PRIOR AUTHORIZATION POLICY

POLICY: Hepatitis C – Vosevi Prior Authorization Policy
- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets – Gilead)

REVIEW DATE: 08/19/2020

OVERVIEW

Vosevi is a direct-acting-antiviral (DAA) indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor and for patients with genotype 1a or 3 infection and who have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Additional benefit of Vosevi over Epclusa® (sofosbuvir/velpatasvir tablets) was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor. The recommended dosage of Vosevi is one tablet, taken orally, once daily (QD) with food for 12 weeks.

Vosevi contains sofosbuvir, a nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, a new HCV NS3/4A protease inhibitor. Sofosbuvir has previously been available as Sovaldi® (sofosbuvir tablets) and as part of Harvoni® (sofosbuvir/ledipasvir tablets) and Epclusa. Velpatasvir has previously been available as part of Epclusa.

Guidelines

For the most up-to-date guideline information always refer to the American Association for the Study of Liver Diseases (AASLD) guidelines.[3] Vosevi is recommended in the circumstances outlined below (Table 1).

Table 1. AASLD Recommended and Alternative Regimens that Include Vosevi.[3]

DAA	Duration	FDA Approved (Y/N)	AASLD Level of Evidence
Genotype 1 Chronic HCV Previously Treated with Non-NS5A Sovaldi, Adults – Recommended			
Vosevi	12 weeks (GT 1a ± compensated cirrhosis)	Y	Class I, Level A
Genotype 1 Chronic HCV Previously Treated with NS5A, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	Y	Class I, Level A
Genotype 2 Chronic HCV Previously Treated with Sovaldi + NS5A, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	N	Class I, Level B
Genotype 3 Chronic HCV Treatment-Naïve Adults – Alternative			
Vosevi	12 weeks (compensated cirrhosis, if Y93H is present)	N	Class IIa, Level B
Genotype 3 Chronic HCV Previously Treated with Pegylated Interferon/Ribavirin, Adults – Recommended			
Vosevi	12 weeks (compensated cirrhosis)	N	Class IIb, Level B
Genotype 3 Chronic HCV Previously Treated with Pegylated Interferon/Ribavirin, Adults – Alternative			
Vosevi	12 weeks (no cirrhosis)	N	Class IIb, Level B
Genotype 3 Chronic HCV Previously Treated with Sovaldi + WBR, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	Y	Class I, Level B
Genotype 3 Chronic HCV DAA-Experienced, Including NS5A, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	Y	Class I, Level A
Vosevi + WBR	12 weeks (prior NS5A failures with cirrhosis)	N	Class IIa, Level C
Genotype 4 Chronic HCV DAA-Experienced, Including NS5A, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	Y	Class I, Level A

Table 1 (continued). AASLD Recommended and Alternative Regimens that Include Vosevi.[3]

DAA	Duration	FDA Approved (Y/N)	AASLD Level of Evidence
Genotype 5/6 Chronic HCV DAA-Experienced, Including NS5A, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	N	Class IIA, Level B
Genotype 1, 2, 3, 4, 5, 6 Recurrent HCV Post-Liver Transplant, DAA-Experienced ± Compensated Cirrhosis, Adults – Recommended			
Vosevi	12 weeks	N	Class I, Level C
Genotype 1, 2, 3, 4, 5, 6 HCV Kidney Transplant Recipients, DAA-Experienced, Adults – Recommended			
Vosevi	12 weeks (± compensated cirrhosis)	N	Class IIa, Level C

AASLD – American Association for the Study of Liver Diseases; FDA – Food and Drug Administration; Y – Yes; N – No; HCV – Hepatitis C virus; DAA – Direct-acting antiviral; WBR – Weight-based ribavirin.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vosevi. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vosevi as well as the monitoring required for adverse events and efficacy, approval requires Vosevi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vosevi is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1b, 2, 4, 5, or 6.** Approve for 12 weeks if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A);
   - **C)** Patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV direct-acting antiviral regimen containing an NS5A inhibitor; AND
     Note: Examples of direct-acting antivirals that are, or contain, an NS5A inhibitor include: Daklinza (daclatasvir tablets), Epclusa (sofosbuvir/velpatasvir tablets), Harvoni (ledipasvir/sofosbuvir tablets/oral pellets), Mavyret (glecaprevir/pibrentasvir tablets), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged), Zepatier (elbasvir/grazoprevir tablets).
   - **D)** Vosevi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus, Genotype 1a or 3.** Approve for 12 weeks if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A); AND
   - **C)** Patient meets ONE of the following conditions (i or ii):
     - **i.** Patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV direct-acting antiviral regimen containing an NS5A inhibitor; OR
       Note: Examples of direct-acting antivirals that are, or contain, an NS5A inhibitor include: Daklinza (daclatasvir tablets), Epclusa (sofosbuvir/velpatasvir tablets), Harvoni

(ledipasvir/sofosbuvir tablets/oral pellets), Mavyret (glecaprevir/pibrentasvir tablets), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged), Zepatier (elbasvir/grazoprevir tablets).

ii. Patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV DAA regimen containing Sovaldi (sofosbuvir tablets/oral pellets) + a non-NS5A inhibitor; AND

Note: Examples of regimens that contain Sovaldi (sofosbuvir tablets/oral pellets) + a non-NS5A inhibitor include: Sovaldi + NS3 inhibitors (Olysio [simeprevir capsules], Victrelis [boceprevir capsules], or Incivek [telaprevir tablets]) or Sovaldi + ribavirin ± pegylated interferon;

D) Vosevi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Other Uses with Supportive Evidence

3. **Chronic Hepatitis C Virus (HCV) Genotype 1b, 2, 4, 5, or 6.** Approve for 12 weeks in patients who meet the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A); AND
   - **C)** Patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV DAA regimen containing Sovaldi (sofosbuvir tablets/oral pellets) + a non-NS5A inhibitor; AND

     Note: Examples of regimens that contain Sovaldi (sofosbuvir tablets/oral pellets) + a non-NS5A inhibitor include: Sovaldi + NS3 inhibitors (Olysio [simeprevir capsules], Victrelis [boceprevir capsules], or Incivek [telaprevir tablets]) or Sovaldi + ribavirin ± pegylated interferon;
   - **D)** Vosevi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

4. **Patient Has Been Started on Vosevi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vosevi is not recommended in the following situations:

1. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs).** Vosevi provides a complete antiviral regimen.

2. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** According to the AASLD guidelines, patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy do not require antiviral treatment.[3] Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert. Chronic HCV is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of HCV treatment in patients with a limited life expectancy (< 12 months) owing to non-liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized and palliative care strategies should take precedence.

3. **Pediatric Patients (Age < 18 Years).** The safety and efficacy of Vosevi have not been established in pediatric patients < 18 years of age.[1]

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vosevi® tablets [prescribing information]. Foster City, CA: Gilead; November 2019.
2. Bourliere M, Gordon SC, Flamm SL, et al. Sofosbuvir, velpatasvir, and voxilaprevir for previously treated HCV infection. *N Engl J Med*. 2017;376(22):214-2146.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated November 6, 2019. Accessed on August 11, 2020.
4. Peralman B, Perrys M, Hinds A. Sofosbuvir/velpatasvir/voxilaprevir for previous treatment failures with glecaprevir/pibrentasvir in chronic hepatitis C infection. *Am J Gastroenterol*. 2019;114(9):1550-1552.