Drug Coverage Policy

Effective Date……11/01/2025
Coverage Policy Number……IP0736
Policy Title…Vosevi Prior Authorization Policy

Hepatitis C – Vosevi Prior Authorization Policy

- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets - Gilead)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required 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.

NOTE: For Individual and Family Plans, this product also requires the use of preferred products before approval of the requested product. Refer to the *Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy for Individual and Family Plans (PSM026)* for additional preferred product criteria requirements and exceptions.

Vosevi is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

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 above criteria sections (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 Covered

Vosevi for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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]

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 December 19, 2023. Accessed on July 28, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	07/01/2025
Early Annual Revision	No criteria changes.	11/01/2025

The policy effective date is in force until updated or retired.