PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/07/2024

OVERVIEW

Vosevi is a direct-acting-antiviral (DAA) containing sofosbuvir, a nucleotide analog NS5B polymerase inhibitor, velpatasvir, a hepatitis C virus (HCV) NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor.[1] It is indicated for the treatment of adults with **chronic HCV** with or without compensated cirrhosis who have:

- Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor;
- 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/oral granules) was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.[1] The recommended dosage of Vosevi is one tablet, taken orally, once daily (QD) with food for 12 weeks.

Guidelines

The American Association for the Study of Liver Diseases guidelines recommend Vosevi in several circumstances in adults, mainly in patients who are direct-acting antiviral-experienced (outlined below). Some of these recommendations are based on very limited data and are not FDA-approved indications for Vosevi (e.g., retreatment with Vosevi in patients who have failed Vosevi in the past [one case report]).

Vosevi is recommended in the following situations:

- **Genotype 1 through 6 chronic HCV, ± compensated cirrhosis, treatment-experienced**
  - Prior sofosbuvir-based treatment failure: Vosevi for 12 weeks; the addition of ribavirin is recommended in patients with genotype 3 HCV with compensated cirrhosis.
  - Prior Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets) treatment failure: Vosevi for 12 weeks; the addition of ribavirin is recommended in patients with compensated cirrhosis.
  - Prior Zepatier® (elbasvir/grazoprevir tablets) treatment failure: Vosevi for 12 weeks; the addition of ribavirin is recommended in patients with compensated cirrhosis.
  - Prior Vosevi treatment failure: Vosevi + ribavirin for 24 weeks.
- **Kidney transplant, genotype 1 through 6 HCV, ± compensated cirrhosis, treatment-experienced**
  - Prior direct-acting antiviral failure: Vosevi ± ribavirin for 12 weeks; the addition of ribavirin should be considered for patients with compensated cirrhosis and multiple negative baseline characteristics.
- **Recurrent HCV post-liver transplantation, genotype 1 through 6 infection of the allograft, ± compensated cirrhosis, treatment-naïve**
  - Prior direct-acting antiviral failure: Vosevi for 12 weeks is recommended; the addition of ribavirin should be considered for patients with compensated cirrhosis and multiple negative baseline characteristics.

Vosevi is an alternative recommendation in the following situation:

- **Genotype 3 HCV, compensated cirrhosis, treatment-naïve with Y93H resistance-associated substitution**
  - Vosevi for 12 weeks.

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 one of 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 ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient does not have cirrhosis; OR
     - **ii.** Patient has compensated cirrhosis (Child-Pugh A); AND
   - **C)** Patient had a prior null response, prior partial response, or 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/oral pellets), Harvoni (ledipasvir/sofosbuvir tablets/oral pellets), Mavyret (glecaprevir/pibrentasvir tablets/oral pellets), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged), Zepatier (elbasvir/grazoprevir tablets).
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV), Genotype 1a or 3.** Approve for 12 weeks if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient does not have cirrhosis; OR
     - **ii.** Patient has compensated cirrhosis (Child-Pugh A); AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient had a prior null response, prior partial response, or 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/oral pellets), Harvoni (ledipasvir/sofosbuvir tablets/oral pellets), Mavyret (glecaprevir/pibrentasvir tablets/oral pellets), 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 relapse after prior treatment with an HCV direct-acting antiviral 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) The medication 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 if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient does not have cirrhosis; OR
      ii. Patient has compensated cirrhosis (Child-Pugh A); AND
   C) Patient had a prior null response, prior partial response, or relapse after prior treatment with an HCV direct-acting antiviral 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) The medication 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 of 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. **Pediatric Patients (Age < 18 Years).** The safety and efficacy of Vosevi have not been established in pediatric patients < 18 years of age.[1]

3. 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 October 24, 2022. Accessed on July 23, 2024.