STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** the following criteria?
   - Patient at least 18 years old
   - Patient has a current HCV infection documented by at least **ONE** detectable HCV RNA level within the past 6 months
   - Medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient is concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
   - Patient has moderate or severe hepatic impairment (Child-Pugh B or C)
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - Genotype 1-6, treatment experienced and previously failed a full course of therapy with DAA regimen that includes NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination)
   - Genotype 1a or 3, treatment experienced and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other HCV protease inhibitor in combination with Sovaldi))

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR** requires the following rule(s) be met for approval:
   A. You are 18 years of age or older
   B. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
   C. Documentation of hepatitis C virus infection with at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
   D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (liver inflammation) such as a hepatologist, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   E. You have failed a full course of therapy with a DAA (direct-acting antiviral) regimen that includes NS5A inhibitor (class of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR you have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (class of hepatitis C drug such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis c virus protease inhibitor in combination with Sovaldi))

   (Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following:

A. You are concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
B. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
C. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 7, 2017.
- Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 08/17
Client Approval: 02/20
P&T Approval: 01/20