MEDICAL MUTUAL®

Drug Policy

Policy:	Vosevi ® (sofosbuvir/velpatasvir/voxilaprevir tablets)	Annual Review Date: 11/16/2023 Last Revised Date: 11/16/2023

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.

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.

POLICY STATEMENT

This policy involves the use of Vosevi. Prior authorization is recommended for pharmacy benefit coverage of Vosevi. Criteria are based on the guidance issued by American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)/International Antiviral Society-USA (IAS-USA), prescribing information, clinical data, and expert review. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 long-term efficacy, initial approval requires Vosevi be prescribed by or in consultation with a physician who specializes in the condition being treated. Vosevi is subject to the Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy.

RECOMMENDED AUTHORIZATION CRITERIA

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

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) 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, 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) This 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 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) This 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 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).

Approval Duration
See criteria above

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Vosevi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs).** Vosevi provides a complete antiviral regimen. In the opinion of a specialist physician reviewing the data we have adopted this criterion.

2. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Patients with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment. According to AASLD guidance, little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (less than 12 months) due 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] In the opinion of a specialist physician reviewing the data we have adopted this criterion.

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

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically

necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vosevi™ tablets [prescribing information]. Foster City, CA: Gilead; November 2017.
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. HCV Guidelines: Recommendations for Testing, Managing, and Treating Hepatitis C. Available at: http://www.hcvguidelines.org. Updated May 24, 2018. Accessed on 17December 2018.
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.