STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA	43561		GPI-10 (1235990265)	

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** of the following criteria?
   - The patient is at least 18 years old
   - The patient has a chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the last 6 months
   - The patient is currently supervised by 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?
   - The patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
   - The 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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GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?
   - Genotype 1 HCV infection
   - Treatment naïve
   - No cirrhosis
   - No HIV co-infection
   - Pre-treatment HCV RNA level < 6 million IU/mL
   - Not of African descent (Patient is not African American)

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient had a trial of Harvoni 8-week regimen, or does the patient have a contraindication to Harvoni?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have decompensated cirrhosis **AND** the requested medication will be used with ribavirin?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient one of the following:
   - Treatment naïve and genotype 1-6 infection
   - Treatment experienced, genotype 1-6 infection, with prior treatment with one of the following: 1) peginterferon/ribavirin or 2) NS3 protease inhibitor triple therapy (Olysio, Incivek or Victrelis with peginterferon/ribavirin)
   - Treatment experienced, genotype 1b or genotype 2 infection, with previous treatment with Sovaldi (sofosbuvir)-containing regimen (e.g., Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio) that does not include NS5A inhibitor

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

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 (Epclusa)** requires the following rule(s) be met for approval:

A. You have a diagnosis of hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
B. You are at least 18 years old
C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), 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
D. 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
E. If you have decompensated cirrhosis (symptoms related to liver damage), you must be using a ribavirin-containing regimen
F. If you do not have cirrhosis (liver damage) or you have compensated cirrhosis (no symptoms related to liver damage), you must be treatment naïve (never previously treated) or treatment experienced with a previous regimen of:
    1. peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin), OR
    2. Sovaldi (sofosbuvir)-containing regimen that does not include NS5A inhibitor (type of hepatitis drug) such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio, with genotype 1b or genotype 2 infection

Epclusa will not be approved for the following patients:

- Patient using any of the following medications concurrently (at the same time) while on Epclusa: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

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.

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SOFOSBUVIR/VELPATASVIR

RATIONALE

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

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 28, 2016.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

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