vosevi® + RBV	No								
	Comp								12w <sup>8</sup>

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin;

pegIFN = peginterferon; w = weeks

<sup>#</sup>An alternative regimen for patients when Y93H is present.

<sup>1</sup>For patients who have failed pegIFN/RBV.

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

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

<sup>8</sup>For patients who have failed a NS5A inhibitor.

<sup>9</sup>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 <sup>6</sup>		12w <sup>6</sup>		12w <sup>6</sup>
	Comp		12w <sup>6</sup>		12w <sup>6</sup>		12w <sup>6</sup>
Vosevi® + RBV	No						
	Comp						

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

<sup>6</sup>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](http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf).
2. <http://hcvguidelines.org/full-report-view>.
3. Medi-Span.

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