VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

VOSEVI (Sofosbuvir/velpatasvir/voxilaprevir)

Effective Date: 10/24/2017

Date Developed: 10/24/17 by Catherine R. Sanders, MD and ESI P&T

Date Approved by P&T Committee: 10/24/17, 1/23/18, 7/24/18, 1/22/19

(Archived 1/22/19)

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.

Pre-Authorization Criteria:

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 criteria (A, B, C, and D):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** Vosevi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient has a fibrosis score of ≥ 2, AND
   - **D)** The patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV direct-acting antiviral (DAA) regimen containing an NS5A inhibitor. [Note: DAAs that are, or contain, an NS5A inhibitor include: Daklinza® {daclatasvir tablets}, Epclusa {sofosbuvir/velpatasvir tablets}, Harvoni {ledipasvir/sofosbuvir tablets}, Technivie™ {ombitasvir/paritaprevir/ritonavir tablets}, Viekira Pak™ {ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged}, Viekira XR™ {dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release tablets}, Zepatier™ {elbasvir/grazoprevir tablets}]; AND
   - **E)** The patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A).

Vosevi is 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.[1] The recommended duration of therapy with Vosevi is 12 weeks.

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)** The patient is ≥ 18 years of age; AND
   - **B)** Vosevi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient meets ONE of the following conditions (i or ii):
     - **i.** The patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV direct-acting antiviral (DAA) regimen containing an NS5A inhibitor. [Note: DAAs that are, or contain, an NS5A inhibitor include: Daklinza {daclatasvir tablets}, Epclusa {sofosbuvir/velpatasvir tablets}, Harvoni {ledipasvir/sofosbuvir tablets}, Technivie

{ombitasvir/paritaprevir/ritonavir tablets}, Viekira Pak {ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged}, Viekira XR {dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release tablets}, Zepatier {elbasvir/grazoprevir tablets}]; OR

ii. The patient had a prior null response, prior partial response, or had relapse after prior treatment with an HCV DAA regimen containing Sovaldi + a non-NS5A inhibitor. (Note: regimens that contain Sovaldi + a non-NS5A inhibitor are Sovaldi + NS3 inhibitors [Olysio® {simeprevir capsules}, Victrelis® {boceprevir capsules}, or Incivek® {telaprevir tablets]) or Sovaldi + ribavirin ± pegylated interferon); AND

D) The patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A).

Vosevi is 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.[1] Additional benefit of Vosevi over Epclusa was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with Sovaldi without an NS5A inhibitor. The duration of Vosevi is 12 weeks.

Vosevi is not to be approved for the following: HCV treatment in combination with any other direct acting antivirals (DAAs), Life expectancy less than 12 months due to non-liver related comorbidities, pediatric patients (age < 18 years).

Dosing Forms:
Oral tablet: Sofosbuvir 400mg, velpatasvir 100mg, and voxilaprevir 100mg

Revision History:

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1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
7/24/18	Yes	Catherine Sanders, MD	Updated fibrosis score of ≥ 2
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